
Models of information systems devoted to medical-imaging labs: an experience in the CNR clinical physiology institute

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Abstract: At the end of the 1990s, the SPERIGEST project, supported by the Italian Health Ministry, and fully developed at the Institute of Clinical Physiology, established an operative integrated clinical and healthcare information system. Continuously evolving and dynamically optimising procedures and protocols solve problems of: harmonisation of instrumentation of different brands; management of multimedia data provided by different medical imaging labs; satisfaction of both clinical and research needs; legal and economical requirements; user-friendship of the system. A ten years experience shows positive approach by medical and healthcare operators, coordinated activity, higher efficiency, simplified procedures, major concentration on medical decision-making.

Keywords: information systems; healthcare management; medical imaging.

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1 Introduction

The effective and efficient overcoming of fragmented diagnostic and therapeutic procedures is today a challenging target. The project of integrated network-based medical information systems involves complex technologic, legal and healthcare solutions. The aim is both limiting healthcare expenditure and facing the increase in the demand of health services, as a result of the improvement of socio-economic conditions, ageing of the population and progress in medical knowledge and technologies. To reach such target, it is necessary to achieve a three-dimensional integration: in the space, in the time and among the component levels of the health services. Spatial integration means overcoming and optimising the appropriate addressing and access of the patient to the required clinical and healthcare services, providing medical operators with every necessary tools and data under their hands in real time, to yield the best service for the patient. Time integration means to offer an important help to the decision process at all levels by providing access, via appropriate authorisation, to the entire clinical history of patients. The integration into the Health Systems, with reference to the various levels (prevention, home or hospital care, general or specialised medicine ...), implies the overcoming of the differences between the various health professional figures, as well as the harmonisation of software and hardware varieties available in the clinical environment (Ferdeghini et al., 1995; Mazzarisi et al., 1995; Taddei et al., 1999). Therefore, the resulting setting combines scientific competences in the fields

of healthcare, informatics and telemedicine, together with industrial research units able to assure both view on market evolution and support for implementation of the model at a suitable scale. Another goal of this system is to have available functionalities to improve patient care and administration, clinical decision-making, and to get an optimal use of the healthcare resources. Today, the discipline of 'Health Informatics' takes care of the design and implementation of this kind of systems including supporting tools, from the collection of clinical and administrative data, to their organisation, processing, integration, storage, distribution and management (Goodfellow et al., 2008). Here, the presented project is a complex information system, mainly devoted to cardiology and pneumology, which enhances the important role of contemporary Information and Communication Technologies (ICTs) for the management of information and how this can act as a foundation for a KM-based system, as also recently focused on other environments (Bali et al., 2007).

2 The IFC information system

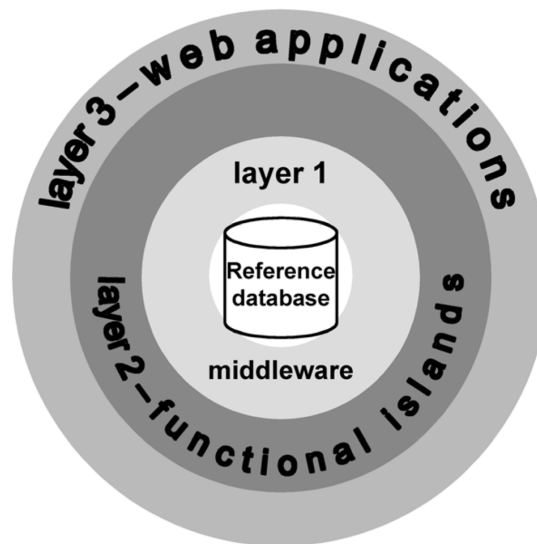
In the late 1990s, the CNR Institute of Clinical Physiology was entrusted with the 'SPERIGEST' project; the project, granted by the Italian Health Ministry, received a budget of about 2.5 millions of Euros. The goal was the re-design of a healthcare structure to get a full integration of clinic, technologic, epidemiological and administrative activities, including hospital planning and management (Ferdegini et al., 1995; Macerata et al., 1995; Mazzarisi et al., 1995; Taddei et al., 1999). Among the technical challenges of the project, the following issues were faced:

