eHEALTH HANDBOOK

for managers of healthcare services and systems

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Preface

This eHealth Handbook for Managers of Health Systems and Services is intended to facilitate decision-making processes concerning the incorporation of information technology (IT) into public strategies in the area of health and healthcare. It discusses almost all the fields in which IT can be applied, clarifying concepts, pointing out benefits and explaining requirements.

Information technology tools can enhance the quality, safety and continuity of healthcare. They also enable patients and families to play a more active role in the care of their health Furthermore, they allow the rising healthcare costs derived from the population's ageing and the increase of chronic conditions to be more efficiently controlled.

In order for these tools to be effectively incorporated into public sector healthcare, an active commitment on the part of the government is essential. The leadership of health authorities is of key importance in developing regulatory frameworks that support the redesign of traditional work processes. The role of such authorities is also crucial in articulating the interests and needs of the many different stakeholders involved.

The European experience, particularly that of Spain, can serve as a valuable lesson for the countries of Latin America and the Caribbean, both in the formulation of policies and strategies and in the actual implementation of eHealth projects. For this reason, the Economic Commission for Latin America and the Caribbean (ECLAC) and the Spanish Society of Health Informatics (SEIS) have been working together, over the last three years, to spread knowledge and exchange experiences. It was in this context that European and Latin American experts were asked to create a guide that would facilitate the task of decision makers and contribute to the knowledge of the professionals taking part in these innovation processes.

This book is the result of almost a full year of work by an interdisciplinary team of 38 specialists, comprising both the authors of the contents and also reviewers and editors of the same. To each of them we express our sincere gratitude for their efforts.

Alicia Bárcena	**Luciano Sáez**
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Executive summary

David Rojas
Javier Carnicero

The application of IT to healthcare systems, a trend known as eHealth, is the fruit of a public policy decision to improve the effectiveness and efficiency of the health sector. Its specific objectives vary from region to region and country to country, but they generally respond to two facts.

First of all, today's social reality is marked by the growing needs of citizens, whose expectations are also growing because they have access to vast amounts of information. In Europe, the greatest challenge is probably the increasing demand for ongoing care for chronic patients, due to the aging of the population. In Latin America and the Caribbean (LAC), however, the priority is to improve access by patients to healthcare that is timely and of high quality, something often hampered by social inequalities and the population's geographic dispersion.

Secondly, there is an urgent need to guarantee the sustainability of healthcare systems, as these systems are at risk as a result of today's economic-financial situation and increasing budget restrictions, and also because of the increasing cost of care due to the appearance of new medical techniques and the change in epidemiological profiles. Controlling costs, optimizing processes and reallocating resources are ongoing challenges in any healthcare system. But they are of even greater importance when they enable improvements to be made to health coverage, especially primary care, for those who are most vulnerable.

A characteristic common to most European countries is that government bodies have been very much involved in the great strides made in this field in Europe over the past 25 years. Early projects, for the most part, were carried out in local and regional settings, and naturally the next steps to be taken were aimed at expanding the solutions put in place and at improving them by adding new functions. With the large-scale consolidation of these solutions and the creation of the European Union (EU), the strategy became one based on the integration of existing systems so as to allow for the exchange of citizens' clinical information and thus facilitate care provision from any place within the EU.

In LAC, on the other hand, the public sector has been much less involved. The majority of the significant experiences in this field in LAC have been University-based projects, with precarious budgets and low rates of population coverage. Donations, from the international community and also from the private sector, have played a fundamental role in some of these projects becoming more visible and more financially stable. The main challenge in this part of the world is to transfer these projects to government agencies, in the form of alliances with universities, so that they can be developed at the national level.

Despite the different stages of development, in both parts of the world, processes aimed at innovating and incorporating IT into the health sector often end up stalling and never seeing

completion. This has to do with the combined effect of budgeting problems and resistance to change, and is exacerbated by the fact that concepts are often poorly defined, real experiences are not properly disseminated and evaluation studies are rarely conducted. These shortcomings make it difficult for governments to formulate long-term public policies and suitable strategies.

Progress in eHealth has countless implications in the fields of prevention, diagnosis, treatment and patient monitoring, and also in the planning and management of health services and systems. It can cover applications as diverse as electronic health record systems, pharmacy management, clinical-administrative management, medical imaging, departmental information systems, the various telemedicine services, public health and occupational health surveillance systems, distance learning programs in the area of health education, and many others. These services are associated with several basic needs, such as the technological infrastructure with which such services operate, the interoperability that allows for data exchange between systems and the security measures taken to ensure adequate data protection.

With this publication we hope to help clarify concepts, identify functions and applications, illustrate benefits and warn against risks and difficulties that will no doubt be encountered along the way, providing guidance to the directors of healthcare services and systems, as well as to other agents involved in the making of public policy and strategies in the health sector. A further aim of this publication is to contribute to making eHealth an integral part of the general health strategy. Ultimately, the challenge is a political one: it requires that society as a whole take action and finally acknowledge that everyone has the right to health.

Hospital information systems

One requisite of clinical activity is the proper management and planning of all the resources involved, both human and material. This facet takes on particular importance if we consider the dimensions of health services, the complexity of their activity, the high number of patients under their charge, and of course the fact that such resources are limited.

To be able to coordinate these resources and meet existing demand for care, rigorous procedures must be established and they must cover the following activities:

— Positive identification of patients and professionals, to ensure that patient information is not duplicated or disaggregated.

— Definition of all the services provided, specifying characteristics such as whether or not an appointment must be made in advance, how long the results remain valid, any special conditions required, appointment restrictions, all necessary resources, estimated time required for provision of the service, etc.

— Service requests, understood as the act by which a clinician makes an order that a service be performed on a particular patient. It does not necessarily correspond to the appointment-making process.

— Configuration of agendas, defining and assigning time slots for the provision of specific services. This must be achieved in such a way that the best possible use is made of the time and resources available but some flexibility is maintained so as to be able to respond quickly to certain situations that may arise, such as emergencies or equipment malfunction.

— Appointment-making process, by which the clinical and personal needs of the patient are negotiated with the needs of the health service. Frequently appointments are made for various services in relation to a single episode. In this case it is helpful to concentrate the appointments in the shortest

time period possible, while taking into account at all times the restrictions or incompatibilities that may exist between different tests or procedures.

— Patient admission, which means registering the patient's arrival, confirming that the requirements for service provision are met, obtaining the appropriate authorization when doing so is necessary.

— Service provision, recording the information generated in the appropriate information system.

— Others: management of stocks and supplies, bed management, etc.

It is absolutely necessary that these procedures be specific and adaptable to the circumstances of each situation: outpatients receiving specialized care, hospitalized patients, emergency departments, surgery wards, etc. Also, all necessary steps must be taken to guarantee the confidentiality of patient data, taking into account that this process involves administrative personnel in addition to clinicians.

Finally, statistical use of the data generated is very useful for monitoring activity and for strategic planning. Certain indicators such as the number of visits, average waiting time in the emergency room, the average length of stay at the hospital or the number of surgeries that had to be suspended are an extremely valuable asset for the organization, especially in areas in which situations of special risk for patients may arise, such as in emergency services or surgery wards.

Electronic health records

A health record can be defined as the repository that contains all the information related to a patient's health. Therefore, it is an instrument that plays a vital role in the professional being able to perform his or her activity and provide the patient with the best care possible at all times. In fact, its usefulness is such that it goes beyond purely care-related purposes, to also include functions related to research, teaching, planning and management, quality control and even legal matters.

Currently, the vast majority of clinical records are paper-based, but this has a number of disadvantages related to accessing, entering and processing data, both within a single institution and between various institutions, and also in terms of security and confidentiality. Electronic health records (EHR) remedy these shortcomings and offer additional advantages as well. The features that such systems offer can be grouped in the following functionalities:

— Health information management

— Results management

— Management of medical orders

— Decision-making support systems

— Electronic communication systems and connectivity

— Patient support

— Administrative processes

— Reporting systems and public health systems

— Issue of medical reports

All of these features offer solutions to the different needs of the agents involved, whether they are health professionals, clinical services or health organizations. The structure, functions and ways in which information is presented in the EHR vary depending on each specific case, but there absolutely must be adequate integration of the different clinical and clinical-administrative information systems that feed into the EHR. Achieving this is a laborious and complex process that represents, along with the

need for an appropriate computer infrastructure, one of the main technical barriers to EHR adoption. In addition to technical barriers, there are others, such as: economics (high initial investment and maintenance costs, uncertainty regarding the return on the investment, etc.), time factors (long execution periods for this type of project), psychological factors (skepticism of users), social-organizational factors (need for ongoing collaboration between professionals of different profiles), legal reasons (legislation concerning data confidentiality), factors related to the organization (size of the organization and complexity of its activity), and, finally, issues related to change management (lack of incentives and leadership).

Additionally, certain requisites must be fulfilled to ensure that the introduction of the EHR system is effective: positive identification of individuals, use of corporate models for the representation of clinical information, use of standards to guarantee system interoperability, suitable presentation of clinical information, easy-to-use computer applications, compliance with applicable legal requirements, information security, appropriate change management, etc.

Fulfilling these requisites and dealing appropriately with existing barriers will make it possible for any EHR implementation project to successfully reach its objectives. The benefits of the EHR system include the following:
— Accessibility and availability of data
— Configurable presentation of data
— Active communication with other professionals and with patients
— Data aggregation
— Access to knowledge bases
— Decision making support systems
— Care quality improvement

Integrated management of medical orders

All care processes start with a diagnosis, so performing diagnostic procedures is one of the fundamental aspects of clinical practice. In today's medicine, this is a very complex task at the organizational level, since a request for diagnostic support may entail various different tests and involve a number of professionals, both clinical and administrative staff. Furthermore, it is not an isolated process, since it also must be coordinated with the following related actions:
— Managing appointments, since diagnostic tests usually require that appointments be made in advance.
— Detecting incompatibilities between a test and other diagnostic or therapeutic procedures.
— Confirming that redundant tests are not performed, so that patients need not undergo more procedures than are strictly necessary.
— Informing patients, explaining the method and purpose of these tests, furnishing all instructions that he or she must follow and obtaining any necessary authorizations.

The electronic management of medical orders (commonly referred to as CPOE, for Computerized Physician Order Entry) does not bring major changes to pre-existing work schemes, but simply means the implementation of a system that centralizes the control of the activity. This does not mean that a CPOE module takes care of the entire process, which would be quite difficult considering its dimensions, but rather directs and co-ordinates it from the perspective of the ordering physician, who

is the person at the beginning and also at the end of the process. For this reason, interoperability among the different information systems involved, both clinical and clinical-administrative, is the key to managing medical orders electronically.

The principal functions of a CPOE module are the following:

— Test ordering: catalog of services provided, definition of the degree of priority, predefinition of the most frequently made orders, issue of alerts in the case of similar tests performed recently, etc.

— Management of orders: preparation instructions, coordination between service areas and departments, consultation of test status, broadening or modifying the order, etc.

— Checking results

— Statistical use of the information

— System administration: catalog maintenance, patient management, auditing, etc.

The model used for the integration of information systems involved in CPOE can include a wide array of components, but the most important ones are the Electronic Health Record, appointment management systems and the systems used in the departments where the tests are performed, apart from the CPOE itself. To illustrate the interaction between these systems, the chapter includes a sample medical order calling for various diagnostic procedures: a basic blood analysis, an evaluation by a cardiologist and a CAT scan. This practical case study goes over each of the different stages of the process and shows the different data exchanges taking place between the systems, and from it the following requisites can be deduced:

— The functional design must be such that each task is assigned to a single system

— There must be positive identification of patients, orders, tests, professionals and physical locations.

— Test catalogs must be created and maintained

— The information shared by the different systems must be of high quality

— The number of systems used by each professional must be kept to a minimum

— There must be an appropriate hardware, software and communications structure

— There must be clearly defined collaboration agreements with suppliers

Especially important among the benefits provided by a CPOE module are that it allows the whole process to be monitored much more thoroughly and precisely, unifies the actions that must be taken, facilitates the statistical use of the data and eliminates the need for certain tasks, such as the printing of documents.

Clinical laboratory information systems

Initially, a clinical laboratory information system (LIS) consisted of little more than data records for the introduction of lab requests and the printing of results. However, the development of large auto-analyzers and robotic equipment –along with the enormous strides in IT–, has made it possible to automate a large part of the tasks and has brought about an extraordinary increase in the productive capacity of laboratories.

Currently, the LIS participates in the management of all facets of laboratory activity and therefore plays a critical role in the functioning of the lab. An LIS must have a database that includes

information about the patient, the lab request, the sample, the test and the results, while guaranteeing at all times the confidentiality of this data and the traceability of the entire process:

— Pre-analytical phase: request, appointment, collection of samples, data entry, reception and distribution of samples and distribution of tasks.

— Analytical phase: connection with the analyzers, quality control, the entering of results and technical validation.

— Post-analytical phase: medical review and validation, preparation and distribution of reports, and archiving of samples.

Also, the LIS has tools that support lab activity (supplies, quality control, web portal), and that facilitate the statistical use of data for purposes of both research and management. All of these functions must take into account the specific requisites of each lab:

— Emergency labs, which have a limited range of services and must be able to provide results very quickly. Sometimes there is a 24-hour lab, which provides services around the clock, combining routine activity with emergency activity.

— Microbiology labs, which perform very specific procedures and must be able to manage them correctly: growth of cultures, long-term strain storage, etc.

— Hematology labs, for the management of blood banks and anticoagulation control.

— Point-of-care analytical systems, which for reasons of speed are used at bedside by non-laboratory personnel but must also be integrated with the LIS so as to ensure the traceability of the process.

At a more general level, there are two fundamental requirements that must be met in order for an LIS to be able to guarantee such traceability, and they are not always met satisfactorily: the first is positive patient identification and the second is the use of a standard for coding the tests that make up the laboratory's catalog of services.

Digital pathology and telepathology

As with Laboratory Information Systems, Anatomic Pathology Information Systems (APIS) are vital for these services to be able to do their job. The following are the primary functions of such systems:

— Patient identification and management
— Registration and management of samples
— Preparation and issue of reports
— Sample coding and archiving
— Macroscopic study
— Image management
— Microscopic study
— Management of special techniques
— Workflow planning and control
— Quality control
— Use of the information

These functions cover all three basic aspects of the work carried out in AP services: report management, image management and laboratory technique management. They also ensure the traceability of the processes, facilitate data use and quality control and they enable telepathology activities to be performed.

An APIS must be integrated with various systems and types of equipment within the AP service: automated stainers, digital recording, voice recognition, tumor registries, biobanks, databases, libraries, datawarehouses, telepathology portal, etc. Beyond the AP service itself, the APIS must be integrated with other information systems, especially the following:

— Electronic Health Record system

— Computerized Physician Order Entry (CPOE) module

— Picture Archiving and Communication System (PACS), which is where medical images are stored.

— Terminology servers, in order to update vocabularies and catalogs

To achieve interoperability among all of these electronic health systems, a positive patient identification system is absolutely necessary. It is also vital that medical imaging standards (DICOM) and clinical terminology standards (SNOMED CT) be adopted.

Digital medical imaging

Medical imaging is one of the most frequently-used diagnostic tools in the health services. In this case, the application of eHealth involves the implementation of two systems:

— The RIS (Radiology Information System), which manages all the activity taking place in this service: the scheduling of appointments, patient admission, explorations, preparation and issue of reports, invoicing and data use.

— The PACS (Picture Archiving and Communication System), which stores the archives of the images obtained in the explorations.

While the RIS is the system in charge of the workflow as a whole, the PACS is noteworthy because of its associated infrastructure, which includes the exploration modalities (the ones in charge of image capture); the image file storage system; and the diagnostic stations at which the clinician works to interpret the exploration and which must have high-definition screens and special software functions for image processing, such as zoom, brightness and contrast control, image reversal, etc. This infrastructure must be sized according to the service's activity patterns, since each type of exploration has specific image quality requirements, meaning that there are different needs in terms of storage space and screen resolution.

Both the RIS and the PACS must be integrated with the other clinical and clinical-administrative systems described in other chapters (the HL7 standard is usually used for this purpose) and also with the modalities that generate the diagnostic images (here the use of the DICOM standard must be used, as it is specifically designed for the storage and transmission of medical images).

The benefits of RIS and PACS include: the optimization of certain parts of the workflow, thanks to the elimination of radiological film; new features in medical image handling, such as multidimensional viewing (3D or video); and the possibility of teleradiology. They also bring a reduction in costs as certain

expenses related to materials, physical storage space and personnel devoted to the archiving and transport of film are eliminated.

Although there is a tendency to associate this kind of system with radiology services, the scope of PACS can actually reach any service that uses images as a professional tool, and in fact images from equipment such as electrocardiographs, endoscopes, etc. are now being stored.

Telemedicine

Telemedicine can be defined as the transmission of medical information from one location to another – using telecommunications– with a view to improving a person's state of health. Although the earliest developments in this field date from the beginning of the 20th century, the greatest advances have been made in the last few decades, thanks to the great strides in IT.

The application of telemedicine is mostly of a clinical nature (diagnosis, treatment, supervision, interprofessional consultation, etc.), and it can be used in practically any medical field, in either real or differed time: radiology, cardiology, encephalography, neurophysiology, dermatology, pathology, oncology, ophthalmology, pediatrics, psychiatry, intensive care, trauma, emergencies, surgery, rehabilitation, home visits, etc. However, telemedicine can also be extended to other spheres such as education and training, research, public health or health management.

The potential benefits of telemedicine include the following:
— It can enhance the accessibility of healthcare.
— It improves the quality of the health services provided.
— It reduces the need for patients to move from place to place.
— It reduces waiting times.
— It optimizes primary care systems.
— It increases the timeliness of the care provided to critical patients.
— It makes the system more efficient.

To successfully implement a telemedicine program, it is very helpful to keep in mind the following recommendations:
— The domain, functionality, applications and technology to be used should be clearly defined.
— An integrated EHR system that centralizes all patient information should already be in use.
— Professionals should be made aware of the benefits associated with the ability to access structured and integrated data.
— Standards that ensure system interoperability should be adopted.
— All levels of the organization should be involved, including the health service directors, who must display their commitment and leadership.
— Professionals who are enthusiastic about the use of IT should be singled out for fulfilling special roles.
— Professional training activities.
— Assistance should be made available to professionals throughout the process of adopting new technology and transferring from the old system to the new one.
— Institutional business processes should be included in the new care model.

— The model's sustainability and cost-effectiveness must be ensured.

Teleradiology

The combination of digital medical imaging systems with telemedicine results in one of the most potent (and possibly the most important) applications in telemedicine: teleradiology, which makes it possible to electronically transmit radiological images from one place to another. The benefits of this application include the following:

— It increases the accessibility to health services, by serving health centers that do not have radiologists on staff for reasons of patient volume or type of facility.

— It reduces waiting times.

— It makes it possible to provide 24 hour service, by means of on-call shifts from specialized centers or even from the radiologist's home.

— It reduces the costs associated with patient travel and hospitalization.

— It enhances the quality of medical training.

In terms of the barriers to its adoption, the most significant ones are:

— High initial costs, resulting from the implementation of the necessary technological infrastructure.

— Concern by patients and professionals about the confidentiality of information.

— Resistance shown by professionals to changes in their working methods or to increases in their areas covered and the number of patients under their responsibility.

Teleradiology tends to be more highly developed in large geographical areas, where it is vital that resources be used wisely, so as to be able to provide care to the entire population. Examples can be found in various Latin American countries, such as Panama and Brazil.

Electronic pharmacy management

Once the patient has been diagnosed, the next step is to apply the appropriate treatment, which usually involves the administration of pharmaceuticals. The management of pharmaceutical therapy, like the management of medical orders, is a complex process requiring a global and integrated vision, since the medicine chain includes acquisition, prescription, dispensation, administration, invoicing and the use of data in decision-making. These stages have very different characteristics and a number of actors take part in them (doctors, pharmacists, health services, suppliers, etc.), so when eHealth is applied to this field it necessarily involves the participation of various information systems.

Electronic pharmacy management is based on two principal elements:

— The Drug Database, which stores in a well-structured manner all specific attributes of each medicine or health product: active ingredient, dose, pharmaceutical forms, prices, packages, etc.

— The Information System used by the health service, which contains the data concerning the prescriptions invoiced to the health system (the ones paid for by the health system) and also hospital acquisition and consumption.

Along with these two components there are also databases of patients, of professionals, of the users of the information system, of the prescriptions dispensed and the pharmaceutical treatment record of the patient. This set of systems and elements has the following objectives:

— To obtain a thorough understanding of the pharmaceutical benefits provided in the health system.

— To provide prescription support tools.

— To facilitate the preparation of reports on prescriber activity.

— To assist in quantifying, measuring and increasing the transparency of the health service objectives.

— To create a core of data for pharmacoepidemiological and pharmacoeconomic research.

There are two modalities of electronic prescribing: computer-assisted prescription writing, which uses paper as the information vehicle, although the paper is generated by electronic means; and e-prescribing, which includes connectivity with the pharmacy and almost entirely eliminates the use of paper, since the different information systems are fully integrated and all necessary data is exchanged electronically, with all the advantages this brings to professionals, patients and those involved in health management. Although the essential aim may be to put in place an e-prescribing system, computer-assisted prescription writing is often an intermediate step that facilitates its implementation.

The use of electronic prescriptions has several requirements at each stage of the process, with the following being especially important:

— At the prescribing stage: database of prescribers, patient identification system, mechanisms for the authentication of professionals, adequate user training, etc.

— At the dispensing stage: mechanisms for the authentication of pharmacists, associated technological infrastructure, integration with the pharmacy's own management systems, user training, etc.

— At the invoicing stage: determination of invoicing conditions, mechanisms for verifying and validating invoices, etc.

The application of these systems in the hospital setting requires that similar actions be taken in a uniform and coordinated manner, since the patients, professionals and providers are the same in both settings. The most important elements in this case are hospital prescribing procedures, management of the hospital pharmacy service and the drug administration record maintained by the nursing staff.

Among the difficulties often faced by this type of project, the following are especially noteworthy: the need for firm institutional support by the health services' directors, the necessity of ongoing dedication of human and material resources for the maintenance and evolution of the different information systems involved, and a certain opposition often shown by the collective of dispensing pharmacies and the professional organizations that represent them.

International exchange of clinical information

Thanks to the great advances in transport and communications infrastructure, more and more people are traveling to other countries, for professional, social, leisure or humanitarian reasons. In this context of geographical mobility, it is increasingly frequent for these citizens to need medical care in a country other than their own, and this makes the ability to access their clinical information very important. Thus, interoperability between electronic health systems must extend beyond a health service, and allow for the cross-border exchange of clinical data.

As explained in other chapters, interoperability requires that strategies and agreements be defined at the organizational and technological levels. However, when it comes to the international sphere, there are several additional difficulties that must be considered, such as the use of different languages and the existence of different legal frameworks. This means that it is necessary to clearly define the following:

— The scope and objectives of the information exchange, the procedures to be used to obtain patient consent, patient and professional identification and authentication systems. This guarantees the traceability of the process, the integrity of the information and the non-repudiation of the actions taken by professionals.

— The model of cross-border interoperability, specifying which information is to be available, the structure it must have, which terminologies will be used to ensure homogenous use and interpretation in all participating countries.

These are the working methods being used in the European epSOS project (European Patients Smart Open Services), the aim of which is to develop a patient summary and e-prescribing system that allows Member States to readily access the basic health information of any EU citizen, when doing so is necessary. In the case of the epSOS project, the following aspects are of special interest:

— The legal framework is the EU Data Protection Directive.

— Patient identification remains the responsibility of each country, so there is no European database of patients.

— The data model has been defined by teams of health professionals.

— The standards used are: CDA, which belongs to HL7, on the syntactic level; and ICD-10 on the semantic level, with some variations and specific uses of SNOMED CT.

Public health information systems

The health of the population is a common good that results from the interaction between the risks inherent in human nature, the environment we live in and the measures put in place by the community to avoid or minimize its negative consequences. In the area of public health, there must be health and non-health information systems that make it possible to observe and analyze in real time the phenomena related to health and its determinants, generating knowledge and leading to decision support tools that help guide actions aimed at the preservation and improvement of health and control of diseases, injuries, disabilities, deaths and the physical and mental suffering of the population.

Actions in public health are generally taken in accordance with the following stages:

— The first step is to observe with the greatest precision possible the health-related phenomena occurring in a population. This can be done with population-based information systems, which offer "a little information about a lot of people", or sentinel systems, which have "a lot of information about a few people." In the case of specific surveillance activities, monitoring systems or virtual time systems can be used.

— The next step is to analyze the information gathered, comparing it with other data, so as to perceive differences between groups and populations, between periods of time, places, characteristics, etc.

— Assess whether a "public health problem" exists.

— Decide whether the situation requires a response (either immediate or deferred) by the community.

A public health information system is one that is capable of generating reliable data using population-based sources: health parameters, the performance of the health system and infrastructure,

factors that contribute to health and health inequalities, extent of coverage and use of services, etc. These sources can be health-related (clinical activity registries, records of microbiological or biochemical tests results, registries of specific diagnoses, the Minimum Basic Data Set, the vaccination registry, pharmaceutical consumption records, microbiological surveillance of drinking water, bibliographical databases, etc.) or they can be unrelated to health (civil registry, municipal registry of inhabitants, health surveys, control of installations that pose a risk to the community, weather data, etc.).

Information Technology plays a key role in public health bodies having access to the information they need, since it enables data to be gathered, sent, received and stored using secure, fast, convenient and reliable systems, in constant technological evolution and adapting to growing information needs. This requires:

— A single storage unit for data pertaining to the population's health parameters. The data must be correctly refined, easily accessible, well-structured and interrelated.

— Interoperability among the systems involved.

— A close, collaborative relationship between people, bodies and agencies that possess data and have the intention and the means with which to analyze and make use of it.

— Technological support resources that guarantee the stable functioning of the information system over time, its operational stability and regular technological updates.

Occupational health information systems

Occupational health information systems exist in a context characterized by the interaction of various elements and organizations with different activities and interests, some of which are beyond the scope of health services themselves: social insurance systems, companies, insurance mutuals, risk prevention services, labor authorities, etc. The immediate consequence of this situation is that some sources of information in this field are unrelated to the health services, and the data they provide tends to present deficiencies or shortcomings in terms of its clinical value, since it comes from private or public organizations that do not belong to the care sector. The final result of this situation is that activities are carried out by all of these institutions with no co-ordination whatsoever.

Yet collaboration among these organizations is necessary in order to understand the real situation of workers, to detect hidden professional pathologies, to adopt the necessary preventive and corrective measures, while still meeting the economic, administrative and care-related objectives of the bodies involved. One of the measures needed to facilitate such collaboration is the implementation of an occupational health information system that has the following functionalities:

— Data reception: massive data loading from various external sources, real time reception of information, automatic alerts, etc.

— Management of medical orders and consultations: orders made, consultations regarding their status, messaging between the parties involved, etc.

— Use of data.

— System administration.

In order for the system to fulfill its objectives, it must fulfill certain requisites, as follows:

— System interoperability, achieved by appropriate integration processes.

— Quality control of the data entered.

— Clear identification of the participants.

— Maintenance of catalogs and records.

— Functional model with no duplicated or unassigned tasks.

— Communications infrastructures.

— Conventions and agreements between the different bodies taking part.

The benefits of a system of these characteristics include the following:

— It helps identify problems and plan for preventive and corrective measures.

— It assists in epidemiological surveillance by means of alert systems.

— It contributes to epidemiological studies and other types of research.

— It allows for easy consultation and issue of reports.

— It allows resources to be managed more efficiently.

— It improves administrative and care efficiency.

Distance learning in the area of health

Distance learning (DL) is a learning modality that enables the generation and exchange of knowledge among various people to take place with no need for these people to be in the same place at the same time. In other words, it makes access to knowledge possible for any person, in any place and at any time. Therefore, it can be an important educational strategy for attending large groups of students and for facilitating ongoing updates of the knowledge generated by modern science.

In the field of health, DL can be an effective method for helping overcome the significant barriers that exist in the public sector: limitations in terms of budgetary resources, schedules and access to learning opportunities at work; difficulties regarding access to information; and the lack of opportunities for training in the public network. Also, ongoing education is necessary to increase the confidence and reduce the isolation of professionals located in remote areas, which in turn facilitates their setting up practice in these areas.

Nowadays many countries have incorporated DL to all levels of learning, especially in projects for the large-scale training of health professionals. In the public sector of Brazil, the main initiatives underway focus on primary care, as one of the best means to organize and coordinate patient care. Analysis of the results obtained in Brazil reveals the presence of certain difficulties, such as the lack of continuity of projects, the tendency of the public administration to forget lessons learned in the past, political and cultural obstacles that hamper the adoption of more rigorous criteria in the evaluation of programs and projects. At any event, the process should be gradual and, with time, reach all educational levels.

DL programs should be based on the following guidelines, among others:

— The training offered must be compatible with professional responsibilities, based on the profile of the target audience and designed to meet their needs.

— The courses must be well-organized and technical support must be available to participants and students.

— Reusable learning objects should be used.

— There must be a formal process of expectation management, to understand and fulfill the expectations of students and instructors.

— There must be tools that permit ongoing communication between participants and students.

— The courses offered and their content must be subject to an ongoing process of evaluation, improvement and updating.

The positive aspects of the Brazilian experience include the institutionalization, at the end of 2010, of the Open University of the Unified Health System (UNASUS), to promote the production of distance learning courses in the field of healthcare. The UNASUS system is comprised of the following elements:

— UNASUS network: network of public institutions of higher education that have been authorized by the Ministry of Education to offer distance learning, acting in harmony with the Ministry of Health to ensure well-coordinated actions.

— Common Educational Resources in the field of health (Acervo UNASUS): public collection of educational materials, technologies and experiences, built in a collaborative fashion, that can be accessed freely through the internet.

— Arouca Platform: national database integrated into the nation-wide information system of the Unified Health System, which contains the historic registry of SUS workers, their qualifications and their professional experience.

Information systems for planning and overseeing management in health services and systems

The ultimate aim of a health service is to carry out clinical activity, understood as a combination of care provision, research and teaching. In order for such activities to take place, certain human, material and financial resources must be available in a timely manner. To guarantee the availability and timeliness of these resources, a health service or system must engage in a complex set of management tasks.

From the conceptual point of view, the management of health services and systems, just like that of any other type of institution, can be divided into four basic functions:

— Planning, the result of which should be a strategic plan that considers the initial situation, the goals set, the strategies to follow, the specific operational actions comprising these strategies, and the allocation of funding and necessary resources for the implementation of the plan. This plan must be designed starting at the highest level of the institutions and descending progressively through all of its levels, breaking down the general objectives into more specific ones for each institutional area. In any case, an objective must be clearly defined and perfectly measurable, so that it is possible to evaluate the degree of fulfillment.

— Organizing, for the implementation of the strategic plan at all levels of the health service or system and for the allocation of the resources needed to do so. This involves the existence of specific management bodies and persons who will take on a leadership role in each institutional unit.

— Overseeing, to check that all the strategies and measures are being applied correctly, to detect possible deviations and to make appropriate modifications, when necessary. Therefore, overseeing management is not limited to acquiring an exhaustive understanding of the situation at a given time; it also encompasses taking action to correct anomalies.

— Information, as a vital tool for the entire process to take place. Electronic health systems are instruments for consulting and recording all the data generated by clinical activity, which means they are very important assets in the management of a health service. For example, both planning and

organizing must take into account the information found in population databases, disease registries, activities registries and financial-administrative systems. With regard to the oversight function, the most valuable tool is the Balanced Scorecard, a set of indicators that helps an organization keep track of its performance in reaching institutional objectives, set forth in a concise, reasoned and uniform report.

Appropriate use of the clinical information contained in the eHealth systems can facilitate the analysis of the impact of healthcare on the population. A clear example is the evaluation of the degree of control of chronic patients, studying the list of patients in relation to the treatments prescribed and the outcomes obtained. This represents the completion of the management cycle, which began with the planning of the health services based on the population's needs in terms of care, and the planning of the new period can begin.

Interoperability

One of the fundamental requirements for implementing eHealth is interoperability among systems. The term interoperability refers to the capacity of various systems or components to exchange information, to understand the information received and to make use of it. In this way clinical information is shared and can be accessed from any point in the care network at which it is needed, and data coherence and quality throughout the system are guaranteed. The benefits of this in terms of care continuity and patient safety are evident. The key to achieving system interoperability is the use of standards that define the methods to be used for such information exchanges.

The different types of interoperability are as follows:
— Syntactic interoperability focuses on defining the syntax to be used for the construction of messages that the information systems use to exchange data.
— Semantic interoperability focuses on the homogenous interpretation of the data exchanged, whether transmitted or received. This way each system can incorporate the received information into its own databases with no need for any type of analysis or processing.
— Organizational interoperability is based on defining the business rules and procedures that govern the participation of the different agents in the organization's processes.

To achieve interoperability it is important to take into account the following requisites:
— Information systems must be adapted and standards must be adopted at three levels: the systems level, the network level and the information and service infrastructure level (interconnection among networks).
— Utilization of technological standards (HL7, DICOM, CDA, etc.) and semantic standards (ICPC2, ICD9, ICD10, SNOMED CT, etc.).

Information security

The concept of information security can be defined as the sum of information's availability, integrity and confidentiality. The availability and the confidentiality of clinical information thus become two requisites as necessary as they are mutually conflicting, whether the setting is one of traditional clinical records or one that uses eHealth. While Information Technology certainly makes available new tools that are helpful in reaching a compromise between these two aspects, the problem of information security is far from being an exclusively technological problem, since any action taken in this field must be firmly

rooted in the organization as a whole. In other words, information security management is no different from any other line of activity or strategy adopted by the health services. An information security plan must be based on the following action areas:

— A well-defined corporate security strategy.

— A compromise between availability and confidentiality.

— The use of technological tools to implement the necessary security measures.

— Training and awareness of professionals and patients.

The legal frameworks in force in each country vary considerably, but certain similarities can be found in their fundamental aspects:

— It is established that all citizens have an inalienable right to respect for their private life.

— Specific regulations exist for the protection of personal data.

— Personal information is classified into different levels of sensitivity.

— In each country a supervisory authority is designated.

— There is always a duty to inform the citizen.

— The access principle is recognized.

Parallel to the legal mandates, there are various voluntary technical standards, of which the most important is undoubtedly ISO/IEC 27001:2005. This standard was designed specifically for the comprehensive management of information security, but at the same time it is flexible enough to adapt to any professional sphere and to the particular features of a specific organization. This is very useful considering the special characteristics of health services, such as their magnitude, the complexity of the care activity they provide and the highly sensitive nature of the information contained in patient health records. Although broad consensus exists as to this last point, the studies conducted to date have revealed significant shortcomings in health services' compliance with data protection regulations and standards.

Taking the ISO 27001 standard as its starting point, this chapter discusses the various lines of action that should be followed by health services:

— A security policy must be defined

— A security committee must be formed

— An inventory of assets must be created

— A detailed risk assessment must be performed

— A plan must be developed to implement specific security measures to respond to the risks detected

— Roles and responsibilities must be defined

— Sufficient resources must be allocated for the proper application of the measures

— The controls and security measures must be implemented

— Efforts must be made to provide training and increase awareness among the staff

— There must be an evaluation process followed by action to further improve information security

Managing electronic health projects

The execution of electronic health projects affects several areas of the health services: care provision, organization, records and analysis of information regarding activity, etc. This means that it is very important that the work teams taking part in these projects include clinical professionals and health managers, in addition to technical experts.

Some key factors to be considered in relation to the execution of these projects are the following:

— Traditional barriers: on the functional level, the low level of interoperability between different systems, and on the financial level, the costs of the development, implementation, maintenance and ongoing improvement of these systems.

— Success criteria: compliance with the expected scope (functional requirements met), time frame (development of the tasks and delivery of results within the period established) and cost (project development takes place without surpassing assigned budget and resources).

— Risk factors: design flaws, flaws in the mechanisms for making decisions, flaws in project management or in the support services provided by suppliers outside the organization. These factors depend to a large extent on aspects such as the nature of the project, the dimension and heterogeneity of the working group or groups taking part, the use of formal project management methods, firm and decisive support by the upper-level management, and the number of final users the system will have.

— Key issues: situation at the outset, budget restrictions, need for validation and evaluation, the attitude of final users, the system's ease of use, data security, use of standards and training of users.

Using systematic methods for project management makes it possible to estimate resources and deadlines in advance and to draw up plans for intermediate milestones that make it easier to control and monitor the project. Some examples of this type of methods are PRINCE2 and PMBOK. The latter addresses various general processes in project management:

— Feasibility study

— Creating a work plan

— Organizing and carrying out project execution

— Monitoring and control

— End of project

To these general processes, various management domains must be added. These are of a more specific nature, because their importance depends on the project's particular characteristics:

— Integration management

— Scope management

— Time management

— Cost management

— Quality management

— Human resource management

— Communications management

— Risk management

— Supply management

Likewise, the management methods can be improved by applying lessons learned during the execution of each project:

— Dialogue and collaboration among designers, implementers and final users.

— Clear and reasoned description of the benefits to be gained from introducing the system.

— Balance between process standardization and the specific needs of each user.

— Clear explanation of the advantages of the system and clear instructions for making the most of these benefits during the user training process.

— Determining security characteristics and functions, in terms of both patients and the data handled by the system.

Infrastructure and basic requirements of electronic health systems

One of the most important ideas that this manual hopes to convey is that the introduction of eHealth is by no means a purely technological project. However, this does not mean that technology does not play a major role, since the different information systems of course need an extensive technological infrastructure with which to work.

The main components of this infrastructure can be classified into three large groups:

— Software, which can be either *application software* (i.e. specific systems, such as eHealth systems) or *system software*, the software elements necessary for the functioning and control of the computers equipment (operating systems, database managers, utilities, programming environments, etc.). Currently, software development is based on layered programming, which consists of dividing an application into several separate levels, so that a change made in one of them does not require that big changes be made to the others.

— Hardware, which is the physical element that hosts the software and enables it to function. In highly critical systems such as those comprising eHealth, it is important to understand options such as high-performance configurations and high availability configurations, and also the possibility of server virtualization.

— Communications network, which allows for collaborative work between the different users of a system. Whether an application functions within a network is one of the most important factors to be considered while defining its structure, beginning with the presence of a server that manages its functioning at a central level.

Software, hardware and communications come together in a very important way in the data processing centers (DPC), the role of which is so critical that very strict security and conditioning requirements must be met.

The management of technological infrastructures in eHealth projects can be a very complex task, and it is worth keeping in mind the following key issues:

— The work team should be comprised of clinicians, technicians, managers, directors and representatives of the suppliers.

— It is important to use standards and established working methods for software development, the management of support and maintenance services and DPC management.

— There must be thorough, medium-term planning of the acquisition of infrastructures, with specific budgets, contracting of specialized suppliers and detailed studies of the features of the components to be acquired.

— Employee training.

A use case: the corporate electronic health project in the Chartered Community of Navarre

Each chapter in this manual deals separately with a specific system or aspect related to eHealth, and with the relationships existing between them, emphasizing that they are not isolated entities but rather the elements of a single macro information system. In other words, the implementation of electronic health requires that great coordination and integration efforts be made while these elements are under development.

To illustrate the dimensions and complexity of an electronic health project, in terms of both resources and execution time frames, this chapter looks at the project undertaken by the region of Navarre in Spain, which began in the 1980s and continues in full swing to this day. The main actions undertaken as part of this project are the following:

— Positive patient identification, based on strict adherence to certain organizational procedures designed specifically to guarantee the quality of the patient database.

— Electronic Health Record (EHR) system that integrates the primary, specialized and nursing levels of care provision.

— Medical imaging, with the deployment of a corporate PACS infrastructure that allows the network load to be distributed and backup systems to be established.

— Medical order management, which covers the following services: Allergology, Digestive system, Cardiology, General Surgery, Pediatric Surgery, Genetics, Hematology and Hemotherapy, Internal Medicine, Nuclear Medicine, Pneumology, Neurophysiology, Obstetrics and Gynecology, Ophthalmology, Radiodiagnostics, Rehabilitation, the Sleep Unit and Urology. Access for primary care professionals was recently established. These physicians can now use this system from their own clinical record application.

— Management of appointments for specialized care, available throughout the care network.

— Electronic prescribing, currently in the pilot phase.

— Use of a corporate infrastructure for the communications network and for the application of security measures, to guarantee the confidentiality of patient information.

In each case, a brief analysis of some particularities and difficulties is presented, while pointing out that despite these advances paper is still widely used in hospitals, mainly for three reasons:

— There are still health systems and equipment not integrated into the EHR system.

— There are professionals who still do not use eHealth systems.

— There is a large amount of information on paper, in documentation generated prior to the introduction of the EHR system.

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Introduction

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The incorporation of information and communications technology (ICT) into health systems (eHealth)[1] is the fruit of a public policy decision to improve the effectiveness and efficiency of the sector, in other words, to meet social and economic impact objectives.

The specificity of the objectives will depend on the varying realities and circumstances of each region and each country. The epidemiological profile and the stage of demographic transition in the area are two of the most relevant factors, along with the extent of social inequality and the geographic dispersion of its inhabitants.

In Europe, for example, it is becoming more and more important to achieve higher levels of patient adherence to the treatment of chronic conditions and to control the costs that these conditions generate. In Latin America and the Caribbean (LAC), on the other hand, the priority continues to be the reduction of the serious limitations that large segments of the population face in accessing high quality and timely healthcare, especially those with the lowest incomes and those who live in isolated areas. Large differences in child mortality –up to four times between the first and fifth income quintiles and up to three times between urban and rural areas– are a clear indication of this situation.

Furthermore, the challenge for LAC is two-fold. Health systems in this part of the world must deal with the overlap of distinct epidemiological profiles, as a consequence of the increase in deaths caused by chronic and degenerative diseases and by external causes, while high rates of perinatal death and death by transmissible diseases persist.

For several years now healthcare services have been facing pressure by citizens, patients, professionals and also by public and private institutions. The ageing of the population, higher standards of living, and more informed and educated citizens mean that both patient needs and patient expectations are growing. These rising demands, along with the appearance of new and costly health technologies and increasing budget restrictions, invite health managers to invest wisely in ICT and to carefully assess its opportunity cost in the current context of rising health expenditure and economic crisis (Carnicero, 2002).

Keeping costs under check, optimizing processes and reallocating resources are certainly ongoing issues for any healthcare system. But they take on even greater importance when, ultimately, they are the factors that allow improvements to be made in primary care coverage for the most vulnerable segments of the population. The tools offered by ICT can play a major role in meeting these challenges.

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[1] The term *eHealth* is commonly used as an abbreviation for *electronic health*.

In Europe, over 25 years of experience has already been gained in the incorporation of ICT into public sector healthcare; 25 years of successes to replicate and also of failures from which to learn. In LAC, on the other hand, the role of governments has been more passive. With a few exceptions[2], most experience in eHealth has been limited to academic projects[3].

Investment in eHealth should be considered a decision of key importance for the health system. This means there must be, in addition to an accurate estimate of costs, an evaluation of its benefits, both in economic terms and in terms of improved quality and efficiency in the services provided. Nowadays ICT tools must be included among the many instruments used in a health system, whose functioning can hardly be conceived without tools of this type (Carnicero, 2010a).

Despite their uneven degrees of development, both regions show a certain tendency to paralyze processes of innovation and ICT incorporation in the health sector. Usually, no further advance is made beyond the definition of terms and the formulation of preliminary ideas and pilot projects. But another phenomenon, a consequence of governments periodically changing hands, is that even initiatives already in the execution stage are sometimes cancelled.

While it is true that financing problems may be at the root of this situation, it is no less true that resistance to the changes brought by this type of innovation can also be a hindrance to the necessary financing agreements. This vicious circle is exacerbated by insufficient dissemination of the projects implemented, by the scarcity and partiality of evaluation studies and by persistent confusion regarding certain concepts, all of which complicate decision-making in investment issues.

Despite the fact that ICT tools have seen considerable development in all sectors, greater knowledge by health authorities and professionals regarding its applications and benefits is necessary in order to speed up the introduction of ICT into health systems. Without conceptual clarity, health authorities will not have enough arguments at their disposal to convince their governments of the need to make the necessary investments.

Conceptual weakness also leads to a deficit of indicators and methodologies with which to measure social and economic impacts. This shortcoming, in turn, makes it difficult for countries to take on projects of greater magnitude and it inhibits the formation of long-term strategies and public policies.

For the past three years, the Economic Commission for Latin America and the Caribbean (ECLAC) has been promoting dialogue and cooperation between Latin America and Europe in the political, social and technological issues related to the incorporation of ICT in the health sector. The Commission has created a regional working group to strengthen South-South cooperation[4] in this field, and the Pan-American Health Organization (PAHO) recently selected this group to be the advisor to its Knowledge Management and Communications area[5]. In addition, ECLAC has systematized information concerning the regional progress made in the formulation of eHealth policies and strategies, comparing their context and evolution to those of the European Union. It has also worked on the identification, definition and prioritization of social, demographic and epidemiological indicators to accompany the

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[2] One important national public policy initiative that is gaining strength can be found in the national telehealth program in Brazil.

[3] Private hospitals, however, are making significant progress in the incorporation of ICT.

[4] This group is comprised of 31 specialists from 11 different countries in LAC. The SEIS collaborates regularly.

[5] Third Ministerial Conference on the Information Society in Latin America and the Caribbean, held in Lima from 21-23 November 2010.

formulation of eHealth policies and strategies in an effort to reduce inequalities (Fernández, 2010a; Carnicero, 2010b; Fernández, 2010b).

The origins of the Spanish Society of Health Informatics (SEIS) date back to 1977, the year the Spanish Society of Medical Informatics (SEIM)[6] was founded. The Society's activities include preparing reports or opinions within the field of health ICT, when requested to do so, promoting publications that provide information and facilitate communication among members, collaborating with national and international entities with similar aims, publicizing the opinion of eHealth professionals and encouraging debate on the problems and progress of this sphere.

In 2010 SEIS published a text entitled *Strategic Lines in Health Information and Communications Technologies in Spain.* This text summed up the Society's proposal to strengthen ICT in the health sector in Spain, keeping in mind the specific characteristics of this country's National Health System, its participation in the construction of the European eHealth initiative and, of course, the global dimension of today's society (SEIS, 2010). These lines of strategy include the promotion of policies and strategies aimed at increasing the presence of health ICT in governmental administrations and health organizations, and the activation of international cooperation.

It is in this context that ECLAC and SEIS have been working together –since the middle of 2009– to promote political dialogue between Latin America and Europe, identify significant experiences, propose strategic alignments and cooperate with governments in order to introduce ICT into health public policy.

Primary challenges

Europe shows great achievements, and quite varied ones, in eHealth, albeit with certain heterogeneity from country to country. One common feature, which marks a difference between Europe and Latin America, is the extent of government involvement. Such involvement can be at the national, regional or local level. This commitment by the State is no doubt related to the fact that public healthcare systems play a very important role in Europe, where there is universal health coverage and government funding for health services.

However, the European countries that have set up eHealth services still face significant challenges, such as the incorporation of new functionalities or the expansion of the ones already in place, and the integration of legacy systems into the new ones. In the first case, for example, one of the most difficult tasks has been implementing Electronic Health Records (EHR) in hospitals; this task is still pending in many places, although it is essential in achieving better integration between care levels and greater patient safety.

But furthering the integration of legacy systems also requires greater effort in order to keep projects on schedule, in other words, to achieve political and financial stability. The government changing hands after elections, with the appointment of new authorities to manage health systems, can have a negative effect on the continuity of strategies and on financing, even in the absence of a severe economic recession like the one currently underway.

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[6] In 1990, SEIM made significant changes to its orientation, objectives and organizational set-up, prompting it to adopt the name currently used.

Despite the foregoing, the main challenge for the European Union at this time is to implement eHealth at the cross-border level, to ensure that the new demands and needs arising as a result of increased citizen empowerment and mobility can be met. To be able to guarantee the quality of the care received by patients when they are not in their countries of origin, health systems must be capable of exchanging clinical information.

In response to this situation, the European Union has undertaken two projects (Carnicero, 2010b) which, in turn, offer Latin America a valuable source of formative material in the area of technical-political dialogue, which will be useful for the Latin American experiences that are just getting started. First there is the European Patient – Smart Open Services (epSOS) project, which aims to make patient summaries available so that health professionals all over Europe can quickly find essential information about any patient who needs health services while outside his or her country of residence. Included in this project is the functionality known as e-prescribing, which makes it possible for a patient to acquire needed prescriptions regardless of where the medication was prescribed and where the patient is at the time of dispensation.

A second project is the CALL for InterOPErability: Creating a European coordination network for eHealth interoperability implementation (CALLIOPE). The objective of this project is to create forums and platforms for dialogue and collaboration among EU member states, with a view to developing unified eHealth services and a network that has cross-border interoperability within the European Union, and also to share experiences, results and best practices.

Along with these two initiatives, several Baltic countries are engaged in a project called Baltic eHealth. Its aim is to promote eHealth in the rural areas of Denmark, Estonia, Lithuania, Norway and Sweden through the creation of a transnational network, by connecting the national and regional networks already in place in these countries. This larger network is intended to facilitate service provision across borders, the main service being telemedicine, which is desirable due to the population's geographical dispersion. This network will guarantee that people have access to healthcare throughout the territory, and will help counter the loss of population in rural areas.

Furthermore, the adoption of the EU Cross-border Healthcare Directive[7] confirms the commitment of European institutions to guarantee citizens the right to high quality healthcare regardless of where such care is provided. The importance of eHealth is highlighted in Article 14 of this Directive, which calls for the creation of a network that brings together, on a voluntary basis, all the national authorities responsible for eHealth, as designated by member states. The network's objectives are to draw up guidelines to allow the clinical information of citizens to be shared for purposes of care provision and research, to promote common measures for the identification and authentication of patients and professionals, to obtain healthcare with higher levels of quality, continuity, efficiency and accessibility, with the economic and social benefits that this will bring.

To this end, a proposal for a Joint Action was submitted to the European Commission and accepted. The Joint Action takes the form of the eHealth Governance Initiative (eHGI), the objectives of which are: (1) to overcome the barriers between governance, strategy and operational levels that currently hamper the progress of eHealth and (2) to establish a structured, efficient and appropriately managed platform to support member states in the identification and analysis of existing and emerging challenges, and the deployment of interoperable electronic healthcare infrastructures and services.

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[7] Directive 2011/24/EU of the European Parliament and Council of 9 March 2011 on the application of patients' rights in cross-border healthcare. OJEU of 4 April 2011.

In Latin America the concept of telehealth is becoming more and more present. The term telehealth is somewhat broader than telemedicine, as it encompasses telemedicine but also can refer to distance learning for purposes of training or ongoing education for health teams in large geographic areas with a shortage of specialized human resources or with limited access to education and training programs.

Some telehealth plans are maturing, such as in the case of the Institute of Security and Social Services for State Workers (ISSSTE) in Mexico, and debates are underway to take projects beyond the pilot stage, for example in Ecuador, or in Peru, which has had a national plan, approved by Executive Decree, in place since 2005. Colombia, for its part, recently passed Law 1419 (2010) which lays the foundations for the development of telehealth programs and also addresses sources of financing.