- the definition of a system architecture able to conjugate a centric view, as required by data integration needs, with flexibility and modularity, to satisfy the different laboratory typologies or healthcare environments
- the creation of local information systems devoted to the management of each single laboratory activity
- the creation of a suitable network to exchange information both inside and outside the hospital
- the overcoming of safety and security issues in the treatment of healthcare data
- the data processing for extracting knowledge from the archived data and for supporting the diagnostic/treatment process
- the education of healthcare personnel
- the adoption of standards for both storage and distribution of data.

Today, this appears fully accomplished with the need to maximise the benefits of ICT as well as to facilitate the rapid sharing of information and effective knowledge building, "required for the development of coherent objectives and their subsequent attainment" (Wickramasinghe and Bali, 2008).

The solution was the development of an information system with a three-layer architecture, as shown in Figure 1 (Macerata et al., 1995). The first layer is the central database; the second layer is the set of specific applications, i.e., local information systems host by diagnostic laboratories; the third layer represents the consultation level of data, which are stored in the central database. The central database is the core of the system; it is the reference repository of all the patient data and it is continuously updated by the peripheral islands. In between the first and second level, a middleware channel allows communication and exchange of data between the central database and the external applications. These applications are devoted to the management of peripheral activities or specific functions; for instance, subsystems oriented to personnel/instrumental organisation and diagnostic examination planning and execution inside a specific laboratory, or subsystems for the management of the ward nurse activities. Each of these subsystems has generally been named 'functional island', to identify its main specificity given by its function. The third level is made by web applications for consultation of all the collected patient data, which are made available on all the workstations of the intranet hospital network.

Figure 1 Three-layer architecture



3 The 'functional island'

A central information system makes all the patient data always available, so yielding an exhaustive view of the patient information, necessary to ensure the continuity of care. The modular approach, adopted in the SPERIGEST project, was the way towards an open structure of high interoperability, safety and privacy of data and size modulation on the basis of laboratory needs.

'Functional Island' is more a logical than a physical concept, larger than that of a simple local Information System dedicated to peculiar clinical specialisation. It has, therefore, the same features of a larger Hospital Information System, which,

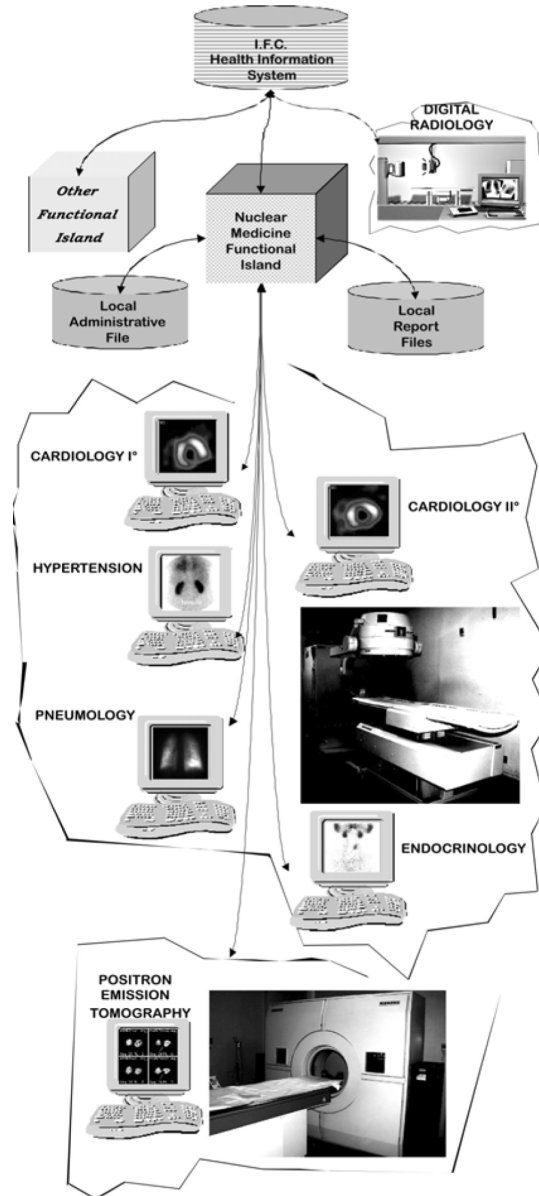
on its side, integrates the single functional islands as components. The functional island results from the lab instrumentations, human resources, management and clinical protocols and procedures, networking, and everything can characterise and provide a specific, self-referenced and autonomous activity and outcomes. In a typical hospital environment, different clinical, administrative and management functions refer to different data sources or hospital information subsystems. Modularity is the keyword to correctly approach a project, which could take into account similarities and differences. In fact, each of the data sources can functionally be considered as part of the local Information System, dedicated to peculiar clinical activity or specialisation ('functional island'). Each local system can live of autonomous life, by restraining to the local environment everything that is not performing or useless for the Hospital Information System. This improves the behaviour and the efficiency of the whole system. Different models have been studied and applied to plan the integration and the operative protocols, by harmonising different clinical practices, instrumental resources and human expertise (Ferdegini et al., 2000, 2003; Ferdegini, 2002).