Nonetheless, most of the experience in telemedicine and telehealth is found in the university setting, and many initiatives have been, or continue to be, academic projects with little financial sustainability and low population coverage. Some of these projects, however, especially those involving the private sector or those supported by favorable legislation regarding donation, have reached greater visibility and a certain degree of financial stability.

In Latin America, the main challenge is to generate government-university alliances that can rescue and further develop these experiences, with a view to implementing them at the public healthcare level. A good example of this can be found in the strides made in Brazil towards a telehealth model.

Since the beginning of 2000, when demonstration eHealth projects began to be implemented in Brazil as part of the European Union @LIS program, there has been steady growth in internal dialogue, with positive repercussions on interinstitutional associations. This has enhanced the sustainability of the Telehealth Core Groups involved in service provision in the area. Many such core groups, which are located in universities, now provide services for the public sector.

It was in this context that in 2004, in parallel to the foregoing, the University Telemedicine Network (RUTE) was created, also as a result, in part, of the @LIS program. RUTE works to improve the telemedicine infrastructure that already exists in university hospitals and it supports the integration of projects among participating institutions. It is an initiative of the Ministry of Science and Technology, and receives support from the funding body FINEP and the Brazilian Association of University Hospitals (Abrahue), with the coordination of the National Network of Teaching and Research (RNP).

The program links family health teams to specialists based at universities so as to facilitate diagnosis and educational second opinions, and also to set up ongoing training programs. At this time there are 1,100 connection points throughout the country. The progress achieved in this area can be attributed to the National Telehealth Program, which has been in place since 2007 and was recently redefined and broadened (October 2011). It is now called the Telessaúde Brasil Redes.

The road to innovation in health is certainly not a smooth one. However, experiences like the ones described above show that progress can be made, but for this to happen participants must have long-range vision, there must be effective channels for participation by different stakeholders and sufficient intersectorial and interinstitutional coordination must exist.

Concepts, functionalities and benefits

Making ICT tools a part of the health sector, what we call eHealth, opens up a multitude of possibilities. Applications can cover many if not all of the activities related to prevention, diagnosis, treatment and follow-up, and they can also be of great assistance in planning and supervising tasks related to health management.

The concept of eHealth encompasses applications as diverse as electronic health records, different types of telemedicine, epidemiological surveillance, health portals, management systems and distance learning programs focused on health and medicine. Its users and beneficiaries are equally diverse. The applications help meet the needs of health professionals, those of patients and their families, those of healthcare authorities and experts and also those of input and service providers, among others. Most of them are discussed in the different chapters of the handbook.

There can be no doubt that eHealth represents an equitable, effective and efficient way to increase accessibility, safety and quality in healthcare. eHealth tools can be used to increase the availability of medical resources, thus optimizing care processes. They enable specialized knowledge to be taken to different places or to isolated locations, through distance appointments or teleconsultation[8]. They facilitate the provision of timely healthcare, partnership projects, etc. They can also help reduce the costs incurred by systems and by families.

Health services tend to make intensive use of existing data and they also constantly generate new information that is vital in the institution's ability to do its job. So, particularly in a field such as health, the application of ICT can play an essential role in reaching quality and efficiency objectives. Furthermore, the implementation of eHealth services exerts something of a traction effect on the ICT sector, which finds itself obliged to emphasize innovation and R&D; eHealth thus has a beneficial effect on the economy as well.

In eHealth, two large spheres can be distinguished from one another, for purposes of analysis. There is, on the one hand, what is known as health informatics, that is, technological solutions for applications used to provide care, which allow information to be recorded and processed: electronic health records and department-specific applications, population management systems and systems that support planning and management are a few examples. And, on the other hand, there is telemedicine, which refers to health services and care provided from a distance. Applications already exist for many of the specialties: teleradiology, telecardiology, teledermatology, teleophthalmology, telepathology, telepsychiatry, and others[9].

As regards its educational potential, eHealth offers an array of possibilities, from systems designed to help convey useful information and messages of a preventive nature to the community in general, to university portals designed to provide training and skill updates to health professionals. Especially relevant are the distance learning opportunities eHealth brings to people who live and work far from the main teaching centers, with the positive effect that such opportunities have on professionals' willingness to accept and stay in positions in isolated areas. Similarly, it can reduce the need for professionals to temporarily be away from their clinical activity for training purposes, it minimizes interruptions in the care provided to people living in isolated areas and it enables professionals to further their training with no loss of salary and no negative effects on their family life[10].

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[8] Teleconsultation refers to interprofessional consultation between doctors in different places.
[9] See Chapter VII.
[10] See Chapter XIII.

As mentioned above, the concept of telehealth – understood as the integration of telemedicine with distance learning opportunities – is becoming increasingly prevalent.

As for hospitals, it is no longer possible to conceive of them without a hospital information system (HIS) with which to manage their always scarce resources. Among the range of applications that have been developed, especially worth highlighting are those used for scheduling activities and for managing patient records, admission and discharge. The HIS also makes it easy to furnish the economic/financial management systems with the information they need[11].

One of the most valuable instruments, due to its administrative and clinical applications, is the electronic health record, or EHR. EHR systems allow all patient-related information to be recorded digitally; they make it easy to manage the results of any complementary tests performed and of prescriptions and interventions that have been ordered. In the clinical area, they provide decision support because they give health professionals contextual information that is useful in making diagnoses, choosing among treatment options and prescribing pharmaceuticals. Additionally, data aggregation processes make it possible to generate reports for epidemiological surveillance. Also important is the fact that they provide a means of communication between members of the health team and the patients, which shortens the time needed to arrive at the correct diagnosis and treatment and also increases care continuity. In terms of benefits for patients, these systems enable patients to have immediate access to the health information appearing in their medical record, they help patients monitor their chronic conditions and make notes of their ailments[12].

The management of clinical orders is one of the most critical processes for achieving efficiency and quality in healthcare, because this is the system that links all the different clinicians involved in the care of a particular patient. The strides made in this area – from a handwritten slip of paper, illegible more often than not, to a genuine information system – have been made possible by ICT[13].

Similarly, laboratory information systems (LIS) have evolved from simple electronic records to the automation of many of the lab's operational processes, greatly increasing productivity and facilitating the planning and execution of lab work. When the LIS is integrated with the EHR system, through a clinical order management module (commonly known as a CPOE system, for Computerized Physician Order Entry) information can move quickly among the clinicians providing care and the professionals in the laboratory, thus reducing the time that passes between the sending and the receiving of the clinical orders and their results[14].

The incorporation of ICT also means better management of images and reports in anatomic pathology services, guaranteed traceability of the processes taking place therein and the possibility of performing telepathology[15].

The arrival of digital medical images has brought great changes to radiology services. The use of radiology information systems (RIS) and picture archiving and communication systems (PACS) allows improvements to be made in organization, in diagnostic procedures and in network-based activities. They also play an essential role in teleradiology[16].

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[11] See Chapter I.
[12] See Chapter II.
[13] See Chapter III.
[14] See Chapter IV.
[15] See Chapter V.
[16] See Chapter VI.

The case of teleradiology is a clear example of the advantages of telemedicine. Small or rural communities that cannot sustain an on-staff radiologist can benefit a great deal from professional activity performed at a distance. Local hospitals can send images to a larger care center in order to obtain a second opinion, whether from the general radiologists who work in such centers or from radiologists with particular subspecialties. Emergency rooms can send, any time day or night, their images to affiliated centers or even to the homes of radiologists. Teleradiology as a teaching tool can also enhance the quality of ongoing medical training. And finally, teleradiology offers direct benefits to the patient, by reducing the costs of transportation, accommodations and board that would be incurred if the patient had to travel to where the doctor is based[17].

Medication is the most frequently used health technology and a significant proportion of health expenditure goes to pharmaceuticals. Making rational use of them has become a top priority in all health systems. Fully integrated pharmacy management includes, among other processes, the prescription, acquisition, dispensation, invoicing and payment of medications. This process involves hospitals, primary care centers, dispensing pharmacies, professionals, patients and the health system[18].

As mentioned above, the increasing globalization of today's world indicates the need for cross-border services that use ICT. This new situation brings specific requisites in terms of interoperability and also legal requirements that must be taken into account[19].

The use of ICT can also bring significant improvements to the management of public health, in terms of areas of surveillance and also in the planning and overseeing health service management. ICT tools contribute to the design of safer, timelier and more reliable processes for data gathering and storage and also to better statistical use of the information. This has positive repercussions on the effectiveness and efficiency of the macro system that encompasses everything from the analysis of health needs and problems to the evaluation of health outcomes obtained in the population[20].

Advances in ICT can also take the form of extremely useful systems designed to manage data security, allowing accurate and complete information to be available when and where it is needed, but only to authorized persons[21].

eHealth has quickly become a powerful tool with which to optimize processes and improve resource management and planning. Its impact on clinical activity and patient safety has been very positive. However, interoperability between systems is a fundamental element for achieving the integration of different information systems. Many of the potential benefits of eHealth will never be attained if this condition is not met[22].

With the expectation that it will be useful in decision-making processes, this handbook also addresses two other relevant topics: the management of eHealth projects and their requirements in terms of technological infrastructure. The first of these topics points out the traditional barriers that must be overcome as well as the success criteria and risk factors that must be considered while designing and

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[17] See Chapter VIII.
[18] See Chapter IX.
[19] See Chapter X.
[20] See Chapter XI.
[21] See Chapter XVI.
[22] See Chapter XV.

monitoring the execution of such projects. It also sets forth some of the lessons learned by others, which can be useful in fine-tuning project management methods[23].

With regard to the second topic, it is important to keep in mind that an eHealth project is, first and foremost, a health project. However, information systems need extensive underlying technological infrastructure upon which to function. For this reason, the requirements in terms of software, hardware and communication networks are identified and described[24].

Finally, in its description of the corporate electronic health project undertaken in the region of Navarre, the last chapter discusses the coordination and integration efforts that are necessary in a real case of the implementation of this type of innovation[25].

It is our hope that this publication will help clarify concepts, explain functionalities and applications, identify benefits and caution against risks and difficulties and that it will therefore be useful for managers and directors of health systems and services and other decision makers involved in the formulation of public policies and strategies in the field of health. The aim of this work is to contribute to eHealth becoming part of the general health strategy. Ultimately, the challenge is a political one: it requires that all members of society make their voices heard and that the right to health finally be recognized as such.

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[23] See Chapter XVII.
[24] See Chapter XVIII.
[25] See Chapter XIX.

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Chapter I

Hospital information systems

Alberto García

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Summary

A HIS (Hospital Information System) is an integrated information system designed to manage all clinical, administrative and financial aspects of a hospital. It also allows general statistics to be obtained on patients, epidemiology, occupational health, public health, etc. These topics will be further developed in specific chapters of this book.

The HIS can be comprised of one or more software components and a wide variety of subsystems for different medical specialties, such as the RIS (Radiology Information System), LIS (Laboratory Information System), AP (Anatomical Pathology) systems, etc.

In this chapter we will focus on the administrative process carried out in connection with every patient, for either hospital care or ambulatory care provided at appointments with specialists. The process follows the logical steps that must be taken, which are; identifying the patient (personal data), requesting the services, scheduling the appointment(s) for such services and the actual provision of the services.

We will also analyze the particularities of patient hospitalization, in terms of both admission management and the control of patients admitted to a hospital unit. Because of their importance at the hospital, there is a section devoted to the special cases of emergency services and the management of operating rooms.

Finally, brief mention will be made of the statistical use of the information generated, for the benefit of hospital management teams and the different departments in the hospital.

Introduction

Hospital information systems were developed in the 1950s to assist in the administrative aspects of patient management, i.e. they were records of the activity performed on patients, and included systems to manage product supply and stocking, financial and accounting matters, etc.

In the 60s, 70s and 80s, independent systems were developed within hospitals to meet the information needs of specific departments or sections. At the same time, centralized information systems became more functional, enabling them to better address the needs of medical and nursing staff. As a result various information systems co-existed at hospitals, often with duplicate information and

with no connection or integration among them. Thus, a single patient had to be registered in all the different hospital subsystems that were involved in that patient's care.

Starting in the 80s and throughout the 90s, great efforts were devoted to integrating all the information systems, a task which was facilitated by the development of personal computers, local network technology and the reduced price of hardware.

For the past 20 years the tendency has been to develop decentralized subsystems that are specialized in addressing specific problems. These systems obtain necessary information when they need it and make the most relevant data available to the other systems to which they are connected. Of particular interest among these systems are the RIS/PACS (Radiology Information System and the Picture Archive and Communication System), LIS (Laboratory Information System), anatomical pathology information systems, etc. These are all described in more detail in later chapters.

Another important subsystem in the HIS is what is known as the "clinical station," which can be designed for use by either medical or nursing staff. It contains the patient's clinical information transmitted by the subsystems of the different medical specialties present at the hospital and the information generated by the main HIS system. The clinical station brings together the data that make up each patient's electronic health record (described in another chapter) and thus constitutes one of the main tools enabling health professionals to provide care to patients.

Currently, although any information subsystem used at the hospital in relation to patient care is considered part of the HIS, when people speak of the HIS often they are referring only to the system that manages the administrative aspects of patient management.

The first section of this chapter provides a brief description of the permission system that a HIS must have, both to enable actions to be performed within the system and to allow information to be viewed.

The rest of the chapter describes the process that a patient in need of hospital care would follow. Figure I.1 shows the example of a patient who asks for an appointment with a certain specialist. In this case the patient is seeking a cardiological evaluation. The process for a hospitalized patient is similar, while naturally in the case of emergency care no appointment is made.

To make the appointment the patient must be identified in the system, or registered in it for the first time, whichever is appropriate. These procedures are described in the section Master patient index. In order to make the appointment, the service that is to be requested must first be selected. It is therefore necessary to have previously described and characterized the basket of services available at the hospital, a task which is dealt with in the section Defining services. Once the patient and the service have been identified, the service is requested, as described in the section Requesting services. This topic is addressed in more detail in other chapters so this section will be limited to a description of some of the issues that can affect the appointment-making process.

The next step is to make an appointment for the service that was just requested. Before looking at the appointment-making process, the section Configuration of agendas describes how the agendas of the resources involved must be configured in order to optimize the use of these resources. Then the appointment is scheduled, as described in the section Appointment-making process.

On the day of the appointment, the patient goes to the hospital, so once again the master patient index will be used to correctly identify the patient. The patient may carry the document with details about the appointment. At the hospital's Admissions service, the patient is admitted to the hospital, through a process described in the section Patient admission. The patient then goes to his or her appointment with the specialist, as described in the chapter Provision of services. The specialist can request one or more services, such as a CAT scan (managed by the RIS, with images managed by the PACS), or lab work (managed by the LIS). The medical findings, along with any other data entered and the rest of the information in the patient's clinical record, can be consulted at the clinical station. The specialist can see the patient again to explain the diagnosis obtained and the treatment, as appropriate. The specialist prepares a medical report, either through the clinical station itself or through a specific application, and if payment is required, the administrative system prepares the corresponding bill. There may also be many other subsystems at the hospital, not appearing in Figure I.1, which ideally will be connected to each other and fully integrated. Normally, specific tools are used to connect programs with others, called service integration buses or engines, meaning that the subsystems do not actually communicate with each other but rather with this bus, which is in charge of managing the information flows.

Figure I.1. Diagram of patient care (Source: Compiled by author).
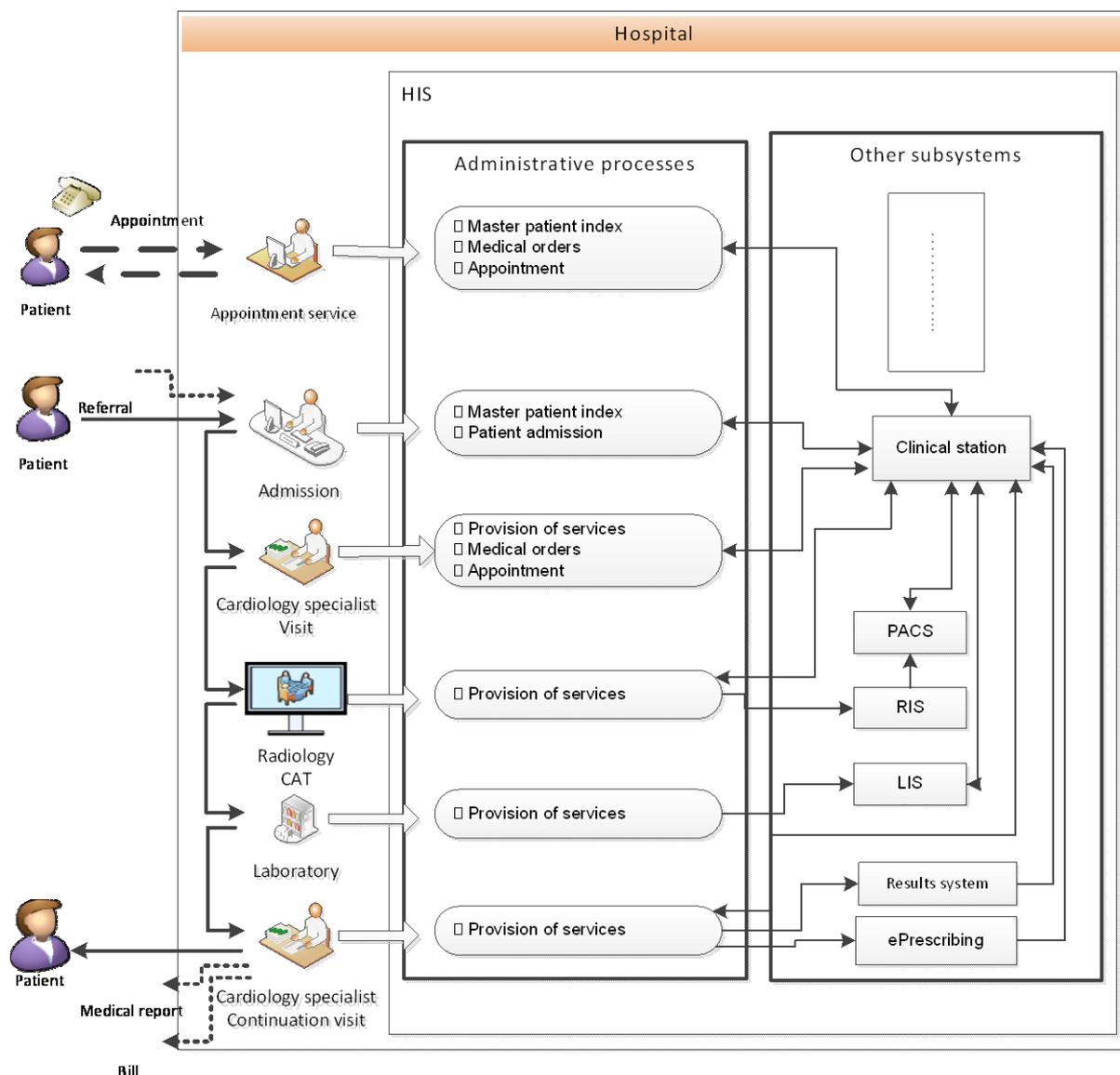
The configuration chosen for the processes described above, along with the other HIS subsystems, should reflect the strategic plan that the administration wants to implement in the hospital. The HIS is a tool that can be used to help adjust a hospital's policies to the strategic objectives it has set.

Security configuration

One of the first steps to be taken in developing a HIS is the definition of the system users and their levels of access. Shared user names should not be allowed; all of the user names must be personal. In other words, each person using the system should have his or her own user name that is personal and nontransferable.

Institutions must draw up and constantly update what is known as the "security document," which details the security characteristics required of the automated files, local files, equipment, systems, programs and people involved in the computer processing of personal data, both that of patients and of other people associated with the hospital.

When a user is going to interact with an information system various steps must be taken:
1. The first step is for the person to identify him or herself in the system, that is, the user says who he or she is.
2. The second step is authentication, by which the system verifies the identity of the person who wants to access the system. In general there are three possible authentication methods:
   — Systems based on something known by the user. This is the case of the user name/password system.
   — Systems based on something possessed by the user. This might be an electronic ID card, a personal card provided by the institution, etc.
   — Systems based on a physical characteristic of the user. These are known as biometric methods, based on the analysis of the person's fingerprint, iris, etc.
   If the institution opts for a user name/password system, the security document needs to specify the characteristics that the password must have (length, uppercase/lowercase, letters/numbers) and how often it must be renewed.
3. The third step is authorization. In compliance with data protection laws, each user must be allowed to access only the functionalities and patients that are necessary for that person to perform his or her job. Also to be taken into account is the issue of types of permission, that is, whether a given user has permission to enter new data or modify existing data, or only to view it.

It is also important to keep track not only of when and by whom information is entered or modified, but also the specific access of each user to information pertaining to each patient (when access took place, who viewed the information, who the patient was and what the user viewed). Patients are entitled to know this and it is the institution's duty to gather this information and audit it regularly, as the security document should indicate.

The subject of information security is addressed in greater depth in another chapter.

Master patient index

One of the first steps in using a HIS is the entering of patient data. All information systems include some amount of data about their patients, such as their full name, sex, address, telephone numbers, e-mail, ID number, Social Security number, etc.

Traditionally, each hospital has used a unique identifier for each patient, called the clinical record number. This kind of identifier has been in use since before current information systems. It provides positive identification of the patient in that particular system and normally it is widely used within the hospital. On occasion these identifiers have been extended to a regional health system but generally each hospital has its own, so a patient who is registered in two hospitals in the same or different regions will have two different clinical record numbers.

As indicated previously, a HIS can consist of various subsystems, the vast majority of which handle patient data. Often each subsystem will have its own master patient index. Thus, one issue that must be dealt with is positive patient identification in all the HIS subsystems, to allow information to be exchanged between them. This positive identification, in most cases, is the clinical record number. Systems that permit communication between subsystems and that maintain this positive identification must be developed and integrated by means of integration buses or similar tools.

In addition, in order to exchange patient information between regional and national systems, etc., it must be possible to identify the patient in the same way in the various systems involved. Other chapters will look more closely at interoperability between systems and the exchange of clinical information at the international level.

Spain is trying to use the individual health card (TIS for *tarjeta individual sanitaria*) as a unique identifier. The TIS is the document that accredits each citizen's right to receive care from the public healthcare system. Each autonomous community that holds powers in the area of health issues this card to its citizens. Although this may appear to be an ideal solution, it in fact has some problems, since the initial intention of the card was not to provide positive patient identification but rather to demonstrate that citizen's right to receive care. Other countries have adopted solutions that are more or less similar to the Spanish one.

All the information systems must use the same identifier for each patient if they are to achieve interoperability, that is, be capable of sharing patients' clinical information.

A serious problem that sometimes arises in daily activity is the risk of duplicating a patient in the master patient index. For example, patients who are registered under a compound name (for example, José Manuel or Betty Sue) may come to the hospital and identify themselves only with the part of the name they use habitually (Betty or Manuel perhaps). If no further verification is made, that person will be identified as a new patient and a new medical record will be opened. To avoid this problem to the extent possible it is necessary to follow a hospital-wide procedure for the identification of patients in the system. One method is to ask the patient various questions, such as name, last name and date of birth. If the person has a document that proves his or her identity the likelihood of error is much lower (although there is always the risk of mistakes while transcribing an ID number), but sometimes the patient does not have one (as in the case of children or foreigners) or is not carrying it at the time (in the case of emergencies, etc.). Once the patient data has been obtained, a search is performed on the master index. It is quite valuable to be able to perform phonetic searches of names, because sometimes there is

uncertainty as to how the name was entered into the system. Patient identification should always involve more than one piece of information, to minimize the chance of mistakes.

One way to greatly reduce the chance of mistakes in the identification of patients who are physically present is to use biometric characteristics, the most convenient of which may be the fingerprint. It is important to remember that these systems are not fail proof nor are they always applicable to all patients, so an alternative method must also be available at all times. In addition, the idea of saving biometric data may meet with resistance by patients.

The problems caused by having duplicate medical records are varied and quite serious, in terms of both organization and healthcare provision. For example, health professionals may not have access to important medical information when treating a patient (if for example patient allergies are specified in one record but another record is being viewed), services may be requested repeatedly, etc.

There must always be a tool that allows two different records of the same patient to be merged. Furthermore, this unification has to take place not only in the master patient index of the HIS, but in all of the hospital's subsystems as well.

It is easy to see that the price of having duplicate records is much higher than the extra work of establishing and following a protocol for correct patient identification.

Definition of services

The term "services" refers to all actions that can be performed in relation to a patient, such as diagnostic tests, therapeutic procedures, visits with doctors, nurses or other groups, surgical interventions, interdepartmental consultation, etc. This chapter does not look at the prescription of medicines because this matter is discussed in detail in another chapter.

Similarly, how to manage service requests is the topic of another chapter, so the contents of this section will be limited to service characteristics that may have an influence on the making of appointments for patients:

— First of all, there is the issue of whether the service in question needs to be scheduled (which means that it follows the entire appointment-making process) or can be provided on demand (with no need for an appointment). Most services require that an appointment be made in advance. For example, although the examination of a biopsy in the anatomical pathology division probably does not require a previous appointment, the taking of the biopsy in the dermatology unit most likely will require one.

— Validity period of results. This informs the person requesting the appointment that there is already a valid result for the same action, and it is therefore not necessary to request it again. This avoids unnecessary expense, further inconvenience for the patient, etc.

— Special conditions for service provision. These can be used to add conditions to the search for available times in the resources involved in the provision of the service.

— Whether the appointment can be made only by the department that will provide the service.

— Type of resources that will intervene in the provision of the service. "Resource" means any room, equipment, person, etc. that is used in the provision of the service. In general, specific resources are not named, but rather the type of resource. Thus, for an appointment in Internal Medicine the type of resource indicated will be "Internal Medicine Specialist." This way, the appointment is independent of the doctors who are defined in Internal Medicine at any given time. Normally, each

service for which appointments are scheduled will have only one type of resource linked to it, and to which the appointments are assigned (hereafter referred to as the "primary resource"). This resource should be the scarce one, that is, the resource whose availability conditions the provision of the service. In the case of visits with doctors, this is usually the doctor, while in diagnostic tests it tends to be the equipment or the room in which it is performed. Sometimes a given service has more than one scarce resource but for the sake of simplicity only one of them is used. Besides the type of resource linked to the appointment the other types of resources that intervene in the provision of the service must be defined. For example, in the definition of a colonoscopy, the room may be the primary resource linked to the appointment, but the endoscopists, the nurses, auxiliaries, etc. must also be defined. This is important because it allows data to be compiled on the workload of the hospital's resources.

— For each type of resource involved in the provision of a service the estimated time that the resource will be occupied is defined. When the appointment is made, the time that must be kept in mind is that of the resource linked to the appointment. In addition to these times, the time that the patient will be occupied during the provision of the service can also be defined, which may not be the same as the time of the primary resource. For example, a CAT scanner might have two booths in which patients get ready for the test. The time the CAT scanner is occupied is calculated from the time the test starts until it is finished, while the time the patient is occupied is greater, because it includes preparation and the time needed to get dressed again after the test. So, while one patient is in a booth getting ready for the test, another patient can be tested and another patient can be getting ready to leave.

Managing service requests

This topic is addressed later in the book, in the chapter devoted to medical order management. Here just a few aspects will be discussed, mainly for purposes of continuity in this chapter.

Once the patient has been identified in the system, the second action is usually to make a request for a service. Sometimes the ideal date for the appointment is indicated as an additional piece of information, and the appointment-making module should allow for this.

In general the request for a service is distinct from the making of the appointment. Some services do not require that an appointment be made, for example, certain tests in hospitalized patients, tests associated with others, etc.

In general all the departmental information systems have their own module for service requests. Some years ago, each system had to be accessed individually to be able to make a request for a patient, but current HIS integrate service requests in one place. The HIS must then transmit this information to each subsystem.

After a service has been requested, before the appointment is made, the request may be put on a waiting list. This waiting list is comprised of all the services for which appointments still need to be made and which are generally linked to the same type of resource. Various types of priorities can be set in connection with the scheduling of these appointments, depending on the needs of each hospital.

Configuration of agendas

The first step to being able to make appointments for a service is to define and configure the agendas of the resources involved in the provision of the service.

Having resource agendas that are correctly configured is essential in making the best possible use of each resource. Another important matter, which sometimes clashes with the foregoing, is giving the agenda enough flexibility, so that space can be reserved for services, patients, etc. under certain conditions. For example, in a doctor's agenda a given time slot on certain days can be reserved for urgent interdepartmental consultation. However, if it turns out there are no appointments for services under these conditions on a given day, it should be possible to fill these time slots with regular services. The way to condition the appointments in certain spaces is to introduce restrictions that the service requests must meet in order for the appointment to be made, as discussed below.

The first step in configuring an agenda is to define time slots, specifying a starting time, an ending time and the days of the week that they apply. In each of the slots the services or groups of services for which appointments can be made must be defined. For example, a doctor may have Monday through Thursday from 09:00 to 14:00 reserved for new patients and follow-up appointments, with Friday being saved for interdepartmental consultation.

Sometimes it is worthwhile to specify a maximum number of services of a given type that can be performed during a time slot. This is the case of a doctor who limits the number of follow-up appointments so that there is always time for seeing new patients.

Time slot restrictions make it possible to reserve or exclude certain spaces in the case of services that meet certain conditions. As discussed in the preceding paragraph, the first restriction is to limit the services performed per time slot. Further examples of restrictions include:

— Exclude services requiring anesthesia, when there is no anesthesiologist available during that time slot.

— Exclude hospitalized patients from diagnostic tests performed in time slots when ambulatory patients could make better use of them.

— Differentiate time slots in equipment depending on whether the diagnostic test is to be performed on a new pathology or if it is a follow-up. In the latter, explorations tend to be more focused and the specialist's supervision does not have to be as exhaustive.

— Include a specific time slot for diagnostic tests and therapeutic procedures performed on children, because of the special care these patients require.

— Reserve certain time slots for urgent tests or procedures.

Each hospital must configure both the best time slots for resources and also the restrictions best suited to the hospital's functioning. Introducing restrictions in resource agendas can result in time not being fully optimized, with time slots left unoccupied because there are no service requests that meet the restrictions.

One way to avoid this problem is to define certain periods of time (hours or days) in which restrictions are not in effect. For example, 24 hours before the selected date the restrictions do not apply, and therefore the time slot is open to all types of appointments for that resource. So, if a time slot

has been reserved for performing abdominal CAT scans on outpatients, 24 hours before the selected date appointments can also be made for hospitalized patients.

Lastly, it is also necessary to determine the way appointments will be made, that is, how the search for spaces for each of the services will be performed. The simplest way is to divide the time slot into equal intervals, so that each service occupies the same amount of time in the time slot. This system is valid when the services take a similar amount of time.

Often, however, there will be services that take considerably different amounts of time, in which case the aforementioned system will produce inefficiencies. It is possible to design distribution systems that allow for spaces of different duration, in an attempt to make the best possible use of time. Such systems are more complex and are therefore beyond the scope of this chapter.

Another special case that may exist is the possibility of two services occupying the same space, such as when an attending physician is on duty with a resident. The resource linked to the appointment is the attending physician but actually two patients can be seen, one by the attending physician and the other by the resident.

Finally, for each resource, its location in the hospital must be defined, in a way that allows the patient to find the physical space in which the service will be provided. This information will also appear in the "care program" that is described below.

Appointment-making process

Once a service has been requested for a patient, the appointment-making process begins. Sometimes there will be various services for which appointments are needed, so it is important to co-ordinate among them.

The first step is to select a range of dates in which to look for available times, one of which will be chosen to match the patient's preference. Usually the search is for the available time closest to the current date, but in the case of scheduled follow-up appointments, it is also possible to search for available space next month or in a year's time, for example.

For each of the services for which an appointment is to be scheduled, a search is performed for the type of primary resource. The system searches, within the specified time period, for available times in the time slots defined for this type of resource.

The system must take into account all the restrictions defined in the time slots, to then show the available times. One option worth considering is the possibility of showing available times that last a certain percentage of time less than the service lasts. This way, if a service lasts 50 minutes and there is an available space lasting 45 minutes, it will also be shown, if the defined percentage is sufficient.

It is also sometimes useful to group resources that share a particular characteristic, so that only the times available for these particular resources are shown. This may be the case of some of the physicians within a department who are highly specialized in a given pathology.

Once the system has shown the times available for the specific resources, the patient is given the opportunity to choose according to his or her preferences. Before the appointment is made, the system must check that the times do not overlap and that the restrictions related to interactions between tests are respected. In other words, the system knows if a particular service cannot be performed within a certain amount of time of another one. This may be the case for diagnostic tests that use contrast media and for colonoscopies.

Also, if the service has a validity period defined for its results, the system will inform the user if the same service has already been performed on the same patient and the results remain valid, when this is the case, and then give the user the option of continuing, changing the date or canceling the service.

If the service is linked to two different types of primary resources, the appointment system must find the times that both of them are available. This situation complicates the appointment-making process considerably and should be permitted only in exceptional cases.

In any event, there should always be a manual appointment-making system that can be used for a service in a given resource, even when it is not the right time slot or has no available times. Sometimes what is restricted is the type of user that can make appointments manually. Generally it is limited to just some of the users within the department to which the resource belongs.

Another feature that may be useful is being able to identify appointments that can be brought forward from the date originally given by the system, in the event that an earlier date becomes available. The option of assigning an earlier date is not applicable to all appointments; for example, if it is a scheduled follow-up appointment it must be on the appropriate day and not before it. But it is valuable to have a system by which appointments can be brought forward when other patients' appointments are cancelled.

As mentioned in the section on the definition of services, various resources are involved in the provision of any given service. Giving an appointment to a patient is much more than telling him or her to go to a certain place at a certain time. Various hospital resources must be mobilized in a coordinated fashion in order for the service to be provided. Taking into account that these resources may also be involved in providing other services, it is easy to see that having a correctly-configured appointment-making system contributes a great deal to making the most of hospital resources. A good, coordinated system enables the same resources to provide more services, with the resulting reduction in waiting lists, etc.

However, the entire appointment-making system is useless if the patient does not show up for the appointment or if it is cancelled for other reasons. Certain departments of certain hospitals have recorded patient no-show rates of up to 20%; this is an unacceptable waste of the hospital's already expensive and limited resources. The use of applications by which reminder letters are mailed to patients' homes or text messages are sent to their cell phones has improved this situation.

Patient admission

The next step is the patient's arrival at the medical center, either for ambulatory care or for admission. If it is an outpatient appointment, the data that must be entered is simply the services that will be provided, the payer and whether any additional information is furnished (appointment slip, etc.). It is important to

remember that the services may have to be provided on several different days. To assist in analyzing hospital efficiency it is useful to record the time at which the patient arrived.

In some hospitals or medical centers there is a single, central place where all patients are received, while in others the various units receive their patients directly.

In the case of patients who have not already done so, it is advisable that they be asked to sign a document in which the hospital informs each patient that his or her personal data will be used for administrative and care-related purposes, something that is required by most data protection laws. Also, if research or teaching activities are to take place, this should be indicated in the document signed.

This is usually an appropriate time to give the patient a "care program" that details the services, times, locations in the hospital and any special instructions that the patient must follow. An example of a care program can be seen in Table I.1.

Provision of services

Hospitals usually have department-specific systems that manage the provision of certain types of services, such as the RIS for radiology services, the LIS for laboratory services, anatomical pathology systems, microbiology systems, etc. For the provision of other services, the HIS must have a system that organizes and co-ordinates this activity.

When a patient arrives at the place where the service is to be provided, the time of arrival should be noted. In addition to confirming that the conditions required by the service have been met (no food, preparation, etc.) the patient's informed consent must be obtained, if it is necessary for the service and has not yet been given.

When the patient enters the room in which the service provision takes place, the service status changes to "underway" or "in progress" and when the service ends the status changes again, to "completed."

Recording these three moments (patient arrival, beginning of service provision and end of service provision) makes it possible to monitor patient waiting time, the real length of the services as compared to the theoretical defined length, etc.

Although generally there is only one primary resource per service, a variety of resources intervene during service provision. In the case of endoscopic testing, if the room is the primary resource, the other resources involved may include the endoscopist, the nurse, the endoscope, etc. It is helpful for the HIS to have the ability to record, when service provision has ended, the time dedicated by each of these resources. Having this information allows resources to be adjusted according to their real utilization.

If the services are managed by systems other than the HIS, they usually have their own statuses, but it is still useful for these moments to be transmitted to the HIS, so that all the pertinent information can be studied in one place.

It is also desirable to have a system that avoids the need to call patients by name when their turn comes, out of respect for their privacy. This can be a turn system, such as a panel with a number or other meaningful identifier to call in patients. Ideally this system should be integrated into the HIS.

Table I.1. Care program (Source: Compiled by author).						
LAST NAME, FIRST NAME, MIDDLE NAME					CLINICAL RECORD NUMBER	
PÉREZ JIMÉNEZ, JOSÉ MIGUEL					**123456**	
Type of payment		Company	Doctor in charge			
P – Private		A - Private	Dr. A. García (Check-up unit)			
APPOINTMENT/TEST	DATE	TIME	UNIT	BUILDING-FLOOR		COMPLETED
Appointment with Internal Medicine specialist	17.06.11	10:00	Internal Medicine	Ground floor		☐
Orthopedia - Specialist evaluation and report	17.06.11	11:00	Orthopedic Surgery and Trauma	Building 4 – Fifth floor Entrance B		☐
Cardiology - Specialist evaluation and report	17.06.11	12:00	Cardiology	Building 4 – Third floor		☐
Abdominal ultrasound	17.06.11	13:10	Radiology	Ground floor		☐
Thorax PA and LAT	17.06.11	13:40	Radiology	Ground floor		☐
ECG	17.06.11	13:50	Cardiology	Building 4 – Third floor ECG		☐
Second appointment with Internal Medicine specialist	17.06.11	16:00	Internal Medicine	Ground floor		☐
Administrative conclusion of care	-	-	Co-ordination/Payment department	Building 4 – Ground floor		☐

General view of services

In a HIS there are normally two modes in which to view services, corresponding to the two approaches that may be taken in considering service provision. The focal point of our discussion up to now has been the *resource* involved in the service provision. By using the viewing mode that focuses on resources, users can access any given day and see the services scheduled for a particular resource, along with their statuses. The services that have not yet been performed on a given day will appear on the task list for that day and that resource.

The other approach, and the corresponding viewing mode, focus on the *patient* and enables users to view the services that have been performed on or are scheduled for a given patient. At any time the user can see if the patient has arrived at the hospital, if a test or other activity is in progress, how many services remain pending, if there are delays, etc. This mode also shows the services that do not require appointments. Normally this mode will also allow the user to view the clinical information being generated, such as the results of diagnostic tests or therapeutic procedures, the information that the professional adds to the system (anamnesis, physical exploration, etc.).

It is usually complemented by other applications that inform the user when information regarding the services performed for the patient has been validated and made available, but this topic will be explored further in a later chapter.

Management of admitted patients

Normally hospitals are divided into units by medical specialty. These divisions may be restrictive, meaning, for example, that only internal medicine patients will be admitted to the internal medicine unit, or merely recommended. In the first case, the nursing staff has greater specialization in specific pathologies but a certain degree of flexibility is lost. For instance, the case may arise in which one unit has available beds but another has a waiting list. In the second case, the nursing staff must be able to deal with more varied pathologies but there is greater flexibility, enabling improved hospital bed management).

As mentioned above, a hospital usually has units specialized in specific types of care, such as ICU (Intensive Care Unit), the coronary unit (for patients with heart pathologies), the nursery (newborns), the psychiatric unit, etc.

Similarly, there may be different types of beds in the unit, such as isolation beds for treatments involving radioactive iodine, beds for infectious patients, beds in individual rooms for patients in critical condition, etc.

To schedule an admission the medical specialty and the doctor who will be ordering the admission must be indicated, along with the desired date of admission. As additional information, it is very useful to have the reason for admission and how long it is estimated that the hospitalization will last.

The department that manages admissions (generally called the Admitting Department or simply Admissions) confirms the proposed date and makes a provisional bed assignment. The patient is also assigned to an inpatient co-ordinator, depending on the unit to which he or she is to be admitted.

The Admissions department is often in charge of managing patient transfers as well. Normally, the inpatient coordinator to whom the patient has been assigned requests a transfer, specifying the reason (change in specialty, change in the patient's condition, etc.). The admissions department then looks for a bed to which the patient can be transferred, and informs that unit's inpatient coordinator. When the patient is ready, the coordinator admits him or her to the reserved bed.

Beds go through a series of statuses. The management of this process varies among hospitals, depending on how they operate. In general, the statuses of a bed are:

— Available: the bed is ready to be occupied by a patient.

— Occupied: the bed is occupied by a patient.

— Reserved: this status is generally used by the admissions department to indicate that there is going to be an admission to this bed, either a direct admission or a transfer.

— Bed cleaning in progress: when a patient is discharged, the bed must be prepared so that it can be occupied by another patient.

— Physician's orders: in the case of double rooms, sometimes it is necessary to indicate that the other bed cannot be occupied, due to first patient's pathology (an infectious disease, a psychiatric disorder, etc.).

— Maintenance underway: this status is used when the bed is in need of repair.

Other statuses can also be used, to best suit the hospital's needs.

When the patient arrives at the admissions department, normally he or she will be informed of the rules and other relevant information (mealtimes, what time the doctors do rounds, etc.) and will then go to the assigned room. Once he or she is in the unit, the admission takes place and the patient occupies the appropriate bed.

To assist in the management of the unit, the inpatient coordinators usually have a map of beds, showing all the beds assigned to this coordinator, and their current status. In some HIS the map may take the form of the actual physical distribution of the beds in the unit.

It is helpful to have a series of notices associated with each patient to facilitate management. These may include allergies to certain medicines or foods, whether the patient must be isolated (and the type of isolation), whether the patient has signed a living will or a Do-Not-Resuscitate order, if the patient must not eat anything, etc. It is also useful to indicate whether the patient is in his or her bed at the time or if a test or intervention is underway.

Emergency rooms

Emergency rooms (ER) have similarities with both ambulatory facilities and units where hospitalization takes place. Patients can be attended as outpatients, as in other types of doctor's offices, or their stay can be prolonged in observation units, which behave like other units in the hospital.

The obvious difference is that the visits are not scheduled, although the data that must be collected when the patient arrives is the same as in ambulatory care. When the patient arrives a request is submitted and an appointment for an emergency visit with a doctor is made, when appropriate. As in all other cases, the primary resource must be defined (a doctor, a specific treatment room in the ER, etc.). In all cases the doctor in charge of the patient must be specified.

Some HIS also incorporate the layout of the variously-equipped rooms and the observation rooms, as if it were a hospitalization unit. This way the physical location of each patient is known at all times.

In hospitals with a high volume of emergencies, the norm is to dedicate specific resources to this unit, such as equipment (electrocardiogram device, conventional radiology equipment, scanners) or various types of specialists, etc.

One type of information specific to emergency rooms is the classification of patients based on the severity of their condition (triage), which takes place when the patient arrives. This information must accompany the patient throughout the time he or she spends in the ER.

Just as with regular medical visits, there must be a record of the patients being attended at all times, both ambulatory patients and those who are in observation. For each of these patients it must be possible to view the diagnosis upon arrival, the triage performed, services requested and their status (whether they are pending, underway, completed and whether results are available yet).

Likewise, it is useful to have an application in which the system informs users of the arrival of results, at the moment they become available. This can be especially helpful in the case of lab work, of which there is usually a great deal. Having such an application means that the user does not have to continually check the system to see if new results have come in.

An emergency room is one of the entrances to the hospital, so the first thing that must be done is the identification of the patient in the master patient index, using the same procedures as the ones followed for ambulatory care or hospitalization. But an ER must also have a disaster plan that describes the process to follow, in terms of the HIS, when the arrival of high numbers of casualties within a short time is expected, a situation in which correct identification is difficult. The most common procedure is to open provisional medical records for patients who cannot be identified, to subsequently merge them with their real records.

Operating room management

Operations are services that could conceivably be considered resources that can be requested by users, to be provided in operating rooms, but in practice it is usually the staff of the operating room (OR) that schedule appointments, and they do so manually.

When a request is made for an operation, certain specific information must be provided so that the OR personnel can plan for the operation accordingly. This information includes:

— The anatomical area involved.
— Surgical position of patient.
— Position of extremities.
— Type of operating table needed (flat-top, traction, urological, etc.).
— Whether an anesthesiologist is required.
— Whether intraoperative radiology is required.
— Patient destination after operation. If it is the ICU, bed availability there must be confirmed.
— All necessary instrumentation, from the items used by the surgeon to any microscopes, endoscopy towers, etc. that may be needed.
— Whether blood or blood-product transfusions are expected and in what amount.
— Whether it is expected that an intraoperative biopsy will be performed, so that the anatomical pathology service can be informed.
— Type of preoperative antibiotic prophylaxis to be administered to patient, when necessary. Ideally this will be connected to the drug prescription system.

Additional information, from the patient's health record, that must be known is whether he or she is allergic to latex (so that any material containing latex can be substituted by something else) or has an infection that requires that the OR be disinfected after the surgery. Normally these operations are performed last on the day's schedule.

Also, it must be kept in mind that in a single operation various interventions may take place, sometimes even by different departments. This is the case when, for example, a mastectomy is performed by the general surgery unit, followed by a breast reconstruction performed by a plastic surgeon. In such cases it is necessary to consider the needs of both departments, the length of each intervention, whether they can take place at the same time, etc.

All of this data is used to organize the OR's daily schedule. For example, if it has been indicated that a particular tower is needed in two operations, and there is only one such tower, both operations should be scheduled in the same operating room, to avoid having to transfer the tower from place to place.

Once the daily OR schedule has been set, the OR coordinator is responsible for ensuring that the surgical team has all the material needed for the operations. It is important to remember that the "operating room" resource, with all that it entails (surgeons, anesthesiologists, equipment, material, nurses, assistants, etc.) is among the most expensive resources at the hospital. Cancellations or delays in surgical interventions entail a very significant increase in costs at the hospital.

In addition, prior to the operation, the anesthesiologist should be able to plan his or her work in relation to the intervention, specifically the following aspects:

— Anesthesia technique to be used.

— Warnings regarding possible problems during anesthesia induction, such as the risk of regurgitation, increase in blood pressure, airway trouble, etc.

— IV lines to be used during surgery.

Special applications have been developed to assist in the management of operations, since they have their own series of statuses, such as:

— Patient reception. Patient identity is confirmed and existence of signed consents checked, for both the operation and the anesthesia. A final check of the patient's condition is made: no medicines contraindicated by the surgery have been taken, his or her physical condition is good (no fever, no airway infection, etc.), no other procedure incompatible with the surgery has been performed, etc. The patient is moved to the anesthesia induction room.

— Patient in OR. This is the status when the patient has been moved to the operating room.

— Anesthesia begins.

— Anesthesia is sufficient.

— Preparation of patient begins (position, stirrups, marking of procedure site, etc.).

— Preparation of patient completed. At this time, or slightly earlier, there must be what is called a "surgical time out." This is a specific time during which all personnel intervening in the operation confirm that everything is correct: patient, anatomical site, procedure to be performed, antibiotic prophylaxis administered, etc.

— First incision.

— Suturing begins.

— Suturing completed.

— Preparation for transfer.

— Patient moved out of surgical unit. The patient may be sent to the post-anesthesia recovery unit or directly to the Intensive Care Unit.

This list of statuses should be configured to suit the needs of each hospital.

The OR management application must allow any necessary medical information to be entered in each of the steps to be taken. Also, it must be possible to monitor the patient, manage medicines, request blood products, etc. Lastly, preferably before the patient leaves the surgical unit, the surgeon must complete a post-op form indicating the intervention performed, any incidents, the pre-op and post-op diagnosis, etc.

Exploitation of the information gathered

To ensure that the hospital functions properly, the hospital management team must have tools that assist them in their decision-making, in both strategic and operational issues. Information regarding hospital activity can be extracted from the processes described above. This is part of the information that the hospital scorecard must contain. It must be complemented by economic and medical information to obtain a complete vision of the hospital.

All of this information should be stored in a DataWarehouse. To view it, Business Intelligence (BI) tools are often used. Each hospital must define the indicators it deems necessary, depending on what it wants to monitor. Some of the most common are mentioned below.

As for information regarding different types of hospital activity, various indicators tend to be used. The indicators for activity related to outpatient medical visits may include the following:

— New processes begun for patients. These are visits regarding new pathologies.

— Follow-up visits.

— Interdepartmental consultation.

— Diagnostic tests by specialty. To ensure that valid comparisons can be made, it is usually necessary to group tests by type. Thus, it is not a good idea to group together different types of radiology tests, because they are of very different nature, in terms of the consumption of resources, time required, etc. They are usually grouped in MRI, CAT, conventional radiology, interventional radiology and ultrasound. Endoscopies can be classified into either colonoscopies and derivatives (ileoscopies, anuscopies, etc.) or gastroscopies and derivatives.

— Therapeutic procedures: lithotripsy, radiation therapy (in the variants of modulated radiotherapy, brachytherapy, intraoperative radiation therapy), chemotherapy, etc.

— Appointments cancelled or re-scheduled, broken down by cause of cancellation: patient no-show, medical causes, hospital problems, etc.

— Average waiting time before patients are attended on the day of the appointment.

— Utilization of resources, that is, how many services were performed compared to those that theoretically could have been performed.

— Another interesting indicator in the area of appointment scheduling is to calculate the average number of days between the time that an appointment is made, with its corresponding restrictions, and the first available time slot. This gives an idea of the flexibility of the agenda's configuration.

The following are some of the most frequently used OR indicators:

— Total number of operations. As mentioned above, a single operation may be comprised of various interventions, and they may even involve different departments.

— Hours devoted to operations.

— Number of interventions using general anesthesia and number of interventions using local anesthesia.

— Interventions suspended, by cause; problems of a medical nature (patient taking medicine contraindicated by the surgery, patient sick, etc.) or of an administrative nature (no available bed in ICU for post-op care, lack of signed informed consent documents, etc.)

— Average occupation of operating rooms.

Hospitalization indicators usually include:

— Number of admissions.

— Length of stay. This is the number of days the patient is hospitalized. In this case it is necessary to separate general hospitalization from hospitalization in special units, such as ICU, coronary unit, nursery, psychiatry, etc.

— Number of discharges. This information is not as useful as the two items mentioned above.

— Average hospital occupation. This is the average number of hospitalized patients divided by the number of patients that could have been hospitalized. This data should also be broken down by type of unit.

— Number of patients admitted to units other than the one corresponding to their condition.

The following are some of the most frequently used ER indicators:

— Total number of patients attended. Sometimes it is worthwhile to measure them by day of the week, time of day and by severity (triage index).

— Average wait by patients before being attended, also broken down by triage index.

The hospital directors must select the appropriate indicators, reflecting them in what constitutes that hospital's management scorecard. This scorecard provides general information about the hospital, and can even sound alerts when a department varies from the previsions in some way. It should always offer the possibility of delving further into the data at the departmental, medical or some other level.

Similarly, each manager of each service should have his or her own departmental scorecard, with the option of breaking down the information at the medical level, whenever this is possible.

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Chapter II

Electronic health records

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Daniel Luna

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Summary

Clinical records are an essential tool in the daily activity of all health professionals, at the levels of care-giving, teaching, research and also management. Today most of these records are paper-based and thus present a number of disadvantages. Electronic clinical records (commonly known as electronic health records) have great potential, far beyond simply overcoming the inadequacies of the paper version. But despite the advantages, certain obstacles and controversies regarding this kind of recordkeeping persist. Information continuity at all points of care and the clinical decision support they can provide are among the most desirable characteristics offered by this type of application.