By means of a secure telecommunication infrastructure, each functional island deals with clinical, administrative and management functions, locally reproducing the components of the overall hospital information system (Figure 2); this appears helpful to improve the level of efficiency inside the functional island. Benefits outcome for the medical, paramedical, administrative components is pair to those achieved by the patient, without significant changes for the clinical routine. The model reorganises the laboratory in a set of activities, which are related to the instrumental resource and the peculiar clinical employment. This means that, with respect to a fixed model of procedural steps from the admission up to the patient checkout, only the procedures strictly related to the clinical activities are subjected to a formal re-design. According to the indications of the laboratory personnel and the internationally adopted clinical guidelines, the system can adapt itself, with very few changes of the original model. In this framework, the set of protocols has been defined, as much as possible, adopting current standards or their extensions, also taking into account their flexibility in consideration of the continuous evolution of the health domain.

The personnel operating in a typical medical-imaging laboratory has to manage a wide variety of data generated, processed, transferred and used for diagnosis, therapy suggestion, research and education, administration and planning. Therefore, while facing the project of a functional island, part of the problem is the identification of common procedures and protocols, which do not relate to the peculiar activity of the laboratory. Inner differences are necessarily taken into account while considering, for instance, what is valid in the practice of the radiology laboratory, which is not appropriate for the nuclear medicine or the magnetic-resonance-imaging labs.

Another relevant problem is the consideration that consolidated practice can introduce conflicts or resistance in applying new work procedures. Efficiency of the functional island is not only the organisation of protocols but also of the personnel, by creating an operating diagram, which takes into account the organic integration of clinical, paramedical and administrative activities. Consequences of a bad organisation or a misuse of the available resources can increase real healthcare costs, with a not corresponding enhancement of quality of the service offered to the patient.

Figure 2 Example of the path covered by the digital data through the ‘functional islands’ and the central information system



4 The imaging-based ‘functional island’

By focusing our attention to laboratories, we can identify a single specialised functional island by considering for instance the imaging modality. Moreover, this specific functional island can serve different medical branches, so being characterised by their own peculiar clinical protocols and procedures. To obtain the best synergy

between clinical needs and available resources, each laboratory includes a complete set of hardware and software tools for data acquisition, image processing and storage, report compiling and archiving. Commonly, this system is provided of a dedicated local digital network, which allows a fast and easy transfer of data among the lab workstations and diagnostic instrumentation without interference with the general LAN lines and services.

The laboratory staff includes physicians, nurses and technicians: all of them are functional to the correct, synergic activity around the patient, with no redundancy and with optimisation of costs and time consumption for the clinical examination.