Issues such as individual identification, interoperability, the use of standards, the representation of clinical information, usability, security, privacy, confidentiality and the management of change must be addressed while considering the implementation of systems of this type. These topics will be analyzed in depth throughout the different chapters of this book.

What is a clinical record and what is it for?

The healthcare process, regardless of where the services are provided or by whom, necessarily generates information, and such information is usually stored in a repository known as the clinical record. The term *clinical record* is often used interchangeably with the terms *patient record*, *medical record*, *health record*, or *medical chart*. All of them refer to the set of documents that contain data, assessments and any other type of information about the patient's situation and clinical evolution throughout the care process. The clinical record comprises documents, both textual and graphic, about the episodes of health and illness experienced by that person, and the healthcare activity that takes place in relation to these episodes (Carnicero, 2003).

Historical development of the clinical record

Different moments over the course of history have marked the stages of the development of clinical record models. The Hippocratic school of medicine, when it appeared over 2500 years ago, focused on recording the experiences of the patients. The doctor recorded the course of the illness by noting down the patient's observations regarding his or her symptoms. For many centuries thereafter, doctors based their records on what the patients could perceive with their senses, and this was the center of the documentation process. With the development of new exploration instruments and the amplification of the senses, the focal point of the documentation process switched from the observations made by the patient to the observations made by the doctor. The appearance of ancillary

tests (laboratory analysis, imaging diagnostics, etc.) generated an array of sources that provided data for medical records. As recently as early in the 20th century, the idea of keeping one clinical record per patient took hold (Siegler, 2010) and it was not until the end of the 1960s that a new way of structuring the information began to be used; a list of problems and the ordering of the clinical changes in the context of a specific problem (Weed, 1968). This problem-orientation was one of the very few structural changes to occur in health records over their entire historical development, and this shift was originally conceived to make it possible to computerize the records.

Currently, most health records are organized around the sources that generate the information (clinical progress notes, ancillary tests, medical indications, problem lists, etc.) and chronological order is used within each source (Luna, 2002).

Clinical record functions

The main functions that clinical records must fulfill are in the following five domains (Carnicero, 2003):

— Care provision: this is the primary function of all medical recordkeeping. The clinical record is the repository of all patient information and where all actions taken by the healthcare team are documented, with the aim of ensuring the continuity of care provided to patients.

— Teaching: they also serve as a source of information for learning about clinical cases when the records reflect the care-giving process adequately.

— Research: they are also important sources of data for clinical and epidemiological research, for preparing analytical and retrospective studies at the individual and at the population levels.

— Management: they are useful in clinical and administrative management, for billing and keeping track of medical services. They also facilitate the evaluation and administration of healthcare resources and of the quality of the services provided.

— Legal: they can also be useful as proof of professional conduct and diligence in the care provided.

The problematics of clinical records

The traditional format of clinical records has always been paper. This storage medium brings with it certain problems, related to availability and accessibility, format and content (Dick, 1991; Hersh, 1995; Powsner, 1998):

— Availability and accessibility: one important problem is that there is no integration between the different levels of care (ambulatory, emergencies, hospitalization, home care, care of chronic conditions in institutions). This lack of integration means that the clinical records can be available only in one place at a time, thus reducing accessibility and increasing fragmentation and duplication. Because the records need to be accessible to other health professionals, the desired guarantees regarding confidentiality are often not met.

— Format: clinical records on paper are generally not very well structured (they tend to be too personal) and they lack organization and uniformity. With paper-based records there is increased likelihood that parts of the clinical record will be misplaced, partially filed or mistakenly filed. They deteriorate over time and their storage and handling consume a lot of physical space and resources.

— Content: hand-written records are often illegible or incomplete, and information can easily be altered. Chronically-ill patients can accumulate unwieldy amounts of paper over time and retrieval of information from the past is a time-consuming, manual process.

Changing the storage format

The arrival of computers in the 1960s created new possibilities for storing, retrieving and viewing the information within the medical record, by changing the physical nature of records to an electronic format. Electronic Health Records (EHR) have undergone a historical development parallel to that of its paper correlate. At the beginning they were restricted to academic and experimental settings and the information model used was designed mainly to support administrative processes. As technology progressed and personal computers became more prevalent, efforts in development focused on clinical areas and other areas where departmental or complementary tests are performed, but there was no integration between them and therefore each one ended up being an information silo. The importance of integrating the information generated by the various departmental systems made it necessary to connect these systems by means of a common Clinical Data Repository (CDR), leading to the creation of component-based clinical information systems. One of the premises of these new systems was to respect the care process, making medical acts the backbone of their information model. From that time onward, the decentralization of healthcare into care networks has given rise to the need to connect multiple systems, beyond the walls of an institution, and thus enable fluid communication of clinical information.

What is an electronic health record and what is it for?

There are many terms related to the concept of Electronic Health Record, such as computerized medical record, digital patient record, electronic health chart (Häyrinen, 2008). Although they all tend to be used indistinctly, some sources differentiate the Electronic Medical Record (EMR) from the Electronic Health Record (EHR), suggesting that the former exists within a single health institution while the latter integrates all of a patient's information beyond the limits of a single institution (Marietti, 1998).

Definition

In the 1990s, an Institute of Medicine (IOM) report on Electronic Health Records (Dick, 1991) defined this resource as follows:

"…An electronic patient record that resides in a system specifically designed to support users by providing accessibility to complete and accurate data, alerts, reminders, clinical decision support systems, links to medical knowledge, and other aids.…"

In an updated version of this report (Dick, 1997) the IOM broadened the definition of EHR, as follows:

— Longitudinal collection of electronic information on people's health, where health information is defined as information relevant to the health of an individual and the care given to them by any health team member.

— Immediate electronic access to personal health information is given only to authorized users.

— It contains knowledge bases and decision-making support systems that improve the quality, safety and efficiency of patient care.

— It has the primary aim of supporting the efficiency of healthcare processes.

This definition confirms that EHRs go far beyond simply computerizing the clinical chart. They represent a set of systems that must be highly integrated and require a significant investment in time, money, process changing and human factor engineering.

Key capabilities

Continuing with the IOM publications, just a few years later another report was issued expressing concern about medical errors (Kohn, 2000), proposing that in order to make significant improvements in patient safety and care quality, the medical community must implement information systems applicable to patient care-related activities, such as EHR systems (Institute of Medicine, 2001).

Subsequently, to reinforce the progressive development of these systems, the IOM published a new report underlining eight key capabilities that an EHR system must have in order to improve patient safety, achieve effective service provision, facilitate the management of chronic illnesses, and improve efficiency (Tang, 2003). These capabilities include:

— Health information management: an EHR must contain information about the patient's current problems and medical history, his or her medications, allergies and the contacts he or she has had with the health center. This includes clinical progress notes either in narrative text (written by the doctor, nurse or technician) or using structured templates. For members of the healthcare team to make the best evidence-based decisions, a large quantity of precise data is needed.

— Results management: this refers to the representation of results of laboratory analysis and other ancillary tests such as images, anatomical pathology, etc.

At the inpatient care level, the reports and results are generally sent directly from the different service areas and/or departments. At the outpatient level, this kind of data is sent from internal and external providers to the health center. Speedy access to information about ancillary tests saves time and money, avoids redundant ordering and improves healthcare coordination.

— Management of physician orders: the entry of a physician's orders into the system, whether they involve requests for laboratory analysis or other auxiliary services, or medication entry through order entry systems, is the first step in enabling the EHR to play an active role in patient health, and cease to be merely a passive system. The system can contain a knowledge base that permits more efficient information management and interacts with the health professional, collaborating in his or her decisions.

— Decision-making support systems: initially these support systems were directly related to physician order management systems, providing support for diagnosis and for treatment, through alerts or reminders regarding potential interactions or problems. Their usefulness has increased and they now have a wide variety of functions.

— Electronic communication systems and connectivity: to be able to receive information from external ancillary services and other systems, the EHR system must allow communication through standard messaging and using an agreed terminology. And in turn it must allow communication among colleagues and with applications used by the patient (see personal health record, discussed below).

— Patient support: most EHR provide output media by which to send information to the patient about his or her health conditions, diagnostic tests or treatment. This information helps improve the doctor-patient relationship and patient education.

— Administrative processes: depending on the care level involved, the EHR can be closely linked to administrative processes, through electronic scheduling of appointments, the electronic billing of services provided, verification of eligibility, automatic messages regarding drug prescription renewals, automatic registration of patients for purposes of research and artificial intelligence.

— Reporting and public health system: new EHR systems allow for automatic reporting (of adverse events, reportable diseases) to national databases. Other systems may allow patients to enroll in clinical trials, furnishing patients with information about how to follow a given protocol.

— Issuing of medical reports, discharges, consultations, etc.: just as it should offer support for managing physician's orders and test results, it should be possible to view the information in multiple viewing modes and to enter data for different care-related reports.

Two other interesting reports should also be kept in mind when considering the characteristics and capabilities of an EHR system:

— The one issued by the Health Information Management System Society (HIMSS) provides a clear definition along with the essential attributes and requirements that EHRs must meet (Handler, 2003).

— The Electronic Health Record System Functional Model (EHR-S FM) proposed by the organization Health Level 7 (HL7) includes an exhaustive reference list of functions that an EHR system can have (Dickinson, 2004). The list is based on the perspective of users (health professionals) and is organized into Functional Profiles (FP). The EHR-S FM allows a standardized description of functions by care level (inpatient care, outpatient care, emergency care), by user, by domain, etc. These Functional Profiles offer the possibility of designing a profile with functionalities listed in the EHR-S FM in order to meet a specific objective, and then, in accordance with this profile, deciding which functionalities the EHR system should have.

Different levels, different needs

An EHR system is an information system that can be implemented in a number of ways, keeping in mind its structure, purpose, data and intended use (Häyrinen, 2008). Both its functionalities and its components will vary depending on whether it is:

— An EHR system for the individual medical practice of a health professional who works with outpatients.

— An EHR system for an institution that covers all or several care levels (ambulatory, emergencies, general hospitalization, home hospital and tertiary care).

— An EHR system that contains the information of multiple institutions and different levels, where the need for standardization and communication protocols increases the complexity of the project considerably.

Modern clinical information systems comprise a variety of components and the true challenge lies in achieving appropriate articulation for each of them. Each of these components will be addressed in other chapters of this book. Figure II.1 shows the relationship between them.

The EHR is conceived as an interface used by members of the healthcare team to record their care-related activities. It is the main place where all clinical information must be entered. It comprises different information loading interfaces that respect the recordkeeping needs of the ambulatory setting (longitudinal records that store contacts) as well as those of care settings structured around episodic care (periods of time with a clear beginning and end). The backbone of both types of recordkeeping is the problem list, which concentrates patient morbidity in one place (Luna, 2006). The rest of the modules contain basic aspects of recordkeeping in progress notes, interdepartmental consultations, pharmaceutical prescriptions, ancillary tests, visualization of results and data entry structured by specialty and pathology. In recordkeeping related to episodic care, special loading modules are often added, such as anesthesiology, surgery, nursing reports, etc.

Information is stored in the CDR, which has mirrored databases containing de-identified information (to protect the privacy and confidentiality of the data) to facilitate secondary analysis of the information (for research or business intelligence purposes). This CDR also stores clinical documents sent by the departmental services component (ancillary tests, multimedia files, etc.).

Figure II.1. The EHR and its relationship with the components of a clinical information system.
(Source: Compiled by authors)
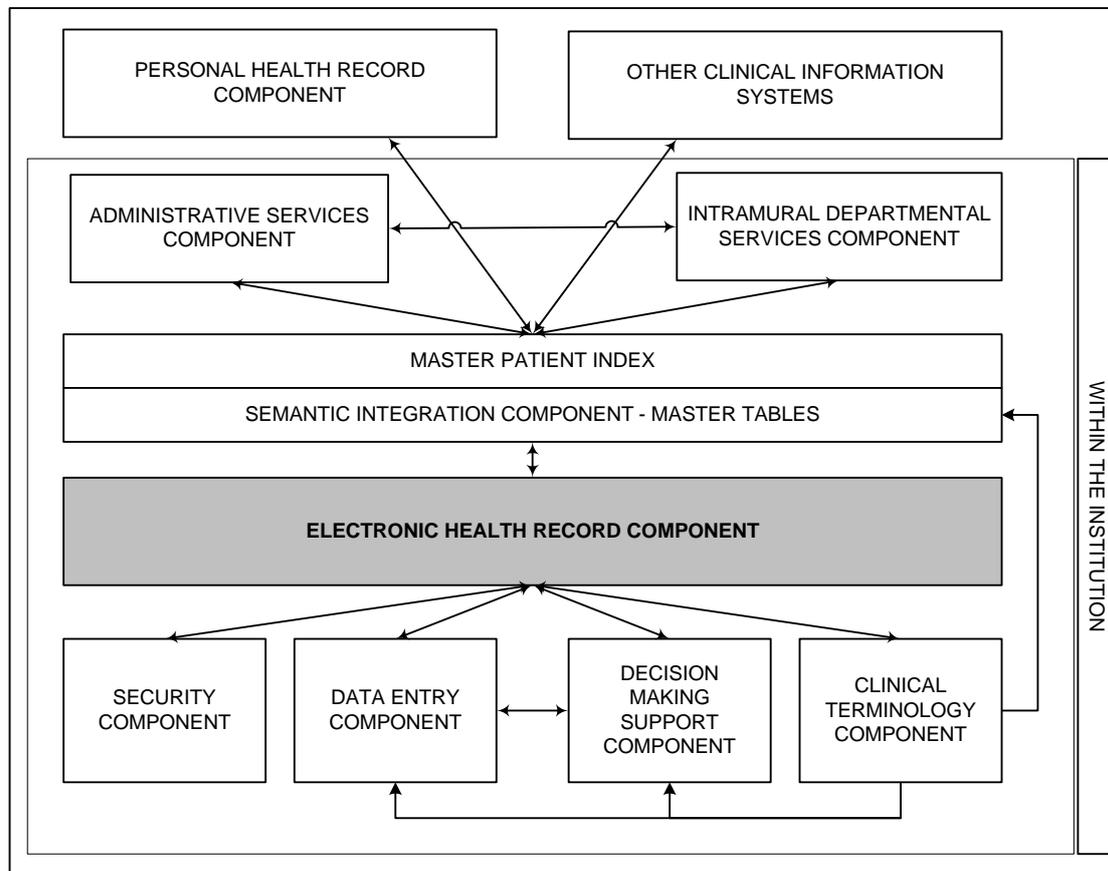
In recent years the approach to EHR has been shifting to include what is called the personal health record (PHR), understood as follows (Tang, 2006):

"…An electronic application through which individuals can access, manage and share their health information, and that of others for whom they are authorized, in a private, secure, and confidential environment. [...] Ideally, the PHR should include as much relevant data as possible over the individual's lifetime, from multiple sources, including health care facilities as well as the individual. [...] integrated PHR systems will have to interoperate with other systems throughout the entire health information environment. At a minimum, PHRs must export data to and import data from other systems in a standardized way…."

This concept does not involve simply giving patients access to part of their health records. The idea is more like the generation of a "Health Portal" in which information from all the components of the information system is shown from the perspective of the patient and his or her needs. It will thus provide pertinent information about the members of the team in charge of that patient's care, the option of viewing the appointments scheduled and of requesting appointments for visits or services. The CDR will show selected information from ancillary tests, the problem list and it must also allow fluid communication with the professionals providing care. The decision-making support systems must manage resources enabling access to pre-selected sources of information in accordance with patient morbidity, as well as reminders and alerts related to the patient's self-care. In addition, the use of

standards is necessary to achieve intercommunication among multiple sources of information that are later stored in an integrated fashion.

Barriers to adoption

Despite high expectations and interest in EHR all over the world, their overall adoption rate continues to be low (Arnold, 2008), demonstrating that some barriers to adoption persist (Carnicero, 2010). A systematic review of the literature reporting these barriers, from the perspective of physicians, has led to the creation of a taxonomy of issues related to these barriers (Boonstra, 2010):

— Financial issues: high costs associated with initial investment, high maintenance costs, uncertainty regarding the return on the investment, lack of funding sources.

— Technical issues: lack of adequate computer infrastructure (hardware, software and communications), insufficient computer skills on the part of physicians and auxiliary staff, lack of training and support, high degree of complexity, limitations, obsolescence and insufficient options to customize the systems. Reliability and high levels of availability are important aspects to take into account. Problems related to interoperability and interconnection with other systems were also an important barrier.

— Time issues: time barriers refer to time that must be devoted to system selection, acquisition and implementation. Time needed to receive training in how to use the system. Time required for data entry. More time per patient. Time required to transfer information contained in paper-based clinical records to the new EHR system.

— Psychological issues: skepticism and negative perception of EHR systems, need felt by professionals to have control over changes, and loss of professional autonomy.

— Social issues: uncertainty regarding companies that market EHR systems, lack of cooperation among all members of the health team, interference in the patient-physician relationship.

— Legal issues: aspects related to patient privacy and information security.

— Organizational issues: the size of the organization (physicians who work in larger organizations adopt EHRs more readily) and the type of organization (adoption rates are higher in healthcare networks than in individual office practices).

— Change issues: inadequate transition in the organizational culture when migration to EHR occurs, lack of incentives, participation and leadership.

Necessary requirements

Keeping in mind the barriers mentioned above, the following requirements should be considered in the design, development and implementation of an EHR system, in an attempt to overcome such barriers:

Positive identification of individuals

Both at the local and the national levels, the greatest difficulty in integrating a person's clinical information is how to achieve positive identification (Carnicero, 2003). The crux of the problem is no longer obtaining a universal identifier but rather identification services as a whole, which must cover the identification process and also the coordination of multiple databases of individuals and the constant monitoring of the quality of the data in the master patient index (Garfi, 2002).

Integration with other systems

Interoperability is defined as the ability of two or more systems (or components) to *exchange* information and *use* the information that has been exchanged (IEEE, 1990). The EHR system must not be treated as an island. It requires information from other systems (from inside or outside the institution), and therefore the EHR system must be developed keeping in mind this potential exchange of electronic data. This can be achieved by creating dedicated interfaces for each case, something feasible when there are just a few systems to link but more complicated and costly when the number of systems to be integrated rises. There are different levels of interoperability (Bisbal, 2011) and ideally this aim should be achieved using standardization (Hammond, 2007). Both of these subjects (interoperability and standardization) will be dealt with in greater depths in other sections of this manual.

Standards

The need for standardization, in its different forms, has been the object of discussion for a long time and it is widely-recognized as one of the most common barriers to EHR adoption (McDonald, 1997). There are many standards to be used in developing and implementing EHR systems, each with different orientations. Some are focused on data exchange and electronic messaging, others on terminology, documents, conceptual organization, applications or, finally, architecture (Kim, 2005).

Effective representation of clinical information

It is important to keep in mind that the members of the health team are accustomed to using narrative text to record their care activity. This type of recordkeeping maintains a large amount of contextual information necessary for communication with other professionals and ensures a correct diagnostic and treatment process. However, the information described in narrative text can be ambiguous, since various concepts can be represented by a single term (polysemy) or a single concept represented by various terms (synonymy). These situations tend to pose quite a problem for computers. The encoding (putting something into code) of this narrative texts is one possible solution. Another way to reduce ambiguity is to require structured data entry, which allows for rapid use by information systems, necessary for the feeding of decision-making support systems and for subsequent analysis of aggregate data. However, primary encoding and structured entry are not always well-received by clinicians.

Maintaining this narrative text in the EHR is essential for proper data interpretation, as both objective information and subjective interpretation of such information must be recorded, so as to be able to preserve and transmit it. Limiting this type of clinical documentation meets with resistance by professionals, since it has negative repercussions on their clinical activity. Using interface terminologies (also called user terminologies) is one of the solutions proposed to mitigate this problem (Rosenbloom, 2006). The availability of centralized terminological services makes it possible to find the right balance between the freedom of narrative texts and the benefits of structured data entry, both at the institutional level (Gambarte, 2007; López Osornio, 2007) and at the interinstitutional level (Luna, 2010).

Aspects related to usability

Topics related to usability and the design of human-computer interactions have a direct correlation with the acceptance and use of the EHR system by its users (Rose, 2005). That the applications have good ergonomics is one of the most important aspects to consider in supporting a clinical documentation process that is effective, efficient and facilitates day-to-day work (Armijo, 2009).

Legal aspects

Because the technologies related to EHRs are quite new, there is still much debate and discussion about legal issues in the different countries where they have been implemented (Haugen, 2011), although there are several countries in which this problem has been solved. This is the case of Spain, for example, where the electronic format has the same legal validity as the traditional paper-based one (Carnicero, 2003). Recognition of the probative value of electronic documents is a pre-requisite for the implementation of EHR systems (Steward, 2005).

Security, privacy and confidentiality

It is very important to keep in mind issues related to the privacy of patient data (Barrows, 1996). Clinicians wonder if the EHR is a secure place to store information and are concerned about the possibility of unauthorized access, often more so than patients themselves (Simon, 2007). Even among physicians that use EHRs, the majority believe that there are greater security and confidentiality risks in the electronic format than in the paper-based clinical record (Loomis, 2002). However, it should be pointed out that even the most basic EHR implementations are more secure than the current physical files on paper, thanks to security measures and the implementation of access profiles that restrict access to the information contained in the EHR. Also, steps must be taken to ensure: proper division between system development, testing and production environments; the creation of user profiles and accesses; and systematic tracking of user activity in the system, in such a way that allows tracing of such activity. This simply cannot be done in traditional paper records.

Whenever possible digital signature capabilities should be implemented (through asymmetric encryption standards using public and private keys) for documents contained in the EHR (Blobel, 2007). These issues will be addressed in detail in another section of the manual.

Change management

How change is to be managed is one of the most important issues to address in EHR implementation (Carnicero, 2010). That members of the health care team display resistance to change appears to be a constant in all clinical record computerization processes, whatever the institution (Lorenzi, 2000). Studying the implementation process from a social-technical point of view will make it easier to obtain a greater commitment by the representatives of all areas involved in the care process (Berg, 2001). The creation of a multidisciplinary team to define the scope of the project and to plan tasks related to the design and eventual selection of an EHR system will contribute a great deal to the implementation's success (Souther, 2001).

Transition management

Certain problems are associated with the period of transition from paper-based records to the use of the electronic records. Inconsistency between the information contained in paper medical records and their electronic counterparts can lead to major problems for the health care team in their daily activity (Stausberg, 2003). It is also important to avoid what is known as the paper paradox, where the organization's use of paper does not fall following transition to EHRs and sometimes even increases (Sands, 1998).

Loss of productivity

It is to be expected that some professionals will report a feeling of reduced productivity, at least at the beginning of implementation. EHRs do have an impact on the time devoted to documentation (Poissant, 2005). On a similar note, simply offering access to the centralized clinical information

provided by the various care levels (without specific decision-making support systems) will improve decision-making throughout the care process. This is something physicians perceive clearly once the initial learning curve required to become accustomed to the changes has been overcome (at around 6 months).

Benefits of EHRs

A recent review of the literature shows that the application of information technologies brings benefits to organizations (Buntin, 2011). As for EHRs in particular, various works have described the benefits that the use of this type of computer application will bring (Carnicero, 2003; Dick, 1991; Hersh, 1995; Powsner, 1998; Sujansky, 1998; van Ginneken, 2002). These benefits can be classified into the following types:

Accessibility and availability

Paper charts are for single users; they can only be seen by one person in one place. EHRs can be used by more than one person at a time and they can also be accessed from different locations. This is one of the benefits that new users most quickly come to appreciate.

Multiple display modes

EHRs also have the potential of offering various ways to view the information, since users sometimes prefer to see information in different formats depending on their needs. A good EHR must allow data display to be configured in different ways, offering these options to users. Another useful function in clinical practice is to be able to view trends. These can be generated instantly, by putting the trends shown by a lab value or a vital sign (such as blood pressure) into graphic form.

Communication with other professionals

EHR systems can serve as vehicles for communication among professionals. This capability need not be limited to physician-to-physician communication, but can also include other members of the healthcare team. Many EHR systems include features similar to e-mail or instant messaging, thus allowing the different professionals to send messages to other professionals involved in the care of this patient.

Communication with patients

EHRs can also improve communication with patients. As mentioned above, the personal health record can potentially be used as a communication channel between the patient and the health team caring for the patient (Tang, 2006).

Data aggregation

EHR systems also have data collection capabilities, which makes it possible to create data groups and summaries. Obviously, to ensure effective data aggregation, it is vital that data quality be very carefully controlled and that medical knowledge be correctly represented (through the use of semantic constraints). This functionality can be applied to the reuse of stored information for purposes of clinical management, clinical research or the preparation of public health reports.

Access to knowledge bases

Another potential benefit of using an EHR system is that it permits access to knowledge bases in a contextual manner. This means that the EHR can provide contextual information concerning each patient and provide the user with information that is useful in decision-making, extracted from different knowledge bases (Cimino, 2007).

Integration with decision-making support systems

Decision-making support is really the *raison d'être* of EHRs. The aim of these applications is to contribute to the care process, offering support to professionals, showing updated contextual information and suggesting alternatives to their decisions.

These *computerized decision-making support systems* are difficult to achieve and are not very advanced due to the complexity inherent in their development and implementation. They consist of a rule engine that uses information based on the patient (from his or her EHR) and information based on scientific knowledge (from the system's knowledge bases), with which they generate different outputs, such as reminders, alerts, diagnostic or treatment suggestions based on the automation of clinical practice guides, etc. Their ultimate goal is to prevent errors and to enhance care quality (Greenes, 2007). A review of the literature on these tools shows clear evidence of the positive effect they can have on professional conduct as well as incipient evidence of clinical improvements in patients (Chaudhry, 2006), although there are also controversial reports (controversial because they use secondary data) about their lack of effectiveness in some spheres (Romano, 2011).

Cost benefits

The issue of whether EHR system implementation brings cost benefits is clearly a controversial one, with literature containing evidence in both directions. This inconsistency arises in part because of the different perspectives used for analyzing returns on investment (ROI) (the individual physicians, service providers, insurance companies, governments) and the type of health care system that predominates in each country. More information is needed before more precise calculations can be made of the ROI related to EHR systems. Although a recent systematic review suggests that EHR implementation brings economic benefits at least at the organizational level, no data is available in relation to the regional or national level (Uslu, 2008).

Care quality improvement

A recent study of the evidence furnished by systematic reviews focusing on the impact of information systems on the healthcare sector shows that this type of system is associated with an improvement in care quality (Lau, 2010), while other studies report improvements in the efficiency of professionals (Furukawa, 2011) and an increase in adherence to clinical practice guides (Jamal, 2009).

EHR adoption

Despite broad consensus on the benefits of EHR systems, adoption rates around the world are quite disparate (Arnold, 2008), with high rates in countries such as the United Kingdom, Netherlands, Australia and New Zealand (Jha, 2008), and also in Spain (Carnicero, 2010) and Scandinavian countries (Heimly, 2010). In the U.S. the adoption rate is low, at both the outpatient (DesRoches, 2008) and the inpatient (Jha, 2009) care levels, but the latter has shown a slight increase following the introduction of fiscal incentives by the government (Jha, 2010). These incentives are awarded upon the basis of meaningful use of the EHR functionalities (Blumenthal, 2010).

One very good tool with which to analyze and classify the degree of functionality attained by health institutions is the "HIMSS Adoption Model" (HIMSS Analytics, 2011) (see Table II.1). This classification of eight functional stages makes it possible to quantify the degree of progress in the area of EHR use by the health organizations of a given country. In the survey conducted by the aforementioned organization, in 2010 in the United States, only 20% of the institutions surveyed were at level 4 or higher.

Table II.1. Level of EHR capabilities in organizations according to the HIMSS Adoption Model. (Source: Compiled by authors)	
Level	**Characteristics of the capabilities attained**
7	The hospital no longer uses paper charts to deliver and manage patient care.
6	Full physician documentation with structured templates and discrete data is implemented in at least one inpatient care service area for progress notes, consult notes, discharge summaries or problem list & diagnosis list maintenance. Level three of clinical decision support provides guidance for all clinician activities related to protocols and outcomes in the form of variance and compliance alerts. A full complement of radiology PACS systems provides medical images to physicians via an intranet and displaces all film-based images.
5	The closed loop medication administration with bar coded unit dose medications environment is fully implemented. The Electronic Medication Administration Record application (EMAR) and bar coding or other auto identification technology, such as radio frequency identification (RFID), are implemented and integrated with Computerized Physician Order Entry (CPOE) and pharmacy to maximize point of care patient safety processes for medication administration.
4	Computerized Physician Order Entry (CPOE) is implemented and reports are stored in a shared Clinical Data Repository. Second level of clinical decision-making support related to evidence-based medicine protocols to medication administration is implemented.
3	Nursing/clinical documentation (e.g. vital signs, flow sheets, nursing notes) is implemented and integrated with the CDR for at least one inpatient service in the hospital; care plan charting is scored with extra points. The Electronic Medication Administration Record application (EMAR) is implemented. The first level of clinical decision support is implemented to conduct error checking with order entry (i.e., drug/drug, drug/ food, drug/lab conflict checking normally found in the pharmacy information system). Medical image access from Picture Archive and Communication Systems (PACS) is available for access by physicians outside the Radiology department via the organization's intranet.
2	Data is fed directly into a Clinical Data Repository by the major ancillary clinical systems, with physicians having access to the CDR. Rudimentary decision-making support (checking for conflicts) and controlled clinical terminologies are used. Information from document imaging systems may be linked to the CDR (not the images).
1	All three major ancillary systems have been installed (laboratory, radiology, pharmacy).
0	The organization has not installed all three of the major ancillary systems (laboratory, radiology, pharmacy).

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Chapter III

Integrated management of medical orders in electronic health[26]

David Rojas

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Summary

The performance of diagnostic procedures, whether tests or visits to specialists, is one of the basic pillars of healthcare, inasmuch as the results obtained provide vital information about the patient's state of health and assist clinicians in determining which steps should be taken to preserve or reestablish that patient's health. The process is quite complex, from an organizational standpoint, due to the high number of professionals and actions involved in the ordering, carrying out and reporting of the results of each one of these procedures. Furthermore, various conditions and restrictions must be taken into account, such as the need to schedule an appointment in advance, the existence of incompatibilities between different tests or between a test and a treatment or the possibility that the test is not necessary because a similar one was performed recently. The process is thus a combination of clinical and administrative tasks.

The application of electronic health to the complex area of medical order management does not bring major modifications to the working scheme. It primarily offers a management application that centralizes the process and, very importantly, integrates it into the different information systems involved: electronic health records, professional and patient identification, configuration of agendas, departmental systems, etc.

Introduction

From the very origins of Medicine, all care processes have begun with the need to evaluate the patient's state of health and detect the problems that may exist, with the result being a diagnosis that indicates the appropriate treatment to follow. The progress of science and technology has led to the continuous development of new diagnostic techniques and the improvement of existing ones, and has also contributed to the creation of the different specialties that characterize modern Medicine.

Nowadays, diagnostic activity continues to be the vital first step in clinical practice, but since it usually calls for the participation of various specialists other than the physician directly attending the patient, it is a collective activity that requires considerable organization and coordination. The process can be divided into the following stages:

1. Review of the patient's medical history, anamnesis and physical examination.

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[26] The concept of medical orders encompasses both diagnostic procedures performed on patients and pharmacotherapy that is administered to patients. This chapter focuses exclusively on the management of diagnostic procedures, while pharmacotherapy is addressed in a different chapter.

2. Studying the results of diagnostic tests and interdepartmental consultations[27] performed previously, to decide if new tests are necessary.
3. Ordering the new tests.
4. Order management, forwarding each order to the corresponding diagnostic service.
5. The performance of each test.
6. Sending the results to the physician who ordered the test.

It is important to clearly distinguish between two concepts that will be mentioned repeatedly throughout the chapter: a *test* is a specific diagnostic procedure ordered by the physician in charge of the patient's care, while an *order* refers to the act of requesting diagnostic support. The order may be comprised of one or more tests and may be intended for one or more specialists.

Key issues in the management of medical orders

In traditional, paper-based medical records, the basic instrument used in the management of medical orders is the request sheet, or order form. In addition to specifying the tests to be performed, these forms identify the patient, the professional making the order and the diagnostic service that is to perform the tests. They also include clinical justification for the test and complementary information useful for carrying out the tests. Based on this information, various related actions (both clinical and administrative) must be undertaken. They include the following:

— Appointment management. The first requisite for the performance of a test is that the patient go to a certain area of the health service, where a sample is collected or an exploration takes place. To facilitate the organization of activity in these areas, many of the tests require that an appointment be scheduled in advance. When an order includes various tests, the appointments should be concentrated in the shortest period of time possible, to avoid unnecessary coming and going by the patient, while always keeping in mind that there may be possible restrictions between tests (for example, the amount of time that must pass between radiological examinations).

— Detection of incompatibilities between tests. It may be the case that certain tests distort and therefore invalidate the results of others, so all tests must be planned and performed in the appropriate order. Such incompatibility can also exist between a test and a treatment that the patient is following.

— Checking to make sure that no redundant tests are performed. Subjecting the patient to more tests than is strictly necessary may pose an unnecessary risk to his or her health, besides being a waste of resources and time. An order should not contain redundant tests or any tests that have been performed recently.

— Informing the patient. In addition to obtaining the patient's informed consent for the performance of each of the tests and providing him or her with the details of the appointment, the patient should be given a complete explanation of the tests to be performed and the instructions that he or she must follow regarding preparation for and performance of all the tests included in the order (for example, not eating on the day of the test).

In electronic health, this process does not undergo any essential alterations, although the application of technology makes it possible to optimize several of these activities (MTC, 2006). However, it must be pointed out that a medical order management module (commonly called CPOE, for Computerized Physician Order Entry) does not take control of the entire process (for example, it

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[27] To facilitate the reading of this chapter, the formula *diagnostic test or interdepartmental consultation* will hereafter be shortened to the term *test*.

does not manage the scheduling of appointments). Rather, it centralizes coordination of the process from the point of view of the professional at the beginning and end of the process, who is the ordering physician. So that all of these activities can be carried out in a complete and effective manner, it is indispensable that the CPOE system be integrated with other information systems, as explained below.

Basic capabilities of a Computerized Physician Order Entry system

A CPOE system should offer the following functionalities (Rojas, 2006):

— Test ordering:
  o   Availability of a catalog of services listing all the tests that can be requested.
  o   Definition of the test's level of priority (urgent, normal, etc.) and the ideal date of performance, when necessary.
  o   Possibility to define frequently-used orders: favorites, predetermined profiles of clinical analyses, protocols related to certain pathologies, periodic follow-up actions, etc.
  o   Automatic alert system when similar tests have been performed recently (unless it is necessary to monitor the patient's short-term progression) or when there is an incompatibility between tests.
  o   Preloading of information already present in the system: details of patient and of the professional, data shared with orders already entered, etc.
  o   Generation and printing of specific informed consent documents for each of the tests comprising the order, and of instructions regarding patient preparation.
  o   Additional information about the test. For example, it may be necessary to consult similar or complementary tests performed recently in order to assess the patient's progression.

— Management of orders:
  o   Instructions for the professional who is to perform the test: correct condition of patient (no food, full bladder, etc.), material needed to perform the test (tubes, glucose bars, contrast medium, etc.) or for patient transport (stretcher, wheelchair, oxygen, etc.), valid time slots for test, etc.
  o   Coordination with departments other than the one performing the test, such as when anesthesia is required, for example.
  o   Consulting the status of the tests comprising an order: ordered, pending validation, scheduled, performed, results reported, cancelled, etc.
  o   Messaging service between the ordering physician and the diagnostic service so that information can be exchanged and any queries related to the order can be answered.
  o   Option of modifying the order, canceling requests or including new tests depending on the patient's progression. These modifications can be made both by the ordering physician and by the specialists in the diagnostic services.

— Checking results:
  o   Consultation of the results available as the tests comprising the order are completed.
  o   Comparison with previous results to monitor patient's progression.

— Statistical use of the information:
  o   Activity indicators to plan and manage resources.
  o   Data to support research and teaching activities.

— System administration:

o Maintenance of catalogs of tests: name, code, parameters (time required, material needed, etc.), compatibility rules and ideal scheduling of tests, etc.

o Management of users: registration, removal and modification; definition of permissions and profiles.

o Process traceability and monitoring capacity.

Information systems for diagnostic test management - An integration model

As explained above, the magnitude of the diagnostic support process is such that various information systems take part in it, which means that integration among them is vital. Each of these systems is discussed in depth in different chapters of this book, so the descriptions provided here are brief and limited to their role in test order management:

— Electronic Health Record (EHR). This constitutes the basic work tool of clinicians, allowing them to consult the patient's medical history, add his or her clinical judgments and prescribe the necessary treatment.

— Computerized Physician Order Entry (CPOE). The physician accesses this to order any necessary tests and check the results obtained. For reasons of efficiency and ease of use, it is recommended that the CPOE module be integrated into the EHR, since the latter is where the physician studies results and compares them with those of previous tests.

— Hospital Information System (HIS). Its functionalities include patient identification and the planning and management of work agendas at health facilities, activities which are the responsibility of clinical service staff and the hospital admission services. In some cases there is an Appointment Management System (AMS) developed specifically for this set of tasks.

— Departmental information systems. These subsystems are capable of managing diagnostic tests and their results. Of particular importance among them are the Laboratory Information System (LIS), the Anatomic Pathology (AP) system and the Radiology Information System (RIS). The latter is closely linked to the Picture Archive and Communication System (PACS), which stores the images obtained from radiological explorations.

To facilitate understanding of the integration model, Figure III.1 shows an example of an order with several of the most common tests:

1. The physician looks at the patient's medical record and performs anamnesis and examination, and then accesses the CPOE module to request a basic panel of blood tests, an interdepartmental consultation in cardiology and a computerized axial tomography (CAT scan).

2. For the blood test, the patient goes to the blood drawing service area. This usually does not require an appointment. It is vital that the sample be correctly identified so that it maintains its association with the patient during the entire diagnostic process.

3. The interdepartmental consultation with a cardiologist does require an appointment, scheduled through the HIS/AMS. The patient goes to the specialist's office on the day and time scheduled.

4. A CAT scan also requires an appointment, which can be scheduled through the HIS/AMS or through the RIS, since both of them have appointment-making capabilities. In either case, the two systems must share the appointment information, since the RIS needs the data to generate the working lists for each room, and the HIS/AMS needs the data to manage all the appointments that the order entails (cardiology and CAT). In the example, the appointment is scheduled through the RIS. Subsequently, the patient goes to the radiology service for the examination, and the resulting images are stored in the PACS.

5. The lab carries out the blood test and the results are stored in the LIS.

6. The cardiology service draws up a report that is stored in the HIS/AMS.

7. The radiologist studies the CAT images and prepares a report, which is stored in the RIS.

8. The ordering physician looks at the results in the EHR, which –using the CPOE module– accesses the LIS, the HIS/AMS and the RIS in order to furnish the physician with the information required. Finally, the physician makes a clinical judgment, prescribing a treatment or ordering new tests if necessary.

Figure III.1. Example of an order with two tests and an interdepartmental consultation.

(Source: Compiled by author)
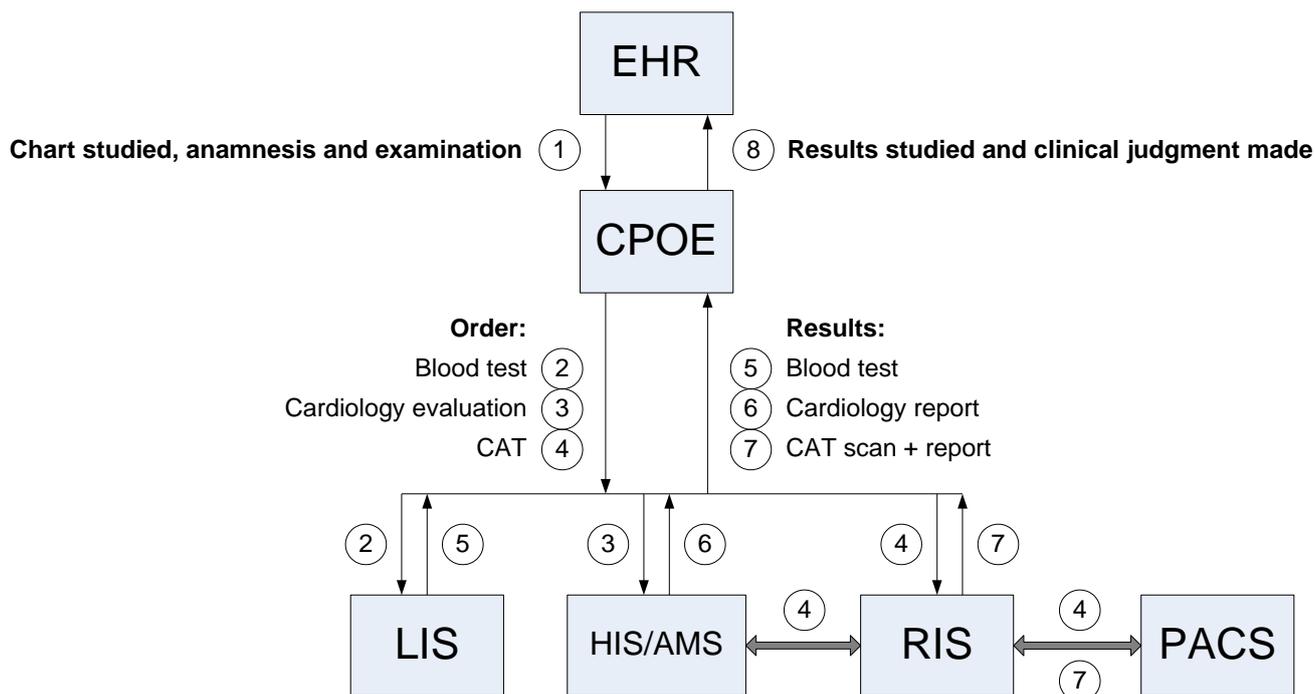
This diagram can have variations or extensions depending on the environment in which it is to be implemented. In some cases there is no AMS and appointment management is performed by local systems that work independently, which can make the forwarding of tests from one center or service to another extremely difficult. This same problem arises if the issue of positive patient identification has not been settled, or if there is no corporate catalog of tests and interdepartmental consultations.

This model can be enhanced by the incorporation of other systems that also take part in the diagnostic support process, although in a more indirect manner. For example, the RIS-PACS can be integrated with voice recognition systems for the automated preparation of reports, with 3D image viewers or video players, and even with computer-assisted diagnosis systems. Also, the PACS should be integrated with all modules that generate digital medical images in the different clinical service areas: radiology, cardiology, ophthalmology, etc.

In addition, the functionality of the CPOE module can be broadened to include the management of therapeutic support requests, such as surgery or radiotherapy, physiotherapy or the administration of blood products, in which case it should be integrated with the corresponding departmental systems (the surgical unit, oncology, the blood bank, etc.).

Requirements of this integration model

The main requisites for the proper functioning of this integration model are discussed below:

— There must be a functional diagram covering the entire diagnostic process, so that there are no "orphan" tasks, that is, tasks that have not been assigned to any of the participating systems. Similarly, each task must be assigned to only one system, so as to avoid duplications and incoherencies. The integration model must also clearly define the roles and responsibilities of the professionals that take part in the different tasks comprising the process, so that each of them is performed only by the appropriate professional and always in the correct manner, guaranteeing the security and confidentiality of the patient's clinical information.

— There must be positive identification of patients, orders, tests, professionals and physical places (doctor's offices, blood drawing service areas, examination rooms, health centers, etc.). This allows for effective traceability of the tests and their movement between different points in the health service network. The identification of patients, professionals and physical places requires integration with the corresponding master index (which is usually part of the HIS), but the generation of order identifiers and test identifiers is the responsibility of the CPOE module.

— Test catalogs must be created and maintained, to facilitate the management and use of the information. The CPOE should probably offer the ordering physician a simplified catalog, since catalogs of diagnostic services tend to be very specific and detailed, which makes them unsuitable for use outside of those services.

— An Information Quality Assurance strategy must be in place. A possible strategy is for test results not to be stored in the CPOE but rather in the departmental system of the diagnostic services that perform them. This fulfils the principle of data uniqueness, according to which each piece of data must be recorded only once and stored in only one place, in order to avoid the risk of inconsistency. An alternative to this model is to have a centralized repository where the results of all tests performed are stored, thus simplifying the consultation procedure and isolating them from possible failures in the departmental systems. However, this model involves the duplication of information and the risk of inconsistency is thus greater.

— The number of systems used by each professional should be minimized, to avoid the sensation of discontinuity in his or her activity. The ideal situation is one in which the ordering physician makes the request and checks the results in an EHR integrated with the CPOE; the administrative teams manage all the appointments needed with the AMS/HIS, or through the RIS in the case of the administrative staff in the radiology service; and the diagnostic services use their departmental services, the LIS in the laboratory and the RIS-PACS binomial in the radiology service, both to receive requests and to store results. In other words, the CPOE module is visible only to the ordering physician, and is transparent for the other professionals in the health service.

— There must be a communications infrastructure that guarantees that the exchange of data among the different systems is secure and of high quality.

— The necessary hardware and software must be available to enable the clinician to make efficient use of these systems: personal computers, high resolution screens on which to view medical images, etc.

— There must be clearly defined agreements with suppliers. Many departmental systems are commercial products developed by specialized suppliers and purchased by health services. The existence of various systems (LIS, radiology modules, etc.) using different technological platforms may cause difficulties or even prevent them from being integrated. To avoid this, supply contracts must include provisions on the integration of these systems, laying down requirements and conditions in a clear manner.

Benefits of a CPOE system

The use of a CPOE module has a clear impact on the diagnostic support process, as it speeds up the ordering and the carrying out of tests and also the communication of results. Table III.1 shows some of the improvements occurring in the different stages of the process.

Table III.1. Impact of a CPOE module on the diagnostic support process (Source: Compiled by author).		
Stage	**Without CPOE module**	**With CPOE module**
Order	Separate order for each test, often with several different procedures Order forms given to patient	Orders made jointly, using uniform procedures Automatic detection of redundant or incompatible tests No need to give patients order forms
Appointment (when necessary)	Appointments managed separately in the different areas	Appointments managed jointly, applying ideal scheduling rules
Performance of test	Status of test is unknown	Status of test can be monitored Orders can be modified Partial results can be consulted
Results	Printed and sent to ordering physician	Automatic alert when results become available and immediate reading Automated statistical use of data

The order management model described allows for the unification of procedures and the elimination of certain aspects of the traditional process, such as the use of order forms and printed results being given to the patient, with the risk to information security that such situations entail. In addition, it greatly facilitates process management and monitoring (Banet, 2006; Rothschild, 2004), improves its efficiency (Asaro, 2008; Thompson, 2004) and increases patient safety (DiFrancesco, 2004; Metzger, 2003). Furthermore, it facilitates the statistical analysis of activity data, which is very useful for planning and managing resources and also for quality control tasks.

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Chapter IV

Clinical laboratory information systems

Antonio López-Urrutia

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Summary

A Laboratory Information System (LIS) is currently an indispensable and critically-important tool for clinical laboratory activity.

The progress of LISs over the past 25 years, together with the development of large auto-analyzers and robotics, has led to an extraordinary increase in laboratory capacity and efficiency, at high levels of quality.

From their beginnings as basic systems that simply stored laboratory data for later printing, LISs have advanced a great deal, becoming powerful systems encompassing all aspects of laboratory work. In terms of healthcare, LISs provide support in pre-analytical areas (test order, appointment, collection of samples, preparation, transportation, sample aliquoting and distribution), in analytical areas (processing, equipment and route management, quality control, technical validation) and in post-analytical areas (medical validation, issuing of reports, distribution, archiving of samples).

A good LIS should also cover laboratory areas with specific functions and requirements, such as microbiology, emergencies, genetics, point of care testing (POCT), etc.

In addition to the care-related aspects, an LIS must include management and communication tools (supply and storage room management, quality system, web pages), along with powerful tools for information use at the managerial, scientific and epidemiological levels.

An LIS, with all its particular features, should be integrated in a comprehensive group of health information systems, in order to achieve maximum usefulness.

Introduction

The development of information systems in the clinical laboratory field has greatly affected all aspects of lab activity, making an impact comparable to that caused by auto-analyzers at the time they were introduced.

At first, these information systems covered the simple recording of service requests and the printing of lab reports. Today's systems manage all phases of the laboratory process. They are integrated into and interact with the other health care information systems – clinical as well as management.

The profile of users, who at first were administrative employees, has expanded to the point that today the computer has become an essential work tool for all the people working in a laboratory.

General features

A Laboratory Information System (LIS) is a group of hardware and software applications that provide support for the activity carried out by a medical laboratory.

Information structure

Generally, clinical laboratories report the results of analytical tests performed on specimens from a patient at a given time in his or her life, for a specific purpose.

An LIS database should have a hierarchical structure including at least the following data structures:

— Patient: demographic and administrative data.
— Service request: type, date, time, motive, ordering physician, etc.
— Sample: whole blood, test serum, urine, CSF, etc.
— Test (with method): glucose, urea, blood count, etc.
— Results (with units or reference interval where appropriate): numerical, alphanumeric, report, comments, etc.

As we will see below, an LIS needs many other associated data structures so as to be able to manage specific aspects of the process.

Criticality

The development of laboratory information systems, combined with the possibilities offered by automation and robotization, has led to a huge increase in the productive capacity of laboratories – thereby heightening laboratory dependence on these information technologies. Currently, a laboratory in a 1000 bed hospital with primary care can receive 3,000 analysis requests each day, corresponding to the extraction of approximately 10,000 tubes, the execution of 30,000 tests and the issuing of reports showing approximately 60,000 results.

An LIS is usually connected in real time to many analyzers that call for a rapid response to their data requirements, otherwise communication is interrupted. As such, quick response is an essential requirement of an LIS. Such responses must be immediately available upon a request from an auto-analyzer. In the example above, the LIS may be directly connected to 50 analyzing devices.

Nowadays, in most cases there is no "manual" alternative to the information system and so when it fails, there is not enough operational capacity. This causes delays in the delivery of results and, on occasion, the irreversible deterioration of specimens, resulting in possible harm to patients.

Traceability

Legal and administrative regulations, along with quality control systems, require that the entire lab process be traceable. This means that the system is able to reconstruct the entire chain of events – from the time the request is issued until the report is received or seen.

This implies knowing which person or instrument carried out any given action at any point in the process, the moment this action occurred and the result of that action. Some examples would be: who made the request and when, who collected the specimen and when, who did the aliquoting and when, how many aliquots were obtained, when was a specimen placed into a particular analyzer, which tests were requested, etc.

In this case, of course, in compliance with data protection laws, any action taken with data – gathering, consulting, validating, reporting, etc. must be recorded.

This vast amount of information can be used to determine responsibilities, to put in place improvement measures and to obtain quality indicators that make it possible to set objectives as well as to monitor compliance with those objectives.