The development process of the functional island is a series of coordinated activities involving both clinical operators and technical personnel. The knowledge of the clinical needs is a fundamental step for defining actual protocols, procedures and resources before outlining the project and translating it into final product design. This preliminary approach allows discovering redundancies or weakness in the lab resource availability and use, and changing or adopting the procedures' workflow (Ferdegini et al., 2001; Ferdegini, 2002).

4.1 Project guidelines

A carefully engineered management system, based on an efficient local Information System and supported by adequate technology, can improve the level of efficiency of the Department, with benefits for medical, paramedical, administrative components and the user (the patient), without significant change for the clinical routine. This goal can be achieved, characterising the system by: modularity, protocol efficiency, resource harmonisation, shortening of total examination duration, standardisation and share of the information (Ferdegini, 2002). The development process of the functional island has been a sequence of coordinated activities, between clinical operators and technical personnel. The information regarding clinical needs has been a fundamental step to know what was really necessary to the definitions of protocols, procedures and resources, before outlining the project and translating it into final product design. This preliminary approach has shown its peculiar importance, while it has allowed the acknowledgement of redundant or, on the other side, missing or usually considered less-important steps of the adopted procedures.

As shown in Figure 3, a typical protocol in a medical-imaging department proceeds through sequential steps. The phase of data acquisition is a technical 'dead' time of inactivity for some of the medical and paramedical actors of the study. Moreover, some procedural steps, marked with the '*' symbol, could be differed owing to clinical thorough investigations, as well as to temporary unavailability of the operators.

The conversion to a 'multitasking' protocol, which is able to perform, simultaneously, procedural steps regarding different patients, can reduce dead times as well as the probability of delayed reporting (Figure 4).

It is possible to attain a standardisation of the clinical procedures, keeping the necessary differences owing to the variety of diagnostic approaches and of medical instrumentation. A major drawback of the parallel approach is that the output from one phase to the next one has a limited cross-functional communication. From the point of view of the project re-design, subsequent to clinical procedure changes, a limited cross-functional communication and feedback does not cause the process reorganisation of protocols and procedures to become very slow, as they do not require too many global

design changes, which are very costly and often of poor quality. By avoiding a long development time, we obtain that any change towards new protocols and procedures is not rejected by the operators because it is either outdated, or unfeasible in terms of operative capability.

Figure 3 Sequential clinical protocol

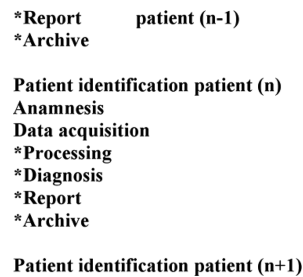
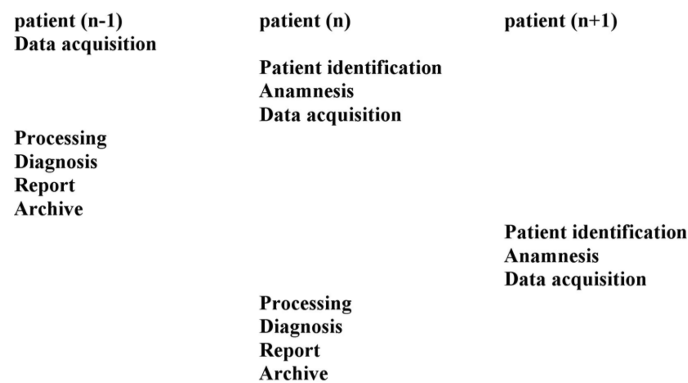


Figure 4 Parallel clinical protocol



An electronic Information System contributes to solve daily archive management problems, overcoming the maintenance and the management of paper reports archives. In fact:

- multimedia digital reports guarantee unaltered data of medical interest, such as images, as time goes by
- optical disks (i.e., CD-ROMs and DVDs) keep, in a reduced space, a large quantity of data, at least for the time limits imposed by the Law; also, by keeping the obligation of a paper storage of the report, the digital archives are the consultation databases for clinical, research, or administrative purposes
- safe access and user-friendly management guarantee data integrity
- secure and real-time access to the local databases from remote workstations makes all the necessary diagnostic information safely available to the authorised personnel.