Other features

— Flexibility: lab features can vary widely and call for systems that are flexible enough to adapt to the organization and needs of the lab, and not vice versa.
— Modularity and scalability: due to the fact that laboratory needs are continually changing, an LIS must have room to grow and allow for the addition of new functionalities.
— Security and confidentiality: given the kind of information being handled, along with the large number (and high level of dispersion) of the people accessing that information, control over security and confidentiality is of utmost importance.

Information systems and laboratory workflow

The laboratory process normally begins with a lab request from a clinician and ends when he or she receives the corresponding report. A series of phases or sub-processes take place between the request and the report, for which information systems play an increasingly important role. The following figure lays out the sequence of these phases. Grouped together, they usually are called the pre-analytical, analytical and post-analytical phases.

The following sections will examine the contribution made by an information system to each of these phases.

The pre-analytical phase

The pre-analytical phase comprises the sequence of events that take place before the properly prepared specimen is subject to the analysis itself.

This is currently regarded as the most critical phase of the process, given that the highest number of errors take place at this stage (identification, extraction, transcription, preservation, etc.). It is also the

stage where the most time can be lost. Until recently, this phase was completely manual, but the current trend is towards computerization, automation and robotization.

Figure IV.1. Laboratory work flow (Source: Compiled by author).
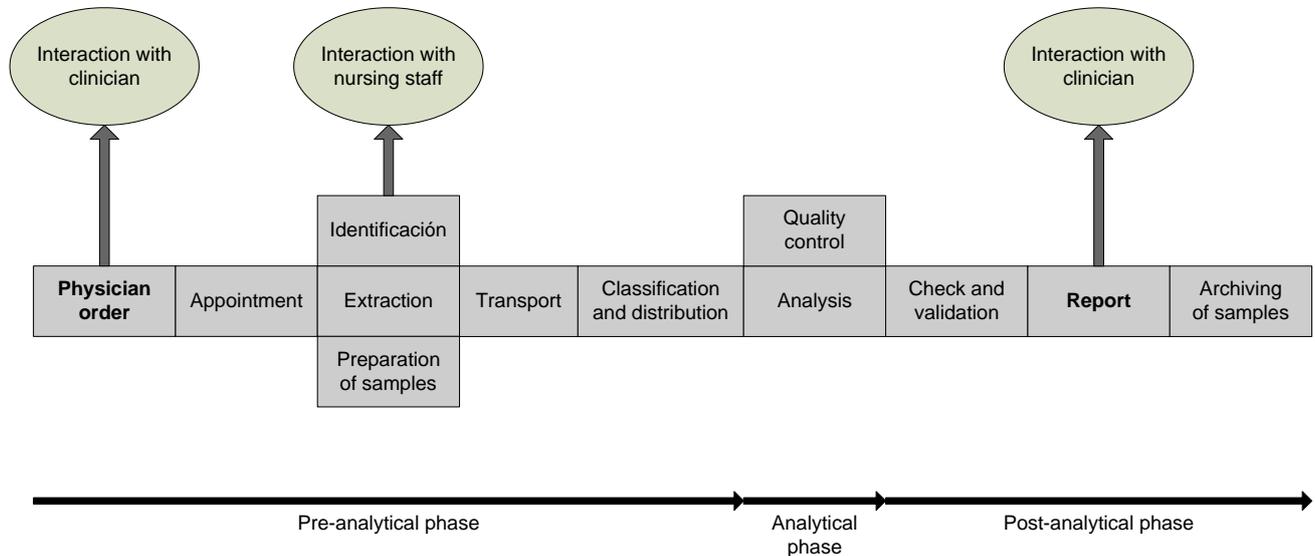
Request. Interaction with clinical systems.

The laboratory process begins with the lab request, which provides the laboratory with the information it needs to carry out its work. The rest of the process will greatly depend on the quality of this request.

The request normally contains different kinds of information:

— Request identification: in the case of an electronic request, the system assigns a numerical code (request number, referral number or physician order number) that unequivocally identifies that request in the system from which it originates.

— Type of request: ordinary, urgent priority, etc. Usually the different types of request will require different logistics.

— Patient personal data: unequivocally identifies the patient while linking him or her to other information. For example: name, surname, health record number, Social Security number, other numbers, etc:

— Clinical and demographic data: these are necessary for correctly interpreting the results, for conducting complementary studies, for reviewing the consistency of the results and for making recommendations from the laboratory. For example: date of birth, sex, diagnosis and other information, depending on the tests requested.

— Administrative data for the request: this data shows which person or organization submitted the request, where the report is to be sent and who is to take administrative charge of the request (ordering physician, origin, destination, validating doctor, etc.).

— Requested tests or studies: this information shows which tests or group of tests is being requested, and on which specimens the tests are being done. For example: blood glucose, amylase-urine or blood count. Frequently these tests are done by profile, i.e., basic biochemistry or diagnostic protocols such as "acute liver disease study" or "first term pregnancy control". In such cases,

agreements are made between the laboratory and clinicians in order to define these profiles and protocols.

The request is issued using order slips on normal paper, optical mark forms or through electronic communication.

The paper request is relatively simple from the clinician's point of view, as long as the laboratories make the job easier by reducing as much as possible the number of request slips needed per patient. But this system calls for a transcription of the information to a computer, thereby increasing the risk of error – sometimes due to the difficulty of understanding the handwriting.

An electronic request allows the doctor to issue that order from his or her place of work. There are two ways of doing this:

— Through direct access to the LIS – if a client server of the lab application is available, or if the laboratory offers the possibility of making requests via the web. This is the simplest way, requiring only network access and the corresponding licenses. This can be inconvenient, however, given the necessity of entering all request information and also because the laboratory data remains separate from the rest of the clinical information.

— By means of a lab test request option within a comprehensive clinical application that, in turn, communicates bi-directionally with the LIS. This is more difficult to implement than the previous option, but it offers many more possibilities, given that it places the laboratory within the context of the patient's entire health record. This guarantees the quality of the data, since it comes from other information systems.

An ideal electronic lab request system should help and guide the doctor through the request process by suggesting the tests to be ordered, depending on the patient and his or her pathological process, offering all information about available tests. It should warn the doctor about incoherent or duplicate requests, provide information about where and when the sample can be collected and note whether the patient requires special preparation. It should also be easy to use, since there are thousands of different tests that can be requested from a laboratory. Simplicity can be attained through the use of templates, profiles, diagnostic protocols and an efficient test search system.

Serious attention should be paid to this area, given that the design of a request system will greatly affect the demand for lab tests.

Appointment

The next possible step once the lab request has been issued is the setting up of an appointment for collecting the sample, if applicable. The system for making appointments for collecting a sample is not substantially different from other appointment systems, and thus will not be addressed in this chapter.

Collection of samples. Interaction with the nursing staff.

Once the request has been issued and the appointment has been made, the patient must go to the place where specimens are collected. In other cases, such as with inpatients, nursing staff employees go to where the patient is located.

The collection of samples is another critically important moment in the process. If the patient is not in the appropriate condition, the samples do not meet specifications, are not properly handled, or if there is any kind of identification problem, then the results of the subsequent analyses will be seriously affected.

The request slip itself has traditionally been used for sample collection as well. In some cases, these papers include text or color codes that show the staff member collecting the specimen exactly how many and what type of samples are to be extracted for each kind of test.

Once the corresponding samples have been obtained, they are labeled with an identification number that corresponds to the request. These labels include numbers, texts and barcodes. They can either be generated by the information system or be pre-printed.

Information systems are making an ever-growing contribution to the collection and identification of samples:

— An LIS can generate lists or sheets specifying collection routes for cases in which employees must go to different places to collect the samples. In order to do this, the system must already have the lab request information available – either because it has been manually or automatically entered, or because it originates from an electronic request system.

— If the requests originate from an electronic lab request system, one useful possibility is for that system to generate request slips that also serve as extraction sheets, containing information about the number and type of containers needed for the requested tests, as well as about any special requirements of either the patient or of the specimens to be obtained. This would keep errors to a minimum while reducing the training requirements for employees collecting the samples.

— The system can also generate barcode labels with information about the type of container to use. This can be quite useful, since the employee collecting the sample does not need to know the number or type of containers to use. These labels can include the lab request identification number, along with other useful information, such as the quantity of the specimen needed, patient information, etc. In order to print these labels, the system will need to have the lab request information beforehand. However, this is not possible in many cases, making it necessary to resort to pre-printed labels for assigning laboratory numbers.

— One problem with having the information system print out the specimen labels is that this creates the need for a high quality barcode label printer at each location where samples are collected.

— Equipment is currently available that is capable of automatically preparing the tubes needed for the tests requested for the patient. These tubes are placed into a personalized specimen box in such a way that the employee collecting the sample need only be concerned with extracting a good sample – and not with the tubes, tests or special conditions– given that these, when applicable, are described on the specimen box or on the tube label.

— Another option is the use of tubes that are pre-labeled at the factory. In this case, the LIS should allow the tube numbers to be associated with the lab request number. It should be possible to make this association from any specimen collection site, which makes this option a bit complicated.

— Radio frequency identifier (RFID) tabs for specimen tubes or containers could be a future alternative, once their cost becomes more reasonable.

— It is becoming increasingly common for specimen collection centers, especially those that handle a large volume of patients, to use collection center management software to help improve patient flow, through the management of staff shifts, booths and priorities. This computer application can form part of the LIS, or be specifically applied and connected to the LIS and to other care systems.

— Such computer applications can also help in drawing up lists or delivery notes that detail the samples that are sent to the laboratory from each collection center (chain of custody).

Data entry

Entering data into the LIS is another critical step. Any error at this level will directly affect the quality of the results. Also, the speed at which the data is entered will condition the entire logistics of the laboratory, since today no sample processing can begin until the data has been entered into the LIS. For this reason, the trend is towards the use of ever more rapid and reliable systems. The most commonly used are:

— Electronic request: this is the quickest and most reliable system, given that it offers the highest quality data (no need for transcriptions). Moreover, the LIS has this information available from the beginning, which facilitates all phases of the process.

— Peripheral registry: this involves entering the lab request data into an external computer or the LIS itself at the place of collection – but starting from a doctor's written request. The data is then transferred to the LIS via disks or the network. Here transcription is involved, leaving open the possibility of error. Another disadvantage is that the system cannot collaborate at the lab request and sample collection phases.

— Requests on optical mark forms: these are very commonly used nowadays. The requests issued on this kind of media are then read by an automatic reader that transfers the information from the optical marks and barcodes into the LIS. This method is used to enter most of the tests and certain demographic data. Normally the demographic and administrative information must be completed manually. This system offers the following advantages: speed, reliability of the data read, and the possibility of including information for the employee collecting the sample (type of containers, special conditions, etc.). The inconveniences include: the cost of the media and readers, the fragility of the media (problems with marks and folds), the need for complementary manual recording, and the increase in demand – due to the many tests that are handled this way to make the automatic reader equipment cost effective.

— Scanners: systems have recently appeared that make it possible to scan conventional request slips and that can even recognize written text. Some advantages are: media and readers that are less expensive than those of the optical mark system, and especially the possibility of saving an image of the original doctor's lab request that can later be consulted over the computer network. The main inconveniences, apart from those shared with optical mark systems, include: slower speed than with optical marks and lower reading reliability (manual validation is often needed).

— Manual: this is the traditional system using a paper request slip and manual entering of information into the LIS. This is the slowest system and involves transcribing the data, possibly producing errors. It also requires more administrative personnel.

Sample reception and distribution

Once the specimens arrive at the laboratory, a series of actions is needed in order to properly prepare them before they are sent to each of the areas where the analyses themselves will be carried out. Most of these actions require computer support, since they are often done on thousands of specimens each day.

The process begins with receipt, which involves accepting the request and the samples. This includes a physical inspection and identification of the specimens when necessary. The time elapsed from the extraction to that moment, along with the temperature under which the samples were stored is checked, sometimes through the use of sensors included in the transportation containers. At this point the computer system can be used to record any incidents detected, the time of arrival, a record of the

presence of the specimen, etc. The LIS can also help in detecting any inconsistencies, duplicates, inadequate protocols, etc. in the lab requests.

Once the samples and lab requests have been accepted (and according to the laboratory's specific organization), the specimens must be classified, centrifuged when necessary, de-capped, aliquoted (divided into various containers), re-capped in some cases and classified according to their destination. Currently –especially in large laboratories– the trend is to automate some or all of these actions by means of robotized pre-analytical systems controlled by the computer system. This makes it possible to increase work capacity, reduce errors and enhance biological security. Applications, modules or complete systems are needed to carry out these functions. The tasks to be performed include:

— Classification of the specimens: the LIS can show the destination (equipment, area or laboratory) where a specimen must go, according to a series of rules that can be based on the type of sample, the requested tests, the results of a particular test, the patient's health record or demographic information, or the administrative features of the request. It is also useful to indicate the complete sequence of destinations planned for this sample, and what has occurred at each one of those destinations. There are robotic instruments –called classifiers– that automatically classify the samples, in connection with the LIS.

— Aliquoting or dividing the specimens: this is a task that involves dividing the primary sample into various secondary containers destined for different equipment, areas or laboratories. The LIS, using rules similar to those involved in classification, can indicate the needed aliquots and the required volume for each. It can also allow for printing identification labels for each of those containers. For this task, there are also robotized instruments called aliquoters that can automatically carry out this entire process, under the control of the LIS.

— Other tasks, such as the uncapping and recapping of primary and secondary samples, along with centrifuging, can also be carried out by robotized systems controlled by the LIS. An LIS has little to contribute when these tasks are handled manually.

— Once prepared, classified and aliquoted when necessary, each sample is moved to the area or device that will perform the analysis. At times it is possible to perform this movement of samples automatically, since many analyzers offer the possibility of being physically connected to pre-analytical systems – either directly or through the use of robotic transport chains.

Work distribution

Once the properly prepared sample is available at the area or laboratory where the analysis will be performed, the LIS can issue work lists or sheets showing which tests are going to be carried out in this area or equipment, along with the information regarded as necessary for performing those tests. In addition to the requested tests, the information may include their level of priority, the patient's health record and demographics, earlier results, results from other tests or any other information that could be regarded as important for carrying out the kind of analysis done in that area. Should this particular device not have a bi-directional connection to the LIS, the LIS can also assign the positions of the samples in the instrument, as well as the target positions, controls and calibrators when present.

When analyzer equipment with a bi-directional connection with the LIS is involved, there are other paperless ways of distributing work based on the presence of the sample or aliquot next to the equipment. The specimen is placed in the instrument, which performs only those tests requested by the LIS. Once the sample is used, the LIS can indicate if there are more destinations for this sample, or direct it towards a sample archive.

The movement of samples between laboratories is a common practice. The LIS should have options that aid in this movement and the management of samples and data for those laboratories. Ideally, the sending of data as well as the reception of results between laboratories is done electronically, minimizing errors and streamlining the work. In the case of corporations or laboratory networks, it would be convenient for the LIS to be multi-center – allowing for corporate management of the laboratories in the network.

The analytical phase

This covers the analysis itself. Working from the sample and information provided, the laboratory makes the corresponding determinations and arrives at a technically correct result. The following sections describe the contributions of an LIS to this phase.

Connections with analyzers

Most laboratory tests are performed in automatic analyzers connected to the LIS. These analyzers are controlled by their own computer, which completely manages the machine and is, in turn, connected to the LIS. This connection can be either unidirectional (if it only sends results to the LIS), or bi-directional (if the analyzer also receives the programming for the tests that it must perform on each sample). This is called a "real time" or "host query" connection when the programming is sent to the instrument at the moment it reads the sample identification and it, in turn, sends the results to the LIS as soon as it obtains them. If the transmission and reception take place upon request by the user, this is called a "batch" connection.

The connection between the analyzers and the LIS is extremely important, as it avoids transcription errors while saving time and resources.

The analyzer-SIL connections use their own communications programs, although they have lately become standardized with such protocols as ASTM or HL7. Given that this connection must be completely reliable, communication protocols usually include systems that guarantee the integrity and reliability of the information transferred.

Programs for communication with analytical equipment usually include a parameterization that makes it possible to modify the results sent by the analyzer according to defined rules, or to automatically order new tests or repetitions according to preestablished rules or protocols. These are usually referred to as reflex tests.

Analytical quality control

In order to carry out laboratory activities at an appropriate level of reliability, it is essential to have an analytical quality control system that monitors the precision and accuracy of the determinations and provides real time warnings of any problems or deviations from the set objectives. The most common kinds of monitoring are:

— Internal control: based on a periodic analysis of control samples evaluated for each technique, comparing them with a target value.

— External control: a periodic analysis of control samples of unknown value, the results of which are compared with those of other laboratories by an outside organization.

— Control with patient data: there are different strategies that, looking at the patient results themselves, can provide information about the quality of those results.

Given the many types of quality control that must take place in large laboratories, computer programs are often used to manage them. These programs study the results of the quality control evaluations, and, through the use of a variety of algorithms, inform the user of any problem in accuracy or precision. They also offer periodic reports in the form of lists or graphs showing the performance of each instrument in relation to the objectives.

Many analyzers have quality control programs included in the overall management software for the device. Such programs compare each of the values provided by the analysis of a control sample for each of the operations carried out by the machine with theoretical values and trends over time. On the basis of different algorithms, the program warns the user of any possible problems with the instrument or reagents by means of sound alarms or messages. This process assures that the lab results from patients' samples have been obtained from equipment in perfect condition.

Programs that are pre-installed in analyzing devices offer the advantage of accessing, in real time, information from the different control points since they use the equipment's database. There is thus no need to transcribe the results to another system. One drawback is the fact that many devices are not equipped with quality control programs – or if they are, those programs are rather basic. Moreover, the dispersion of quality control information in different media (the various devices) makes it difficult to comprehensively evaluate the laboratory.

One alternative is the use of specific quality control software for the entire laboratory. There are number of different programs on the market that are quite adequate, but they all present the problem of having to enter the quality control results. If results must be entered manually, not only is this very labor intensive, but the real time feature is lost. This takes away much of the usefulness of the information, since the alerts generated by the system call for immediate action by the user. One solution is to enter the control results online, but since the device connection is usually occupied by the LIS, connection to other systems must be made through that LIS, which is not always possible.

The use of the LIS –equipped with a quality control application or module that collects the results of the controls online– offers many advantages, among them the possibility of access from any work station, the online entry of the results of analyzer controls and the possibility of linking patient results with the quality control status at the moment those results were obtained. It is also possible to obtain evaluations of the quality levels of the entire laboratory with the same tool, given that the LIS collects information from all devices.

Entering of results

Test results may be entered into the information system either through a direct connection with the analyzer, as described above, or manually. There are usually tools that help in manually entering data. The task of manually entering results can be accompanied by possible user warnings through colors or sounds in order to avoid serious transcription errors. Such warnings may be set off by a data entry that is inconsistent with the other results, or because the entry conflicts with panic values (very high or very low). When these alarms occur, the system can request a data confirmation.

Technical validation

Once the test results are available to the LIS, such data is regarded as a "raw" information, since it may contain significant errors. Such errors can be caused by problems in any of the items involved in carrying out the test (samples, materials, reagents, gauges, instruments, employees, etc.). At this point,

the technical staff normally has a procedure showing the checks or actions (repetitions, dilutions, calibrations, changes in reagents, warnings, etc.) that should be carried out according to certain criteria that are normally based on result values or ranges, on equipment alarms or on quality control results. This is normally referred to as a technical validation, in order to distinguish it from a doctor's validation – which will be discussed below. At times the technical and medical validation may be done in the same step.

Information systems can facilitate this process a great deal by generating notifications based on rules that take the aforementioned information into consideration. The more information contained in the LIS (results, alarms, quality control, etc.), the greater the role it can play in supporting the process.

The post-analytical phase

The post-analytical phase covers the sequence of events from the moment the LIS has the results available until the report is seen by the doctor.

Review and validation. Expert systems

Once the results are available in the LIS – and before this data becomes visible outside of the laboratory, it must be validated by a legally-qualified laboratory doctor. In this process, the doctor reviews the internal coherence of the results, the coherence of those results with the type of patient, pathology, treatment and prior analytic record. Other cases might require access to more detailed information about the analysis process and equipment (other patients with the same test, graphs, instrument readings, quality control, etc.). Having reviewed all of this, the doctor may order repetitions, dilutions or more tests to complete or confirm the findings. He or she may add interpretive comments and recommendations, or in some cases immediately contact the physician that ordered the tests, to inform him or her of results that may require immediate action.

Once the laboratory doctor approves and validates the results, the report can be issued and consulted.

This validation serves as the last filter for detecting possible errors. Due to the ever-growing number of tests carried out, the contribution of the LIS is essential. It is practically impossible to review and validate hundreds, and sometimes thousands, of reports without computer support.

Computer support can include everything from filters that select lab requests of a certain type for viewing –including those that show results within a certain range of values– to complex expert systems capable of selecting requests that must be manually reviewed because they are incoherent or require comments or recommendations.

The criteria most commonly used in these filters, rules or expert systems are reference values (or benchmarks) according to age and sex, panic values (very high or very low values), a delta-check (change of value with respect to an earlier value within a period of time), mathematical relations between internally related tests, the diagnosis, the origin, etc.

Once the lab requests have been selected, and the reasons for their selection duly noted, the LIS must be capable of automatically performing certain actions (repetitions, the generation of new tests, cancellation of tests, etc.), provide the laboratory doctor with access to more information (demographic,

clinical, administrative, health record, quality, about the instrument used, etc.), and carry out actions related to his or her request (repetitions, dilutions, new tests, cancellation of tests, comments and recommendations.

Consultations and reports. Interaction with the clinician

Once the results have been reviewed and validated, the report is sent to the clinician's office. Traditionally, the lab report was a paper print-out showing the test results, the benchmarks and the corresponding comments, which would be sent to the clinician and added to the patient's health record. With today's computer systems, intranet and internet, there are many ways to deliver the information to the clinician.

The reports can be generated directly by the LIS, or can be sent to other information systems within the hospital or community, which then generate the report.

The main ways to obtain reports are listed below, along with their primary features:

— Printed report: this is the traditional way and many electronic transmissions also end up as printed reports (email, remote printing, etc.).

— Faxed report: this has the advantage of immediacy, large scale diffusion and the low cost of fax machines. Negatives include the lack of confidentiality and slowness. Moreover, laws in some countries do not allow test results to be sent by fax.

— E-mail: this is cheap, fast and secure, but requires subsequent printing and the availability of a computer at each possible receiving end.

— Access to the LIS: this makes it possible to offer clinicians more functions, such as searches, progress reports or graphics, and all in real time. Drawbacks include the need for a computer with the application installed, the number of licenses needed and the fact that it involves an application separate from others the clinician may also use.

— Web-based LIS access: this has the same features as described above, but without the need for installing any client application. It has no problem with licenses and may be integrated with other clinical applications as long as they are in web environments.

— Access from clinical applications: this offers all the advantages mentioned above. In addition, it is much more useful for the clinician to have all laboratory information integrated with the other clinical information within the context of homogeneous applications. Some further advantages are:

  o The user need not enter and authenticate him or herself in another application

  o It is not necessary to search for the patient in another application

  o The results of the analysis are associated with a specific health episode or problem

The trend has been to reproduce the same results on a computer screen as are issued on paper. However, the fact that a clinician is interacting with the screen provides a great opportunity to offer a more interactive, visual and graphic lab report. Using a system of hyperlinks, the clinician can move from the report to information regarding the patient's progress over time in terms of the selected test. He or she can obtain more information about the test, any interferences or interpretations, and can even navigate to internet sites or bibliographies that are specialized in this kind of test.

Sample archives

Once they have been processed, the specimens are stored for different periods of time in order to carry out checks and to offer the clinician the possibility of ordering other tests upon seeing the results. At other times specimens are stored for scientific or legal purposes.

Due to the large volume of samples that large laboratories handle each day, it is very useful for the management of these archives to be done by the LIS.

Managing sample archives involves the creation of a variable number of specimen storage rooms where each specimen occupies a set location that is manually or automatically assigned and controlled by the information system. There are search functions for locating specimens or groups of specimens that employ specific criteria.

Some systems use automatic sample archiving instruments that are controlled by the information system or by middleware systems of robotized chains that allow samples to be archived or retrieved directly from the chain.

Other issues

Emergency laboratory

Emergency laboratories are those that offer a very limited array of tests and very fast results (often in less than an hour). Unlike more "routine" laboratories, which usually carry out each phase of the process by batches (or groups) of patients, samples or tests, emergency room labs work patient by patient.

In order to manage an emergency laboratory, an LIS must be equipped with functionalities that can support the work request by request, in real time and without paper. The other functions, as well as the structure of the information, should be the same as in routine laboratories.

Today the usual notions of emergency labs and "routine" labs are overlapping. The trend is towards 24-hour laboratories that work round the clock and are capable of offering a portfolio of services and different response times depending on agreements with clinical units.

To be able to offer these services, there must be adequate computer support that facilitates task organization.

Microbiology

Compared to other clinical laboratory disciplines, the field of microbiology has a number of specific needs, which means that specific modules or systems that respond to these needs are required.

The usual sequence for the clinical laboratory process is the following:
— One or more specimens are collected from a patient
— The samples are prepared
— The prepared samples are subjected to analytical processes

— The analyses produce one or more results

— A medical report is drawn up based on the test results and other data

The sequence is the same when performing serological or molecular tests on the sample. If cultures are involved, however, the following sequence would be followed:

— One or more specimens are collected from a patient.

— The specimens are inoculated into different culture media and incubated for a number of days, weeks or even months at specific temperatures.

— One, various or no microorganism colonies are isolated.

— A report is issued if no colonies have been isolated.

— When one or more colonies are isolated, they are submitted to identification tests and to antimicrobial sensitivity tests.

— A provisional, preliminary or definitive lab report is drawn up based on the test results.

This work method involves specific requirements for the information system:

— Information structure: the usual information structure for most laboratories is combined with a specific structure for cultures.

— Samples: samples have greater importance in microbiology, since there is a very wide variety of them and they have different specific collection requirements according to the analysis to be performed. There is also the concept of multiple specimens (sputum 1, sputum 2, etc.), and of similar samples from different anatomical locations (right leg injury, for example).

— Inoculation procedure: microbiology information systems should include a function for performing manual or robotized inoculation operations. Working from definable rules, this function would show the plates that must be inoculated, printing out identifying labels for the inoculation plates or tubes if necessary.

— The microbiology LIS must contain a database of all microorganisms, anti-microbes and diagnostic tests.

— Validation: as with the general LIS, the programs may have definable automatic validation rules, or rules for other actions. For sensitivity tests, however, they must have specific rules that help to select the information that will appear on the medical report.

— Reports: preliminary or provisional reports are the most frequent type in microbiology. Moreover, the structure of the information itself requires that reports have a higher number of tables.

— Use of the information: microbiology calls for the availability of powerful information use tools that make it possible to obtain –in addition to the usual management data– epidemiological information, epidemiological maps, alerts, sensitivities, etc. The collected information can be automatically sent to epidemiological alert systems.

— Microorganism strain archives: microbiology labs maintain microorganism strain archives for scientific or epidemiological purposes. The information system should include functions for managing this area (location, subcultures, etc.).

— Other aspects: the remaining aspects of a microbiology lab have the same general requirements as the other disciplines, which have been covered in their corresponding sections.

Specific functions

While some other areas within laboratories can be managed jointly with the lab's generic information system, they may have needs that require specific LIS functions or specialized computer systems. Some examples include anticoagulation control, blood bank management in the area of hematology, drug dosage adjustment in the therapeutic drugs area, along with some lab areas focusing on reproduction and genetics.

Point-of-care analytical systems

With the aim of increasing the speed and simplicity of obtaining results for some tests, easy-to-use portable analytical systems have been developed that can perform such tests alongside the patient – devices that can be handled by non-laboratory employees. In the past all information related to such devices has been beyond the control of laboratories and outside health care information systems.

The regulatory legislation in some countries, combined with the experience gained over time, has slowly led this point-of-care equipment to be regarded as part of the service provided by the laboratories, with the results obtained receiving the same treatment as those obtained at the lab.

In order to put this into practice there must be information systems that are specialized in managing the point-of-care equipment connected to the LIS and to the hospital systems.

Such computer systems must collect the results from this equipment as well as information about the patient, the person operating that equipment, quality control of that process and the status of the equipment. They must also offer functions making it possible to remotely act upon that equipment, even to block one or more tests.

Due to the number, size and dispersion of these devices, the potential of wireless connections and mobile technology in general is particularly important here.

Exchange of data with other services

The progressive computerization of health centers and the mainstreaming of computer networks have made new kinds of reports possible – reports with combined data from different services. One example offering great possibilities is the combination of pharmaceutical with laboratory data, making it possible to establish automatic alerts in treatments involving certain pharmaceuticals or pharmaceutical groups. Some examples include notifications concerning the deterioration of the renal or hepatic function in patients taking nephrotoxic or hepatotoxic drugs, alerts on the interference that these treatments may cause in lab tests, or epidemiological alerts.

Recent years have seen the proliferation of specific departmental systems that call for laboratory data in order to obtain, in combination with clinical data or information from electromedical devices, indices or calculations that allow for closer patient supervision. This is the case in dialysis, intensive care, newborn care, and other types of systems. Such cases call for a connection between those systems and the LIS, along with the transmission of the tests necessary for such calculations and/or indices.

Quality system

Management systems based on the principles of total quality have undergone substantial progress in the healthcare field. Laboratories have been one of the main areas for the implementation of such systems, with many labs being certified or operating under a certified quality system.

Due to the complexity of the laboratory process and the high number of procedures, devices, incidents, etc., computer tools must be available for managing the quality system. Such tools should provide support for:

— Document management: shared preparation of documents, control of document versions, control of distribution, etc.

— Implementation of records: design, maintenance and management of all kinds of records: incidents, complaints, maintenance, training, etc.

— Obtaining indicators: working from LIS records and data, it is possible to obtain activity, quality and cost indicators and to generate scorecards.

— Management of actions: preventive, corrective, and those related to non-conformities. Recording, monitoring and alerts.

Laboratory website

Nowadays it is necessary to have a laboratory website that serves as a communications center for users. These sites should offer a wide range of information about the portfolio of services, lab request systems, the collection of samples, procedures, organization, information consultation, etc. This information should proceed from the LIS databases themselves, which also assists in information maintenance.

These websites can also offer authorized users access to LIS information, so that they may consult reports or the status of lab requests, or even issue lab requests from the system itself.

Management

Apart from their healthcare activity, laboratories –like any other service– need the support of information systems for management. In this case, however, specialized tools are employed. These needs are summarized below:

— Billing and accounting.

— Management of storage rooms, orders and inventories.

— Maintenance management.

— Employee management.

— Cost management.

Exploitation of the information gathered

An LIS should have an integrated, reliable, easy-to-use and very flexible data use system that allows the authorized user to obtain any administrative, management, epidemiological or scientific information without the need for specialized staff.

Datawarehousing and business intelligence tools that facilitate the use of information –even integrating it with data from other healthcare or management systems– are becoming ever more popular.

Such systems use independent data repositories containing copies of LIS data, so that even their intensive use does not affect the LIS itself.

Current issues

Patient identification

Laboratory activities normally take place in a number of areas. A hospital laboratory has hospital inpatients, patients from the emergency room, from outpatient appointments with specialists, from specialized hospital care, from primary healthcare, from other hospitals, etc. In many cases the same patient is involved, but each time he or she is identified with a different number

The unification of patient identification would be very beneficial to the healthcare system. For laboratories this would eliminate duplicate lab requests and nuisance for the patient – transforming the laboratory into a bridge between the different levels of healthcare, fostering quality, communication and best practices.

Test catalogs and the transferability of results

In order to integrate the information within a laboratory along with other clinical data, there must be a standardization process that unifies and reconciles that information. This is a complicated task, given the massive number of lab tests and the continual appearance of new tests.

The standardization should at the very least unify the test code, test description, measuring units and test types. The standardization of microorganisms and anti-microbes is also useful.

There are a number of different standards or catalogs that cover lab tests, drawn up by different national and international scientific associations. Many of them are incomplete, not translated into Spanish or are not updated on an ongoing basis. These include the LOINC (Logical Observation Identifiers Names and Codes), the IUPAC (International Union of Pure and Applied Chemistry), the SNOMED (Systematized Nomenclature of Medicine) and the EUCLIDES (European Clinical Laboratory Information Data Exchange Standard), along with Spanish catalogs such as that of the INSALUD (Spanish National Health Institute) or those drawn up by some autonomous regions. Other standards include the TC 251 WI 130.1.1 –developed by the CEN/TC 251– that define lab request messages and results reports between information systems.

As of yet there is little use of these standards in Spanish laboratories; an effort must be made to move in this direction.

Another special feature of laboratory determinations is that some determination methods are not standardized. Thus, two determinations working from the same sample with different methods could offer different results – and neither of them can be regarded erroneous. For this reason, the determinations must be accompanied by the unit of measurement, the benchmarks (or reference values) and the method if applicable, in order to assure a correct interpretation.

In designing a system that groups results from different laboratories, it is important that the databases store –in addition to information about the test and the results– the method used for the determination, the unit of measurement and the reference values for the patient's age and sex.

IHE (Integrating the Healthcare Enterprise) is an international initiative that promotes the use of standards for the interoperability of health information systems. IHE periodically publishes its Technical Frameworks, which in the case of laboratories refer to the use of communication standards –within a hospital as well as community-wide– in six integration profiles based on the HL7 standard.

— Laboratory Testing Workflow (LTW)

— Laboratory Device Automation (LDA)

— Laboratory Point Of Care Testing (LPOCT)

— Laboratory Code Set Distribution (LCSD)

— Laboratory Specimen Barcode Labeling (LBL)

— Sharing Laboratory Reports (XD-LAB)

The progressive implementation of these recommendations would lead to effective interoperability, allowing laboratories that belong to the same healthcare system –but have different LISs and coding procedures– to interrelate as if they were the same.

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Chapter V

Digital pathology and telepathology

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Summary

Today the term digital pathology refers to the three fundamental aspects of the work performed in anatomic pathology services: report management, image management and laboratory technique management. It also covers the activities of telepathology, both for primary diagnoses in intraoperative biopsies and for second opinions or teleconsultation. All of these functions are performed by the Anatomic Pathology Information System (APIS), although the system delegates the management and storage of images to the hospital PACS (Picture Archiving and Communication System), since the images must be centralized. The management of lab processes is possible thanks to traceability tools that keep track of all the steps taken in the laboratory. Semantic interoperability with patient health records is based on the use of standardized terminologies such as SNOMED CT© (Systematized Nomenclature of Medicine – Clinical Terms). Over recent years, progress towards full digitalization in anatomic pathology has increased the use computer-assisted diagnosis tools that improve the quality of clinical care.

Introduction

Anatomic pathology services play an essential role in healthcare and in programs aimed at early detection of disease. Making correct and reproducible anatomic pathology diagnoses is the ultimate aim of these services as such diagnoses are the cornerstone of the treatment of all oncological diseases –and many non-oncological diseases– within the medical field's endeavor to advance stratified medicine.

To carry out this mission, information systems have become basic tools helping professionals provide better care and offering support to the teaching, research and quality assurance activities performed by anatomic pathology services.

The term digital pathology, a homologue of the term digital radiology, is currently used to refer to the three fundamental aspects of the work carried out in the field of anatomic pathology, which are: report management (based on the APIS), imaging management and also laboratory technique management.

Activities that make use of telepathology also fall within the concept of digital pathology. Because the diagnoses and prognostic and therapeutic evaluations made by AP services are considered definitive, it is vital that the conclusions set forth in the final report be objective and based on consensus. Therefore it is of great importance to have tools that enable second opinions to be obtained from pathologists at other centers, who have ample experience and resources specific to the subspecialty needed.

Modern anatomic pathology is undergoing major changes as a result of certain developments: the expansion of special techniques such as immunohistochemistry and molecular pathology; increased automation of processes that until just a few years ago were exclusively manual; changes in hospital care circuits (strategies that seek high levels of case resolution in a single visit, ongoing surgical activities) and the wider range of activities performed in local health centers (skin biopsies, gynecological cytologies, etc.); the creation of tumor banks and other biobanks; and the certification and accreditation of processes carried out in AP services.

According to a survey conducted by the Spanish Society of Anatomic Pathology (SEAP) in 2007, at that time only 4.5% of Spanish hospitals were outfitted with dynamic telepathology equipment or with slide scanners. Despite this low rate of penetration, 80% of the pathologists surveyed believed advanced telepathology systems to be very useful (Giménez Mas, 2009).

To perform the three basic functions of an AP service (information, imaging and techniques), not only must there be specific information systems (an anatomic pathology information system, a digital imaging management system and a system that manages automated laboratory devices), it is also important that the hospital consider these systems a strategic element of patient health records.

Anatomic pathology information systems

The primary objective of an AP information system is to efficiently manage the data and images needed to generate AP reports, which are incorporated to the patient's health record and which also have secondary uses (statistics, cytohistological correlation, tumor registries and biobanks). To achieve this, there must be tools available, such as electronic physician orders made via the electronic health record (EHR) system, that facilitate patient identification and the registry and management of samples (biopsies, cytologies, autopsies and molecular biology), and the grouping of data or statistics, which is of great assistance in decision-making.

Web-based information systems represent the best option at this point, as their installation and update in computer equipment is much easier, apart from other advantages. In Spain there are currently about six commercial software products available for the management of anatomic pathology, but only two of them are available as web client applications (and thus do not need to be installed in each computer). The College of American Pathologists website offers information about 24 anatomic pathology products, of which seven (30%) are available as light web clients (College of American Pathologists, 2011).

The functionalities of an APIS can be summarized as follows:

— Patient identification and management.

— Registration and management of samples (biopsies, cytologies, autopsies, molecular pathology).

— Preparation and sharing of reports (clinical data, macroscopic and microscopic descriptions, final diagnosis, conclusions, forwarding to other information systems).

— Sample archiving (tissue and liquid-based cytology), paraffin blocks and preparations.

— Macroscopic study. This refers to biopsy sampling and autopsies.

— Traceability and laboratory workflow control. Generally speaking, this function manages the tasks performed by AP specialists and biologists. It can be subdivided as follows:

- o Biopsies and autopsies: fixing, embedding, staining
- o Cytologies: fixing, staining
- o Immunohistochemistry and immunocytochemistry
- o Flow cytometry
- o Molecular pathology: generally, fluorescent in situ hybridization (FISH) or chromogenic in situ hybridization (CISH) and polymerase chain reaction (PCR)
- o Cytogenetics

— Management of imaging (which include gross images, microscopic images –including digital slides– and molecular pathology images). Such tasks are performed by technicians, biologists and pathologists.

— Management of requests for special techniques, such as immunohistochemical and molecular studies.

— Microscopic study. Interpretation and diagnosis. This is done by the pathologist. In cytology, it usually involves the assistance of cytotechnicians.

— Coding. This is the process by which various codes are used to summarize samples, procedures and final diagnoses.

— Work planning and distribution.

— Data management (reports, statistics, lists).

— Decision-making support (clinicopathologic and cytohistologic correlation, diagnosis support, prognostic evaluation, therapeutic optimization).

— Pretreatment of data for tumor registry and biobank or tissue bank.

— Quality control of technical processes and diagnoses.

These functions can be grouped into the following categories:

— Generating information and integrating data from other sources. The integration of clinical, radiological and pathological data requires that information be collected in a structured manner and that communication flows in both directions, so as to keep the information up-to-date.

— Imaging management. Images come from multiple and heterogeneous sources (a wide array of modules), since images are captured both during the processing of the samples and during the interpretation of images.

— Quality control of technical processes (quality of staining, amount of DNA obtained, etc.) and of information processes (correct identification of containers, tissue blocks and slides/coverslips, for example). This information is collected using traceability systems and the results of external quality assurance programs are also taken into account. Proper use of this data allows improvements to be made to the processes.

These functions allow indicators and statistics to be obtained and they contribute to datamining processes, so all of this information can be used to achieve the best possible resource planning. To this end, the indicators to be evaluated must be normalized (catalog of samples or specimens, complexity associated with each type of study). The complexity of an anatomic pathology study is directly correlated with the final anatomopathological diagnosis, and for this reason also it is very important that there be consensus regarding the coding of this type of diagnosis, and that a subset based on SNOMED CT (Systemized Nomenclature of Medicine – Clinical Terms) be established.

The final product generated by the AP service is the patient report (on the biopsy, cytology, autopsy or molecular pathology findings). This report, once it has been validated, becomes part of the

patient's health record, along with the images (or links to them) that can be included in the report. The topics of a normalized structure for AP reports and how they should be sent to the electronic health record or the public health registers, such as population-based cancer registries, are already being addressed by Integrating the Healthcare Enterprise (IHE).

This organization has published a technical framework that defines the structure that standardized AP reports should have, based on HL7's Clinical Document Architecture (CDA) (IHE, 2011).

Integration

The APIS must be integrated with information systems used outside the AP service:

— Electronic health records (EHRs) documenting the primary care and hospital care provided: there must be a unique identifier for every patient and clinician; it must be possible to request anatomic pathology studies electronically, and to obtain results and the pertinent AP report in the same way. At specialized ambulatory care facilities, in hospitals and operating rooms, and at local health centers, APIS integration with the EHR must offer the following functions:

  o Electronic order of biopsies, cytologies, autopsies and molecular pathology
  o Appointments for fine needle aspirations (FNA) performed by the pathologist and other services requiring appointments
  o Preparation of containers and liquid fixers
  o Transport of fresh and fixed samples
  o Study of AP reports and images (preferably through a web client)

— Terminology servers. These maintain and update the controlled vocabularies used to refer to specimens, surgical procedures, service packages, as well as clinical and anatomopathological diagnoses and observations. Generally, they are based on SNOMED CT.

— Imaging servers. Picture Archive and Communication System (PACS). Both photograph-type images (gross or microscopic) and digital slides must be available in a central server.

The entire AP-related care circuit (operating room scheduling, intraoperative biopsy planning, orders for cytologies or autopsies, the selection of clinical data especially relevant to the sample to be studied, etc.) must be integrated with the hospital's clinical information system (the EHR system) and the APIS.

The APIS must also be integrated with other information systems that generally exist within the AP service:

— Automated laboratory devices (conventional and special staining apparatus, immunostainers). Work orders are generated and managed by the APIS.

— Digital recording or voice recognition archiving system. This is used for transcribing text for inclusion in the gross and microscopic description sections of patient reports.

— Telepathology portal (telemedicine). This can be used for primary telediagnosis, teleconsultation or second opinion and discussion forums. It can also contain reports from one or more APIS (this is the case of portals used by health organisations in the same region).

— Hospital tumor registry. Each tumor is registered with the information initially furnished by the APIS, with the addition of other essential data from the EHR and other departmental systems such as medical oncology and radiation therapy oncology.

— Biobanks (tumor banks). In the samples collected for research purposes, it is important to gather essential clinical and pathological data. Integration with the APIS improves the traceability of all the samples used in research.

— Quality management. Some information systems maintain incident registers and also furnish standardized working documents, protocols and procedures, which should also be accessible through the APIS.

— Bibliographical databases. Hyperlinks and efficient searches of databases such as Medline and also of consensus clinical guidelines (such as the 2001 Bethesda guidelines on cervical cancer, 2007 Bethesda guidelines on thyroid cytopathology, cancer protocols developed by the College of American Pathologists, consensus guidelines published by the Spanish Society of Anatomic Pathology).

— Libraries of images and cases of special interest, for teaching purposes.

— Datawarehousing and datamining. Besides providing up-to-date data regarding times and other statistics, this integration speeds up response times and improves diagnostic quality, as it offers clinical-pathological correlations (comparing initial and final clinical diagnoses to the anatomopathological diagnosis) or cytohistological correlations (comparing diagnoses based on cytology to diagnoses based on surgical specimens). Such an analysis also reveals trends that can assist in forecasting future needs in human and material resources.

Traceability in the management of samples and intermediate products

Electronic ordering of anatomic pathology studies

Ordering an anatomic pathology study requires correct identification of the sample to be studied, making sure that it is associated with the correct patient. Sample labels are not usually printed at this point (they are printed only within the AP service). Instead, it is quite common for patient identification labels to be printed with a bar code (preferably a two-dimensional bar code, with the health record number), using the computerized physician order entry (CPOE) system. The Operating Room management module, integrated with the CPOE system, must manage all the samples generated for the AP service and any possible incidents that occur during their collection and transport.

Receipt of samples

Each container sent to the AP service is associated with an electronic order. Theoretically, a properly-labeled sample can travel from the operating room or the doctor's office to AP with no need to be accompanied by paper documentation. In practice, in many centers the order for the anatomic pathology study is printed, so as to confirm patient identification and sample identification on paper, instead of using computer screens, or because the order form is used by the AP service itself to note down details of the gross study or regarding the identification of tissue blocks or the techniques to be used.

The receipt of samples is managed by the APIS. This is a critical step, as here is where integration between the CPOE and the APIS is put to the test. Confirmation is carried out by a technician specialized in AP, who must confirm that all the containers have arrived in good condition in terms of identification and conservation. If this is not the case, any incidents must be recorded.

Registration of biopsies, cytologies, molecular pathology and autopsies

Once the sample has been accepted, the following step is to register the study by assigning the sample a number that unequivocally identifies the sample received. This is generally a sequential number

(for example, 11B0011123) and sometimes a letter, if the order includes various containers (for example, 11B0011123-A for the specimen removed in a breast quadrantectomy and 11B0011123-B for the lymphadenectomy specimen from the same operation).

The APIS should be capable of generating labels for containers and these labels should contain the name of the patient, the date of receipt, the type of sample or organ and the unique identification number in legible format and in the form of a bar code (either 1 or 2 dimensional).

Macroscopy

At this point labels are printed for the plastic cassettes that will later become the paraffin blocks, which are the basic tissue units most frequently used for treatment purposes and also in research). Blocks are labeled by the technician specialized in AP, using the APIS, and the label can include a two-dimensional bar code, in addition to the block number in legible format. Since tissue blocks may be sent to other facilities, it is advisable to also include the healthcare center's name in the block's label, for example HCR11B0011123-A2.

Block preparation, sectioning, staining and mounting

Currently there are several traceability systems for AP laboratories available on the Spanish market. They all have three essential components in the room where block preparation and sectioning takes place: tactile screen, bar code reader and a printer to produce slide labels. The printing of slide labels can be done directly on the slides or by printing special adhesive labels capable of resisting the chemical products to which the histological preparations will be subjected. It is a good idea for the traceability system to be integrated as yet another function of the APIS.

Automated laboratory devices

A growing number of automated devices can now be found in AP services, including tissue processors, automated stainers, immunostainers, coverslip placement, hybridization readers for low-density matrix, real time PCR, flow cytometers, extraction and amplification of nucleic acids, sequencers, pyrosequencers and One Step Nucleic Acid Amplification (OSNA) systems for the sentinel ganglion.

However, to date, there is no standard for communication between these automated devices and the APIS. In many cases, communications use HL7 messages created ad hoc thanks to agreement between manufacturers. In the future, IHE will have to address the issue of standardizing these messages. The main distributors of autostainers have systems that make it possible to manage, using the APIS, requests for conventional stains (hematoxylin-eosin, commonly called H&E), special stains (PAS, for example) and immunohistochemistry.

Microscopic description and diagnosis

If the microscopic study is to be performed with a conventional microscope, the pathologist receives a tray of histological or cytological preparations at his or her work station. The pathologist should use the bar code reader (which will read the codes appearing on the slides) to write the biopsy or cytology reports, to reduce the likelihood of error and ensure that the descriptive text or the diagnosis issued following the microscopic study is associated at all times with the right report. If additional techniques need to be ordered, this should also be done using the bar code appearing on the slide.

If the microscopic study is to be performed using digital slides, the pathologist goes to that day's list of tasks and checks the reports that must be prepared that day. When the pathologist opens the report application and enters each report, he or she will have direct access to the relevant digital slides, which can be examined on the same screen or in an additional, high-resolution screen attached to the same computer.

Imaging management in anatomic pathology

Some medical specialties (dermatology and hematology, for example) require direct access to the macroscopic and microscopic images generated in AP services, as this makes it easier for professionals in these fields to correctly evaluate a clinical episode. For this reason, anatomic pathology images must be part of the patient's health record.

Efficient management of anatomic pathology images should follow a model that is similar, although not identical, to the one used in radiology. It begins with a request for the generation of an image in a specific device or modality, next a worklist is drawn up detailing all the requests pending, and finally, when the images have been generated in their respective modalities, the system must notify the user of correct storage in the PACS of the generated image. All of these management tasks should be centralized through the APIS. However, since the image acquisition devices used in AP are not generally compatible with the DICOM standard (the medical imaging standard created by Digital Imaging and Communication in Medicine), an additional step (the "dicomization" of the images) is necessary before these images can be stored in the PACS.

Unlike radiology, in AP the focal point of images is samples and not patients, which means that orders for images originate only within the AP service area itself, through the APIS.

The work scheme recommended for the acquisition of images is as follows:
— The APIS creates a task list of the images that must be generated.
— Middleware (in the telepathology portal) sends this list to the corresponding device or module.
— The pathologist or technician reviews the list and generates the corresponding image (either gross or microscopic), which will automatically contain the identification data.
— After the quality of the image has been confirmed, it is sent to the PACS.
— The telepathology portal receives confirmation of the correct storage in the PACS and this information is transmitted to the APIS.
This scheme works especially well when the images are small (photos of macroscopy systems in JPEG format or microscope photos).

In the case of digital slides, where a single preparation can occupy over 1 GB, even after efficient compression, a specific solution is needed for these extremely large files. DICOM suggests two alternatives. The first is to use special servers for large images (such as JPEG2000) (Tuominen, 2009). The second solution, proposed by the DICOM Working Group 26, is to fragment the large images into thousands of small pieces, which can then be stored in the same servers that are already storing radiology images (DICOM, 2010). However, the high number of image fragments that the PACS would have to manage may compromise PACS performance. The decision is an important once, because if it is decided that a special AP server will be installed in order to improve performance, the server maintenance expenses in the informatics department will likely increase.

At this point in time, the main limitation of digital imaging in pathology is the slow speed at which slides are scanned. Currently existing systems need an average of 15 minutes to scan a single slide with 40x enlargement. Therefore, generally-speaking, only about 100 slides can be scanned per day with one scanner. Considering that a medium-sized anatomic pathology service generates about 500 slides every day, taking into account cytologies, biopsies and autopsies, five slide scanners would be necessary to handle the daily workload. Fortunately, scanning technology is evolving very quickly and there are now a few systems on the market that take just one or two minutes to scan a slide with 40x enlargement.

A great deal of storage capacity is required for AP images but, technologically, some very efficient solutions are available. We have calculated that about 100 TB of storage per year is needed to store all the digital slides used in an AP service in a 500-bed hospital.

With regard to the viewing of digital slides, since the DICOM viewers currently used to view radiology images do not have the tools needed to move through large images, specific viewers must be used for digital slides. Web viewers are recommended, as they do not require that slide viewer programs be installed in each one of the computers on which the images are to be viewed. This makes it easier for specialists such as dermatologists or hematologists to access the digital slides.

The digitalization of microscope images allows the pathologist to use certain tools that assist in the interpretation of these images. There are some FDA-approved algorithms for automated image analysis that automatically quantify the immunohistochemical expression of certain biomarkers, such as estrogen receptors, progesterone receptors, Ki67 proliferation index, Her2-Neu, all of which play a fundamental role in the diagnosis and treatment of breast cancer. Other algorithms that are being developed allow specialists to detect which areas of a histological preparation or a cytology are most suspicious of cancer (Bueno, 2008). In some specific applications, such as the study of Parkinson's, Alzheimer's, or early prostate cancer, researchers are looking into the potential role of 3D reconstruction of microscope images based on digital slides. In order to perform such research projects today grid-based massively parallel computing architectures are used (Bueno, 2009).

Figure V.1 shows the architecture of pathology imaging and report management, integrated with the electronic health record (EHR) system and the telepathology portal, following the model used in the Serendipia project of the Health Service of Castilla-La Mancha (SESCAM).

The telepathology portal

The output of the AP activity (reports, imaging, second opinions) of an entire network of healthcare providers can be centralized by using a telepathology portal that brings together all the data and images of the AP services of all the hospitals in the network. The high degree of geographical mobility shown by patients nowadays makes it necessary to have a single point of entry where all the AP reports and associated images can be consulted. This is especially advantageous for clinicians and can contribute to the implementation of patient summaries at the national and international level. This platform is also a meeting point for all the pathologists who work for that provider network, so it is recommended that it also be used as a teleconsultation or telepathology service, for primary diagnoses (for example, intraoperative biopsies) or to seek second opinions.

A telepathology portal is feasible even in provider networks in which hospitals have heterogeneous APIS. Using the IHE recommendations it is possible to create central repositories for AP reports, based either on the sending of an updated copy of the AP report (for example, by sending a

PDF document to the repository), or through a distributed system of consultations made to the AP databases of each hospital, which dynamically generates the pathology reports requested.

Figure V.1. Integrated management of AP imaging and reports (Source: Compiled by author).
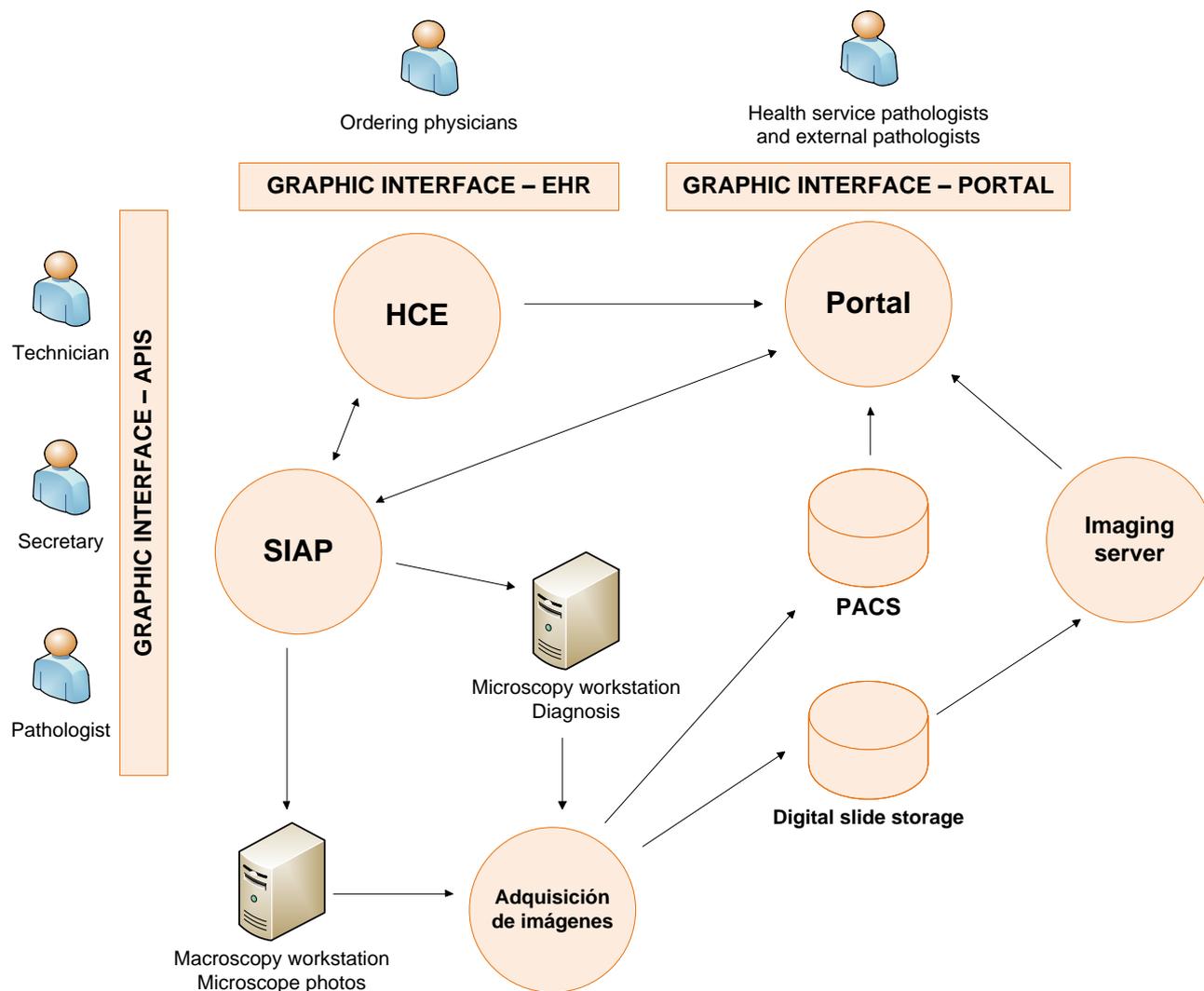
It is important that the reports sent by hospitals to the telepathology portal use SNOMED CT, especially in references to the type of sample and the final diagnosis.

The telepathology portal developed by SESCAM (Serendipia) contains the following areas:

— Digitalization services. This area is for examining images or requesting that slides be scanned (in the case of centers that do not have their own scanner). These services cover gross images, microscope photos and digital slides.

— Reports. This area is for examining pathology reports from all associated healthcare facilities, using flexible criteria (patient name, personal identification number, center, health record number, etc.)

— Discussion. This area is designed to facilitate consultation with other service areas in the same healthcare network (generally with a certain individual), to put queries to a public forum (all pathologists can respond to these cases), or to organize clinical-pathological sessions at the departmental, hospital or regional level.

— Training and knowledge management. Because all the information and images generated by the portal are perfectly structured and encoded, they can easily be transformed into very valuable teaching material, once patient identification data has been removed. This makes it possible to create libraries of interesting cases, atlases, on-line exams, for use in teaching medical students.

Semantic normalization

The definition by IHE of a proposed workflow for AP services, set forth in volume 1 of the Anatomic Pathology Technical Framework (IHE, 2010), meant that pathologists had to start using a common nomenclature for objects as common as the sample received, the container, the tissue fragment selected for histopathological study, each of the fragments that appear in a histological preparation, etc.

Semantic normalization in anatomic pathology has since been expanded to:

— Identification of procedures to be performed

— Identification of samples

— Variables discussed in the AP report

— Final diagnoses

Three terminologies are used for this purpose: LOINC (Logical Observation Identifiers Names and Codes), SNOMED CT and PathLex (IHE, 2011).

Pathologists must be encouraged to stop using the classic coding system provided by SNOMED II, which uses topography (T), procedure (P) and diagnosis (M) lists, because this system is not maintained by the International Health Terminology Standards Development Organization (IHTSDO). The recommendation is to instead use SNOMED CT, which is a system based on relationships between terms and contains about 311 unique concepts. For this reason, in AP services that still use SNOMED II or their own coding system, it is advisable to convert these codes to SNOMED CT, so that all information can be exchanged in a structured manner (for example, to send anatomic pathology diagnoses to the EHR), using a SNOMED CT unique concept identifier for each term.

Conclusions

Anatomic pathology information systems will develop considerably thanks to the progress being made in molecular biology and in systems for the digitalization of microscope images.

The digitalization of histological and cytological preparations for AP activity will enable these images to be available from the patient's health record as well. This will allow other specialists, such as a dermatologist or a hematologist, to have access to this kind of image and will contribute to the education of medical students and residents.

The use of teleconsultation and distance diagnosis, based on digital slides, can help alleviate, at least in part, the problems caused by the shortage of specialists in some countries. Telepathology services will grow quickly once all pathology images are available in a standard digital format. In research this will revolutionize the validation of new physiopathological concepts and therapies.

At this point in time, digital slides pose a significant challenge for existing standards. Application of the DICOM standard, which is now available for digital slides, is necessary if interoperability is to be

achieved in the long term. Fortunately, great efforts are being made towards normalization in digital pathology and the results are becoming visible. Normalization is what enables interconnection between telepathology networks, which will allow efficient access, exchange and update of EHR data, even by Internet.

Digital pathology now offers unprecedented flexibility in the preparation of AP reports, because it is possible to generate different types and formats of reports for different users who have varying levels of expertise.

Digital pathology solutions integrated with the EHR and centralized imaging storage will improve cooperation between clinicians and pathologists, with the aim of increasing patient safety and the quality of the care provided.

It may be that in the future it will be necessary to obtain 3D information from histological and cytological preparations. 3D navigation, high-performance imaging viewers, tools to detect areas of interest and even the appearance of specific hardware will no doubt allow pathologists to replace the microscope with devices that improve the quality and efficiency of their work.

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Chapter VI

Medical imaging

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Summary

Recent years have seen a considerable expansion of the diagnostic imaging departments in health organizations. Information technologies are making such expansion possible, through the implementation of Radiology Information Systems (RIS) and Picture Archiving and Communication Systems (PACS) in these departments.

RIS and PACS support the activities carried out in diagnostic imaging departments – from the scheduling of appointments, through the examinations and the storage of studies to the diagnosis and drawing up of the report. The implementation of a digital medical imaging system offers a wide range of benefits, as much for the organization as for the patient. Such systems can help organizations save on costs and optimize their resources. For the patient, these systems can prevent the repetition of examinations due to studies being lost or to redundant image requests – with the consequential reduction of exposure to ionizing radiation. For medical imaging specialists, the RIS and PACS imply a substantial change in work procedures, offering such benefits as easier handling of medical images through specialized tools, and the option of applying post-processing functions to the studies (e.g., viewing the images in a multi-dimensional format). Digital imaging systems were first implemented in radiology or diagnostic imaging departments, although they can also be used for any digitally-formatted medical image that may be generated in a health organization.

RIS and PACS technology

An RIS is an information system that supports the management of all activities in a diagnostic imaging department. This includes scheduling medical imaging examinations, planning the use of medical imaging devices and modalities, managing the imaging process itself, and also the diagnosis and preparation of the pertinent report (Huang, 2010). The RIS can either be a component or subsystem of the HIS (Hospital Information System), or it can function as an independent system. If the RIS operates independently and is not part of the HIS it can be integrated with the HIS through the HL7 (Health Level 7) protocol. The PACS, on the other hand, takes care of managing the medical image itself. This activity includes image acquisition, storage and later distribution for the preparation of reports (Haramati, 2000).

RIS

The RIS functions as the central nervous system of a diagnostic imaging department (Dreyer, 2006). It can also be said that the RIS directs that department's workflow, given that the department's tasks and activities are all in one way or another performed with help from the computerized RIS.

In addition to the clinical functions of an RIS, the system can also manage the billing for any examinations performed, as well as provide help in using data to analyze the efficiency of imaging studies, evaluating the quality of the orders received, etc.

The scheduling of the appointment is the patient's first contact with the RIS. This task is handled by the appointment management system (AMS) if there is one. This process brings together all clinical information needed for deciding which examination or type of test is to be performed on the patient. This is also the time to identify the patient and collect his or her demographic information. Patient identification is an essential step in the process, given that it is the nexus that connects all the information about the patient – even when it is distributed among different systems.

Information related to the patient's appointment –both clinical and administrative– will be very important in the process of performing the imaging tests. On the one hand, this information will be forwarded to the PACS in order to advise that the imaging modalities will be sending medical images that will have to be associated with a particular patient and test. The information will also be used by the technicians performing the tests, who will have access to information on the patient and the kind of test to be carried out. Once the test has been performed, the technician will inform the RIS that the test has been done, and the images will be sent to the PACS.

From the moment that the images from the radiological examination are duly stored in the PACS, they are available for viewing and report preparation. At that time, the diagnostic imaging specialist will interpret the image and draw up a report on any significant findings that may be seen in that image. This interpretation task is done on the RIS, which commonly employs specialized voice recognition programs. Thus, the diagnostic imaging specialist either directly writes up the report or dictates it by means of a computer program that automatically transcribes the text to the RIS.

Once the report is signed by the radiologist it becomes part of the patient's electronic health record, and is available to physicians, who may gain access to this image and its corresponding report through computer access points of the health network.

PACS

A PACS (Picture Archiving and Communication System) comprises three subsystems that are connected through computer networks and controlled by specialized software: medical image acquisition, storage in archival structures and image viewing at work stations (Huang, 2010).

Medical image acquisition

Medical image acquisition is the activity by which a diagnostic modality interacts with the PACS in order to send it the imaging study, duly identified and error-free.

A modality is associated with the methods by which the diagnostic images are obtained. These procedures depend not only on the physical phenomenon on which they are based (ultrasound, X-rays,

magnetic resonance, photon emission), but also on the pre-process employed (digital subtraction angiography, computed tomography, film digitization, etc.) (Chavarría, 2004).

Figure VI.1. Integration of systems and equipment for medical imaging management.
(Source: Compiled by authors)
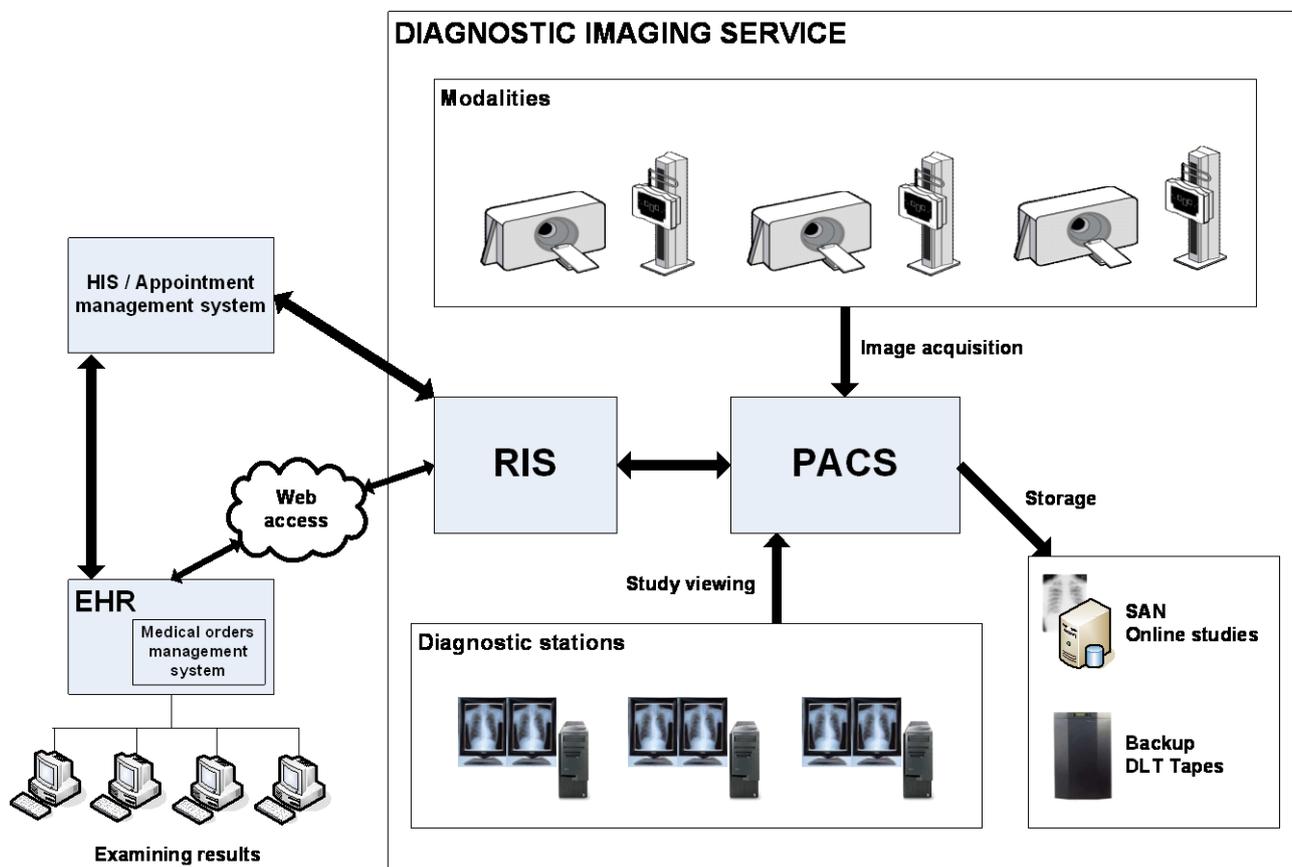
We can also say that diagnostic modalities are the devices used for carrying out the medical imaging explorations. Some examples of diagnostic modalities are magnetic resonance imaging (MRI) equipment, computed tomography (CT) scanners, nuclear medicine (NM) devices, ultrasound (US) devices, etc.

All images must be in digital format if they are to be used in the PACS. Towards this end, the images are either directly acquired in this format (digital modalities) or, in the case of analogue modalities, they are subjected to a digitization process. Accordingly, digital images are those that have been acquired by means of a digital modality, while digitized images are those that have been transformed by means of a digitization process. In either case, both kinds of images are handled in the same way by the PACS. An ever-growing number of modalities provide images directly in a digital format, such as magnetic resonance, digital subtraction angiography or computerized axial tomography. On the other hand, the analogue modality par excellence –conventional radiology– provides images on standard radiographic film (Chavarría, 2004).

A wide range of methods is available for digitizing images obtained through analogue modalities. One way to digitize images in radiology film format is through the use of a film scanner. In this case, the

radiology films are placed in a CCD technology scanner, which converts them to a digital format through a process in which uniform light is passed over the surface of the film.

If a modality that generates a moving image or video is available, but without the possibility of a direct digital connection, then the video image is digitized with the use of a frame grabber. For this process, the device's analogue video output is connected to a computer that reproduces the video generated by that modality, thus making it possible to capture images that may be of clinical interest, which can later be stored in the PACS (Li, 2003).

Likewise, two technologies are available for directly obtaining digital format images using conventional radiology – thus avoiding the need to develop the radiology film: Computed Radiography (CR) and direct Digital Radiography (DR). In CR technology, the image is generated from special, reusable phosphor plates located inside a cassette similar to that used with conventional radiography. The state of these plates is altered when they are exposed to X-ray energy. The cassettes are then inserted into a device that interprets and constructs the digital image from the information contained on the phosphor plates (Seeram, 2011). Direct digital radiography uses digital receptors that directly transform the energy emitted by the X-rays into completely digital signals. It is important to point out that the tremendous growth and widespread use of PACS was made possible by the digitization of conventional radiology – through the use of either CR or DR (Chavarría, 2004).

Three parameters are used to measure the quality of a digital image: spatial resolution, density and signal-to-noise ratio (Huang, 2010). Spatial resolution is related to the number of pixels –the dots that comprise an image– per inch or centimeter. Density, meanwhile, tells us about the number of possible values used for representing a dot or pixel. An image can thus be described by three values, with the first two corresponding to the spatial resolution and the third value showing the density or number of bits for each pixel. For example, an image taken with computed tomography (CT) could be defined by the values 512x512x12 – which means the resolution is 512x512 dots per inch, with each pixel or dot represented by 12 bits. In other words, each pixel or dot on the screen has 2^{12} = 4,096 possible values.

The resolution and density needed to obtain diagnostic-quality images differ depending on the modality and image type. The density can vary from eight bits for a digital subtraction angiography (DSA) –which corresponds to 256 gray levels– to 24 bits for a True Color ultrasound image, which corresponds to 16,777,216 possible colors. Images with a higher level of resolution and density require larger volume digital images. Image compression techniques are commonly used for reducing storage requirements. Normally we speak of lossless compression with factors of 2:1 or 3:1, and also of compression with losses that can be as high as 10:1.

Similarly, each modality requires a different number of images for each study or examination. The volume of information in a PACS system is usually measured in the magnitude of terabytes[28]. Table VI.1 shows the types of image by modality and their size (Huang, 2010).

Storage

Storage is one of the basic elements in a PACS. The images must be stored and available to those requesting them at any time. Due to the large volume of information that has to be managed, the storage system must be secure, fast and reliable.

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[28] 1 Terabyte = 10^{12} bytes

Until recently a distinction was made between primary and secondary memory. Primary memory was characterized by the quick access to images it offered, along with its limited size. Secondary memory offered slower access, and was used to store older primary memory studies. The main reason for this distinction was the cost of the storage infrastructure, with primary being more expensive than secondary. These days the cost of storage devices has dropped considerably. Accordingly, it is no longer common to differentiate between primary and secondary, and just one memory is used for storing imaging studies.

Table VI.1. Medical image resolution and size by modality (Source: Compiled by authors).			
Modality	**Bits/image**	**No. of images/examination**	**Size/examination (Megabytes)**
Nuclear Medicine (NM)	128x128x12	30-60	1-2
Digitized radiology film	2048x2048x12	1	8
Computed Radiography (CR)	2048x2048x12	1	8
Digital Mammography	4000x5000x12	4	160
Computer Tomography (CT)	512x512x12	10-1000	starting from 5
Magnetic Resonance (MR)	256x256x12	100-1000	starting from 2.5

The current trend in PACS storage technology is the use of a SAN (Storage Area Network). A SAN is a central data repository that can be used by different servers or processes for managing data. SAN disks are usually configured with RAID (Redundant Array of Independent Disks) technology, because it offers greater integrity, higher failure tolerance and better performance. With the application of this technology, there is no data loss if a disk fails, since the system is able to regenerate the data stored on a failed disk.

DLT or LTO type magnetic tape drives, which are managed by a library or jukebox, are normally used for long-term copies. There are different kinds of DLT drives that can store up to hundreds of Gigabytes. Access to the information on these drives is quite slow, so they are not recommended for direct access to images. This solution is used for backup copies.

Another current solution for storing images is through the use of an external storage provider. This is known as storing images in the cloud – or cloud computing.

Viewing the imaging studies

A display workstation makes studies available to the diagnostic imaging specialist for interpretation and subsequent report preparation. This workstation accesses the RIS in order to obtain information from a study, while using the PACS for obtaining the images associated with said study (Boochever, 2004).

A workstation basically comprises four hardware components: a computer, a graphics card, one or more monitors and local storage devices. The workstation is connected to the data network for access to the studies stored in the PACS. The computer and graphics card are responsible for transforming the images provided by the PACS, so that they can be viewed on the monitors. The features of the graphics card have a huge influence on the quality of the image shown on the screen, as well as on the speed with which the images can be handled while being displayed at the workstation. The local storage devices are used for saving studies at the workstation, when doing so is necessary.

Monitors equipped with special features are used for viewing images. Cathode ray tube (CRT) technology is currently being replaced by LCD (liquid crystal display) screens. The main advantages of

LCD over CRT include greater brightness, lower energy consumption, lighter weight and smaller size. On the other hand, CRT monitors offer a higher level of color consistency. Apart from the size, which is measured in inches, the characteristics used for determining a monitor's suitability are resolution, brightness and contrast.

Resolution is specified in the monitor's number of dots or pixels. The display area of a monitor is made up of a matrix of dots – called pixels (for picture elements). Thus we can speak of monitors offering 2 megapixels or 5 megapixels, meaning that the monitor can display 2 million pixels or 5 million pixels. A 2 megapixel resolution corresponds to 1600x1200 dots in the monitor. In order to take full advantage of a monitor's resolution, the graphics card must have sufficient power to display, at least, that monitor's resolution. The need to use monitors with more or less resolution will depend on the kind of imaging studies to be displayed; viewing mammographies requires monitors with a resolution of 5 megapixels.

Brightness, meanwhile, measures the amount of light that a monitor is capable of displaying. Contrast depends not only on the brightness of an image, but also on the intensity of the ambient light.

Medical imaging workstations

The workstations used for the management of medical imaging can be classified into six groups (Huang, 2010): diagnostic, review, analysis, digitization and printing, interactive instruction and, lastly, research. The most common are the stations for diagnosis and others for digitalization and printing, which are described below. We will also mention some special stations for post-processing that have appeared in recent years.

Diagnostic stations are used by diagnostic imaging specialists for drawing up reports on the imaging studies. Such stations should offer the highest possible image quality and the fastest performance within a user-friendly environment. Diagnostic stations require a voice recognition system to help the specialist report on the findings. As mentioned above, the level of monitor resolution needed for diagnostic stations will be determined by the kind of imaging studies to be diagnosed. A diagnostic workstation will usually be equipped with at least two high resolution monitors for viewing images, and a conventional monitor for accessing the RIS (Carter, 2010).

Digitization and printing stations are used for digitizing radiology films and for printing images on printing plates. They are equipped with scanners for digitization and film printers for printing the images. Although a hospital may be fully equipped for digital imaging and have completely eliminated film media, such stations will still be needed for exchanging information with the exterior; for incorporating into the PACS any film format imaging studies that have been performed outside the hospital, as well as studies of interest from the historical archives, or for printing an imaging study that is to be sent to a healthcare environment that still uses only radiology film.

In recent years, multidimensional imaging technology has grown exponentially. This advance has had two consequences: the generation of hundreds or even thousands of images for every study done and the need to view these studies in a multidimensional way – in three dimensions (3D) or four dimensions (4D). Post-processing workstations must be equipped with tools and functions that make it possible to properly handle such multidimensional reconstructions. Some methods used in these stations include (Huang, 2010): multiplaner reconstruction (MPR), maximum intensity projection (MIP), shaded surface display (SSD) and volume rendering (VR). Post-processing workstations are equipped with special software that makes multidimensional modeling possible.

The functions and tools that are essential for workstation operation include the following, among others:

— Zoom and scroll. These tools make it possible to center the area of interest of an image on the monitor.

— Brightness and contrast control.

— Image reversal, which makes it possible to change the pixel value of an image.

— Measurement of distances, angles and areas.

— Background elimination, which makes it possible to highlight and isolate important elements.

Image distribution

Implementing a PAC system brings a drastic reduction in the use of radiology film as media for medical imaging. However, the elimination of film has significant repercussions on the way that imaging studies are distributed in a hospital. Given that the aim of any diagnostic imaging department is to deliver the properly detailed imaging studies to the specialists who have requested them, a new way of distributing the digital images is needed so that they may be accessed by these clinicians. The web is the technology used for distributing images from the PACS in the most cost-effective manner. This way, imaging studies and their associated reports can be accessed from a workstation within the health organization, or from any remote equipment with internet access – using a conventional computer without needing to install any specialized program. Although it depends on the manufacturer of the various PACS on the market, computer access to PACS imaging studies over the web usually takes place by means of a one-time automatic installation of a software component in the computer browser the first time such access is sought.

A web server is also necessary for distributing the images stored on the PACS. When a client computer requests an imaging study from the web server, the server then consults with the PACS in order to deliver the requested images. Usually the image quality is adjusted to the characteristics of the computer connecting through the web. Generally, the quality of images obtained over the web is lower than that of images accessed through a workstation equipped with a special graphics card and high resolution monitors. A web server used for image distribution will perform the following specific functions:

— Interpret the image orders from a browser in HTML or Java format and convert them to DICOM and HL7 standards.

— Support DICOM operational modes for the ordering and retrieval of images from the PACS.

— Provide format conversion functions for DICOM images to JPG, which will be displayed on the web browser.

Accordingly, the tools used in computer programs at workstations are more powerful than those used when accessing images through a web interface. For these reasons, such workstations are meant for diagnostic imaging specialists who must diagnose and prepare the pertinent reports. Access to the PACS through a web browser, meanwhile, is designed to provide access to the specialists who have ordered the studies and who must see the images and, more importantly, the associated report.

HL7, DICOM, IHE standards

In a healthcare environment, information systems and diagnostic devices communicate through standardized protocols. The diagnostic imaging field employs DICOM (Digital Imaging and

Communication in Medicine) and HL7 (Health Level 7) protocols, which enable communication between all the systems used: the HIS, the medical order management system, RIS, PACS and the diagnostic modalities, among others. In addition, there is a model that focuses on workflows and is designed to contribute to systems integration. This model is known as the IHE (Integrating the Healthcare Enterprise) (Dreyer, 2000).

DICOM[29] is a communications protocol used in healthcare environments. It was promoted by the ACR-NEMA (American College of Radiology-National Electrical Manufacturers Association) in 1985, and its appearance marked the beginning of the standardized use of medical images in health organizations. This protocol facilitates interoperability among medical imaging devices from different manufacturers, making it possible to send and receive medical images with standardized procedures that are independent of the brand and model of the modalities and of the PACS. DICOM defines the communication layer for message interchange, command syntax and semantics, and also the archival storage format. This protocol is the standard used by diagnostic devices or modalities and the PACS for exchanging images and associated information.

A medical imaging device must use the DICOM protocol in order to communicate with the PACS. Accordingly, when purchasing a medical imaging device it is important to make sure that it includes the licenses necessary for DICOM services, and that they are compatible with the PACS. Similarly, collaboration between PACS suppliers and diagnostic modality suppliers is essential for the optimal functioning of a medical imaging system, given the high level of interaction required of them.

The HL7[30] is another important protocol used in healthcare environments. It was presented in 1987, promoted by healthcare organization suppliers, who months beforehand had formed a commission for standardizing the exchange of data between hospital computer applications. HL7 is a reference framework for the exchange, integration, sharing and retrieval of healthcare information in electronic format, which provides support for clinical practice and the management of healthcare services. By means of this standard, a patient's health and administrative information can be exchanged between such systems as the HIS, the medical order management module, the RIS or the PACS – automatically and without the direct intervention of an employee.

IHE[31] is a joint initiative of the RSNA[32] (Radiological Society of North America) and the HIMSS[33] (Healthcare Information and Management Systems Society) in which a variety of health organizations and technology suppliers participate. Its aim is to improve the integration of diagnostic devices and healthcare information systems through the standardized use of DICOM and HL7. IHE focuses on the resolution of interpretation conflicts regarding DICOM and HL7 implementation. Towards this end, it first identifies integration problems in process administration, workflows, information access or in the infrastructure being used. Then the IHE chooses standards to cover the integration needs and the details of implementation are documented in the IHE. As a result, when a manufacturer develops its products in accordance with the IHE, integration of information in the healthcare environment will be less complex.

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[29] http://medical.nema.org/
[30] http://www.hl7.org/
[31] http://www.ihe.net/
[32] http://www.rsna.org/
[33] http://www.himss.org/

Aspects related to care provision

New workflows

The implementation of a PACS offers a wide variety of potential benefits. Of particular importance among them are improved productivity and the optimization of workflows due to the elimination of radiology film and its associated printed documentation. In addition to optimizing the production of medical images, the PACS offers further advantages in relation to film storage. In a healthcare environment where radiology film has been eliminated –a filmless environment– there is no need to use physical space for film or document storage, nor is it necessary to have the film taken to patient care areas. Rather, the imaging studies are electronically available and accessible from any point in the network (Huang, 2010).

Replacing radiology film with digital images is not always easy. It calls for a substantial change in culture, which must be applied not only in the diagnostic imaging department, but in the entire healthcare organization. One of the most effective ways to foster this change is to stress the possibility of immediately accessing –at any time and from any location– the complete radiological record of any patient.

Digital images lead to changes in workflow in three central ways: automation, integration and simplification. Automation comes in the form of replacing manual tasks with others that are performed with the help of an information system – for example, setting up patient appointments or sending the work list to the modalities to be used, thus avoiding the need for technicians to write down a patient's demographic data before carrying out a test. Integration implies the use of a single set of patient identification data, available through the exchange of information between systems. Simplification can be seen in the way complex, time-consuming tasks are transformed into other, more streamlined activities. One example of this can be seen when a diagnostic imaging specialist accesses earlier studies of the patient in order to compare them with the current imaging study, so as to make a better diagnosis.

The list below provides a rough idea of a possible workflow in the context of digital imaging:

1. The patient is registered in the HIS. The radiological test is ordered by the medical order management module and an appointment is arranged by the appointment management system – or by the RIS if there is no such system.
2. The RIS sends the required patient demographic data in HL7 format to the PACS, which is now ready to receive images from the study.
3. The patient arrives at the modality, which receives the worklist from the RIS.
4. The technicians uses the modality to obtain the images, which are then sent in DICOM format to the PACS. The image is now available for viewing from a diagnostic station, or to be accessed from a web station.
5. The diagnostic imaging specialist accesses the PACS images from his or her diagnostic station through the RIS. The specialist then dictates his or her report using a voice recognition system, or manually writes it. From that time on, the report will be available, together with the associated images, to the clinicians who need them.

Teleradiology

Teleradiology is the electronic transmission of medical imaging studies from one place to another, in order for those studies to be interpreted or consulted. In this way, medical images can be simultaneously accessed from different locations. Used appropriately, teleradiology can improve the interpretation of imaging studies and, as a result, improve patient care (Caffery, 2004).

Among the essential components in teleradiology are the communication lines used for transmitting images from the location where they are obtained, directly from the modality or from the PACS, to the place where they will be viewed for consultation or diagnosis. Given the considerable size of medical images, the speed of the communication lines is a vital factor. The compression of the imaging studies is associated with this speed – the greater the compression the faster the transmission time. Transmission security is yet another essential feature of communication lines, in order to protect the confidentiality of the data, its authenticity and its integrity (Struber, 2003).

Teleradiology has the following objectives:

— To provide medical imaging study consultation and interpretation services, such as second opinions.
— To make diagnostic imaging reports available without the need to have a diagnostic imaging specialist physically present.
— To enhance training in diagnostic imaging.
— To provide support for telemedicine.

Cost benefit and return on investment

Implementing a PACS necessarily brings a transformation to the healthcare organization. Benefits can be tangible as well as intangible. The tangible benefits are those that can be measured in terms of cost reduction, which in a PACS implementation project are the following:

— Elimination of radiology films –the physical media– which implies a considerable reduction in costs for the diagnostic imaging department.
— Much less storage space required.
— Disappearance of a whole set of radiology film operations and equipment, including developing machines, the liquids used, and the time needed for developing a radiology film. Savings also arise from optimizing how time is used by diagnostic imaging specialists, technicians and administrative personnel.
— Fewer employees needed to move radiology films to patient care locations.
— Unnecessary repetition of examinations reduced.

Intangible benefits are more difficult to recognize and identify, but the PACS offers substantial advantages to any clinical service by helping to improve the efficiency of the patient care process. Such benefits are derived from the possibility of having medical imaging studies available at the right time, in the right place and in the appropriate format. This helps to increase cooperation and interaction between health services (Ayal, 2007). Such intangible benefits can be appreciated over the long term.

The future of medical imaging

PACS can now be regarded as a mature technology. These systems are able to store any medical image generated inside a healthcare organization, in addition to the images originating from diagnostic radiology services. Accordingly, they store images generated in electrocardiographs, ultrasound images that are used by different health services inside the organization, endoscopic images, etc. (Yu, 2010).

In addition to the growing number of modalities, the trend in medical imaging is towards the use of more specialized computer tools that recognize the different areas of a medical image and, by comparing them with pathology patterns, offer diagnostic support. Specialized tools for 3D and 4D modeling are also worth highlighting. These technologies are capable of presenting a virtual recreation of organs and body parts that can be of considerable assistance in diagnostic examinations and in planning surgical treatments and non-surgical interventions.

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Chapter VII

Telemedicine: general considerations and clinical areas of application

Giselle Ricur

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Summary

The support provided by information technology (IT) to the medical profession has made it possible to practice healthcare more creatively, while heightening its efficiency and productivity. In areas such as accessibility, mobility, service management and quality, transparency, etc., IT is currently contributing an unprecedented level of added value.

With telemedicine, patient-physician interaction transcends geographic and time boundaries by avoiding unnecessary travel, shortening waiting times for treatment and allowing diagnoses and treatment decisions to be made from specialized centers far away. Telemedicine thus helps fill the gap caused by the lack of qualified human resources, or the excessive concentration of such resources in urban communities, to the detriment of more rural areas, which also tend to be less equipped in terms of physical resources.

Asynchronous applications (such as the use of email to transmit patient images or to facilitate patient-physician communication) and also synchronous applications (such as videoconferences for inter-physician consultations or to examine patients in real time) are being widely used in major medical centers all over the world.

Telemedicine today should not be perceived solely as a technology, but rather as a new organizational system for the medical profession. The application of telemedicine represents a new way of organizing and providing healthcare services, one that benefits patients, medical professionals and the healthcare system as a whole. The use of telemedicine shortens the time and distance between primary and hospital care. The medical fields of telestroke, teleophthalmology, teledermatology and teleradiology are the ones in which the most collaborative work has taken place between primary and specialized care.

Introduction

The original concept of telemedicine has evolved over the years, especially with the arrival of the digital era, or the information society, as we understand it today. The emergence of IT tools has had a revolutionary impact on our society, radically changing the way we work and relate to each other. Communication itself has taken on a new personality, another role, another dimension. The multi-directional and simultaneous nature of the new format has given rise to a new concept of collaborative communication that is network-based and on demand – unaffected by time and distance.

While many sectors of society have been participating in this global phenomenon for some time, healthcare has only recently found its place within this new communications scenario. In the beginning, the concept of telemedicine was described as medicine practiced at a distance[34]. It was Willem Einthoven who first used the prefix *tele* –in 1905– when he invented the first tele-electrocardiograph. In the 1970s Thomas Bird popularized the term telemedicine. The literature provides many examples of medicine being practiced at a distance thanks to the different communications tools available at that particular time, in the analogue era starting in the 18th century and continuing into the digital age with the appearance of the computer and internet in the 20th century (Craig, 2011; Sosa-Iudicissa, 2001; Rashid, 2009; Strehle, 2006).

Today the American Telemedicine Association (ATA) defines telemedicine as "the use of medical information exchanged from one site to another via electronic communications to improve patients' health status"[35]. The term is closely connected to telehealth (which is somewhat broader, as it includes health services and care, management, education, etc.). It is also related to health informatics, the field that offers technological solutions that serve as the structural support for implementing health applications (integrated clinical information systems at the hospital or organizational level, electronic health records, etc.).

However, what is most significant may not be simply the semantic definition, but rather the transcendence of the meaning of the term telemedicine, which suggests a paradigm. Here, the status of health and the art of curing are no longer geographically or temporally bound – or even limited to a particular sector. Rather, they are conditions or actions that must be within the reach of all those or need or participate in them – in time and form. Today our sector can and must search out the individual – whether healthy or ill. We must not wait until they come to us. Accordingly, the healthcare model is mutating, camouflaged behind new, technologically altered versions of such concepts as progress, accessibility, equality, quality, privacy and security. The Aristotelian essence of caring for, curing and containing illness remains the same, apart from the technological progress and new tools that will surely continue to surprise us with the passing of each year.

We have yet to see IT integrated into healthcare to the fullest extent, yet undoubtedly the experiences that have accumulated to date have been enriching and encouraging.

Taxonomy

In the literature we find a number of taxonomies or ways of classifying and describing the most common telemedicine applications. However, for any of these services and applications to exist, there must first be networks over which information can be transmitted; then there are the different services that enable users to take advantage of these networks, and finally, the applications which are what offer specific solutions to a group of users (Tulu, 2007).

All of this must be structured around the basic concepts of standards, interoperability and quality of service (QoS). If consensus has not been reached regarding the need to adhere to legislation and standards in order to ensure the compatibility of all systems and solutions and thus guarantee quality of service, it will not be possible to interact globally, and much less to generate the critical mass needed to expand the telemedicine market.

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[34] From the Greek *tele* ("distant") and *medicine,* which comes from *mederi* ("to cure") or from the Latin *medicus* ("to cure").
[35] American Telemedicine Association (ATA) Telemedicine Defined.
http://www.americantelemed.org/i4a/pages/index.cfm?pageid=3333

A simple guide can be created by dividing services into their most generic categories – clinical and non-clinical. These can then be divided more specifically, depending on the pertinent branch or medical discipline (see Table VII.1). Clinical services per se can be divided into triage or emergency services, primary care, secondary and/or tertiary care (clinic and surgery), inter-professional consultations, remote monitoring and decision-making support. Non-clinical services include medical management and public health monitoring services, research and development, education for patients and ongoing medical training for the medical community (both under-graduate and post-graduate), etc. (Tulu, 2007).

Table VII.1. Taxonomy of telemedicine (Source: compiled by author).			
Target area		**Domain-application area**	
Clinical	**Non-clinical**		
Triage	Ongoing medical training	Radiology	Emergency medicine
Diagnosis	Community education	Cardiology	Intensive care
Clinical treatment	Research & Development	Pathology	Obstetrics-gynecology
Surgical treatment	Public health	Dermatology	Surgery
Consultation	Health management	Ophthalmology	Oncology
Monitoring / surveillance		Mental health	Microbiology-immunology
Primary care supervision		Neurology	Otolaryngology
Delivery of specialized care (tertiary care)		Pediatrics	
Second opinion services			
Applications	**Environment**	**Telecommunications network**	**Synchronism**
Electronic data transmission	Hospital	Satellite	Asynchronous – deferred time
Email	Clinic-Institution	Microwave link	Synchronous – real time
Fax	Health center	Radio link	Mixed
Telephone	Community center	Internet	
Web platforms/portals	Schools	Mobile telephony	
Terminal-server platforms	Homes	Digital telephony	
Local platforms	Workplace	Analogue telephony	
VoIP teleconferencing	Mobile	Bluetooth device	
HD videoconferencing- tele-presence		Infrared device	
ISDN/ADSL videoconferencing			
IP videoconferencing			
Social media Apps 2.0			
Tablet/Mobile phone Apps - PDAs			
Video-streaming / Audio-streaming			
Medical devices and peripheral devices			

Thanks to the implementation of different information technologies and tools, these services can take place in real (synchronous) or deferred (asynchronous) time, depending on the clinical application. They can take place at hospitals and other types of healthcare facilities, or at public places, homes, recreation centers, schools, the workplace, etc. All of this depends on the type and level of network organization connecting each of these places.

These services can also take place in the form of interactive consultations with the active participation of health professionals and patients; the reading and interpretation of information transmitted solely for diagnosis in deferred time; or inter-professional consultations in which –either in

real or in deferred time– health professionals send clinical information for discussion, with or without the patient present (in other words, getting a second opinion).

It is easy to see that the different aspects of telemedicine, such as functionality, applications and technology, are inextricably woven together. Rashid Bashur, a true telemedicine pioneer, has proposed a new way of classifying all of this in a three-dimensional model represented by a cube. Each dimension of the cube represents functionality, applications and technology, while each face represents the components of each dimension (functionality: teleconsultations, telediagnosis, telementoring and telemonitoring; applications: specialties, illness, place, treatment; technology: synchronism, network design and connectivity) (Bashur, 2011).

Applications

Traditionally, certain clinical areas have benefited more than others from telemedicine, mainly because of the large amount of information and images that these specialties may find it useful to transmit from one point to another. This has been the case with teleradiology, teledermatology, telepathology and teleophthalmology. Another specialty that has made especially good use of telemedicine is telepsychiatry or telemental health, although progress in this area is not related so much to diagnostic images as to the ease of carrying out a therapy session from a distance. In any case, by now almost all medical-surgical specialties have incorporated IT into their usual settings. Moreover, new applications have emerged based on certain illnesses, or on the locations in which they are used. One example is telestroke, which has become an application in and of itself – almost independent of teleneurology. Another example can be found in tele-ICU, which is based on the concept of remote care provision and monitoring in situations of intensive care (O'Reilly, 2011).

Each application takes on distinctive nuances depending on service modality, synchronism and connectivity. For this reason, it is very important to define, justify and delimit the area of action for telemedicine applications, by means of standards or best-practice guides such as those offered by the American Telemedicine Academy, the United States Federal Food and Drug Administration (FDA) and the ISO Standards[36].

Applications working in deferred time

Applications that involve transferring content from one place to another –for processing and interpretation at one time and return at another– are known as deferred time, or asynchronous applications (Della Mea, 2011). Such applications make it possible to transmit audio, text, images and video from one center to another over different channels, whether telephonically by modem, or by fax, email or cell phone. It is even possible to upload content onto the internet via ftp, so that other users can access that content from their own location. The most classic examples of this are telepathology, teledermatology and teleradiology, in which diagnostic images are sent by email or uploaded and stored in PACS web servers to be read and/or downloaded at a later time.

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[36] American Medical Association's Guidelines for Physician-Patient Electronic Communications. www.ama-assn.org/ama/pub/about-ama/our-people/membergroups-sections/young-physicians-section/advocacy-resources/guidelinesphysician-patient-electronic-communications.page
American Telemedicine Association's Core Standards for Telemedicine Operations. Nov 2007. http://www.americantelemed.org/i4a/pages/index.cfm?pageid=3311
FDA Guidelines Related to Telemedicine. http://www.americantelemed.org/files/public/standards/FDA_Guidances_Related_to_Telemedicine.pdf
ISO TC 215. Health Informatics. http://www.iso.org/iso/iso_technical_committee?commid=54960

Applications working in real time

The feasibility of sharing information in real time –synchronically– thanks to the use of various videoconferencing techniques, has enabled many specialties to make rapid progress in implementing and expanding different telemedical initiatives (Wooton, 2011). This particularly applies to such specialties as telepsychiatry, telenursing, telerehabilitation and telepediatrics, which have grown dramatically over the past five years. Meetings of this kind make it possible for places to link up in real time, with or without the patient. It should be noted that such consultations between physicians can take place with the patient present, during the patient's appointment with the doctor, or simply as inter-consultation between colleagues. Such consultations can also take place through the presentation of the case to another type of health professional, again either with or without the patient. The truly enriching aspect of this experience is the dynamic nature of the exchange, which provides a sensation of "presence" instead of merely a virtual sensation. This is thanks to new high definition video technologies that offer face-to-face realism, even in front of a monitor.

Sometimes the same specialty can make use of both modalities. This can be illustrated by teleophthalmology, in which diabetes screening is usually carried out by capturing images of the posterior pole of the retina, which is later sent to reading centers for interpretation and diagnosis (Zimmer-Galler, 2006). However, the use of slit lamps connected to video-teleconferencing (VTC) equipment enables real time eye examination. Surgical microscopes equipped with video cameras and IP outputs, which enable surgical telementoring sessions, are another example (Ricur, 2006; Tang, 2005).

Areas of application

Teleradiology[37]

Radiological images have been electronically transmitted for thirty years now, making radiology one of the first successful clinical applications of telemedicine. This activity grew and became consolidated thanks to the efforts of the scientific community, which worked hard to normalize the signals and processes used by establishing standards – such as the DICOM standard, which facilitated the standardization and interoperability that characterize this discipline[38].

While most radiological information is handled in deferred time, thanks to the implementation of PACS (Picture Archiving and Communication Systems), there are also dynamic or interventionist imaging studies that take place in real time. Bandwidth requirements vary, depending on the type of synchronism – from the simple exchange of images in secure format over a low-bandwidth line to real time consultations, where movements of the parties and heavy content traffic call for the use of high speed links ($\leq$ 768kbps) (Langer, 2011).

As mentioned above, most current diagnostic equipment is digital and has its own archiving and processing systems built in. This translates into very transparent management for the final user, whether sending, consulting or accessing content. In locations where analogical radiology still predominates, however, the situation is a bit more complicated, as film scanners or digital cameras are required for capturing the analogue image and digitalizing it so that it can be sent electronically (Cone, 2005). Such procedures have their limitations, given that the specialist receiving the image can only view, and not

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[37] Teleradiology is covered in greater detail in its corresponding chapter.
[38] American College of Radiology's Standards for Teleradiology. http://imaging.stryker.com/images/ACR_Standards-Teleradiology.pdf
DICOM Standard. www.medical.nema.org

biometrically interact with it. In other words, he or she cannot increase the resolution, make measurements or "play" with the information that an original digital image contains from the very beginning. Nonetheless, in an isolated location with few resources and a pressing need for a diagnosis, a simple .jpeg image attached to an email can prove extremely useful.

Telecardiology

The transmission of heart sounds (as heard in cardiac auscultation), of heart rates measured through electrocardiography and of ultrasound and interventional cardiac studies form the basis of what is now known as telecardiology (Backman, 2010; Koehler, 2011). The use of digital stethoscopes connected to telephone systems makes it possible to transmit the heart sounds to a specialist. They can also be recorded and sent as an audio clip attached to an email. Echocardiograms, eco-dopplers and cineangiographs can all be sent from one place to another, although they require greater bandwidth in order to avoid high compression levels that can affect the quality of the diagnostic information. Of course, the type of synchronism needed depends on the application to be used. Nevertheless, a minimum bandwidth of 768 kbps is regarded as sufficient for a good transfer, with no risk of losing packets with diagnostic signals.

Since all bioelectrical signals can be captured and retransmitted, the comments made above concerning electrocardiography also apply generically to electroencephalographic signals (teleencephalography), to evoked potentials and to other routine physiological studies (telemetrics, teleneurophysiology, etc.). Today's technology allows us to gain access to any vital parameter –rate, flow, volume, concentration, etc.– in digital format. Moreover, this information can be captured, processed, parameterized, transmitted and stored in integrated clinical information systems, making it possible for patients to obtain diagnoses performed by remote specialists.

Teledermatology

Teledermatology is currently among the most widely-used clinical applications, due to the scarcity of such specialists, particularly in disadvantaged urban and rural areas. Interestingly, teledermatology was one of the first fields –along with teleradiology and teleophthalmology– to have validated and published best-practice guides in conjunction with their respective scientific associations, thus facilitating standardization and growth[39].

Like telepathology, teledermatology is a very visual discipline, with images that can easily be transmitted from one point to another, through either deferred or real time communications[40]. In the former, photographs of lesions are sent –along with relevant patient health information– to the consulting physician, who stores and processes them in order to reach a diagnosis. In the second case, video-teleconferencing (VTC) systems are used, which enables patients and professionals to interact live. This activity entails the use of special digital cameras such as dermatoscopes, along with other peripheral devices such as episcopes (with powerful enlarging and image freezing capabilities), polarizers and other mechanisms for angular viewing and contact plates.

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[39] American Academy of Dermatology's Position Statement on Telemedicine.
http://www.aad.org/Forms/Policies/Uploads/PS/PS-Telemedicine%206-15-07.pdf
American Telemedicine Association's Clinical Guidelines for Teledermatology.
http://www.americantelemed.org/files/public/standards/Telederm_guidelines_v10final_withCOVER.pdf
[40] American Telemedicine Association's.
http://www.americantelemed.org/files/public/membergroups/teledermatology/telederm_protocolstoreForm.pdf
American Telemedicine Association's Teledermatology.
http://www.americantelemed.org/files/public/membergroups/teledermatology/telederm_protocolrealtimeForm(1).pdf

Relatively low bandwidth can be used for image transmission, given that this transfer is usually done over a simple telephone line or by internet (by uploading to specialized sites using ftp (file transfer protocol) or by email as attached files). However, a minimum bandwidth of 386 kbps is recommended when using VTC, since movement can cause image pixeling. This undesirable phenomenon can be notably lessened by increasing the bandwidth and thus reducing compression requirements.

Telepathology

This application focuses on the transfer of anatomical/pathological information between locations, in order to obtain diagnoses and second opinions. It also plays an important role in training and research. The same application can be used for primary histopathologic and cytopathologic diagnoses, frozen section biopsies, microscopy, expert consultations with subspecialists, etc. This can all be done over a distance, thus avoiding the need for an on-site pathologist (Weinstein, 1986).