In fact, the shortening of the total duration of the examination can be achieved by improving both the administrative and the clinical procedures, in particular:

- patient identification is simplified and speeded up by the availability of an Information System with automatic storage of the data, including predefined input options, with a network-based access to the central archive to retrieve eventual previously stored administrative data
- identification data, to be associated to images and other clinical outputs, travel inside the functional island by means of work lists, fed once at the admission of the patient at the laboratory
- report drawing is speeded up, without affecting the diagnostic clinical and technical requirements, by an efficient use of software tools
- complete report printing compacts in a multimedia layout all the necessary data, with the capability of getting a high quality, colour, not expensive printout
- report storage is in real time, both for the local and for the central Information System, making the results of the specialist examination common property to the other clinical investigators; of course, the paper legal copy is immediately available, too.

At present, the Clinical Physiology Institute provides, as image data sources:

- Two gamma cameras serving the cardiology, pneumology, endocrinology and hypertension groups, together with a Positron Emission Tomography (PET) laboratory, enabled for the cardiologic, neurological and oncology studies. The specialist Nuclear Medicine and the PET Lab represent two functional islands.
- A digital radiology unit is an independent functional island, and serves both the inpatient as well as the outpatient departments.
- The PET/CT laboratory, owing to its hybrid instrumentation and polymodality output, is accessed by both the PET as well as the Digital Radiology functional islands, respectively.
- The further functional island of Magnetic Resonance Imaging serves cardiologic and neurology activities.

Today, all the image modalities provide pure digital output; at the beginning of the SPERIGEST project, the reporting workstations were forced to preliminarily convert analogue output into compatible digital formats (Macerata et al., 1995; Ferdeghini et al., 1995; Mazzarisi et al., 1995; Taddei et al., 1999).

Tools for querying the intranet accessible databases are available on each workstation, to get online information about the daily clinical activity of each laboratory or to access reports produced by other functional islands, so ensuring continuity of care. Tools for the creation of clinical reports are available on the workstations available at each of the functional islands. A local central server stores both the administrative and the report data produced by the studies into separated databases, always online for next consultation.

5 Enhanced archiving

The local clinical report and the administrative database servers have been designed paying attention to the problems of data security, unique identification of the patients, and certification of the health operators, authorised to interact with the system by means of appropriate user privileges of access. Aside, a laboratory database of the original raw data preserves them for further clinical and research investigations. The architecture of the report database is based on a client-server configuration. Inside each functional island, the local network is separated from the main Institute network to allow an independent activity of the functional islands, avoiding impairing the laboratory activity in case of external network faults, and contributing to reduce the intrusion of external hackers.

Multifunctional workstations include the clients as well as the tools for the image acquisition and processing, the browsers to access information data provided by the Hospital Information System via a secure Web link. Encryption has been adopted for the transfers between the clients and the server; secure web transactions and firewalls are the main defence from external undesired access. Internally, the access to the data is guaranteed by means of passwords and log files, which record the main activities of the users (log in, log out, admission, reporting, browsing), in a proxy-server-wise way of work.

Databases for the temporary storage of the rough reports on the client workstations are realised to help the users during the editing operations of the final report. To ensure the legal validity of the final report, a unique original printout is produced at the same time the report is stored on the local server. Not legal previews can be printed or viewed, during the editing of the reports (Ferdeghini et al., 2001).