The combination of telepathology and teleradiology, telesurgery and other related disciplines has led to the growth of another area of application called teleoncology. The remote patient diagnosis and treatment offered by this application, along with distance interaction between specialists, has improved patient oncologic care while narrowing the gap between more poorly-equipped areas and tertiary care centers (Alverson, 2010; Hazin, 2010; Qaddoumi, 2011).

Telepathology systems can be divided into three types: static image systems, real time systems and virtual slide systems. Static image systems have the drawback of not being able to show the entire piece at once, although they are quite inexpensive and only require common telephone lines or low-bandwidth internet. Real time systems make use of automatic or robotic microscopes which the specialist handles from a distance – while being able to see the entire slide. With the use of a camera connected to the microscope, the images are captured for later processing. With virtual slide systems, digital scanners process the whole slide image, creating a digital file that is stored on system servers. Later, this can be accessed online and viewed as if it were being seen under the lens of a microscope.

These systems are limited by their bandwidth requirements, since files are large and consultation times are prolonged. For this reason they tend to function better with local wired (as opposed to wireless) networks. Moreover, the necessary microscopes and scanners are expensive – a situation that calls for process flows that have been especially designed for these locations[41] (Weinstein, 2009).

Teleophthalmology

Among the highly-visual medical specialties, ophthalmology is one of the areas that has shown the most growth in recent years. This is due to its considerable progress and impact on the population, with early detection and monitoring of diabetic damage through telemedicine solutions. It has also managed to link the spheres of primary, secondary and tertiary care. In fact, it was the first to standardize the flow of processes for diabetic retinopathy screening. These standards were first accepted and issued by the American Telemedicine Association (ATA), and later brought before the American Academy of Ophthalmology (AAO) for consideration[42].

Given the large volume of images that this specialty handles, the various peripheral devices for image capture that are now included by default in its equipment, and the versatility it offers for transmitting in real and deferred time, teleophthalmology has become a natural choice for those

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[41] American Telemedicine Association's Clinical Guidelines for Telepathology. May 1999.
[42] American Telemedicine Association's Telehealth Practice Recommendations for Diabetic Retinopathy Position Paper. http://www.americantelemed.org/files/public/standards/DiabeticRetinopathy_withCOVER.pdf

institutions wise enough in their day to allocate a basic role to IT in healthcare (Yogesan, 2006). Proper bandwidth for this specialty runs from 128 kbps upward, either because image resolution is of critical importance when making the diagnosis (384 kbps are recommended), or because movement is added to those images. The latter occurs when using a slit lamp or during surgery, for which bandwidth should surpass 768 kbps. There are a number of current equipment models that are designed for this use, such as non-mydriatic digital retinal cameras and digital slit lamps (Saine, 2006) (see Image VII.1).

Image VII.1a. Telemedicine applications: Teleophthalmology (Source: Compiled by author).

Left: use of a digital slit lamp, with video camera installed in the tower for capturing video as well as still photos.

Center: use of video cameras added to a surgical microscope.

Right: surgical images projected from the microscope and interface of the patient's electronic health record.

The integration of information –data as well as audio/video– makes it easier to obtain a more precise interpretation by a remote clinical-surgical staff. It also enables real time interaction between different specialists or services (consulting rooms, operating rooms, recovery rooms).

Image VII.1b. Medical Training Sessions (Source: Compiled by author).

Left: international learning session at the Instituto Zaldívar in Mendoza (Argentina).

Right: Special Interest Group in Ophthalmology (SIG OFTALMO) of the University Telemedicine Network (RUTE), part of the Red Nacional de Pesquisas de Brasil (RNP, or Brazilian National Education and Research Network).

The use of videoconferencing solutions makes real time interaction between centers possible. This facilitates and stimulates ongoing medical training, and allows complex cases to be handled by the consulting specialist.

Telepediatrics

In pediatrics IT is becoming more and more prevalent, in order to provide healthcare and support for babies, children, adolescents and young adults when there is a large distance (geographic or temporal) between the family doctor and the patient, parent, guardian or consulting physician[43]. Information can be transmitted in deferred and real time. As with the other cases, this includes recorded or live bi-directional audio-video signals, the transfer of medical files, radiological or ultrasonic

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[43] American Academy of Pediatrics Position Statement.
http://aappolicy.aappublications.org/cgi/content/full/pediatrics;113/6/e639

diagnostic images, as well as measurements and/or images originating from such telemedical devices as electrocardiographs, spirometers, glucometers, dermal cameras, otoscopes, ophthalmoscopes, etc. Child psychiatry teleconsultations have also increased. Yet perhaps one of the greatest benefits of telepediatrics is that it makes it possible to maintain a connection between parents and their children while the latter are hospitalized. This is especially true for those in neonatology or intensive pediatric care, during which parents not only can keep up to date on their child's condition, but also interact with the child via videoconference (Gray, 2000) (See Image VII.2). Therefore, the applications can be synchronous or asynchronous, with bandwidth requirements that vary accordingly.

Image VII.2. Tele-ICU / Neonatology (Source: Courtesy of Professor Dr. Dale Alverson).

Use of video-telephone solutions in a neonatology environment (left) and ICU environment (right) at the University of New Mexico Center for Telehealth and Cybermedicine Research (USA).

These applications allow for real time interaction between specialists monitoring babies, while offering parents a more personal way of staying informed about their children. In the case of the ICU, adult patients are monitored remotely by a team of specialized care specialists.

Telepsychiatry

The area of telemental health or telepsychiatry includes clinical work, treatment, education, monitoring and collaboration in the psychiatric field, which can take place in hospitals, clinics, schools, centers, prisons or homes[44]. Interlocutors include not only medical professionals, but also the psychologists, counselors, nurses and other auxiliary health personnel that care for patients. These parties attempt to address evident inequalities in access to quality mental health care due to the scarcity of professionals, or the inability to access the system due to a patient's geographic isolation or socio-economic circumstances.

This discipline has been growing exponentially, as audio-video technology has become more widespread[45]. The current gold standard is the use of videoconferencing that connects patients with their therapists, although such technologies as virtual reality, remote monitoring systems, chat rooms, internet forums and even email have also been successfully implemented. With VTC use, high-speed connections are once again important, in order to optimize image and audio transmission quality (at least 768 kbps). In this area as in others, high definition (HD) technology has greatly increased the quality of the sessions by offering body language details not seen before. Experts agree that HD has raised this kind of

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[44] American Telemedicine Association's Guidelines on Evidence-Based Practice for Telemental Health. Jul 2009.
http://www.americantelemed.org/files/public/standards/EvidenceBasedTelementalHealth_WithCover.pdf
[45] American Telemedicine Association's Practice Guidelines for Videoconferencing-based Telemental Health. Oct 2009.
http://www.atmeda.org/files/public/standards/PracticeGuidelinesforVideoconferencing-Based%20TelementalHealth.pdf

exchange to another level. The great disadvantage, however, is the need for a minimum of 4Mbps per HD camera, making this unfeasible in areas not equipped with such networks.

Tele-ICU

Another discipline that is growing at an astounding rate is tele intensive care, or "tele-ICU". Here, networks connecting different therapy rooms or coronary units with a reference center make it possible to provide these highly specialized services to areas lacking such therapist physicians or nurses (Goran, 2010). The rate of critically ill patients has recently been on the rise, pushing up the daily bed occupation rate in critical care units (ICUs, coronary units, neonatology units). This is due not only to an aging population, but also to an increase in cardio-cerebrovascular illnesses, in the number of car accident or violence victims, as well as in high-risk newborns. U.S. reports show many instances in which critical patients account for over 10% of hospital occupation rates, representing over 7% of health costs (Breslow, 2004; Craig, 2011; Young, 2011).

In these cases, remote monitoring solutions (telemetrics), electronic health records (EHR), PACS and videoconferencing applications enable direct communication between the central command and professionals located in remote areas. Thanks to advances in hand-held devices, most monitoring can be done in a mobile manner – for example through the use of cellular telephony with Bluetooth devices and a WIFI connection. This also broadens the reach of alert services, since a population with few intensive care specialists can monitor a large number of patients (rooms) that are widely spread out geographically. It is estimated that one intensive care doctor and four specialized nurses can remotely attend up to 75 patients. The bandwidth requirements and level of synchronism obviously depend on the applications in use. The cost of this kind of set-up is considerable, due to the expense of equipping and maintaining the central command, although studies are now showing that this care modality can bring both direct and indirect savings (Fifer, 2010).

Teletrauma

The next application, tele-emergency medicine or teletrauma, is closely related to the discipline described above. Here, the same structure of networks and technologies as used in tele-ICU applies to the remote monitoring of emergency rooms and transport services. This clinical application has also grown in synch with recent large-scale natural disasters and the outbreaks of violence over the past decade. Thus its basic concepts are used for the study and management of critical patient care processes from initial contact at the disaster site to the research and training of the personnel involved, all intrinsically linked together thanks to the use of IT during disaster preparation and prevention stages, as well as at the time of aid and relief (Balch, 2008; Simmons, 2008).

This way response teams –whether doctors, paramedics, firefighters or the police force– have at their disposal an invaluable decision support system from emergency centers, as well as a guide for optimizing movement and reception of critical patients. The hospital, meanwhile, can receive information on the clinical condition of those patients, along with their needs (procedures, complementary studies, medication, etc.) prior to their arrival (Murias, 2010). Once again different applications can be used – mostly synchronous and in real time, with bandwidth requirements running from a simple telephone line (56 Kbps), to digital lines (≥ 128 Kbps), 3G mobile telephony (≥ 2Mbps), and including satellite telephony when necessary.

Telesurgery

One application that has received a great deal of attention is robotic surgery. This type of operation is minimally invasive and is currently regarded as the most advanced in the world. This

application covers all surgical procedures or interventions performed on an inanimate training model, an animate model or a real patient, in which the surgeon or operator is not in the same place as the model or patient[46]. The viewing and handling of the tissues and equipment takes place remotely, thanks to the use of electronic and robotic equipment. This cutting-edge technology makes it possible to perform computer-assisted surgery that includes a high-resolution, three-dimensional view with articulated micro-instruments and remote controls.

Robotic surgery has great benefits for the patient, since it allows for a shorter hospital stay, a less painful intervention with a lower risk of infection and less blood transfusion, very small scars and speedier recovery. Robotics makes it possible for the surgeon to perform very precise procedures in tiny surgical areas, and also to "train virtually" using simulators and robots, an invaluable opportunity to work in an inanimate manner and acquire the necessary skills. This application grew more popular after the publication in the journal Nature of an article about the famous "transatlantic surgery" of 2001, in which a laparoscopic cholecystectomy was performed on a patient in Strasbourg, France by surgeons working from New York City (Marescaux, 2001; Marescaux, 2002).

Nowadays, improvements in telecommunications infrastructure and bandwidth, along with refinements in robots such as the DaVinci system, have led to a more extensive use of this application. It has moved beyond merely academic settings, particularly in gastrointestinal, cardiovascular and gynecological surgery (Ballantyne, 2002). Nonetheless, it faces limitations due to the high cost of the equipment needed for telesurgery services and its high bandwidth requirements (>4Mbps) arising from the need to cut down on the latency time between maneuvers and to increase the resolution of the surgical field. Also, such procedures have quite a steep learning curve, meaning that surgeons must train extensively at simulation centers.

Telerehabilitation and tele-home care

The revolution in mobile technology has also allowed the rehabilitation field to expand into patients' homes. Healthcare services such as consultation or guidance, monitoring, intervention, prevention and education can be provided to adults and children by physiotherapists, kinesiologists, nurses, speech therapists, occupational therapists, psychologists, teachers and nutritionists. Thanks to this application, such services can be provided on an ongoing basis –after the initial health episode– and in such diverse locations as rehab centers, homes, schools and community centers[47]. The use of video takes on particular importance here because recording or transmitting the sessions makes it possible for them to be remotely evaluated and monitored by specialists.

While almost all specialties have found a place for themselves within telehealth, home monitoring or tele-home care has grown quickly and won many enthusiasts over the past 10 years. In the U.S., this discipline arose out of the need to obtain vital signs from policy holders who were being treated in the "home hospital" mode in order to reduce hospitalization costs and at the same time reduce the need for unnecessary patient visits, in cases in which patient movement may entail certain risk. The signs were sent to remote monitoring centers asynchronously from devices designed for home use (Dansky, 2001).

The use of tele-home care has expanded, and currently includes palliative services, rehabilitation, chronic illness management, post-surgery follow-up as well as patient home care and education

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[46] Society of American Gastrointestinal and Endoscopic Surgeons (SAGES) Guidelines for the Surgical Practice of Telemedicine. http://www.sages.org/publication/id/21/

[47] American Telemedicine Association's Blueprint for Telerehabilitation Guidelines. Oct 2011. http://www.americantelemed.org/files/public/standards/ATA%20Telerehab%20Guidelines%20v1%20(2).pdf

(Stachura, 2007). The same services can take place interactively with VTC between patients and professionals, over networks with speeds starting at 384 kbps. Meetings can also take place asynchronously, with data and vital signs being collected by means of remote interfaces. In such cases, data previously uploaded, either manually or in an automated fashion, is reviewed at a later time. Ad-hoc designed web platforms or software facilitate this activity, for which a basic network connection is sufficient.

Telemonitoring can also be done individually by the patients themselves. Thanks to the use of equipment and accessories that are designed specifically for home use, patients can monitor their own basal signs, receiving alerts when any deviation is detected and contacting the family doctor if necessary. Bluetooth technology once again plays a major role here, helping to collect information. Home networks such as LAN or WWAN (WiFi) are needed for connecting to monitoring centers or to professionals with cell phone applications. In this way, patients themselves take on a more active role in their own care. For this reason, the drafting of best-practice guides for professionals and also for the community is essential in the success of such a program[48] (Konschak, 2008).

Benefits

The descriptions provided above make it clear that the application of IT to healthcare is not only revolutionizing medical activity, but also relations between doctors and patients and among professionals. While this offers a number of benefits to patients, professionals and the healthcare system in general, it also has some drawbacks, especially the risk of improper use and the problem of high costs. Regarding the latter, most economic difficulties can be avoided by effective planning that includes a well thought-out study and analysis of the needs of each specialty or institution. Costs can also be contained by designing strategies of progressive training and implementation.

Experience has shown the implementation of telemedicine to offer the following benefits:

— More equitable access to healthcare services. By expanding communication channels, telemedicine offers the great advantage of favoring universal access to high quality healthcare, regardless of geographic location. There are four kinds of potential beneficiaries of this improvement: municipalities with limited access to local healthcare services, residents of remote, rural areas, disadvantaged urban communities with demographically low healthcare coverage, and generally, any situation with inequalities in the distribution of healthcare services.

— Access to better healthcare services, thanks to more precise, higher quality and faster diagnoses and/or treatment, along with more comprehensive care, i.e., with no loss in quality along the entire healthcare chain.

— Reduction of unnecessary trips for patients, thanks to the availability of specialized healthcare at locations that lack the physical presence of such specialists. Consequently, these patients can receive expert healthcare without having to leave their community. This lowers the costs that patients and their families would have to bear if they had to travel to another city for an appointment with a specialist. It also reduces risks related to patients' moving about, while increasing the quality of the their family life and well-being, given that the family can stay close to the patient but remain in direct contact with healthcare services.

— Improved accessibility. Patients have access to tertiary-level healthcare without having to leave their community. This makes faster diagnosis possible, along with the corresponding treatment, thus

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[48] American Telemedicine Association's Home Telehealth Clinical Guidelines. 2003.
http://www.americantelemed.org/files/public/standards/Home%20Telehealth%20Clinical%20Guidelines(1).pdf

reducing delays that can lead to serious problems for the patient when such hierarchized services are unavailable.

— Optimization of primary care systems. Thanks to the possibility of consulting with specialists at secondary or tertiary centers, attending physicians can obtain more information for judgments and decision-making, while improving their training and skills. Such possibilities can lower the rate of professional turnover that often plagues such positions. Telemedicine also improves information circuits by eliminating the loss of specialist reports due to misplacement, delay in delivery or illegibility, something that remains all too common today.

— Telemedicine facilitates the timely handling of critical patients, before the arrival of emergency staff or transport by conventional ambulance. This not only applies to primary care received on location, but also to the optimization of conditions at ambulance destinations, given the immediate availability of patient information.

— Telemedicine improves system efficiency because there is no need to pay expenses related to a professional having to travel to perform the healthcare service. In some cases, such savings benefit the public system, since it is the public system that bears this cost, while in other cases the benefit is for the patient, in healthcare systems in which private care predominates and it is the patient who must pay such costs. Telemedicine can be cost-effective, depending on equipment investment and on the number of consultations carried out (critical mass). At the same time, by improving communications between healthcare services, support services and management, telemedicine increases the efficiency and productivity of those services, becoming cost-effective over the medium and long-term.

— The healthcare system benefits, by making better use of system resources. This leads to improvements in: the management of public health (because fast and pertinent information is readily available), the level of research and development (because reliable scientific analysis and biostatistics are available), and the level of education and training of the health professionals (because their knowledge and skills are enhanced). Currently, any training facility is within reach of those wishing to continue their training, which in turn benefits the system by increasing the effectiveness of those working within it.

Recommendations before initiating a telemedicine program

Drawing on the experience we have gained over the past 10 years, we have drafted a ten-point list of recommendations that can be of great assistance to organizations considering the implementation of telemedicine programs:

1. The domain, functionality, applications in their environment and the technology to be used must be clearly defined, so as to ensure the efficient use of resources.

2. It is important that electronic health records (EHR) already be integrated into the clinical information system (CIS), so that all patient information (personal, health, surgical, etc.) can be centralized in a single system.

3. It is important to generate collective awareness that the timely and appropriate processing of structured and integrated healthcare information will improve healthcare by providing more pertinent diagnostic and therapeutic support, reducing errors and optimizing patient monitoring, regardless of physical location.

4. Standards should be implemented to help ensure transparency in information flows as well as the required level of interoperability when integrating all processes.

5. Efforts should be made to obtain the involvement and commitment of staff at all levels of the organization, before activity is begun. The commitment and leadership of the management is essential for overcoming instinctual resistance to organizational change.

6. It is helpful to identify the personnel that shows special enthusiasm for IT, so that such individuals can assist in managing the process of organizational change. They will play a key role in maintaining a proactive attitude in the institution while the change is being managed.

7. It is useful to train and update professionals using new communication strategies (collaborative platforms, social networks and video solutions) with programs that focus not only on the pertinent technological skills, but also on medical and corporate aspects. Ideally, these professionals should be involved not only as participants, but also as generators of change.

8. Personnel should feel accompanied throughout the entire process of technological transference and implementation. This is critically important for ensuring their commitment and action.

9. Plans should be made to include institutional business processes in the new care model, attempting to direct affect efficiency and productivity. Such a system will be more competitive in the marketplace because it offers differentiated services with new added value, and it does so in a scalable and replicable way.

10. The cost-effective sustainability of the model must be guaranteed, based on a prior analysis of the demand, the size of the market (critical mass) and costs to be incurred during the design, development, implementation and management process. Do not give in to the temptation of adopting a telemedicine model on a whim, without a prior analysis, just because it is fashionable or to improve market positioning.

Final thoughts

The experience of the past twenty years shows that technology and communications evolve at dizzying speeds, forcing us to move quickly if we want to avoid being left behind. The same can be said for the flow of knowledge currently spreading throughout the community – in the medical-scientific world as well as in the general population. Clearly, the paradigm of today focuses on how best to care for the patient, wherever he or she may be. The implementation of IT provides a unique opportunity with new communication channels and forms of social integration that seek to overcome health disparities, especially in terms of social health determinants. This is the only way to attain equality among communities, overcoming the kind of economic and social gaps that can retard their development and growth.

However, a necessary condition for all of this is the awareness of the need for change and of the role that IT plays in supporting such healthcare reform. As Eysenbach pointed out back in 2001, this field is characterized not only by technological development, but also by a state of mind, a way of thinking, an attitude and a commitment to networked, global thinking to improve healthcare locally, regionally and worldwide, by using information and communication technology (Eysenbach, 2001).

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Chapter VIII

Teleradiology

Silvio Vega

Summary

Teleradiology is the branch of telemedicine that deals with the electronic transmission of radiological images from one location to another, for purposes of interpretation, interprofessional consultation and diagnosis. It is probably the oldest and most successful application of telemedicine currently practiced, and has become a basic part of a modern hospital's imaging services. Its success is due in part to the nature of digital images, the massive adoption of PACS and the progress in telecommunication systems. Such telecommunication advances have allowed radiologists to maintain the structure of their work with minimal alteration while increasing the number of patients, covering more locations and even offering services from the comfort of their homes.

A teleradiology system is made up of devices for acquiring and sending images, situated in local workstations, image transmission and storage networks (including PACS) and systems for the reception and interpretation of images. In an ideal situation, teleradiology directly acquires digital images, but since the right kind of instrument is not always available, analogue images can be digitized and compressed in order to be sent through the system. The American College of Radiology (ACR) recommends that interpretation be based on the original, uncompressed image, or if that is not possible, on an image that has been compressed without data loss.

Teleradiology is a relatively young science that has come to occupy an important place in telehealth. However, the technology still has a long way to go and the market for teleradiology is expected to grow considerably, with such applications expanding throughout the world.

Introduction

Teleradiology is the branch of telemedicine that handles the electronic transmission of radiological images from one location to another, for purposes of interpretation, interprofessional consultation and diagnosis. These radiological images are understood to include those obtained from following sources: X-rays, computed tomography, ultrasound, magnetic resonance and nuclear medicine. The modern concept goes beyond radiology strictly-speaking and includes the capture and management of medical images using information technologies – something that could be called "teleimaging".

The potential for transmitting images is virtually unlimited, and this has led to a major change in the ways that imaging services are provided. Initially, image transmission was slow and limited to studies having relatively low resolution. However, with the development of equipment that can generate digital

images and the increase of transmission speed in telecommunication networks, it is now possible to send large volumes of high quality images and data in a short time.

In terms of user satisfaction, it is clear that radiologists are quite enthusiastic about the system. They are pleased with the quality of the digital image and the user-friendly nature of the workstations – which remain similar to the old radiology stations. Users state that their diagnoses maintain a high degree of certainty, and that they are confident in their ability to attend to interpretation requests from a distance (Krupinski, 2008). For patients, meanwhile, teleradiology has brought improved care quality and shorter wait times, both for image acquisition and for receiving the interpretation and results, while offering the possibility of their health matter being analyzed by experts from a distance.

This is how teleradiology has become one of the most important applications in telemedicine, accepted around the world by over 80% of radiologists – according to a bibliometric analysis of the research and publications in the field (Dimmick, 2006).

In this chapter we will provide a straightforward and explicit description of the most relevant aspects of teleradiology.

Historical background

The oldest information concerning the transmission of radiology images goes back to 1929, when dental radiographs were sent via telegraph (Anonymous, 1929; Kantor, 2005). In 1955, Dr. Albert Jutras, working in Montreal, used the concept of teleradiology to separate the patient from the radiation by means of a lead wall, thus diminishing the quantity of exposure during a fluoroscopy (Duckett, 1981).

In the 1960s and 70s, a number of medical imaging examinations were performed using closed circuit television. Researchers such as Dr. Kenneth Bird of Massachusetts General Hospital set up an interactive television system with Boston's Logan airport. Walter Reed Hospital established a similar system between its emergency room and the radiology department (Thrall, 2007).

Later attempts were made in the 80s, using photographic cameras to record radiographic films and send them in the form of photographs. These were subject to limitations in camera resolution, added image noise and transmission over analogue telephone lines that increased information loss. Teleradiology equipment began to appear on the commercial market from the middle to end of this period, although with limitations in quality and price.

The 1990s saw a progressive rise in the use of teleradiology. The first obstacle to be overcome was the conversion of analogue images into a digital format in order to facilitate transmission. The use of digitizers solved this problem, generating massive amounts of data that maintained an adequate level of resolution, but caused even more difficulties in storage and transmission. This impediment was overcome through the process of compressing images into JPEG (Joint Photograph Expert Group 20:1) and GIF (Graphic Interchange Format 10:1) formats – without a considerable loss of resolution.

In 1994, the American College of Radiology (ACR) established the parameters that should govern teleradiology (ACR, 1994), defining the purposes, professional qualifications, licenses, credentials, the communication system and equipment used, along with quality controls.

The field of teleradiology has changed dramatically over the past 11 years. These changes started with the appearance of better telecommunication facilities and broadband internet, the direct acquisition of digital images, advances in compression systems and mechanisms for assuring the security and confidentiality of patient information. The foregoing, along with the greater functionality of computerized equipment and its more reasonable costs, has contributed to teleradiology becoming an integral part of imaging services.

The benefits of teleradiology

Many significant advantages are derived from the fact that the teleradiology process makes it possible to transmit images from the point of origin to the diagnostic station (ESR, 2004).

Very complex images can be sent from a local hospital to more fully-equipped hospitals that are permanently staffed by general radiologists and specialized radiologists, to request help in interpreting the image. This system also allows for the possibility of obtaining a second medical opinion.

Teleradiology makes it possible to offer interprofessional consultations at emergency rooms round the clock, by sending images to affiliated centers or to the homes of radiologists.

One radiologist can potentially cover a number of remote locations that have no radiologists on staff. These remote radiological services are especially beneficial to small communities with rural health centers and hospitals whose workload is small enough that the presence of a radiologist is not required.

Teleradiology can also enhance the quality of ongoing medical education and training, as radiology images accessible from a variety of locations can be used as educational material.

The technology can be used for group discussions involving participants from different places in real or delayed time, to assist in making complicated diagnoses or in performing radiology-guided invasive procedures.

Teleradiology also offers direct benefits to the patient: it lowers costs of accommodation, meals and transport to other locations, it prevents unnecessary invasive diagnostic interventions, it reduces the time spent waiting for interpretation results and it facilitates patient care provision at the local level.

For society as a whole, meanwhile, teleradiology contributes to the reduction of morbidity and mortality by helping to provide higher quality care, increased efficiency and equal access to healthcare services.

Barriers to implementing teleradiology

As with other new modalities in the medical sciences, it is normal to meet with resistance to a change that involves the implementation of a new technology at the workplace. Other such barriers include the high cost of installing the infrastructure, hardware and software, the poor design of some systems, and high communication costs. Reluctance may also be the result of concerns over confidentiality, the lack of laws and regulations, questionable image fidelity and aversion to new responsibilities arising from increased coverage and higher numbers of patients (SEEIC, 2000).

Most of these barriers can be overcome, since education in the clinical use of Information Technologies (IT) will help correct the erroneous preconceptions that workers may have – ideas that can keep such fears alive. Moreover, many studies show that investment in teleradiology is cost-effective.

The theoretical foundations of teleradiology

A teleradiology system comprises a large number of components, beginning with the equipment that produces the images (X-ray machines, ultrasound, tomography, nuclear magnetic resonance), devices for obtaining digital images, connectivity networks, computerized information and patient management systems, local diagnostic stations, archiving systems and remote stations. All of these components – except the image producing equipment– are included in radiology information systems (RIS), picture archiving and communication systems (PACS) and medical image and information systems (Image Management and Communication System, or IMACS), which together form the backbone of teleradiology. These structures are all based on DICOM and HL7 standards.

Digital Imaging and Communications in Medicine (DICOM) is an open standard that the industry has universally adopted for representing medical information (RSNA, 1995). The standard was created in 1993 in order to promote the transmission and storage of digital medical images (and the associated data) between devices from different manufacturers. DICOM was developed with a focus on diagnostic medical images used in disciplines related to radiology and the other medical sciences (Clunie, 2010; NEMA, 2006).

The DICOM protocol offers a number of services that support exchange processes: storing, consultation and retrieval, printing, and worklist management. Accordingly, all purchased equipment and software must be DICOM compatible in order to be linked up.

Digitization

Images are often acquired by means of a film digitizer, which converts conventional radiological films into digital format for transmission over a network. Two different techniques are used for digitizing films – some use a laser system and others employ a charged coupled device (CCD). Laser digitizers offer excellent contrast and good resolution, but they are much more expensive than CCD devices, and for this reason the latter are more commonly used. Computerized radiography (CR) offers an alternative to obtaining an image on conventional film and then having to digitize it. CR uses phosphor storage plates for directly obtaining digital images. It offers wide dynamic range (WDR) technology, which is especially useful for such applications as portable radiographic equipment.

It is important to clarify that there are two basic methods for obtaining a digital radiographic image – the digitized radiographic image and the digital radiographic image. The difference between them is that a digitized image is obtained through scanning a radiographic film –thereby converting an analogue image into a digital one– while a digital radiographic image is obtained through directly converting X-rays into electronic signals. Given that light is not used in the conversion, the image signal and resolution are highly precise, offering excellent image quality (Quirós, 2005). In contrast to digitized radiography, direct digital radiography uses X-ray-sensitive electronic sensors that are arranged in a way similar to normal film. The electronic sensor is connected to a computer, creating a radiological image that can be immediately viewed on the monitor (Quirós, 2005).

The equipment needed for acquiring digital X-rays includes an X-ray tube, a system of sensors or detectors, a processing station, a printer and a server.

Digital radiographic imaging has a number of advantages. Patients and device operators are exposed to lower levels of radiation. The system also produces less polluting material, such as lead and the chemicals used in film developing. It also offers significant savings by avoiding the need for purchasing radiographic films, developer and fixer, along with maintenance costs for film processors and developing equipment. Direct digital radiography also requires less physical space, and needs no extra room for film archiving. Finally, it undoubtedly avoids the common problem of the misplacement of films, since they are now stored in orderly digital archives.

On the other hand, the most significant disadvantage of the digital image is the ease with which it can be altered – especially for illicit purposes.

Image compression

Given the considerable size of radiological images (8MB for a chest X-ray), they must be compressed in order to be sent and stored. Many teleradiology systems include image compression capabilities, so as to reduce storage requirements and achieve transmission speeds that are compatible with an efficient tele-consulting service.

Image compression can be reversible (without losses) or irreversible (with losses). The advantage offered by reversible compression is that the original image can be retrieved. This means that the original information is preserved, and can be newly accessed in case of review – highly important in the case of legal proceedings. Irreversible compression, meanwhile, offers the advantage of higher compression levels – thus cutting down on transmission time.

The ACR recommends that compressed images not be used for a primary reading, or, if doing so is necessary, that reversible compression be used.

PACS

A PACS is an image storage and distribution system that uses the DICOM protocol. It is physically comprised of one or more servers with secondary storage devices that are managed by software. These systems provide information to their exclusive clients. Structurally, they can be as simple as a pair of machines, or they can comprise a complex network of machines linked together.

RIS

An RIS is a program that manages a radiology department's administrative tasks: scheduling appointments, monitoring patients, room management, recording activities and drawing up reports. Some centers do not have an RIS strictly speaking. Rather, the possibilities for performing these tasks are included in the hospital management software – commonly called a Hospital Information System (HIS). The PACS, RIS and HIS must be properly interconnected in order to facilitate communication. An improved solution is also available in the form of PACS-RIS or PACS-HIS integration (Siegel, 2002).

Image transmission

It is important to take into consideration the telecommunication system to be used for transmitting images. The bandwidth will determine transmission speed and the cost benefit must be evaluated; to raise transmission speed, an increase in bandwidth is necessary – and this implies higher costs. Factors to be evaluated include the kind of studies to be transmitted, the number of such studies to be sent, the size of the files and the frequency with which the system will be used.

Workstations

Workstations include powerful computers with high RAM (Random Access Memory) and hard drive capacity, and a number of high-resolution monitors. These computers must be equipped with an operating system and software for managing images.

The monitor is a vital component that must have certain basic features. Light intensity should be no less than 50 ft-L (foot Lambert units) – a value that measures brightness and contrast. Black and white monitors are preferable for the primary diagnosis, given that they are brighter and offer better contrast than color screens. Monochromatic monitors with 2048 x 2560 resolution and 4096 gray levels are recommended for chest X-rays. Pixel size for the monitor must be 0.26 or less. For images taken by tomography, resonance or ultrasound 24 bit color monitors may be used

Distortion is another important aspect when considering a monitor, especially if it is large or has a pronounced screen curvature. The placement of the monitor is also crucial – it should be located in an area of low or dim light, and set up in such a way that it does not reflect external light. Resolution measures a monitor's capacity to accurately reproduce an object; it should be at or above 1280 x 1024 for small matrices. According to the ACR, for making primary diagnoses, the ideal resolution is 2000 x 2500, with 4096 gray levels, in a very costly monitor (SEEIC, 2000).

Image analysis

One of the advantages of teleradiology is that it includes software for image display and analysis. This software must comply with the following requirements: the capacity to associate patient data with the image, the possibility of choosing image sequences, the availability of magnification functions, the possibility of reversing or rotating images while maintaining their integrity, the possibility of performing measurements on the image, as well as that of brightening or darkening the entirety or part of an image.

Security systems

A teleradiology system must have security protocols that maintain the integrity of the information and the confidentially of the patient. Security concerns must extend to the networks and software. Security in computerized health information systems includes the physical security of the data, control over access to information, control over local private networks, authentication and data encryption in an electronic signature (SEEIC, 2000).

Education and training

Education in all fields of medicine has changed greatly thanks to the influence of the information technologies. Teleradiology is a particularly striking example. From the time that it became possible to manage the accuracy and flexibility of a digital image, it has become a central tool in teaching and instruction. Educational images can be made available locally or internationally on closed systems or on internet sites. They are also available through webcasting conferences, discussion groups and case presentations. They can also be accessed on virtual libraries, which contain a great deal of information on the subject. The system makes it possible to take advantage of experts in different locations, who can meet over the web in order to give a master class. Some claim that the holding of case discussions between small hospitals and larger, better equipped centers, leads, over time, to a drop in the number of requests for second opinions, as a result of the experience and knowledge gained through such a dynamic (Reponen, 2008).

It is also worth mentioning that teleradiology has enhanced research with medical images, since many images can be received from different locations and then analyzed and interpreted in a consistent way by the members of the research team.

Teleradiology networks: web-based collaboration

The ease of digital image transmission has allowed the use of web-based teleradiology to spread considerably – for collaborative work as well as for business purposes. Many companies offer local and international services over the internet. Some firms offer the service of online access to digital files. The service can be used in a secure manner with an internet connection and a simple browser, using data encryption protocols (Actualmed, 2011).

Other sites, such as "Radiólogo virtual" in Mexico, offer routine and emergency imaging interpretation (Radiólogo Virtual, 2010). It should be kept in mind that some countries have regulations that do not permit the practice of medicine beyond their borders, or even across the borders of provinces or states, as is the case in the United States.

Collaboration networks have been set up between countries and universities, offering services such as opinion exchanges and training in this field.

The importance of teleradiology in Latin American countries

Thanks to the recent accessibility of sophisticated systems, modern medicine has greatly increased the number of diagnostic imaging procedures. This has led to an imbalance between the amount of work to be done and the number of radiology specialists. Moreover, specialized doctors in Latin America tend to live in the larger or more important cities, so diagnostic imaging experts are frequently lacking in other areas. Initial attempts to address this problem began with the use of conventional systems enhanced by a radiographic film digitizer.

One of first uses of teleradiology in Latin America took place in 1993, when Dr. Rodríguez and collaborators in Panama transmitted computed tomography images from a remote city 251 kilometers from the capital, to be interpreted at a specialized radiology center (Rodríguez, 1998).

At the annual convention of the Radiology Society of North America (RSNA) in 2009, a number of Latin American projects received awards, including one presented by the Colombian professor Alfonso Esguerra and collaborators entitled "Telerradiología para países en desarrollo" (Teleradiology for Developing Countries). This paper described the development of an economic model for teleradiology in a Colombian hospital (El Hospital, 2010). "The model proposed by Esguerra involves the use of components with low maintenance costs, a multi-purpose radiology room set up at the examination site, a mobile telephone with a camera capable of taking and reproducing images at 2592 x 1944 pixels, an internet server, a wireless network, a personal computer with a high resolution monitor, a software application for image communication and archiving, computing programs that ensure patient confidentiality, with data encryption and access restricted to pre-registered professionals. There must be a radiological technician at the examination site and this technician must receive training in the acquisition, printing and mobile-phone photography of images, and their transmission via internet." (El Hospital, 2010; Esguerra, 2010).

Since 2008, the Panamanian Ministry of Health has had a national teleradiology system with 22 remote digital radiology stations spread throughout the country, all of which consult with a national center located in the capital city.

Teleradiology is a worthy application that can be used to strengthen the ties of friendship and collaboration among Latin American countries – all for the good of that continent's health.

In the area of educational efforts in teleradiology, the example of Brazil is worth mentioning. Since 2004, this country has had a teleradiology training system based on the web and closed-circuit television. The training system makes use of the country's national telemedicine system, the Brazilian Telemedicine University Network, or RUTE (Baptista, 2009).

A number of issues must still be addressed before true integration of teleradiology can be achieved in Latin America. These issues include infrastructures, equipment cost, program accessibility, the accuracy of medical and non-medical devices, the lack of guides and protocols, the shortage of trained personnel, the questionable sustainability of projects and the absence of regulations covering information exchange, privacy and legal issues (Kumar, 2008).

One common problem is the lack of specific training in the field of teleradiology. Although radiology training programs are available, few medical schools have a slot in their curriculum dedicated to teleradiology.

Conclusions

Despite the fact that teleradiology is a relatively new science and undergoes constant change, it has come to occupy a vital position in modern healthcare systems. Traditional radiology systems are rapidly being transformed into teleradiology systems. This change is being met with a high level of acceptance by radiologists and other medical personnel, who are pleased to interact every day without having to move from their departments.

The benefits of this technology are undeniable and promise to revolutionize the integration of medical imaging and diagnostics. More long-term research, however, is needed in terms of patient benefits, cost benefits and security before the technology can be totally integrated into current healthcare systems.

Finally it should be noted that the implementation of teleradiology must be preceded by a meticulous study of the needs of each health network and by consulting –and gaining the acceptance of– the professionals involved. Successful implementation entails careful selection of a system, adaptation, planning, training and maintenance to ensure a smooth and positive transition – one that truly improves the quality and efficiency of patient care.

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Chapter IX

Electronic pharmacy management

Nieves Martín
Judit Ceruelo

Summary

This chapter discusses, in simple terms, the incorporation of Information Technology (IT) to pharmacy management in a large healthcare organization, taking a global approach to the topic without distinction between the classic healthcare levels of primary and specialized care.

However, given the current growth of initiatives related to **electronic prescription**, it was deemed worthwhile to expand the chapter's content, paying special attention to the advantages of such systems and to prescription support tools.

These prescription support tools, their logic systems and their maintenance are the differentiating elements between the various electronic prescription models, and they represent the essence and the foundations of the advantages that these projects bring to prescribers, patients and dispensing pharmacists.

Although IT plays a vital role in the construction of these systems, high degrees of functionality and utility can only be achieved by incorporating the knowledge and experience of professionals who work in the management of pharmacy benefits and also the experience and preferences of the health professionals who are directly involved.

Electronic pharmacy management projects, despite their apparent simplicity, tend to present numerous practical difficulties, mostly related to effective implementation and the need for constant incorporation of improvements, which often become necessary with this type of model. However, the great strides that have been made in Spain in this field mean that these projects can be undertaken with optimism and enthusiasm.

Introduction

The incorporation of Information Technology (IT) into the field of health is already a reality for both healthcare organizations and for citizens.

IT has been used to manage aspects of pharmacological therapy for over 30 years, and as a result most people working in healthcare are already familiar with the field. However, recent years have

brought significant changes in both the implementation levels and the functionalities offered by this technology. Such changes are the result of the effort being made to adapt to the new needs regarding connectivity with other systems and interoperability between healthcare organizations.

For this technological and functional adaptation to be a success, having a global vision of the healthcare system and its needs is essential. It is also important to keep in mind that the main objective of the system is to provide high-quality, safe and efficient health services to all patients, while keeping them informed and promoting in them a sense of shared responsibility regarding the healthcare provided.

Consideration must also be given to the fact that the different care situations, which traditionally derive from the existence of primary care and specialized care settings, require a great deal of co-ordination, and that pharmacological therapy is a key element in care continuity. In the case of pharmacy management, however, the functional differences are more the result of how medicines are obtained than of which care level is involved. For this reason, the discussion will focus, on the one hand, on e-prescribing and electronic prescriptions for the acquisition of medicines through dispensing pharmacies, and, on the other hand, on hospital prescription, or treatment orders, for medicines acquired through hospital pharmacy services.

This chapter attempts to present a global and integrating vision of the whole of electronic pharmacy management in a healthcare organization. Accordingly, the following elements in the medicines chain are taken into account: acquisition, prescription, dispensation, administration, invoicing, the use of information for clinical decision support and in making decisions regarding finances or management.

Figure IX.1 outlines one possible vision of the most relevant processes within electronic pharmacy management and their integration in the care process.

Furthermore, it must not be forgotten that this type of management system is very useful in improving our use of medicines and in furthering research into their use, from quantitative studies all the way to assessments of their impact on the population's health, in terms of both positive outcomes and possible adverse effects.

Having a *global* vision of pharmacy management is important for the following reasons:
— Constant changes in medicine authorizations and withdrawals mean that there is a continual need for updates and modifications.
— Frequent and significant changes in the areas of regulation and management mean that systems must be flexible and easily adapted.
— There is a high volume of transactions and also of the data associated with each transaction.
— All elements need to be properly identified.
— Homogenous coding systems are needed.
— Correct product identification is a vital aspect of patient safety.
— The economic repercussions of pharmacy benefits are enormous. In Spain 30% of the public expenditure on health goes to pharmacy benefits.
— A global vision results in improved efficiency in the maintenance and update of common components.

Figure IX.1. Flow chart of electronic pharmacy management (Source: Compiled by authors).
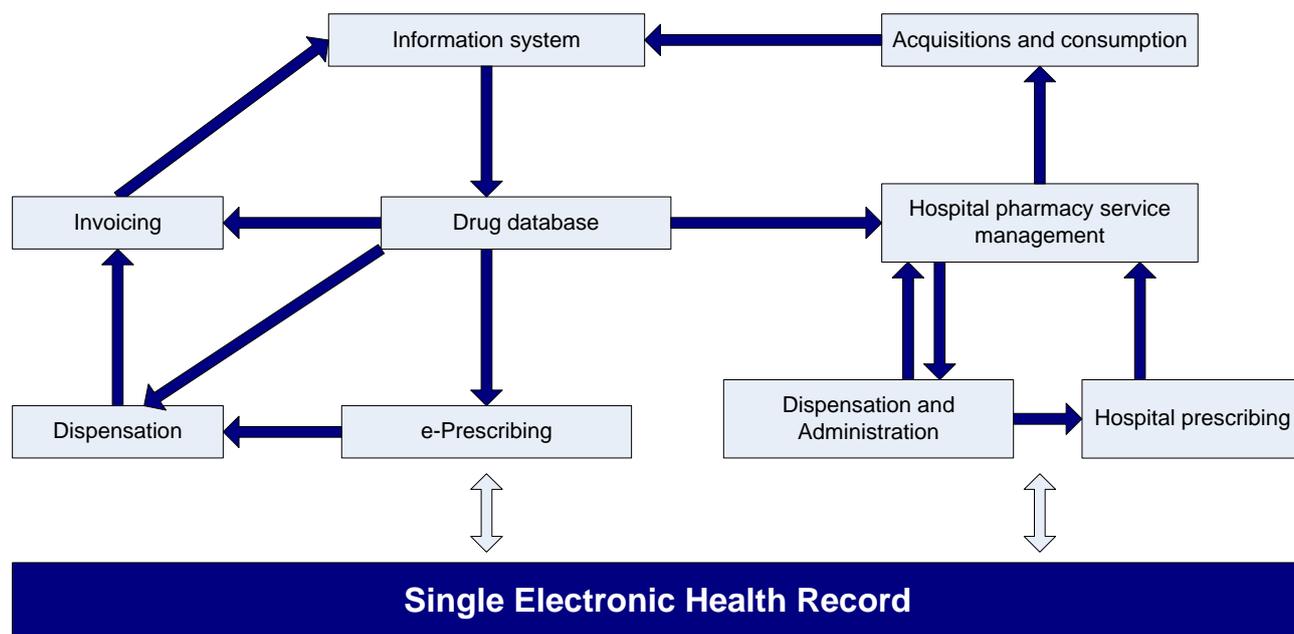
Nonetheless, to organize the chapter's contents, it was decided that there should be separate sections for the developments and activities associated with prescribing in primary and specialized care and those associated with hospital care, always with the understanding that the aim is to have a single health record system in which the prescription and use of medicine are also shared.

The degree of development of these tools, their implementation and their contribution to decision-making can vary considerably as a result of organizational, structural and cost-benefit factors or because the overall approach used in the projects has facilitated or limited their expansion and/or scalability. This is the case both for clinical record projects and for projects related to integrated purchasing management and of course for projects in the area of pharmacy and medicines.

Finally, it is important to note that to undertake this type of project, two basic and common elements are needed for the different developments and their use. These two elements are discussed in the following section.

Basic elements in electronic pharmacy management

For an electronic pharmacy management project to be viable over the long term, its basic elements must have a structure that is organizationally solid but also extremely flexible, so that they can withstand and respond to the numerous changes that occur in the pharmaceutical sector (at both the national and international levels) and must be incorporated speedily and effectively into the daily activity of all healthcare organizations.

Therefore, the key elements that support all the other applications shown in the initial diagram (Figure IX.1) are the following:

— Drug database

— Information System

Drug database

A well-structured drug database is vital for the proper prescription, dispensation and acquisition of medicines, for billing and for making the best possible use of information systems. For the database to fulfill its purpose, the contents must have the attributes necessary for each one of these functions. In fact, there will be specific attributes for outpatient prescribing and others for hospital prescribing and management.

Attributes related to outpatient prescribing include the prescription unit, which may be the packages or a certain number of dose units, as this facilitates the management of package sizes or a treatment's units in relation to its posology or duration.

It is very important that active ingredients, measurement units (mg, ml, UI), pharmaceutical forms, etc. be properly coded, as this allows for the grouping of products with the same active ingredient, pharmaceutical form or route of administration, for purposes of consultation, prescription and data exploitation. In fact, these attributes facilitate prescription by active ingredient, the application of lower prices and increased safety of the dispensation process, by reducing the likelihood of errors.

Attributes that assist physicians in their prescribing tasks can also be added, such as the maximum number of packages that can be prescribed at one time, whether the medicine is a stupefacient and requires a special prescription, if the medicine cannot be prescribed by active ingredient, whether it contains excipients that require specific labeling, safety alerts, market recalls, etc.

Also, thanks to the unique coding of active ingredients and of medicines, prescriptions can be used to access/consult the database on drug interactions, as this database uses the same coding system. The coding also makes it possible to include the recommendations set forth in the Pharmaceutical Guides in the information accompanying a new prescription, for a given health problem.

In many European countries a price intervention system is used to set medicine prices, so another important element of pharmacy management is to be found in the different prices of each product; the ex-factory price, the ex-wholesale price and the retail price including VAT (RP+VAT). If all of these prices are known and added to the database, they can be used to calculate prescription costs and to verify invoicing by the dispensing pharmacy or the manufacturer. In addition, if the rules on applying distribution and dispensation mark-ups are also added, the gross profits of the different agents involved in the dispensing and invoicing of pharmaceuticals can be calculated. Likewise, information on the MSP can be used as a reference for the upper price limit in direct acquisitions or invitations to tender made by hospital pharmacy services.

These attributes –and many others that complete, well-structured databases can have– give a good idea of the many possibilities opening up to the systems that make use of them, if there is unified maintenance to ensure homogeneity in the health system and also an efficient use of resources.

Information System

Pharmacy information systems are essential for monitoring the pharmacy benefits provided by a healthcare organization, for management decisions and for developing policies aimed at more rational use of medicines. They contain their own information and also connect to other databases of the

healthcare organization, such as the ones used for professional identification and for users, so that the best possible use can be made of them.

The basic information fed into these systems is the following:

— Prescriptions invoiced to the healthcare organization by dispensing pharmacies (the pharmacies invoice the organization in order to be reimbursed for the prescriptions they dispense) and the data contained in each of these prescriptions: product, prescriber, patient, etc. On printed, computer-assisted prescriptions, this data appears in legible format and also in code, to facilitate OCR scanning. In the case of e-prescribing, the same data is transmitted electronically.

— Hospital acquisitions and consumption, from the management systems used by the hospital pharmacy services.

The healthcare organization's databases and information system are comprised of the following:

— Drug and health product databases, as mentioned above, which can be independent or a module of the information system.

— The databases of professionals working in the health system.

— The databases of the system's users, with their profiles.

— Digitized images of the prescriptions if they were made on paper and/or proof of dispensation in the case of e-prescribing.

— The patient's pharmacological treatment history.

For the systems to function properly, they must have the following characteristics:

— Quality - All the information by itself is not very valuable if the business logic or rules governing each of the possible transactions are not incorporated. In other words, the information must be refined and validated before it can be considered consolidated. Since large volumes of information are involved, these processes must be automated to ensure reliable, quality information.

— Versatility - Having a large information repository allows for the analysis of historical data aggregated by different attributes and structured according to the different levels of the organization. It is possible to predict the behavior of certain indicators, to estimate expenditure over time and even to assess the impact of certain measures or interventions put in place for educational or informative purposes.

— Autonomy, speed and agility - Another key factor in the information system is that it should be easy to use by managers, at both centralized and local levels, with user profiles that are appropriate for the different functions the various users must perform. This degree of user-friendliness will contribute to achieving the best possible use of the system in the different care settings.

Lastly, the underlying objectives of such systems must also be considered. These objectives can be summarized as follows:

— To lead to a better understanding of the real situation regarding the pharmacy benefits provided by the healthcare organization, so that measures can be put in place to improve both service quality and the population's health.

— To provide prescription support tools and introduce electronic prescribing.

— To prepare reports that provide feedback to each prescriber about his or her activity, prescribing profile and comparative indicators, for monitoring purposes.

— To contribute to the quantification, measurement and transparency of the healthcare organization's prescribing objectives.

— To serve as an essential core of information that permits research into both pharmacoepidemiology and pharmacoeconomics.

E-prescribing

Before introducing this topic, a brief definition is given of the different ways prescriptions can be issued, in the context of this document, according to the format and the support instruments available in each case:

— Manual prescription on paper: this kind of prescription is handwritten by the doctor. In some cases it has a label containing certain data about the patient and the doctor, coded in PDF, for reading by an OCR scanner.

— Computer-assisted prescription on paper: this prescription is written on a computer and then printed. Some or all of the information it contains may be coded in PDF for reading by an OCR scanner.

— Electronic prescription: this is a computer-assisted prescription that is also linked to a dispensation system at the pharmacy.

The many improvements that IT can bring to healthcare include the computerization of doctor's offices and computer-assisted prescription writing. Both of these represent essential advances, as they increase legibility and help prevent errors in the prescription-dispensation-use chain of the medicines covered by the healthcare organization. These improvements are already achieved to a certain extent with computer-assisted prescriptions on paper, although additional advantages can be gained by the different pharmacy decision support tools that may be part of the prescription modules.

Computer-assisted prescription writing is just the first, albeit necessary, step on the way to attaining the final objective, which is e-prescribing in the broadest sense, with all the advantages it brings to patients, the healthcare organization and the dispensing pharmacy, as an associated healthcare facility that provides dispensation services and pharmaceutical care to patients.

However, before examining the topic in more detail, it might be useful to look at some of the questions discussed in the report "Electronic prescribing: toward maximum value and rapid adoption" released by the non-profit group eHealth Initiative in 2004 and updated in 2008. This document offers the following definition of electronic prescribing and its various levels:

— Electronic prescribing: the use of computer-based support to write, modify, review and send or transmit the prescription of pharmacological therapies.

— Levels of electronic prescribing:

1. Basic electronic reference only. There is information about medicines, dose calculators, formulary information, but these features do not appear automatically nor are they integrated into the prescription process.

2. Prescribing system only. Searches by medicine name can be performed and prescriptions can be written. No long-term patient data is available.

3. Helpful information about the patient is included (demographic data, allergies, formularies).

4. Medication management: past prescriptions can be renewed, interactions can be checked, etc.

5. Connectivity: with the doctor's office, with the healthcare organization, the pharmacy, etc.

6. Integration with the Electronic Health Record.

This very complete and interesting document does not differentiate between computer-assisted prescription writing and electronic prescribing, but rather addresses the whole topic globally, as a continuum of electronic prescribing with different levels depending on the support, connectivity and integration capabilities offered by each version.

It is important to stress that these systems must be implemented in both primary and specialized care, and their implementation in hospitals for outpatient visits with specialists, for emergency rooms or for patients upon discharge is especially valuable, because it facilitates the monitoring of treatments begun with medicines specific to the specialized care setting, such as in the case of prescriptions that are initially written by specialists but must be monitored and renewed by general practitioners.

Advantages of computer-assisted prescription writing and electronic prescribing

In both cases the most important advantages are the prescription support tools that can be incorporated progressively into the module as it is developed.

Computer-assisted prescription writing

Computer-assisted prescription writing is considered the prerequisite or the foundations that must be laid before electronic prescribing can be developed. The main objective of both is to improve the accessibility and quality of patient care. Apart from the improvements described above, there are further advantages related to information quality, improved safety in the use of medicines and the financial sustainability of the pharmacy benefits provided by the healthcare organization.

Computer-assisted prescription writing that makes use of different levels of electronic prescribing offers the following advantages compared to the traditional or handwritten paper-based prescription:

Advantages for professionals:

— It simplifies and speeds up the process of filling in the prescription form, as all the basic data required by law is automatically added to the form. This data includes:
  o patient identification (full name, date of birth, patient identification code, type of co-payment the patient must make, etc.)
  o prescribing doctor (full name, job code, professional association membership number,…)
  o name of medicine or health product
  o date of issue and dates of effective prescription, so that the product can be dispensed during a longer period of time
— It assists in product selection, by furnishing the prescriber with updated information about all the medicines, effects, accessories and dietetic products, in terms of:
  o Dispensation requirements.
    ▪ It specifies the maximum number of packages allowed per prescription, whether the medicine is a stupefacient, or exclusively for hospital use, etc.
    ▪ It lists authorized indications for each medicine, safety alerts, known interactions, excipients, degree of therapeutic innovation, etc.
    ▪ It allows access to the technical fact sheet of each medicine or the active ingredient monograph.

- Financial information: calculation of daily treatment cost.

— It manages the length of chronic treatments, offering automatic calculation of prescription dates or pharmacy pick-up dates and the number of packages allowed in each dispensation. It also determines when the next follow-up visit with the doctor is due.

— It takes care of issuing documentation related to the prescription, such as the yellow card used for reporting adverse effects to pharmacovigilance programs.

— It reduces clinical practice variability by making available:

- The recommendations set forth in the Clinical Guides about the treatment of choice, alternatives in specific situations, posology.

- The treatment of choice during pregnancy and breastfeeding.

- Access to the patient's complete pharmacy record, containing all treatments prescribed by any doctor, at both primary and specialized care levels.

Advantages for patients:

— It improves patient access to medicines, with no need to go to the doctor's office again, by including the option of calculating and recording the date of prescription and the date of effective prescription, which is when the dispensation of the medicine at the pharmacy can take place (in the case of prescriptions in which packages can only be dispensed at specified time intervals). This means that a patient can be prescribed several packages at once, for dispensation at the appropriate intervals, thereby avoiding unnecessary visits to the doctor.

— It improves the information available to patients by allowing for the printing of a treatment sheet indicating posology, treatment length, precautions or special conditions related to the use of the medicine.

— It improves the safety of the use of medicines.

- It reduces potential errors in interpreting the prescription because it eliminates problems of illegibility or missing information

- It facilitates the monitoring of possible interactions between medicines prescribed/used.

- It incorporates the patient's allergy history.

- It makes it possible to check that the prescribed (coded) product coincides with the dispensed product, thus revealing any possible errors in the prescription or dispensation – regarding dosage or pharmaceutical form– that may affect the patient. This is because the dispensed and invoiced prescription shows the prescribed product code in PDF format for reading by an OCR scanner.

Advantages for management:

— It promotes certain institutional objectives such as prescription by active ingredient and the use of generics, thus contributing to efficiency and a more rational use of medicines.

— It provides information, orientation and assistance in the prescription process to help attain the objectives laid down in annual management plans, with regard to medicine selection or to adhering to Pharmaceutical Guides.

— It increases the quality and reliability of the information by using coded data that allows for OCR scanning.

— It improves the medicine use by monitoring the incorporation or recall of medicines from the healthcare system for reasons such as safety alerts, prolonged shortages, changes in the dispensation area, or even to increase efficiency.

Electronic prescribing

Electronic prescribing makes a vital addition to all the advantages listed for computer-assisted prescription writing: *connectivity* with the healthcare organization or insurance company and the dispensing pharmacy. The added value of this situation can be summarized as follows:

Advantages for professionals:

— It reduces patient visits to the doctor's office, thus reducing part of the doctor's workload, because complete treatments are prescribed for periods of time from six months to one year in the case of chronic patients.
— It allows the doctor to find out on-line whether the patient is acquiring the prescriptions from the pharmacy on a regular basis and to therefore estimate the degree of treatment compliance.
— It reduces dispensation errors by pharmacists, by incorporating validation procedures between the product prescribed and the one dispensed.

Advantages for patients:

— It improves patient access to medicines with no need to schedule appointments solely to request prescription renewals. This is important for chronic patients who are on stable, controlled medication.
— The introduction of a messaging service between prescribers and dispensers improves communication between these two parties, to address concerns, prevent errors or inform of adverse effects that require changes in the prescription.
— Interoperability between systems allows patients to access health services while away from their usual place of residence, with complete information being available to the clinicians at the point of care.

Advantages for management:

— Elimination of paper-based prescriptions throughout the entire process.
— On-line invoicing. This type of invoicing requires unique identifiers for each and every package dispensed as well as complete traceability.
— Ability to obtain comparative information regarding prescription and dispensation, so that treatment adherence can be estimated and other types of analyses performed.

Although in some cases paper has been completely eliminated from the prescribing and dispensing process, many people consider it very important to maintain the tradition of using paper to inform patients about their treatments with different medicines, especially in chronic, poly-medicated patients, with a view to improving treatment adherence.

Electronic prescribing procedure

Prescription

— It begins with the doctor identifying him or herself in the system using his or her smart card with a digital certificate, for identity verification.

— Then the patient at the health center is identified, using his or her Individual Health Card. The reading of the magnetic strip on the card gives access to the patient's health record and pharmacological history. This pharmacy record is the same for both primary and specialized care levels throughout the health network.

— The doctor then accesses the prescribing module, the same one for both primary and specialized care.

— The prescribing process should allow for the possibility of associating the prescription with the diagnosis and with certain analytical data, incorporating them to the patient's pharmacy record, in order to study adherence and health outcomes.

— Once the prescription is made or the treatment is renewed, it is signed electronically and is immediately sent to a "central server" or an electronic prescription management module, which generates a short-term "credit" for medicines to be used in acute processes and a long-term "credit" for medicines to be used in chronic patients, establishing the rate of dispensation according to the posology.

— When the prescription process has been completed, the doctor issues an information sheet for the patient, specifying the medicines prescribed and available to the patient in the system, along with their posology and conditions of use, and any warnings that must be kept in mind. A prescription identification number can also be added to this document, to make access to the dispensation more secure, and also information about the price of the prescription for a specified period of time.

Dispensation

— It begins with the pharmacist identifying him or herself and accessing the system using a smart card with a digital certificate.

— Then the patient in the pharmacy is identified. This is done by reading his or her individual health card. Optionally, for identification purposes a patient may be asked to provide, in addition to the health card, the numeric identifier printed by the prescriber on paper (usually on the information sheet) and given to the patient when the prescription is written.

— The pharmacist accesses the "central server" where the prescriptions that are pending initial dispensation or that still have "credit" (in the case of long-term prescriptions filled at specified intervals) are listed. The dispensation possibilities are determined, depending on the type of treatment (acute or chronic) and the period of time estimated for the next dispensation, in the case of chronic treatments.

— The medicine is given to the patient only after confirming that the medicine being dispensed is in fact the prescribed one, by reading the barcode on the package and checking that it is corresponds to that of the product prescribed.

— Following dispensation, each product is registered in a central server and in the patient's pharmacy record, so as to be able to assess the patient's treatment adherence.

— After the dispensation, all of the prescriptions must be digitally signed by the pharmacist.

— It is also possible to print patient information sheets and adhesive labels for the packages, with instructions about how the medicine is to be taken.

Invoicing

The invoicing methods used will depend on the characteristics and requirements that have been established by the healthcare organization or insurance company and the dispensing pharmacies or their representatives.

Until there is a system in place that provides a unique identifier for each package dispensed (which prevents the same product from being invoiced twice and is linked to traceability regulations), it will be necessary to carry out parallel invoicing procedures (one for paper prescriptions and another for electronic prescriptions).

One possible way to deal with this situation is the following:

— In this scheme the pharmacist generates a dispensation sheet for each group of dispensations made to a patient using the electronic prescription system. This sheet will contain coded data that identifies the prescription and the dispensation (in barcode or PDF) and will also have a space next to each one of the packages given to the patient, where the cut-out barcode or other proof of dispensation can be affixed. The creation of this dispensation sheet means that the "credit" for the patient's treatment has been used up, and no more packages can be acquired with that prescription.

— These dispensation sheets, grouped by pharmacy, are read by a scanner. The results of the scan, and its processing, are added to the data obtained from the scanning of paper-based prescriptions. Based on all this information a monthly invoice is created by the Professional Association of Pharmacists of each province, so that the pharmacies can be reimbursed by the healthcare organization or insurance company (for the prescriptions they have purchased from suppliers and dispensed to patients), and so that any necessary verifications can be made.

— Finally, the data obtained by scanning the dispensation sheets must be compiled with the information corresponding to the prescribed product, the patient, the doctor and dispensation, all of which is already in the e-prescribing management system, for inclusion in the information system. This facilitates verifications and validations concerning errors, duplications, inconsistencies or any other incident that may arise during this type of process.

In the future, if unique identifiers are added to packages by means of the Datamatrix system or by microchip/radio frequency, it will be possible to do on-line invoicing for all of these products.

Functional requirements of the e-prescribing model

Prescription:

— A constantly updated database of prescribers, allowing even the authorization of substitutes who must immediately start filling in for an absent doctor.

— An accreditation and certification office for the identification and access of doctors to the e-prescribing system, by means of a smart card with a digital certificate.

— A system with which to identify any patient who goes to the healthcare center. To achieve this there must be a permanent connection with a patient database.

— A prescription module for use by all care levels, with requirements similar to the computer-assisted prescription system, so that a common database of medicines and health products can be used. The importance of having a computer-assisted prescribing system in specialized care should be underlined, because such a system helps respond to the need to monitor the prescriptions written the

first time by specialists but monitored and renewed by general practitioners, which have a large impact on pharmacy benefits as a whole. According to different studies, prescriptions that were initially written by specialists represent between 30% and 50% of the overall volume of primary care prescribing.

— Electronic signature capabilities for all professionals, both doctors and pharmacists.

— An e-prescription management system, for the twofold purpose of: permitting centralized storage of prescriptions and dispensations and managing all the transactions along with any incidents that may arise.

— System traceability, achieved by creating and maintaining user profiles and also by monitoring system access.

Dispensation:

— A centralized dispensation module that meets all the needs and utilities established in the procedure.

— A procedure by which the pharmacist accesses the system using a digital certificate.

— Computer equipment in the dispensing pharmacy for patient identification and as the means by which to access the medicines prescribed to the patient and his or her pharmacy record.

— Printing equipment with which to generate dispensation sheets, patient information sheets and labels for the containers.

— Dispensation module incorporated into or integrated with the dispensing pharmacy's computer-based management system.

— For operational purposes, it is very important that there be adequate communication and consensus with the organizations of pharmacies, since in certain circumstances they are clearly capable of influencing the effectiveness of the implementation of these systems.

Invoicing:

— Agreement regarding conditions in which the integration of the invoicing of electronic prescriptions and paper-based prescriptions is to take place.

— Development of new systems for the incorporation of data from the invoicing applications to the information systems, in order to guarantee the consistency of the historic information and the new information.

— Review and update of the invoice verification and validation systems, incorporating the ones corresponding to electronic prescribing.

Technological requirements

The following are necessary for e-prescribing (at primary care facilities, emergency rooms, specialists' offices, and upon discharge from the hospital):

— A single, centralized prescribing system or module must be implemented in all doctors' offices. This system is to be connected with the different health record management systems, both in primary care and in specialized care, and it must allow updates and/or modifications to be made easily, and also ongoing improvement of the contents and support for decisions by prescribers regarding pharmacological therapies.

— Telecommunications and security services must be put in place so that all professionals are connected to the network system. The communications network that supports the application must be powerful, secure and large enough to guarantee ideal response times throughout the e-prescribing process.

— Information about the e-prescriptions issued by doctors must be available, in real time, in the dispensing pharmacy.

— There should be access, from all access points, to the patient database or user database.

— There must be central web and application servers with enough capacity to support the high volume of transactions associated with e-prescribing at all health facilities.

— There must be a computerization project underway in all primary care health facilities, specialists' offices, and for prescriptions written for patients upon discharge from the hospital and emergency rooms, taking into account:

  o The necessary hardware will have to be implemented in some cases and adapted in others.

  o Automated patient identification systems will have to be incorporated.

  o A system for reading smart cards must be available, for the authentication of professionals seeking access.

  o The technological architecture must meet all needs related to data redundancy, availability and recovery in case of failure, and it must have all necessary contingency mechanisms. The application of such contingency systems must be agreed by all the agents involved in the process, so as to ensure the existence of alternatives in cases of prolonged or serious system failure.

— Security and privacy systems must be installed to enforce access restrictions according to profiles and the protection of patient and professional data, in compliance with applicable personal data protection laws. Public-key encryption systems must be used for information that travels by internet, so that only authorized professionals can gain access to it. This guarantees the integrity of the transaction and the inviolability of the component.

— A support center is necessary in order to deal with incidents of a technological or functional nature, and it must be available 24 hours a day, 7 days a week.

— Ongoing training must be provided to professionals, as an integral part of the strategy concerning the implementation and management of change in the organization as a whole.

— An essential aspect of the proper functioning of these projects is the system for the accreditation and authentication of users, digital signatures and time-stamping. Some of the elements that must be considered are the following:

  o System for the accreditation and authentication of professionals to allow them to access the system and sign prescriptions using the smart card with a digital certificate. It can also be based on a user name and password or on an electronic ID card, although the shortcoming of these options are the absence of time-stamping or chain of custody tracking.

  o Digital certificate management system to authorize the digital signature of the prescriptions written by the professional, allowing for revocation or update of the certificate when needed, in a quick and decentralized way. This is useful in the case of substitute prescribers.

  o Digital signature system with time-stamping and chain of custody tracking. The Spanish digital signature law provides for the figure of the "identification services provider," which can be different types of public or private companies.

Dispensation at the Dispensing Pharmacy (DP)

— Telecommunications and security services must be implemented in such a way that all DP have a broadband connection to the system.

— Hardware needed at each DP includes the following:

   o   Connection of each DP to the e-prescribing server.

   o   Barcode and/or PDF or Datamatrix reader to read code on each medicine.

   o   Smart card reader for the pharmacist's digital certificate.

   o   Reader for automated patient identification.

   o   Laser printer to print the dispensation sheet to which the cut-out barcode of each product dispensed must be attached.

— Appropriate access and professional activity at the DP must be guaranteed, by means of:

   o   Accreditation system for the access points at the DP that access the electronic prescriptions.

   o   Accreditation and authentication system to enable access by the pharmacist (with user name and password, electronic national ID card, digital certificate or a PIN). It is also necessary to manage the different access profiles for the personnel working at the DP.

   o   Digital certificate management system to carry out the electronic signature of the dispensations made by the pharmacist and to revoke or update the digital certificate when doing so is deemed necessary or when it is not used during a certain period of time.

   o   Electronic signature system with time-stamping and chain of custody tracking, as a legally-valid guarantee of the pharmacist's professional conduct.

— Dispensation system linked to the e-prescribing system.

— Messaging system between the DP and the professionals working at primary care health facilities and at hospitals.

— Pharmacy and invoicing management application compatible with the e-prescribing system and certified by the health organization or insurance company.

— Contingency application agreed by all the agents involved in the system.

— Technical support centers for the DP, to solve technical or functional problems.

— Ongoing training, as part of the strategy for the management of change in this group of professionals.

Invoicing

The system must facilitate the reconciliation of the traditional invoicing of paper-based prescriptions and the invoicing system used for electronic prescriptions, with the same security guarantees for the patient and for the healthcare system, in terms of clinical, financial and resource concerns.

The security measures introduced must preserve the balance needed to facilitate access by patients and also professional conduct by the pharmacist, avoiding possibilities of fraud or inappropriate use of the health resources connected to pharmacy benefits.

Databases

— Master index of users. This is a registry of all the users of the health organization that are entitled to pharmaceutical benefits. It facilitates patient identification and contains such data as full name, birth date, patient identification code, type of co-payment the patient must make, etc.

— Master index of patients attended. This is a registry of all users attended and it contains the health records that are currently open and patient pharmacy records.

— Master index of professionals. This is a registry of health professionals involved in prescribing, who have been registered in the system. It allows these professionals to be identified and contains details related to the person's identification and the position he or she occupies (full name, health facility, membership number in the professional association, type of employment contract...)

— Master DP index. This contains data pertaining to the DP and the staff authorized to access prescription data and to dispense products.

— Database of drugs and health products, as well as complementary databases that assist in the prescription and dispensation process: interactions, patient information, each drug's technical sheet, the hospital's Pharmaceutical Guide, warnings about use during pregnancy and breastfeeding, etc. The system will perform better if these complementary databases are integrated into the drug database, as this will enhance consistency and allow for unified maintenance, which means greater efficiency throughout the system.

— Electronic prescription database. This stores all information regarding the electronic prescriptions written as well as the dispensation record.

Pharmacy management in specialized care

Although the main purpose of this document is to discuss e-prescribing in primary and specialized care, pharmacological therapy in any health system must, as mentioned above, be based on a global vision and a comprehensive management system. The following are some of the reasons that it is important to act in a homogenous and coordinated manner:

— The drug suppliers are the same pharmaceutical labs whether access takes place through prescription and DP or through the hospital pharmacy service, so it is useful to track data on total sales for the healthcare network.

— The patients who receive the pharmacological therapy are the same, but attended in different facilities or services.

— It facilitates the maintenance and the update of the general characteristics of one large database for all facilities, which brings greater efficiency.

— It facilitates the combined statistical analysis of data regarding acquisitions and consumption in a single information system. This means it is possible to assess the influence of the selection of medicines between the hospital and primary care.

For these reasons, this article also discusses, albeit in less depth, a number of issues related to electronic pharmacy management in the hospital setting.

Before exploring pharmacy management in this care setting, it must be remembered that the essential objective is to move towards a single electronic health record for each patient. This record should reflect the prescriptions and dispensations/administrations made in specialized care, in both hospitalized patients and in other types of patients attended by clinical services, or in patients who receive medicines from the hospital pharmacy services.

However, the hospital pharmacy services also perform other clinical and management activities that tend to be highly automated and supported by information technologies, as part of different projects that must be integrated and coordinated.

All of these instruments must contribute to achieving safe, high-quality pharmaceutical care that is also cost efficient.

The most important elements are:

— Hospital prescription: this can be manual, computer-assisted or electronic

— Integrated program for managing the processes undertaken by hospital pharmacy services:

   o Acquisition

   o Preparation of medication for dispensation in different ways: the stock kept in each ward, unit doses, automated dispensation systems...

   o Distribution of medicines and pharmaceutical care for external patients

   o Preparation of medicines for outpatients: oncology, rheumatoid arthritis...

   o Extemporaneous formulation

— Drug administration record maintained by nursing staff

Hospital prescription: manual, computer-assisted and electronic

The intra-hospital prescribing process should be understood as a care process linked to the patient's clinical record. It must be integrated with this record and with hospital pharmacy service management, but it does not necessarily have to be embedded into such hospital pharmacy service management. In fact, it is advisable to use an autonomous module that communicates with the electronic health record and with the programs for hospital pharmacy service management, by means of an integration bus and the pertinent messaging, so that all improvements and modifications that are necessary and that enhance the quality and security of the prescription process may be effected as quickly and easily as possible.

The hospital prescription process has many particularities related to the selection and use of medicines and to their dosage and administration. This means that the prescription module used for official SNS prescriptions (the prescriptions covered by the National Health System of Spain for dispensation through pharmacies) cannot be used. These particularities include, for example, the fact that in the case of regular prescriptions whole packages are dispensed while at the hospital dose units are dispensed and administered. Also, dose calculation is often based on weight or body surface area, intravenous administration of drugs with solution is frequent, etc. Generally, all of these particularities are reflected in a master drug index which describes the specificities of the drugs and is maintained by the hospital pharmacy service.

Special mention must be made of oncology prescription, due to its complexity. This area of prescription entails the combined use of various medicines, whose dosification and usage guidelines follow established protocols, and which are used for varying periods of time according to patient response. In addition, their preparation must often be coordinated with the results of analyses performed the very same day.

Hospital e-prescribing has several objectives. The following are especially important among them:

— To furnish prescribers with the information and tools that help them make good therapeutic decisions and correctly select medicines, both in active ingredient, pharmaceutical form,

recommended and maximum dose, preferred route of administration, dose calculations based on weight or body surface area, types and amounts of solution, warnings concerning duplication, allergies, interactions...

— To speed up the process, since there is no need to transcribe the prescriptions in the hospital pharmacy services in order to prepare the medicines for the patient.

— To increase the legibility of the product names and dosification specified by the prescriber, thus reducing the likelihood of errors.

— To automatically incorporate the information into the patient's electronic health record.

— To improve communication among all the health professionals attending the patient: physicians, pharmacists and nursing staff.

— In short, the overall aim is to prevent errors and increase the safety of medicine use at the hospital.

Integrated program for managing the processes undertaken by the hospital pharmacy services

Almost all pharmacy services manage their purchases, stocks, dispensation and consumption of medicines with computer programs that assist in every step of the process and that need to be connected to general and specific databases in order to function properly. Clearly one of the most important is the database of all the medicines authorized for use at the hospital, which are the ones that comprise the Pharmaceutical Guides of that hospital. The characteristics of these medicines are found in the hospital's **master drug index**. Added to it are many prescription support tools that physicians can use during the process of selecting/prescribing the medicines.

The most important procedures performed with the help of pharmacy service management programs are the following:

— Acquisition: preparing and receiving orders, confirming delivery orders for invoicing purposes

— Budgeting

— Management of consumption and stocks

— Traceability of batches and expiration dates

— Management of stupefacients

— Preparation of medication and dispensation in different ways: the stock kept in each ward, unit doses, automated dispensation systems...

— Pharmaceutical management and care given to outpatients, especially oncology patients.

— Preparation of medicines for external patients: rheumatoid arthritis, HIV, and others

— Extemporaneous formulation

These management systems furnish data regarding the acquisition and consumption of medicines. This data is then added to the appropriate module of the general pharmacy information system.

Drug administration record by nursing staff

Finally, to complete the circuit that medicines follow at the hospital, it is necessary to guarantee and record that the medicine has been administered to the patient. To this end, as with the prescription and dispensation of medicines for a specific patient, there must be a system that facilitates automatic

recording of administration. This system may consist of scanning the data that identifies the patient and the medicine being administered, which is verified against the prescription and dispensation, thus avoiding confusion and possible errors.

This kind of working method increases safety and allows the situation to be checked in case of doubt.

Difficulties and limitations

Although in terms of the information technology needed there are plenty of companies that can take on this type of project, one of the greatest difficulties is being able to count on firm and solid institutional support within the organization, with awareness of the unquestionable advantages that a global system of these characteristics will bring.

Yet it is also important to remember that the different components that make up electronic pharmacy management cannot be addressed jointly or even at the same time, because there are always programs or systems in the healthcare organization that must be modified or adapted. Another essential aspect to keep in mind are the great efforts required of the personnel involved and also in terms of budgeting. Furthermore, these programs have been developed and are maintained by different companies that are often reluctant to collaborate with one another or simply seek to expand their participation. This means that health system managers/patients/health professionals and of course the personnel responsible for the organization's information systems must all work together.

There also tend to be some agents who are opposed to the aggregation of information or to enhancing the organization's transparency, and who will try to see to it that some part of the project is not implemented. In other cases, those in charge of technological aspects assume the starring role and the leadership of the projects, which may negatively affect: the project's ability to meet functional and care-related objectives, the usefulness of the system, its maintenance and its connectivity with other systems.

In relation to e-prescribing projects, a certain amount of opposition may be expressed by dispensing pharmacies and their representative bodies. Such resistance may be the result of fear of change and of the possibility that the healthcare organization will be able to obtain information directly, quickly and practically without intermediaries.

Conclusions

Electronic pharmacy management in a healthcare organization or insurance company is both a challenge and an opportunity to combine clinical and management activities, with a view to ensuring safe, efficient and quality use of medicines by patients, without regard to the complexity of their condition or to how they access the medicines.

The design and development of these projects must be guided by a far-reaching vision of the system as a whole, a vision in which the following issues take priority: integration of information, homogeneity, consistency, versatility, data security, capacity for statistical exploitation and scalability.

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Chapter X

International exchange of health information

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Summary

A large and growing number of people travel to other countries for professional, social, leisure or humanitarian reasons. This increase in mobility has brought about a greater number of situations in which people need healthcare outside of their own country. This has made access to health information more important than ever.

Information Technology (IT) has opened the door to tremendous advances in information systems, thus helping improve the care provided in the healthcare setting. However, such improvements have generally taken place in local environments that are not always mutually compatible with others, meaning that health information regarding the same patient is distributed without the possibility of being shared.

In order to ensure that a patient's records are accessible, and that the doctor treating that patient has access to all relevant information, strategies for standardization and interoperability must be followed. Such strategies are quite technology-dependent, yet must be coordinated with experts working in the different health areas involved (health professionals with experience in information systems). These are the individuals who can point out real needs and draft the agreements required to achieve standardization.

In the international context, this issue poses a number of additional, specific challenges of great importance, and their analysis will be the subject of most of this chapter. In spite of the difficulties involved, the ability to offer patients the best possible healthcare –even when they are not in their country of origin– is an undeniable benefit, especially keeping in mind the frequency with which such situations now occur. If we also consider that the strategies for sharing information between different healthcare providers, regions and even countries are synergistic, it is easy to see how important it is to have a comprehensive vision at all levels – even for local implementation.

Introduction

A large and ever-growing number of people travel to other countries – for professional, social or leisure reasons or to engage in humanitarian work (WHO, 2010). This upward trend, which seems to be going to last, has led to greater international cooperation –through the WHO– focused on combating the spread of infectious diseases. The basic legal framework that has emerged from this cooperation has taken the form of International Health Regulations (IHR), which were adopted in 1969, modified in

1973 and 1981, and completely revised in 2005 (WHO, 2005). The goal of these regulations is to "*prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade*" (IHR).

In this chapter, however, we will not focus on the kind of information that is exchanged for epidemiological or public health reasons. Such information is already subject to a high level of regulation and wide-ranging consensus. Rather, we will look at citizens in situations of mobility, focusing on access to their health information when they require care in a country other than their own.

When applied to the healthcare field, Information Technology (IT) has brought huge improvements in information systems. However, these improvements have generally taken place at local levels that are not always mutually compatible later on. In other words, each healthcare provider has developed systems of information collection, storage, and at times of data use – with greater or lesser improvements in comparison to their paper-based equivalents. All of this can bring potential improvements in the quality of care and patient safety, but such improvements are usually limited to a particular environment. Patient information continues to be distributed among the different healthcare providers who have worked with that patient, with no way of guaranteeing that professionals needing information will have access to *all* the relevant information. For that reason, in recent years greater emphasis has been placed on studying how to share this health information – in other words, on interoperability within the clinical area.

Since another chapter in this book addresses interoperability, here we will only mention that there are several levels of interoperability, and that the technical level (making information systems "understand each other") is not the most limiting aspect in the healthcare setting. A more complicated issue revolves around the need for information transmissions to be semantically equivalent, within a context that consistently provides its complete meaning. This statement, which is applicable to other fields, takes on particular relevance in the healthcare area, given the complexity and continual evolution of the health sciences. This high degree of complexity and changeability makes the role of health professionals highly important, both in establishing needs and setting priorities, and in defining the best way to handle the heterogeneous representation of knowledge. In short, interoperability requires standardization.

When the data exchange occurs in an international environment, we are faced with specific challenges such as data protection legislation, patient identification, pharmaceutical product identification, multilingualism, etc. This chapter will focus especially on these challenges, within the framework of overall interoperability.

The legal framework

Each country is responsible for its healthcare system and for guaranteeing the services provided. Specific laws and regulations governing healthcare vary from one country to another. In some cases, such as the EU for example, general principles have been laid out in Community Directives aimed at favoring citizen mobility, with each country then transposing these directives, making them into national law. In a few other cases, specific international agreements exist due to geographic proximity or for other reasons. But in most cases there are no common regulations.

In spite of this heterogeneous situation, all countries agree that health information is especially sensitive and that, while access to that data can greatly help in improving the quality of care, such access

must be limited to those who are authorized to do so. These two rights (availability of information and confidentiality) are at the same level, hierarchically-speaking. This creates the need to strike a balance between providing the best possible care –ensuring access by professionals to health data– and implementing the security measures needed to avoid unauthorized access.

With telematic access to data, existing laws and general principles regarding information access are equally applicable. The difference lies in the description of the mechanisms (also telematic) that are to be used for attaining the required level of security (for instance, the need for a digital certificate, data encryption, maintaining traceability, etc). A clear example of such mechanisms are the ones developed to ensure data availability. It is not enough to simply have an information system with which to share information; it is also necessary to establish the requirements that will make the system operational 24 hours a day (ideally). The requirements for such availability depend on mechanisms that are not needed when using paper-based health records (e.g., 24 hour technical service and administrators).

Telematic access is also distinguished by the easy access it provides to a greater quantity of information, and to a higher number of involved persons (physicians, nurses, patients, etc.). The system must make sure that these individuals can access only the information they need, since the attributes of health professionals differ across countries (psychologists, for example). The technological mechanisms to allow for this must be established. When information is exchanged internationally, this means previously ensuring that the concepts handled are commonly understood, or equivalent.

Security issues are covered in greater detail in the chapter devoted to this subject. Here we will limit ourselves to describing the general principles that must be taken into consideration when establishing a legal framework.

Taking the EU as an example, the establishment of a cross-border data exchange system must be based on a common data protection directive[49]. This directive has considered the fact that IT developments will increase the flow of information within the common market, and that mechanisms must be established to facilitate this flow (this basically means having equivalent definitions in terms of data protection). Moreover, a recommendation was made in 2008 concerning the cross-border interoperability of health records[50], along with a new, yet-to-be implemented directive related to the application of patient rights to cross-border healthcare[51]. These have greatly increased the possibility of establishing a common framework for interoperability. However, despite all the efforts made towards establishing common legislation, attempts to define the exchange of health data have run into conflicting laws in different countries – which at times limit data exchange or call for specific actions to resolve certain problems. This has prompted some authors to talk about "legal interoperability" to refer to a previous, also vital step – the creation of a legal framework that will cover information exchange.

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[49] European Parliament and Council of the European Union. *Directive 95/46/CE of the European Parliament and the Council of 24 October 1995* on the protection of individuals with regard to the processing of personal data and on the free movement of such data.

[50] European Commission (2008/594/CE) *Commission recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems.* Official Journal of the European Union [notified under document number C(2008) 3282]

[51] European Parliament. "*Position of the European Parliament adopted at second reading on 19 January 2011, with a view to the adoption of the European Parliament and Commission Directive on the application of patients' rights in cross-border healthcare*" [date of consultation: 29 of March, 2011]
http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2011-0007+0+DOC+XML+V0//EN

In any case, to ensure that cross-border data exchange can take place with adequate security levels, a series of milestones can be defined:

— Establishing the scope and objectives of the data exchange. Creating a system for exchanging health data for epidemiological studies or clinical tests is not the same as creating a system for the exchange of data with healthcare objectives. In the former, the most important issue is to set up a procedure for making the data anonymous. In the latter, being able to confirm that certain health data is that of the person under care is a security requirement associated with access control. This chapter focuses on the security requirements of the second case, in which information is accessed when caring for a patient, when that patient obtains direct benefit from the health professional being able to access his or her health record. However, it is also important that only those health professionals who can contribute to this care be able to access that data. In order to create a legal framework, we must establish the following:

  o The use cases: the information to be shared, under what circumstances, towards which ends, etc.

  o The professionals having access rights, along with the different roles and profiles, if any. In short, it is necessary to establish who is authorized to access the information and for what reasons.

In Spain, for example, a system is in place for sharing information between regions (or autonomous communities), given that the health system in Spain is highly decentralized and most responsibilities for healthcare belong to the autonomous communities. In this system, which is used for sharing information that a patient may have generated in different regions, it has been determined that access will be allowed for physicians and nurses, that the information they can access is different, that they can only access that information if it is the patient who is seeking care, and that the system includes only professionals and centers belonging to the country's public national health system (Etreros, 2009, a). Other structures can be set up, attending to different criteria and national organizations, while also abiding by criteria related to legislation and the logic of care provision.

— Defining a system of prior consent. A process must be devised by which a patient gives consent for his or her data to be accessed. This important issue has been dealt with in very different ways by different countries. It is advisable to address this issue once the use cases have been established, but still in the early phase of system development. Attention should be paid here to striking a balance between respecting confidentiality and the care the patient is receiving. In other words, the goal should be a balance between the availability of information and its confidentiality.

Issues to be considered include distinguishing between situations calling for explicit consent and those in which such consent can be regarded as implicit, the means for obtaining consent (oral, written), the location in which it is obtained (country of origin or country where the care is being provided), and the law that applies in each case – among other important points.

Some countries, such as Sweden and Spain, give citizens the right to conceal the information they do not wish to share (Etreros, 2009, a). This trend towards giving the patient more power over his or her own health information is becoming more and more relevant and is gaining high levels of acceptance. However, there is no common legislation covering this issue, meaning that it must still be taken into account on a country-by-country basis. It will be necessary to establish the ways of informing the doctor about the existence of concealed information without violating the patient's rights, and without providing any information about what kind of data is hidden. It will also be necessary to determine whether any situation exists in which a professional may step around the patient consent requirement. Spain and Sweden once again provide an example of the different ways of addressing this issue. In Spain, a health professional may view the information the patient has hidden only when the patient is unconscious and the professional believes that his or her life is in danger. A special record appears in the system when this occurs. In Sweden, on the other hand, once

a patient has decided to conceal a certain piece of health information, it may not be viewed under any circumstances.

There are still other considerations regarding information security that must always be addressed when health information is exchanged (Abad, 2009; epSOS Project, 2009):

— Systems for the identification and authentication of professionals and patients.

  o For patients: Positive identification can only be assured if there is a unique encoding system that does not change throughout the life of a patient (or one that is securely linked to the earlier codes each time a change occurs), and that cannot be applied to anyone else. This rules out any insurance encoding systems in which the same number can be applied to various family members.

  o For health professionals: Positive identification must be associated with their professional role. The professional database that maintains the records of the unique identification associated with each professional must be kept up-to-date (human resources databases, on the other hand, often take too much time to update and thus cannot ensure that the professional roles described therein remain accurate at the time of access). The identification of the professional and his or her role must be separate from the profile under which he or she works (take for example the following case: a physician may have access to certain information thanks to his or her role as a medical caregiver, yet that person may also have a profile as a researcher at the center; this profile would not necessarily authorize access to the information system). The professional's identification must also be associated with the health center at which this person works and attempts to access must be from that facility in order to be authorized.

  o Authentication: By means of an advanced electronic signature, for example.

— Traceability: Assuring the security of a system means finding a way to ensure positive identification of professionals and patients. Since between countries it is usually not possible for this information to be centralized, each country or region must assume the responsibility for identifying and authenticating patients and professionals, and for assigning a specific professional role to the latter. In cross-border exchanges, given the need to decentralize professional and patient registries, it is especially important to always have a record of all accesses or attempts at access. Although these do not specifically refer to cross-border exchanges, the requirements for identification and authentication can be summarized as follows:

  o Integrity and non-repudiation: It must be assured that information cannot be altered or manipulated during its storage or transmission (integrity). Mechanisms such as a digital document signature are used for this purpose. For documents that are not closed –i.e., that may be updated– a unique document identifier can be applied each time such a document is accessed. In addition, any actions a physician performs must be recorded, so that they cannot subsequently be denied (non-repudiation).

  o Audits: It must be possible to audit any information exchange system. This means that auditing procedures and certification environments must be established. It should be remembered that certification systems can certify technological as well as functional processes. The best course of action is to choose a certification and auditing method that is standardized and widely recognized, but that can be adapted to the specific needs of each case.

The interoperability model in international information exchange

Interoperability is the attribute that makes it possible for heterogeneous computer systems that were not designed for mutual exchange of information to do so efficiently, without the need for human intervention. Semantic interoperability enables the standardization of the exchanged data –along with its

context– so that this information can be understood and interpreted in the same way by all participants in the semantic process (Etreros, 2009, b).

The purpose of this chapter is not to describe the actions that must be taken in order to attain interoperability, as this is covered elsewhere in the manual. We will, however, offer a basic outline in order to explain those features that take on greater relevance with the cross-border exchange of information.

Interoperability has various dimensions: technical or syntactic, semantic and organizational. The first (the ability of different computer systems to "understand each other") is of no greater importance in cross-border information exchange than in ordinary exchange, because the technological solutions are different even within countries. The organizational dimension includes the legal considerations mentioned above and other issues related to varying organizational models in different countries (for example, who has permission to access information in each country). Semantic interoperability, however, is the most relevant issue in an environment that includes a number of languages or a variety of uses in the same language in which semantic equivalency is facilitated, but not guaranteed. One example can be found in Spanish, which has varied usages: a peach allergy can be either an *alergia al melocotón* or *alergia al durazno* (words used in different countries for the same fruit). A strawberry allergy can be an *alergia a frutillas* or *fresas*, the vaccine against pertussis (or whooping cough) could be called *la vacuna de la tos ferina* or *la vacuna del coleuche*, etc. This can lead to considerable confusion when the information is health-related and therefore leads to healthcare decisions. Thus, although the same language is being used, prior efforts to achieve semantic interoperability are required.

For semantic interoperability to be attained, the clinical meanings of transmitted information must be consistently maintained. This requires the following.

— Contextual information (common medical-legal information): agents involved, versions, administrative data, etc. At a national level this might be, for example, a law regulating electronic prescriptions. Since this medical-legal context does not exist at the international level, health professionals must reach consensus on the rules covering such terminology before implementation. This section would include, for example, the definition of roles for each agent (each type of healthcare professional, system administrators, etc.).

A similar concern is the necessity of agreements on the concepts to be handled. Different countries do not always refer to the same concepts in the same way and, even worse, they sometimes use the same name for different concepts. The International Standards Organization (ISO; www.iso.org) has made great efforts and reached agreements on standards at the international level. Many of these have been converted into European standards by the European Committee for Standardization (ECS; www.cen.eu). They have also been applied nationally by different standardization agencies. Specifically, the standards drawn up by ISO technical committee 139 (healthcare computing) provide standards covering concepts and circuits related to care continuity (13940) and medicine descriptions (ISO 11615-6 and 11238-40). Most of these standards, or parts of them, are in the final stage of consensus among countries. Some examples would be how to define a clinical event, a medical act, etc.

— Structure of the clinical data (detailed clinical models, archetypes, templates, etc.): it is necessary to determine which information is to be exchanged. Once we know the framework within which we are working and the concepts to be handled, we must establish the set of health data we want to exchange, and with what structure – i.e., the data model. When the purpose is care-related and the objective is to improve the quality of that care and the safety of the patient, systems usually prioritize the exchange of the patient information that is most relevant. In this area, a number of projects are describing summaries of patient health records – Historia Clínica Resumida (Abad, 2009), Patient

Summary (epSOS Project, 2009), etc. Such summaries also offer the advantage of being a document that can be rapidly consulted in an emergency situation. This is especially important when communication with the patient is difficult (for language reasons, for example) or impossible (because the patient is unconscious). Electronic prescription systems are another frequent priority.

Different countries do not usually have a common structure for documents, making it necessary to decide on a common structure for exchange, while giving priority to the most relevant information. The degree of relevance will depend on the objective that has been set. For example, with care-related objectives, information on allergies, particular health problems or issues with medicines will be more relevant. If the objectives are more related to research, then data concerning that research will be given higher priority.

There are some international standards for information exchange, such as those put forth by the HL7 organization, which has established predetermined templates agreed upon by health professionals. Such templates not only offer the advantage of saving or reducing the time needed to define a data model, they are also international standards. The disadvantage is that it may not be possible to adapt them to specific information exchange needs (particularly, some models have been defined for a health system like that of the United States and are not technologically prepared to support multilingualism). Moreover, there is still no standard that has completely proven its usefulness for each specific situation. In this case standardization, which is always necessary, is based on limited experience, and on a specific context that perhaps cannot be generalized. The most helpful ISO standard in establishing an information model is the 13606, which recommends the definition of clinical models (called archetypes) that are internationally shared. These are to be reused, leading to an international standardization process that maintains clinical coordination. This standard also provides descriptions of circuits, security, etc., while separating the recording of information from the data model definition, such that if the model must be changed due to the evolution of clinical knowledge, the architecture and recording of information are not affected (the so-called dual model).

In other words, ISO standards provide us with a more complete framework and more flexible methodology in the long run, separating health developments from those taking place in technological areas. They do, however, require greater initial effort, since it is necessary to start out by defining the archetype. Currently existing standardized templates present a more specific problem, in that it is difficult to make changes once they are implemented. Yet they may be of value with cases in which the definition of the template is equivalent to that which is to be implemented, or in those cases where the resources needed for a greater effort are lacking. In any case, none of these choices rules out the others.

— Terminologies: Last but not least, transmitted information must be coded in order to ensure that its semantic meaning is preserved through transmission. If, moreover, the exchange is multilingual, information that is not coded cannot be exchanged, since the machines will not be able to interpret the free text. This presents important limitations. We are currently faced with a number of different situations:

  o Fields that are generally coded using international terminologies (ICD, ICPC, ATC, etc.): the main problem here is that these terminologies –mostly maintained by the WHO– were created for data use, and at times when they are used as interface terminology (for data entry), they do not have sufficient granularity[52] for the healthcare professional to accurately express him or herself. In addition, each country changes the core of the international terminology, and may use different versions.

  o Fields that are generally coded with local terminologies: in this case the local terminologies must be mapped (that is, equivalencies must be found) with a terminology considered to be common – called a reference terminology.

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[52] The term *granularity*, when referring to data storage, is defined as "the scale or level of detail in a set of data". Oxford Dictionaries (http://oxforddictionaries.com/definition/granularity)

     o   Fields that are generally not coded: in this case the only way for sharing to take place is to establish a possible coding method that is tailored to meet the needs of those fields. Here this would be a reference terminology (common for all) and an interface terminology.

For some years now. the concept of terminologies covering data entry has been developing – terminologies that have enough granularity to allow a physician to express information with the same level of accuracy as he or she would when using paper-based health records. The SNOMED CT (Systematized Nomenclature of Medicine - Clinical Terms) offers the best example. This terminology, which is maintained by the IHTSDO (International Health Terminology Standard Development Organization, www.ihtsdo.org), includes over 300,000 terms from different health science domains. The advantage of having such a wide-ranging terminology is that it makes it possible to establish a reference terminology with which to map out the varying solutions in different countries, along with interface terminologies where the granularity of the existing terminology for data entry is insufficient from the clinical perspective. The problem with this granularity, however, is that when using the data it may not adequately allow for data aggregation with which to make statistical inferences or to assist in management decisions. For this reason, usually both types of terminology must be available.

Despite the fact that the SNOMED CT is a clearly useful tool, it has not been widely implemented[53].

Benefits and limitations of cross-border data exchange. A use case: European epSOS project

The European epSOS project (www.epSOS.eu) is cofunded by the European Commission and the participating partners. It is a type A pilot project, meaning that it has the highest priority in terms of financing, since it is an initiative of the Member States. Its objective is to design and pilot a system for exchanging Patient Summaries and an electronic prescribing system.

Taking as an example the use case of the Patient Summary (PS), we will briefly analyze the decisions made in relation to the different aspects described in this chapter. Such an analysis reveals that at the moment of actual data exchange, decisions had to be made limiting the scope of that exchange. Since this is a pilot project that must be carried out in a short period of time, decisions must be understood within this practical context – not treating the system as one that is ready to be implemented with no need for further improvements or analysis.

1) Legal framework: as explained earlier, the legal framework has been the European directive governing data protection, along with the work of data protection agencies. A "circle of trust" has been established, in which each country that has signed the project agreement commits itself to fulfilling the requirements laid out in that agreement. The countries establish a National Contact Point and sign a framework agreement with the various agents involved in that country (healthcare centers, for example, or with a company that designs a data processor used for the National Contact Point). The legal framework is completed by the set of framework agreements – with the project's decision-making body as the auditor. The project's underlying principle is not to intervene in any national solution, given that the pilot has a limited duration. Rather, it aims at establishing a framework covering all existent legislation, without the need to sign specific agreements or for a country to alter its laws.

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[53] One example of the implementation of this terminology is at the Italian Hospital in Buenos Aires (www.hospitalitaliano.org.ar). Another model is the use of the SNOMED CT in data models that have been set up for viewing information among different healthcare levels – such as at the Fuenlabrada Hospital in Madrid and its primary care area.

Regarding identification, at this time there is no European registry with positive identification of patients and professionals, although some European Commission projects are currently studying this issue (STORK and NET@CARDS projects, etc.). Each country decides how its patients are identified, and this information is shared on a website. A record is kept of the professionals accessing the system, and their actions. In both cases the responsibility for identification and authentication is national, with that country certifying that the information is accurate and internally establishing security mechanisms[54].

2) The data model was defined by an operational team of health professionals (epSOS project, 2009), who decided which kind of data was of highest priority and should be immediately visible to a physician caring for a patient. To develop the basic document, a Spanish consensus document was used. This consensus document was the result of work by over 40 Spanish professional scientific societies, including societies for professionals of primary, specialized and emergency care, nursing societies, bioethics societies, patient organizations, specialists in health law, healthcare managers, etc. The report of their work was reflected in an Executive Decree[55]. The group decided which fields to remove or add depending on clinical logic, while taking into consideration the realistic possibilities of each country. To obtain this information a survey was distributed to participating countries asking which fields could be shared.

This model was adapted to the international HL7 CDA standard, although it was necessary to make a number of significant variations with respect to the original standard. For example, the fields that the professionals regarded as obligatory or optional did not coincide with those set out in the standard. In fact, so many changes were made that its advantage as an international standard was partially undermined. In spite of this, considering the limited period for this pilot project, the group decided that it was not feasible to propose an implementation plan that was not based on a specific template. Moreover, after the pilot project the template will have the advantage of having accumulated actual use experience. Another problem was related to the fact that the CDA standard is not prepared to be multilingual, which made subsequent developments another necessity.

3) Terminologies: The project also decided that it was not possible, within existing time constraints, to establish a reference terminology with SNOMED CT. A master catalog of values was drawn up by analyzing, in each field of the patient summary, the existing terminology that best covered the needs and was the most commonly used (epSOS Project, 2010). Together, these sets of values comprise the master catalog. ICD terminology was chosen for the problem list. Given that each country uses a different version of ICD, the project opted for version 10, but only up to three digits, so that the countries that have implemented another version could more easily map out the terminology. The ICD has a very low level of granularity at three digits, which has seriously compromised the accuracy of the shared information. It does, however, serve as a first step for testing the viability of the system under sufficient security conditions.

For fields lacking widely-used terminologies (allergies, vaccinations, procedures, etc.), SNOMED-CT value sets were defined.

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[54] A more extensive explanation of this system (in Spanish) can be found in the article *"Algunas consideraciones sobre seguridad de la información en el proyecto europeo de Historia Clínica Digital (proyecto epSOS)" (Abad, 2009). ("Some Thoughts on Information Security in the European Electronic Health Record Project (epSOS project)".*

[55] Executive Decree 1093/2010, of December 3, which approved the minimum data set for clinical reports in Spain's National Health System.

Conclusions

The number of patients living or traveling in other countries continues to grow, and therefore more and more citizens find themselves in need of medical care outside their country of origin. Information Technology can be used to ensure that these patients receive better and safer healthcare.

When systems for the exchange of information are devised, both clinical staff and technicians must be involved, since health professionals must make many of the decisions.

Standardization is a vital first step towards attaining interoperability, especially with cross-border information exchange where free text is not possible. Terminologies are a necessary step but in themselves are not sufficient for the exchange of data.

Strategies to achieve local, national and international interoperability must be synergistic. The use of open technologies and international standards is always advisable.

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Chapter XI

Public health information systems

Manuel Galán

Summary

One of the essential tools for the effective practice of public health can be found in the information systems about the population's health problems and their determinants.One of the essential tools for the effective practice of public health can be found in the information systems about the population's health problems and their determinants. The procedures for data collection, storage, analysis and interpretation for decision-making have been integrated into informational systems, which besides allowing visualization and measurement of health-related phenomena, expand health-related knowledge and facilitate dynamic relationships between professionals who work in many different fields but share the common goal of maintaining and improving public health. The tools developed using information technology (IT), along with the uses that can be made of the social networks, are generating new ways to obtain knowledge and take action to improve public health in the 21st century.

Introduction

Information systems are instruments that facilitate access to information generated in different ways and in different places by different organizations, so that timely and reliable knowledge can be obtained about a specific area of interest.

In the field of public health, the purpose of such systems is to have access to health and non-health related data that allow real-time observation and analysis of health phenomena and their determinants. This analysis facilitates knowledge-sharing and supports the decision-making process to preserve and improve health, control disease, reduce injuries, disability, death and the physical and mental suffering of the population.

Both information systems and public health professionals must constantly evolve (as do the agents and phenomena that determine the population's health). Therefore, it is necessary to have information systems that integrate scattered information and are capable of analyzing it in reliable, powerful and versatile ways so that knowledge management can become "public health intelligence."