The software applications for the management of examinations in the imaging-based diagnostic labs are based on a common user-friendly, intuitive interface, which reflects the traditional structure of the paper record: a folder with tab pages. Each tab page represents one piece of administrative and diagnostic information, including: individual laboratory test results, images and diagnostic and therapeutic conclusions. Menus, intelligent auto-editing, button-driven input of most used expressions are among the facilities for a quicker report edition. The application is started by a password-based login procedure, which allows the identification of the user and the authorisation to access patient information according to user-specific rights. For new examinations, three sources are available for the acquisition of the identification data of the patient: direct input from the central database, where admitted patients are regularly recorded; local server, in the case of recovering of data of formerly examined patients; manual input by the operators. Of course, the data can be integrated or corrected by the operators, before storing them into the local server. A new administrative entry creates a correspondent examination file, which is definitively closed when the test is finished, and the report is printed and signed by the physician. This means that the protocol can be suspended as well as divided into steps, and the report updated time by time. The final report includes the most significant images to integrate the clinical diagnostic response, with the most relevant qualitative and quantitative outcomes of the study.

To monitor the activity of the functional islands, both for administrative and for management purposes, statistical reports can be created and electronically sent to the health management of the laboratory and of the Institute.

5.1 Image DICOM-standard servers

An important component of medical-imaging functional islands is the server collecting all the produced clinical images and studies. The DICOM standard allows characterising each set of images to belong uniquely to a patient, together with the salient characteristics of the diagnostic examination. Actually, the DICOM standard has been universally accepted to digitally distribute and view images and signals provided by the most part of the clinical devices, independently from the brand of both the source and the viewer tools (Hussein et al., 2004a, 2004b). The DICOM servers developed for the SPERIGEST project adopt Open Source software (Ferdeghini et al., 2005). To avoid data loss for the fault of the hard disks, the storage system is protected by Raid 1 technology. Suitable file systems preserve the image data coming from the diagnostic equipments for unexpected reboots, power failure and system lock-ups. Integrated firewall subsystems based on protected IP tables guarantee a total protection in the absence of an external firewall. This solution is strengthened to allow the lab activity in critical conditions also (Marcheschi et al., 2003).

5.2 Integration into the hospital information system

Another aspect of the project concerns the problem of data communication and exchange, to allow the connection through various channels of telecommunication, between users with different computer equipment and the central Information System (Marcheschi et al., 2005). The adoption of commercial multiplatform tools, as well as the development of a suitable network middleware, has overcome these limitations. JAVA programming and JDBC protocols make the input from and output to the central Information System via secure intranet transparent to the user and platform-independent. Common browsers make central and local databases viewable to authorised operators, though custom applications have been developed for local report browsing, to increase safety and security of laboratory archives.

6 Safety and security

The problem of safe and secure storage of and access to the reports is another important issue (Soegner et al., 2000). In the local servers, data safety is guaranteed by the Raid 5 technology, by external backup units, and by periodic storage. Protected access to local database by authorised remote workstations reduces risks for undesired intrusion, and, therefore, the loss as well as the undesired diffusion of patient data. Being the core of the model, a database containing the whole set of data of the patients, both the central Information System as well as the local databases, will be logically concentrated, updated and accessible only by authorised and certified customers, through a safe communication infrastructure. In particular, solutions have been studied or are under development to make data transfer inside the functional island undergoing to safety rules (involving both hardware and software network settings), different from the ones required for the

communication channels between each functional island, the central information systems and eventual external accesses. Secure data transmission from and to the central Information System is made safe by the concomitant employment of firewalls, encrypted data transmission and password-enabled access. The information resident at the Hospital Information System is accessible via a secure intranet. The paperless medical record resident on the local server can be viewed and printed by means of a custom application, allowing both patient care support and playback consultation for clinical research, though it is also possible to access to such data by safe web protocols and the most common browsers. There is also a physical separation between the significant images integrated into the diagnostic reports (Ferdeghini et al., 2005), for documentation of salient findings and results, and the original sets of images collected in the local archives, from which the samples are extracted.

7 Conclusions

After ten years from the on-site use of the prototypes, we have got evidence of the system features that appear to be of functional and technical relevance. The implementation at the C.N.R. Clinical Physiology Institute of Pisa, started during the Italian Health Ministry Project 'SPERIGEST', has shown that the advanced prototype of the local information system improves protocol efficiency, resource harmonisation, shortening of total examination duration, information standardisation and share. Suitable tools allow managing clinical and administrative data, to get a measurement of the cost-effectiveness of the laboratory. A fast and easy integration of old as well new modalities or subsystems is essential to make the system up-to-date and ready to use for the health operator. The information infrastructure must accomplish with the most generality of existing and outcoming standards of data output. By employing a modular approach to solve the problem of taking into account the widest range of laboratory settings, expansions, evolutions and maintenance of the system are made easy, allowing selecting among a wider range of commercial subsystems.

The end-user has appreciated the user-friendly organised, graphical interface, which drives the operators through the various steps of a typical study, as well as the short time required for the training. The possibility to perform also different clinical protocols on different patients in parallel, by adjusting and fitting the operative timetable, reduces dead times, and enhances the efficiency of the laboratory, with superior patient satisfaction.

To reduce the impact for the medical and co-working operators, easy-to-use tools, deputed to the transparent integration of the available instrumental as well as human resources in the clinical environment, guarantee coordinate activity, improving medical efficiency and decision.

The shortening of the total duration of the examination can be achieved improving both the administrative and the clinical procedures. Patient identification is simplified and speeded up by the availability of the direct link to the central information system, as well as to the local server, allowing the automatic retrieval of previously stored administrative data. This solution of an intermediate local server allows the functional island to be active independently from the existence of information systems at a higher level. Manual data input is a last chance solution in case of emergency: predefined settings are helpful for a faster completion.

Image processing is available both on the data acquisition workstation as well as on post-processing systems. Raw data and results are stored in local archives, both on hard disk, for current patients, and on optical discs, for historical storage. Owing to the need to make images available also for clinical and research purposes outside the functional islands, image servers, based on standard protocols for medical image storage and transfer (i.e., DICOM), are actually used. They will contain the current studies images that each laboratory will make available to certified and authorised clients.

An electronic Information System also contributes to solve daily archive management problems: at present, the Italian Law (from the year 2003) allows the digital storage of reports and images, but for what concerns reports, lacking a definitively approved legal instrument for the document certification (i.e., digital signature), paper archives are still available. Digital archiving allows keeping data of medical interest, such as images, unaltered as time goes by; browsing and search tools allow continuous access to the clinicians and researchers, both for clinical and for epidemiological purposes.

Staff continuous training is essential to reach the best results. Unavoidable initial cautious distrust shown by each professional of the laboratory has been quickly overcome by the involvement into the project design, which has taken into account the individual expertise to get the optimised result. Actually, the laboratory personnel finds a strong motivation by perceiving the growth of skillness about the technology in terms of professional improvement.

The success of the adopted approach has allowed the exporting of the system or of its selected functional islands in other hospital environments in different regions of Italy, by means of a further project granted by the Italian Health Ministry. Again, the adopted model allowed developing, after very few adaptations to local needs, functional islands that have improved the clinical activity and administration, by giving the input towards a larger implementation of the computer-assisted clinical management in the realities where the SPERIGEST project was exported.

Together with the technological improvement, new problems need to be faced. On the one side, we have to consider that information technology implies the need to state new rules and a reengineering of the bureaucracy. Though the Italian Government is facing the problem inside and aside the 'modernisation' of the Public Administration, including the administration of Healthcare, technology is evolving really fast. The Law needs to be updated not only based on the actual state-of-the-art, but also looking forward at the new technological trends, to cover all the problems of safety and security of the clinical data, and by giving also directives for their storage and distribution, which can easily harmonise with the clinical practice.

On the other hand, the further important step to allow a full integration of the IFC Health Information System to the other ones available or under development in Tuscany as well as in the National Healthcare system is to direct efforts to the creation of standard clinical document architecture. This is an actual problem of all the advanced world healthcare systems: by integrating and expanding all consolidated standards, as well as creating new rules and operative protocols, it will be possible that the clinical information of any potential patient could travel with him or her everywhere, to receive, the same care as at home, everywhere.

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