Real-time monitoring systems and sentinel health networks are good examples of systems that, thanks to characteristics of the systems and the efforts of the professionals involved, have proven useful not only in public health, but also in clinical practice. Such systems are valued because they provide new information and research possibilities that complement other, more traditional information systems and research methods.

Advances in IT make it possible for different systems generated by different organizations to "agree with each other" (in technical and functional terms), provided the groups are truly interested in collaborating and forming strategic alliances to benefit the health of the community.

Public health, as a scientific and technical discipline that works in favor of community health, needs to have information systems that make good use of technological progress, so as to effectively understand and intervene in phenomena that affect public health. The field of public health will thus be better equipped to contribute to the health and well-being of all people.

Information and public health

The term "public health" contains two concepts that interweave with one another to achieve a common goal. On the one hand, the term "health" represents a personal and collective quality essential for human beings to fully develop their potential. On the other hand, the term "public" represents both a right of the people and a commitment from those who manage their resources. The health of a population is a "common good" resulting from the interaction between the risks inherent in human nature, the environment in which we live and the measures that a community takes to avoid or minimize adverse consequences.

The term "public health" as a discipline has been defined in numerous ways. All definitions agree that it has an essentially strategic mission aimed at "preventing diseases and injuries, and deaths and disabilities by advocating general preventive measures for the whole population and targeting groups considered most vulnerable." The discipline of public health is entrusted with protecting the health of the population at large; controlling and eradicating disease; and preventing injury. Due to its multidisciplinary nature, public health uses knowledge, methods and techniques from diverse sources, including the life, behavioral, social and health sciences.

When a phenomenon, a circumstance, or a situation (generically known as an agent) generates – either by itself or in combination with other agents– short, medium or long term adverse effects on the health of a population, as a whole or in a particular group, its presence becomes a "public health problem." The severity of the problem is measured by different parameters including:
— The number of people affected.
— The severity and duration of the adverse effect on health.
— Its extension among the population.
— Its transferability and speed of propagation.
— Duration of the pathology and its consequences.
— Controllability of the causative agent and of its contagiousness.
— Effectiveness of measures available.

Certain health problems, depending on the severity of their consequences and the speed of propagation, can become serious threats that require rapid and effective responses (through public health interventions acting on the source, the origin, the risk or the mechanism by which it is transmitted to persons, whether it be biological, physical, chemical, or social) to contain its spread and impact, and to allow time to organize a response in terms of care and prevention.

At other times, however, a public health emergency may be a local or national emergency caused by natural phenomena such as an earthquake, a tsunami, extreme environmental factors, war, ethnic or government conflicts, causing damage not only to individuals but also to all kinds of infrastructure, including health-hygiene infrastructure and health information systems.

Information and public health professionals

Public health professionals are the "public health strategists" within healthcare organizations. These strategists are usually found in healthcare administrations responsible for designing and organizing protective measures, prevention, surveillance and the promotion of public health as part of the structure of the healthcare authority. Their tasks include the provision of advisory services and decision-making support and the organization of measures to preserve or improve the health of the population under its responsibility through activities, programs, plans and interventions.

The competencies specific to public health professionals include: monitoring the presence, evolution and impact of public health risks; the analysis of and intervention in the causes of public health problems that affect the population as a whole, and especially vulnerable groups; the promotion of healthy lifestyles, protection against environmental, industrial and food hazards; and the prevention of particularly relevant diseases and of injuries. In short, the role of a public health professional is to preserve and improve the health of the population through collective action.

Information and public health procedures

Using the information available, public health actions follow a methodological circuit that begins with an observation phase, followed by analysis, assessment and decision-making phases, and concludes with appropriate interventions. Sufficient and timely information is necessary for successful completion of each of these steps, which appear in Figure XI.1.

Figure XI.1. Process followed in public health activity (Source: compiled by author).

OBSERVE (monitor / survey)

ANALYZE (person / place / time)

ASSESS (Does this pose a public health problem?)

DECISION-MAKING (What should be done?)

EXPLAIN (Why and for what purpose?)

EXECUTE (carry out measures)

EVALUATE (the results and the process)
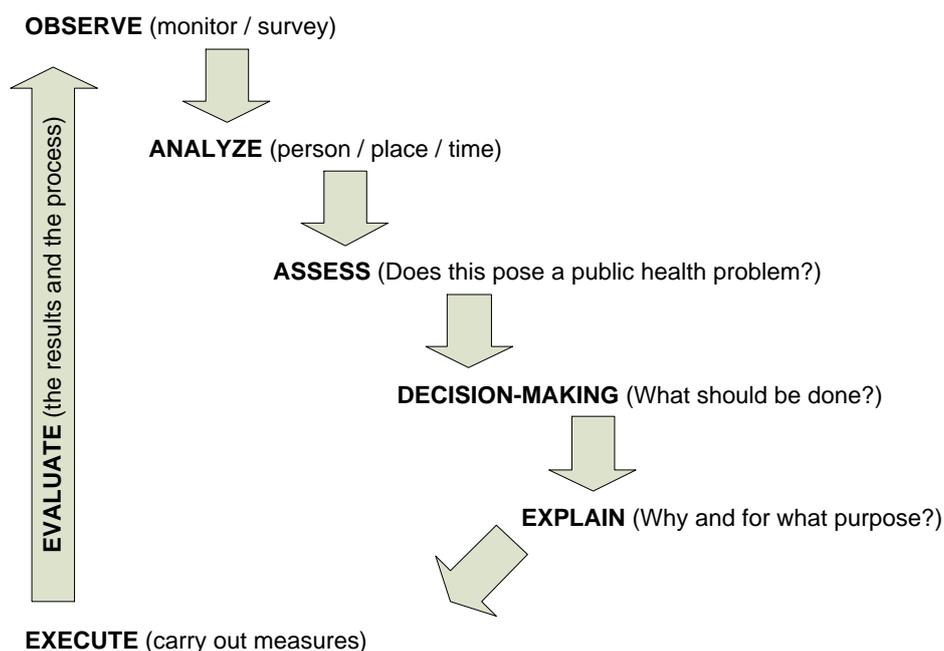
To observe the health phenomena of a population as accurately as possible it is necessary to have an information system that provides a timely, reliable and accurate picture of the volume and characteristics of the phenomenon. To do this, health professionals must choose between having "a little information about many people" or "a lot of information about a few people." Whatever the choice made, it must represent the total population as closely as possible.

In the first case we are talking about population-based information systems (for example, the civil registry of births and deaths, immunization records or hospital discharge records). These are expensive and difficult to manage and maintain technologically. The second case would be a sentinel system, which is less expensive technologically and easier to administer (examples include sentinel networks reporting cases of influenza, meningococcal disease, domestic injuries or birth defects, to name a few). The usefulness of the first type of system is its ability to assess the magnitude of public health problems and resources for intervention, and the second type of system is best for following the specific characteristics of certain issues of particular public health significance in order to intervene effectively and selectively.

When a specific examination of a particular health problem is needed at the time of its occurrence, real time (or near real time) monitoring is carried out, based on selective searches and notification procedures for targeted, short-term emergency interventions. Examples of such situations include legionella outbreaks, food poisoning, measles and meningococcal disease. When more and more detailed data is required, in order to plan strategies and public health measures in the medium term, "virtual" monitoring is carried out, using surveys on perceived health from representative samples of population or qualitative methodology procedures on vulnerable groups.

Table XI.1. Observation and Surveillance Methods (Source: compiled by author).		
Information Systems	**Characteristics**	**Examples**
Population-based	General focus. Obligatory, institutional system. Universal coverage, expensive, complex management. Shows the magnitude of a problem, useful for calculating resource estimates.	Public register of births and deaths. Public vaccination records. Morbidity according to hospital discharge records.
Sentinel	Specific focus. Voluntary and anonymous participation. Covers specific groups, low cost, easy management. Notification or registration	Network of sentinel physicians: influenza, meningitis, injuries or accidents. Systematic search for cases in specific records.
Real time monitoring	Monitoring of specific problems. Automated detection of specific data. Focused and urgent intervention.	Epidemiological surveillance systems for communicable diseases that must be reported to the authorities.
Virtual time systems	Medium-term strategic planning. Large volume of detailed data. Selective searches by records or population.	Health surveys from representative samples of the population. Records of health events in vulnerable populations.

In all cases, it is essential that a cost-benefit analysis be performed to assess the cost of obtaining and managing information in relation to the health benefits gained for the general public. Such analysis

depends on the effectiveness and savings obtained thanks to the timeliness and the quality of the information used.

The second step is to analyze information contrasting it in order to detect differences between groups and populations, across time, in different places, and with different characteristics. For example:

— The frequency of cases compared by age, sex, weight, habits, or identity traits of the individual, the group, the population and their respective scientifically-recognized indicators (for example, colon cancer rates from one region to another).

— Morbidity, mortality, disability among groups or populations in time, in space, level of education, income, ethnicity, among other factors, to determine health inequalities (for example, juvenile obesity rates in relation to the level of education of the parents).

— The number of cases in a specific time period, or in different time periods during the same year, or previous years. This can be compared with previous time periods (for example, the comparison of seasonal influenza curves/rates during the 10 previous years).

— The number of cases before and after implementation of a prevention measure, to evaluate the impact of the measure on public health (for example, morbidity and mortality rates of meningococcal disease before and after putting in place meningitis C vaccination programs).

Once the information about a specific health problem has been analyzed, it is time to make an assessment using local, national, or international criteria combined with healthcare strategy and policy. Such an assessment is a key part of the process of diagnosing a situation from the perspective of public health, possibly leading to its recognition as a "public health problem" that requires a fast response.

This process is not about simply having information about the numerous parameters under observation. It involves working with information which is truly sensitive to the phenomenon of health and by means of which changes can be detected as early as possible, in concordance with the situation's magnitude, severity and possible variations in time, space and characteristics.

When it comes to the decision-making process two phases can be differentiated. In the first phase, a decision must be made on whether the situation requires a response (immediate or delayed) from the community. In the second phase, if action is required, public health professionals must decide what type of response is appropriate for the situation.

An example of this process can be found in the series of events that occurred during the 2009 worldwide influenza A pandemic. In this case, the WHO determined that the developments in Mexico and the United States posed a real and serious threat to global public health, which spurred the healthcare and social structure of almost all participating countries to make decisions and take action. The public health structures in these countries took a series of unprecedented steps for the worldwide epidemiological monitoring of the pandemic, including the detection of cases, the initiation of prevention and containment measures, the manufacture and purchase of specific vaccines to protect the most vulnerable, and the mobilization of health resources to reduce the spread and impact of the influenza. The foregoing suggests that, using the conclusions drawn from an accurate understanding of real phenomena, public health decisions based on scientific evidence lead to greater success and contribute to the consolidation of "public health intelligence," a result of the health experiences of the community and the consequences of the responses applied in each case.

Since the health of the general public depends in large part on people's adherence to the measures recommended by public health agencies, transparency is an inherent feature of public health

that seeks to gain the trust of the population being served. Therefore, the "what", the "why", the "how" and the "what for" of any intervention must be explained in order to enhance cooperation and support to achieve the best results for any community health problem. Information and communication technology are key elements to deliver fast, multi-sensory information (including text, images and sounds), and detailed explanations in order to establish an alliance between public health institutions and the population. This is an exercise in mutual trust that attempts to achieve the greatest possible adhesion to the measures implemented.

Intervention is the organized response to a health problem that affects a community. It entails the prevention and control measures that are thought to be the most effective at combating a particular health problem. These measures take into account the resources available to reduce the extension of the problem, its severity and/or social impact in economic and human terms.

A comparison of the risk and health parameters of a population before and after an intervention can indicate whether the measures implemented were as effective as expected, not effective at all or even if they made things worse. Quantitative evaluation is often used in the field of public health in order to extrapolate from significant results after interventions and determine the adequacy and effectiveness of measures if applied to the whole population. It focuses on verifying specific hypotheses through empirical evidence and explains health phenomena from an observer's viewpoint, placing special emphasis on objective, observable and measurable general issues.

Qualitative evaluation seeks to identify the social representations of many different facets of health that specific groups and populations have, of disease in general, of a specific illness, of the relationship between sick people and the professionals who care for them, of health professionals' acceptance of new forms of management, and of risk perception.

Information systems in public health

Information systems in public health are capable of generating reliable, timely and quality information about health and non-health related issues from data sources based on the population. The quality and capacity of a public health information system is one of the best indicators of the level of development of a public health organization.

Public health information systems must not only collect data on the population's health parameters, the performance of the health system and health infrastructure; they also need to collect information about the determinants of health and health inequalities, coverage and use of services, including key stratifiers for targeted intervention such as sex, age, socioeconomic status, geographic location, nationality and cultural traits.

The ability to generate information in sufficient amounts and of sufficient quality will condition the accuracy with which a public health information system can detect, analyze, assess and recognize any health event or related issue, so that effective interventions can be designed and implemented. Therefore the following questions need to be addressed:

— What information will be used and exactly what data will represent it?

— Where is the data physically located and how can public health professionals gain access to it?

— Who does the information belong to, how will the data be compiled, what procedures will be used and with what degree of precision?

— When and how does the data arrive and how long will public health professionals have access to it?

— Who will do the data processing and interpretation and what tools will be used for this purpose?

— Who will receive the results, how will they get them and what will they be used for?

— What is expected of such information?

— Is there enough information or will more be necessary?

Sources of useful information for public health information systems

From a formal and practical point of view, there are two main sources of information that can be used in a system designed to generate knowledge regarding public health. First there are the "health-related" sources, in which diseases, their causes and characteristics, and those of sick people and the consequences of their illness are the point of departure. Specific examples include records of clinical activity, microbiological and biochemical test results, specific diagnoses, hospitals' minimum data sets, vaccination records, pharmaceutical consumption data, microbiological monitoring of water for human consumption, and bibliographic databases.

In contrast, the "non-health related" sources provide information such as characteristics of the population and its resources, and data from physical, biological, chemical and social environments that determine the health and living conditions of the community. Civil registries, municipal population records, health surveys, the supervision and inspection of facilities that may create community risk, and weather data are some examples of such sources.

Initially, any recordable data that is deemed to have some type of relationship with the phenomenon of health (either as a cause or consequence) may be useful for a public health information system. However, it is essential to evaluate the reliability of the information and the value that it has for the system.

Non-formal sources of information (such as a documented or verbal complaint about alleged risks to public health made by an individual or a group) should also be considered part of the information system as an expression of the health risk felt by the community.

Data entry into the information system is one of the critical steps in ensuring the practical and scientific validity of the entire system. For the information contained in the system to have the quality desired, several premises must be considered, as discussed below.

Considerations for a quality information system

— Use only the information necessary: Not all available data is useful. The usefulness of the information is determined by applying considerations of a conceptual nature regarding its relevance to the system objectives and its validity. The scope, precision and timeliness of the information collected should be evaluated, maintaining a balance between monitoring, database consultation and surveying. This ensures that data collection, always a cumbersome task, does not become inefficient and end up gathering unnecessary data that will never be analyzed.

— Representative and consensual information: From the moment that data is generated to its analysis to its use in decision-making, the data must be a faithful representation of reality and its integrity must be respected throughout the process of information transmission, receipt, storage and custody.

The use of agreed-upon protocols for data collection, forms, templates and electronic formats helps create uniformity and stability in the process of generating information and facilitates its transfer to computer management applications, thus assisting in data analysis and comparability of results.

— Sufficient information that is integrated into a routine: All too often, public health information systems must use incomplete or less accurate information than expected. Sometimes there are difficulties in achieving the desired coverage and other times information is collected inaccurately and incompletely, especially when it is done manually. Therefore, the data entry process for the information system should be designed in such a way that the process is integrated as much as possible into the routine data handling processes that comprise the activity of the person or system that generate the data.

— Accurate and non-redundant information: Attempts to facilitate the information collection process can lead to losses in precision (for example, when age ranges are recorded, rather than exact ages or dates of birth). Similarly, redundant information is sometimes collected due to the existence of parallel information systems that do not communicate with each other and are thus unable to provide cross-referenced information, which would represent a more efficient use of technological resources.

— The information system "belongs" to the users and it is also for its users: Health professionals will identify more closely with the information system if they recognize that they are the primary beneficiaries of its results. Those who contribute data to the system particularly enjoy being the first recipients of the knowledge and practical conclusions resulting from the system.

— An efficient information system: Having motivated managers and staff with the technical capacity to analyze system processes and information in order to generate actionable knowledge for public health, will enhance the information system, help justify resource allocation and demonstrate the cost-benefit of public health actions.

— Diversification of information sources: As there are many diverse health determinants, it is not enough to have a single source of information for public health decisions. A great deal of useful public health information is generated and managed by different bodies, some seemingly unrelated to health, but which offer useful, practical scientific knowledge for many preventive health actions (for example, demographics, meteorological information, environmental pollution data, socioeconomic, cultural, or consumer maps). Thus, establishing means of communication and strategic alliances with agents that generate information useful for public health, in any field (whether public or private), will bring positive results to collective health.

Sending and receiving data

Information technology tools make the collection, transmission, receipt and storage of information possible through safe, fast, comfortable and reliable technology, which is constantly evolving and adapting to growing information needs. Ideally, this process is carried out through interconnected applications from observation points to data repositories located in central bodies that manage information systems.

Undoubtedly, the incorporation of emerging technologies into public health information systems offers great opportunities, especially with regard to social networks, collaborative work and the development of digital content. As a summary, Figure XI.2 shows the stages the data in an information system must go through, from its generation to the making of a value judgment used for decision-making.

Figure XI.2. Stages of Data Development (Source: compiled by author).

SOURCES OF INFORMATION

HEALTH RELATED   **NON-HEALTH RELATED**

Formal / Informal

Professionals   **Citizens**

Pertinence, coverage, reliability, completeness, security, acceptability

Information collection

Sending and storing data

Data analysis

Public health knowledge / intelligence

**Extension   Progression   Severity
Availability of an efficient response**

Decision-making

Health problems (left vertical label)   *Health determinants* (right vertical label)

From "information systems" to "informational systems" in public health

An information system is basically made up of the following components:

— Physical components (observation and reporting systems, data collection and transmission through communication networks, computer applications, etc.).

— Relations and specific processes (observation processes, data generation, transmission and data transfer, arrangement, analysis, presentation, etc.).

— Operating structures (routines, procedures, work practices, etc.) designed to meet a specific objective.

— A specific environment (such as epidemiological surveillance of a community, or early detection of outbreaks) limited to a particular time, place, target population or group of individuals.

— Sources of population-based and geographically distributed information regarding diverse parameters related to or considered health determinants (demographic, economic, meteorological or environmental parameters.)

"Informational systems" are more complex and have different technological requirements. They are designed to analyze data from varied points of view to support decision making by presenting information in a personalized manner, using historical data and even prognostic information such as what ifs.... In order to do this, in addition to the elements listed above, the following elements are also necessary:

— A single data store (data warehouse) for data pertaining to the population's health parameters. The data must be properly refined, updated, easily accessible and well-structured and interrelated. Each user should be able to consult, prepare reports and conduct analyses of varying complexity.

— System interoperability, which means compatibility in terms of the technical language used by machines (interconnectivity, language support, security protocols, accessibility, etc.) and data compatibility (classification rules, coding, formats, etc.)

— Trust and cooperation between people and organizations that have the data, that are interested in it and that have the means to analyze and use it.

— Technical support resources to ensure stable functioning of the information system, operational stability and ongoing technological updating.

The scope and components of public health information systems

A public health information system must cover at least three areas essential to public health. The first is surveillance of epidemiological health problems, their determinants and preventive programs and actions.

Secondly, the system must include analysis tools to assess community health risks, make decisions and assess the impact of interventions on community health.

Third, the system must be able to generate knowledge about the phenomena of health and its determinants by developing new information either on demand or in a scheduled or systematic manner, for distribution to the system's users or to the community.

Spain has put in place a Notifiable Disease System, which is a surveillance paradigm used by medical practitioners after diagnosing a particular disease. Specific, required data is entered into the information system for each diagnosed case of a particular disease. Epidemiologists then monitor the situation and development of related health phenomena by using the system's analysis features to construct tables, charts, and lists of all indicators useful for making decisions about early interventions and evaluating the impact of a given situation.

The same model is transferable to many areas of public health in which the primary source is a qualified observer (doctor or nurse, microbiologist, pathologist, emergency department or inspection personnel) who enters the required essential information (date, diagnosis, case location, etc.) online or directly into the public health information system (which systematically uploads the data into a central data warehouse). Then the information is subjected to programmed routines using specific computer

applications for management, consultation, presentation and statistical analysis, so as to be able to present various indicators of status and evolution (incidence, frequency distribution, statistical parameters and indices) and graphical and geographical representations that can be viewed on screen, printed or published online.

Other public health information systems are based on the use of data previously stored in specific registers to guide preventive interventions and evaluate their medium and long term impact. The most well-known data include the MBDS (minimum basic data set for hospitalized patients), vaccination records, records of mortality, cancer, birth defects, or even the civil registry itself.

Moving towards an integrated information system

Ideally, a public health information system should have an application, or set of applications, that integrates –all on the same platform– the full range of components and functions desirable for monitoring, analyzing and aiding decision making, so that different users, depending on their profile, can access and use the data comfortably and efficiently.

The integration of information collection processes into the normal management routines and procedures that involve administrative, clinical, laboratory and other types of information is one of the key factors in reducing the cost and workload of the data-entry stage. It also ensures the immediate availability of manageable and exploitable data.

However, there is a long way to go yet in terms of connectivity, compatibility and interoperability between systems and agencies directly or indirectly related to public health. Progress will depend heavily on strategic planning and partnerships. Only in this way will it be possible to one day have an integrated system of public health information that contains necessary and sufficient information, in terms of quality, time, and form, and thus enables the system to fully meet all of its objectives.

The future of information systems in public health

Technological developments will undoubtedly offer exciting prospects for public health information systems in the coming years. Inter-agency collaboration and active community participation is ushering in a new era of surveillance, analysis and decision-making regarding the health of the population. Information systems help further consolidate knowledge, enhancing public health intelligence, and strengthen support measures for preserving and improving health based on the principles of scientific evidence and equity.

Considering the population as a whole to be a sentinel for the detection of disease has already begun. The first results came during the 2009 influenza pandemic, with the use of the tool googleflu. Never before has it been so easy, not just to obtain selective, personalized information through telephone platforms and Internet applications, but also to make it available to the community through web 2.0 tools available to both individuals and health professionals. One of the inventors of the Internet, Tim Berners-Lee, predicts that the websites of the future will be full of smart services based on data shared online.

Finally, let this list of objectives, which all public health information systems should help attain, serve as both a conclusion and a challenge to those who are responsible for overseeing community health and who have made these objectives an integral part of their professional and personal goals:

— Determine the health needs of the community by identifying the health problems affecting the population, through the detection of the health risks to which people are exposed.

— Analyze the determinants of the population's health and their effects on it through continuous epidemiological analysis of citizen health, recognizing and trying to understand any changes occurring in health problem distribution and trends.

— Achieve early detection and quick response to potential hazards and health risks, rapidly furnishing the health authorities with the information necessary to adopt preventive and control measures and facilitate health planning, management, assessments and research.

— Disseminate and explain information concerning the prevention and control of diseases and avoidable health problems, developing mechanisms for analysis, advisory support, reporting, informing, evaluating and making consultations regarding the issues of health promotion and protection and the prevention of diseases and injuries.

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Chapter XII

Occupational health information systems

Mariano Gallo

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Summary

An occupational health information system –or, to be more precise, *systems*– are found in a context containing elements and structures from the healthcare sphere and also from other spheres, and it is a context in which a wide range of actors, activities and interests play a role. Sources of information regarding occupational health may be specific, such as in the case of work-related injuries (although they are not always legally recognized as such – and thus must be actively discovered), occupational risks, workers' health surveillance and temporary or permanent incapacity to work, or they may be non-specific (related or auxiliary). Public healthcare systems do not have direct access to much of this data, given that it originates in external organizations more closely connected to Social Security (social insurance system), other insurance systems or bodies that deal with labor relations. Many of these are public, private and semi-public entities operating simultaneously and often in an uncoordinated manner. Data sources often lack content related to health variables or occupational risk, and the quality of such data, when it is present, can be low. Additional difficulties are linked to the fact that work often involves relationships of inequality, so health issues strictly speaking are not the only relevant factors. From a public health perspective, occupational health information systems make it possible to reach a better understanding of the real situation of workers, shedding light on hidden occupational pathologies and leading to appropriate preventative and corrective measures – not to mention other more financial, administrative or care-related benefits.

Introduction

There are many definitions of occupational health. They can have a broader or narrower scope and they can include varying combinations of the concept's static aspects (absence of risk) and dynamic aspects (continual adaptation) (Pedrosa, 2000). A good example is the definition adopted by the Joint International Labor Organization/World Health Organization Committee, according to which occupational health should aim at the promotion and maintenance of the highest degree of physical, mental and social well-being of workers in all occupations, by preventing departures from health caused by working conditions, protecting workers from risks, and adapting work to people and people to their jobs (ILO, 1998).

Similarly, opinions vary as to what occupational health information systems are. A look at the different definitions shows a set of related elements (people, material, services and methods) aimed at collecting, processing, analyzing and transmitting information, starting from processed data concerning workers' health and job conditions, in order to support the formulation, development, monitoring and evaluation of occupational risk prevention and health protection policies (Gallo, 2003). This collection

and analysis of data concerning work-related risk and injury is systematic, with prevention being its main objective.

Occupational health is a far-reaching, interdisciplinary field that involves a number of areas of responsibility, and it goes beyond healthcare strictly speaking (Gallo, 2009). While recognizing the importance of labor relations, labor law, the economic benefits paid out by the Social Security system and other aspects, this chapter will focus mainly on prevention-oriented public health. Accordingly, little attention will be paid here to activities undertaken outside of health service structures (such as in companies, insurance mutuals, etc.). Nor will healthcare for occupational pathologies (diagnosis, treatment and rehabilitation) be covered, since it is very much like healthcare aimed at pathologies in general. Similarly, not much analysis will be devoted to the management of cases of incapacity to work, except for a brief reference as a source of information. We will also avoid references to the safety and health management systems set up for healthcare service employees, since such systems are not aimed at the general population and in any case they are similar to those of other companies, despite the magnitude of some such systems, their diversity of employees and the wide variety of risks present (Gestal, 2003).

Structures related to occupational health

Numerous bodies, agents and users take part in the field of occupational health, although many of them operate outside the healthcare system strictly speaking (Rodríguez, 2007). In the area of medical care services, there tends to be a diversity of structures that dominate, depending on the country, some of which coexist and even overlap (public sector healthcare services, Social Security-based healthcare systems, other healthcare providers, insurance mutuals or insurance pools for work-related health issues, company-based medical services, etc.). There is considerable disparity between different regions in terms of Social Security compensation systems; payments can be managed directly by public insurance systems or by private or semi-public companies that are controlled to a greater or lesser extent. Some large companies manage these payments for their employees. Sometimes other complementary or substitute entities perform this task. Such diversity is even more apparent in Latin America, where one encounters constant renovation, different healthcare and insurance models and different degrees of integration (Cetrángolo, 2009).

Figure XII.1 shows an abbreviated version of the structures that act in the field of occupational health and how the information flows among them. The scheme should, however, be adapted to the conditions of the different locations, making it more or less inclusive according to the particularities of each country. One should also keep in mind that regulations are not homogeneous, and therefore the specific laws and structures of each country must be considered.

Figure XII.1. Structures and information flows in occupational health (Source: Compiled by author).
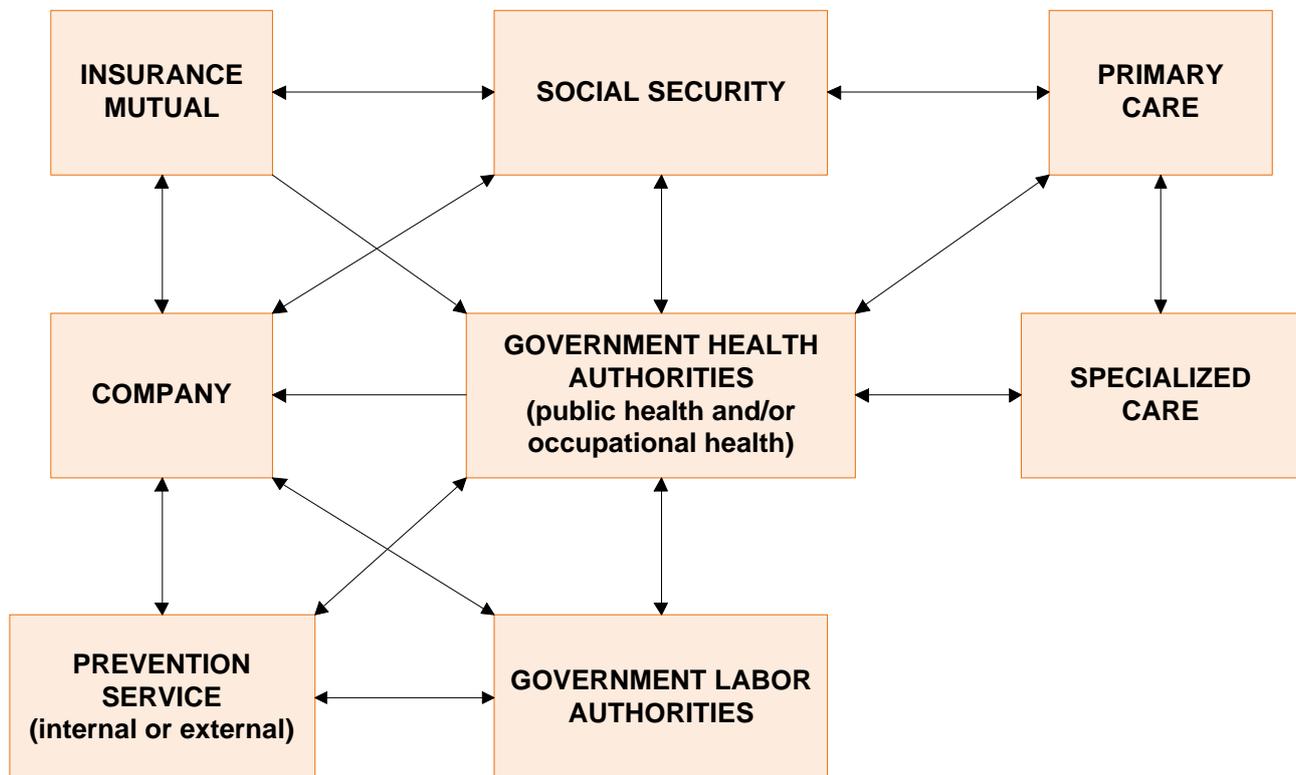
— *Company.* This is the place where workers are found and occupational risks are present (although it should also be noted that in some cases –such as with occupational carcinogens– health problems can appear long after the period of employment). Employers must provide information and allow occupational risk prevention services access to their facilities and workers. Except for large companies with their own healthcare services, all firms must provide information (mostly administrative) to the corresponding insurance mutuals and Social Security bodies. They must also send administrative information to labor authorities (the Department of Labor, the Labor Inspectorate, etc.), and individually report each work-related injury or illness, although at times this is done indirectly through insurance mutuals or other organizations.

— *Occupational risk prevention services.* These go by a number of different names (occupational health services, company health services, occupational medicine centers, etc.). They can be part of the company's own structure or outside contractors (this is more common among small and medium-sized enterprises). These services perform for companies such tasks as the identification and evaluation of occupational risks and the monitoring of their workers' health. They also provide advisory services in the areas of prevention, protection and correction (risk prevention services must provide companies with prevention-related information, although in the case of medical check-ups, this information is limited to conclusions, since personal health information may not be disclosed). They send administrative and preventative information to the labor and health authorities (MSPSI, 1998). They also usually send aggregate health data to the appropriate healthcare bodies, although this information may also sometimes be individual (concerning illnesses of compulsory notification, pathologies that require special monitoring, specific investigations, etc.). In some countries these functions are carried out by insurance mutuals or public bodies).

— *Insurance mutuals.* These organizations usually handle healthcare and, in many cases, economic payments (including the management of temporary incapacity resulting from occupational contingencies (work-related accidents and illnesses). At times they also cover non-occupational, or common, health problems. Generally they provide information of an administrative nature to companies. In addition, they provide Social Security bodies with data related to benefits paid out (except when the mutuals themselves handle all aspects of the insurance compensation procedure up through its conclusion). Such data usually pertains to the occupational disability, but content is partly health-related at times. The health data submitted to government health authorities is most commonly aggregate; individual information is usually restricted to a series of limited situations such as those mentioned in relation to prevention services. However, in some regions further information is provided, especially in the case of work-related illnesses.

— *Social Security.* Social insurance systems are structured differently depending on the country. Frequently, healthcare providers are separate from those managing economic benefits. At times they also may distinguish between professional contingencies and common ailments. They may be managed by public bodies, associations of companies or non-profit insurance mutuals and private companies – with different structures and features in each case (Castellá, 2007). They often supply administrative information (generally concerning benefits) to the insurance mutuals and to the public sector health services.

— *Labor authorities.* These have a number of responsibilities in the field of occupational safety and health: inspections, authorizations, statistics, research, advisory services, etc. Their activities include providing administrative information to companies and prevention services. They commonly receive reports of work-related accidents and illnesses (both of these concepts are defined in a more legal than health sense, with notifications focused primarily on labor statistics, workplace inspections or the management of benefits). The data submitted to the health authorities in relation to these topics is usually aggregate.

— *Primary care.* Health services at this level of care are a chief point of contact with workers, who are treated as patients – with all of their individual, family, social, environmental and occupational factors. Here there is also important two-way contact with specialized care. Primary care services are often responsible for the health management of cases of incapacity to work due to common contingencies (more rarely, they are also responsible for work-related contingencies), and must submit data to the Social Security bodies. They also send health information –both aggregate and individualized– to the health authorities (concerning diseases of compulsory notification, cases that may have their origin in the workplace, etc.).

— *Specialized care.* This is another point of contact with workers, both for processes recognized as having originated in the workplace, as well as other, different types of problems that may be work-related and that warrant later investigation. The health information flow with primary care and other public health entities is important here.

— *Health authorities.* The most important role is played by the bodies in charge of public health, although in some regions there are entities specialized in occupational health. They receive information from most of the aforementioned sources and must respond appropriately to these bodies, depending on the actions carried out (the content will vary from case to case, with special attention paid to the confidentiality of health data – a particularly important issue in the peculiar world of labor relations).

One can see from the description above that there are different sources of information in occupational health, although they are quite disperse, are often not directly handled by health services and vary from country to country. Most of these information sources were not set up with healthcare aims, but rather economic or administrative objectives. They can, however, provide important information, or be the only source for such data. Table XII.1 summarizes the main sources for

occupational health information – specific as well as non-specific (although, curiously enough, the healthcare environment tends to have easier access to the latter).

Table XII.1. Sources of occupational health information (Source: Compiled by author).			
Type	**Source**	**Characteristics**	**Remarks**
SPECIFIC	**Workplace accidents**	Cases reported to the labor authorities	Healthcare sector may have difficulty accessing individual data in this area.
	Occupational illnesses	Generally reported to the labor authorities if they appear on the official list	Same difficulty regarding access to individual data.
	Other types of occupational injury	Work-related illnesses not included in the official list. Sentinel health events and other active search systems	Suspicion of their existence often begins in the health services, but it must be proven that they are work-related in order to be legally recognized.
	Cases of incapacity to work	Permanent incapacity (usually processed by Social Security bodies). Temporary incapacity; usually processed by Social Security bodies or by insurance mutuals (especially those of an occupational type) or by health services (especially common contingencies)	Professional contingencies are specific sources of information in occupational health (health sector has more difficulty accessing this data). Common, or non-occupational, contingencies are less direct, but provide information on the way workers fall ill and can conceal work-related cases.
	Other specific sources	Data derived from the surveillance of workers' health and occupational risks (generally performed by prevention services).	Specific data is difficult to attain.
NON-SPECIFIC	**Cancer registries**	Oncology cases in the general population	They do not normally include occupational data – or they do so only generically. Available to the healthcare sector.
	Diseases of compulsory notification	These are usually diseases with risk of contagion to the community (some are specific to certain professions)	They have the same problem of lacking occupational data or containing little useful information. Available to the healthcare sector.
	Mortality records	These records cover the general population	They do not include employment background or do so only superficially. Available to the healthcare sector.
	Birth defect or congenital disorder registries	These registries cover the general population, mainly children	Work-related agents are usually not well known. Available to the healthcare sector.
	Other, health-related sources	The contents of general health files (electronic health record, minimum basic data set, etc.). Health surveys, etc.	These also commonly lack data related to occupational risk or such information is insufficient. Available to the healthcare sector.
	Auxiliary sources	Company or employee records, censuses, etc.	Available to the healthcare sector (at least in part).

Functions of the information system in occupational health

With such a diverse range of sources that were created with different objectives and are managed by a variety of entities (many outside of the healthcare system), occupational health information systems will be different and have varying scope – according to the available information and resources. It has been pointed out elsewhere that, instead of thinking of a single occupational health information system, it may be easier and more useful to integrate data from different information systems (Benavides 2000). Its functions can be grouped as follows:

— Data reception and processing:

- o Massive data loading from external sources (using different computer media) with varying frequency (monthly, quarterly, half-yearly, yearly, etc.). Manual loading of data available only on paper (still quite frequent).
- o Real-time reception of information (mostly from different levels of the healthcare system itself).
- o Automatic alerts: inconsistencies between different records, omissions in essential fields, classification or codification errors, etc.
- o Interconnection between different systems and interrelated records (administrative, health, etc.).

— Management of medical orders and consultations:

- o Dispatching and reception of requests and orders from health professionals (mainly from primary care) and consultation of their status: received, processed, additional tests, cancelled, terminated, results sent, etc.
- o Reception of requests from workers, companies and other organizations.
- o Intercommunication with the ordering doctor and with other participating professionals and entities in each case.
- o Consultation of available partial or final results.
- o Comparisons with previous cases involving the same person, company, sector, area, etc.

— System administration:

- o Maintenance of different catalogs and auxiliary records (in those cases in which they are specific; in others this will be done from each matrix system): workers, companies, occupations, economic activities, work-related illnesses, sentinel health events, occupational injuries, etc.
- o User management (distinguishing between users from within the health system and the various modalities of users not within the health system, since these are often interdisciplinary actions): registrations and cancellations, modifications, permits, profiles, etc.

— Activities and the use of data::

- o Intervention programs: health programs at the individual level, preventative or corrective programs at the workplace, etc.
- o Health alerts at different levels (workplace, general population, etc.).
- o Statistical and epidemiological analysis and use.
- o Dissemination of results.

The following sentinel physician network for occupational health can serve as an example (INSL, 2011):

A certain number of physicians have been selected as voluntary reporters of health processes that may have an occupational origin.

Since these professionals are not specialized in, or particularly familiar with, the field of occupational health, they will limit their actions to a set number of suspicious diagnoses, detecting pathologies that although treated as not work-related, may in fact have an occupational origin. These will then be linked to their actual cause in order to lay the foundations for preventive action.

If a physician in his/her daily activity is treating a patient who might fall within one of the processes targeted by the program, he/she receives an automatic alert from one of the commonly used computer tools (electronic health record system, appointment management system, etc.) when a diagnosis or process that might have an occupational origin appears.

When the physician accepts this alert, a computer application integrated into the normally used health management system will automatically open. The physician then completes the fields that have not been filled in automatically, then gives the order to send that information to the body specialized in public health or occupational health at the central level.

The cases are then registered and studied by such bodies (those cases in which the worker has not authorized further investigation will be treated in a generic manner only). If the worker has so authorized, the case is investigated in depth by examining the worker's general health record and specific work conditions, finally confirming whether or not the problem is work-related.

A report is drafted and sent to the concerned party, the notifying physician (electronically or through the same system), or at times to other involved entities (company, prevention service, labor authority, Social Security bodies, etc.).

In addition, epidemiological studies are performed, with periodic general release of the information obtained.

In short, the process has four stages: identification, notification, analysis and action.

System requirements

Many of the requirements of this system are the same as those generally called for in different applications. Nevertheless, some specific needs can be noted:

— Given the diversity of information sources and participating structures (many of which are outside of the healthcare environment), systems must be capable of interoperating. This is especially vital in the health services area, where fully integrated information systems are essential.

— Quality of data. Automated (computer-based) quality controls, as well as controls by experts, are necessary. The use of standardized codification in all fields is required here. Where this is not possible due to the plurality of sources, conversion mechanisms are needed.

— Clear identification of the different participants (patients-workers, healthcare professionals, healthcare units, other organizations and people, etc.). Such identification must be integrated within the general health information system. When information is received from outside organizations that may use different identification systems, compatibility mechanisms are needed in order to combine that data with the general system. In this way, a unique, error-free set of personal data is available for each person.

— Maintenance of the abovementioned catalogs and auxiliary records. There should be summarized or simplified versions available for healthcare professionals not specialized in occupational health, in order for these records to be useful to such professionals.

— The many different participants involved, with their different functions and levels of complexity, create the need for operating systems that avoid redundancies or omissions.

— A communication system that can assure data exchange between different systems and entities is needed (to varying degrees depending on the type of information or participating structure), and it must be capable of preserving the quality and security of that data, along with the confidentiality of individual health information. It should be kept in mind that in the field of occupational health, data confidentiality issues are even more important as data disclosure can sometimes lead to discrimination.

— There should be conventions and agreements between the different participating organizations. Technical difficulties, which can be quite complex at times, tend to be easier to overcome than legal problems or those arising from conflicting responsibilities or the lack of coordination.

Benefits of occupational health information systems

Occupational health information systems offer many advantages to health professionals and organizations – both those that are specialized in occupational health (occupational health doctors and nurses) and other types of doctors, nurses, managers, etc. For example:

— They assist in identifying problems, making occupational health diagnoses and planning the implementation of preventative, protective or corrective measures.

— They facilitate epidemiological surveillance, including alarm systems (outbreaks, high-risk situations or groups, etc.) and workers' health-related emergencies (which can also affect the general population).

— They are useful in preparing epidemiological studies and research in occupational as well as general health.

— They enable consultations to be made, reports prepared and recommendations issued.

— They help reduce under-reporting of occupational morbidity and increase recognition of work-related pathologies, which helps identify new or emerging pathologies and expand current knowledge of occupational risk, injury and illness.

— They contribute to rational and efficient use of resources devoted to safety and health at the workplace and to the protection of workers' health, and also of resources devoted to general health (care and prevention).

— They improve public health and strengthen an integrated and comprehensive healthcare system, by offering more well-structured information from different areas (this can be integrated at different regional or care levels). They lead to a better understanding of the population's health while analyzing inequalities by sector of activity or occupation.

— They enhance administrative and services management (process optimization).

— They bring about improved coordination and relations between healthcare levels and structures (among themselves and with other bodies).

— They augment and improve the quality of occupational health information available to professionals working in this field.

Information systems are also useful for parallel structures (Social Security, insurance companies, prevention organizations, unions, business associations, labor authorities, etc.): optimizing communication between the healthcare setting and administrative bodies, disseminating information among different levels of responsibility, providing better monitoring and control of rights and benefits, fostering inter-institutional coordination, bringing direct and indirect economic advantages, offering support in decision making (in terms of labor, prevention, inspection, social issues), in adopting and evaluating policies, in preparing statistics, etc.

They can also be useful for citizens (especially workers), in relation to comprehensive healthcare, recognizing rights and benefits, speeding up procedures and paperwork, obtaining reports and documents, etc. However, it is important to remember certain limitations and obstacles, which are present to a greater extent than is usual in areas that are more traditionally connected to healthcare:

— Difficult coordination (due to the involvement of many organizations and entities with different responsibilities, varying objectives and sometimes opposing interests).

— Limited action by the public sector health system in some countries, especially regarding professional contingencies.

— Difficulties in achieving universality in many systems (in terms of problems or population), with a tendency to compartmentalize different matters and groups.

— Low degree of adaptability, or capacity to respond to continual legislative, social, productive, economic, technological and other kinds of changes.

— Specific sources contain a great deal of data, but there are often gaps, partial content or problems with quality.

— Non-specific sources were not created with occupational health in mind. There are often problems with access, and they lack information about work exposure (and it is often of poor quality when available).

— The need for different sized occupational health information systems, depending on the size and circumstances of each region, entity or center.

— Finally, the constant processes of transformation in protection and prevention systems lead to a number of difficulties that must be taken into account (Haidar, 2009).

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Chapter XIII

Distance learning in the field of health: The Brazilian experience

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Claúdio de Souza

Summary

The special features of distance learning (DL) –a form of education that enables knowledge to be available to anyone, at any time and any place– call for teaching/learning processes built upon new foundations.

This chapter describes these features, discusses the concepts related to educational web conferences and specifies the technical and pedagogical requisites that must be met. The chapter is based on the experience of a distance healthcare education project underway in Brazil, in the context of the National Telehealth Program and the launching of the Open University of the Unified Health System (UNASUS).

One of the most significant advantages of DL is that it offers people greater access to education and training. It can also help reduce the expenses related to education. Factors that may limit its implementation include society's economic inequalities and uneven access to IT, and the levels of maturity and motivation shown by the people taking part. Another critical element is finding professors prepared to use these technologies innovatively.

There are several possible methodological designs, ranging from courses with limited use of images and not much tutor/student interaction, to courses that make extensive use of video, animation and 3D modeling, and give priority to structured interaction. The use of more sophisticated technology makes it possible to dynamically simulate physiological, pathological and anatomical events, thus enhancing students' comprehension of the countless situations that can arise in the healthcare context. This does, however, require greater bandwidth, which could hinder access to this type of course.

Introduction

The World Health Organization (WHO) has stated that in the 21st century, collective health expectations can only be met through improved access to resources –and higher quality resources–, for most of the

world's population. Regarding the use of technology, the WHO advises its members to use telematics as a political and strategic tool in the planning and execution of health actions[56].

Distance learning is a form of education in which communication and knowledge acquisition can take place with the participation of people in different locations and at different times[57]. The basic principle of DL is to provide access to knowledge to any person, in any place and at any time.

DL represents an important educational strategy for serving large numbers of students in a manner that is as effective –or more so– than other, exclusively classroom-based teaching methods that also involve a high number of students. It can respond efficiently to today's needs for high quality universal education, and is a suitable and viable resource for keeping people informed of the most up-to-date knowledge generated by modern human science.

The DL option as it exists today –as a means to meet educational and training needs in a timely way and with high levels of quality– did not come about by accident. There is a long history of experiments, successes and failures in different parts of the world. The origins of this teaching method go back the correspondence-based education methods, which began at the end of the 18th century and had developed considerably by the middle of the 19th century. Different forms of distance learning were in use at the beginning of the 20th century, the most successful were based on postal correspondence. These were later enhanced by the application of the new forms of mass media – primarily the radio. This resulted in projects that were quite innovative at the time, especially those aimed at rural populations (Barros Nunes, 1994; Guaranys, 1979; Luchesi, 1989). According to Barros Nunes, DL works best when the students have some knowledge of the material beforehand.

Distance learning in health

The use of DL can be an effective strategy in dealing with the barriers to continuing education faced by professionals who work in the public sector. Such impediments include budget restrictions, time limitations, few opportunities for learning on the job, difficulties in accessing information and the lack of training opportunities in the public sector health network (Mathauer, 2006).

Continuing education is necessary for physicians working in remote areas, as it increases their confidence and reduces their sense of professional isolation – important factors for attracting professionals to work in these areas (Kinfu, 2009). Studies performed in Africa have shown that access to continuing medical education, staying up to date through post-graduate work, short courses and internet access are important factors in physicians becoming established in such zones (Knebel, 2001). In Tanzania, Manongi found that in remote rural areas, many healthcare professionals are called upon to treat cases for which they have not been trained (Alexander, 2009). Such professionals see the solution to their problems in greater educational possibilities rather than in more hiring.

Today, DL is supported by the use of various media, including printed materials, CDs, DVDs, television, computers, internet, educational videos and even online simulators. Technology used in the teaching/learning process is rapidly moving towards greater use of online data, voice and image transmission, via satellite or fiber optic lines. Moreover, there appears to be a trend towards greater

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interaction between students and the distance learning providers, intermediated through the use of artificial intelligence (AI), as well as online communication between students, teachers and tutors (Guaranys, 1979).

Many countries are now incorporating DL at all levels of education, both formal and informal, and are attending huge numbers of students this way. DL has been widely used to provide training and to expand the knowledge of active teachers and other professionals, as shown by experiences in Mexico, Tanzania, Nigeria, Angola and Mozambique. It is also being increasingly used in the training and skill-building of professionals in areas such as healthcare, agriculture and social work – in both the public and the private sectors (Luchesi, 1989).

In recent decades, for example, the application of DL in Brazil –in both the public and the private spheres– has mobilized large numbers of experts and financial resources. In the Brazilian public healthcare area, the main initiatives are currently focused on primary care, reinforcing the Brazilian Ministry of Health's priority of turning primary care into the organizing and coordinating force in patient care.

Generally speaking, an analysis of the results of DL in Brazil reveals positive aspects as well as shortcomings. According to Nunes (Nunes, 1992), the main problems would be the lack of continuity of projects, the government's tendency to forget lessons learned in the past, and the difficulties –both political and cultural– associated with using stricter criteria and more scientific methods to evaluate programs and projects.

Among the positive outcomes of DL in Brazil, the recent institutionalization (at the end of 2010) of the Open University of the Unified Health System (UNASUS) is of special importance. The UNASUS functions as the framework for encouraging the production of distance healthcare courses in the country. The UNASUS has also served to reinforce the role of the National Telehealth Project, which has helped healthcare professionals in many states experience the potential of new teaching technologies – with web conferences and courses that make heavy use of simulators, organic modeling and animations.

The international organization "Doctors Without Borders" believes that distance courses are a good way to reduce absenteeism in clinical work and to allow professionals to receive the needed training (MSF, 2007). In a review of over 100 articles on DL, Knebel found that the greatest benefit was the convenience and accessibility of training for those not living near training centers or traditional universities (Knebel, 2001). She highlighted the fact that DL gives professionals the opportunity to receive training and knowledge updates without interrupting their care activity, losing salary or disrupting their family life.

Like Knebel, other authors have also pointed out the advantages of DL, most commonly mentioning access to training and cost reduction. Although a number of studies have underlined the advantages of DL in the training of healthcare professionals (I-TECH, 2009; Gallagher, 2001), it should be noted that research comparing the results of DL with those of traditional classroom-based teaching is still lacking (IHEP, 1999; Lorraine, 2010).

However, despite its advantages, implementing DL is by no means an easy process. It must be a gradual process that should, over time, reach all educational levels. Factors that can limit or inhibit its adoption include economic inequalities in society, unequal access to IT, and also people's levels of maturity and motivation. It is never easy to change behavioral patterns, nor the management of

organizations, governments, professionals or of society in general. Two critical factors for DL are access to technology and to professors that are adequately prepared for the innovative use of that technology.

Design of teaching methodologies

There are a number of different methodological designs for DL, involving various types of interaction. On the one hand, it is possible to structure distance courses with only limited use of resources for image production, and with different levels of interaction, starting with self-instruction courses that do not involve interaction with tutors (these are not, however, deemed very effective in terms of learning). Other courses might offer online chats with tutors, forums especially created for the courses with proposed subjects for discussion, specific times for students to interact with tutors, etc. The most innovative experiences, however, are those that employ such resources as video, animations, 3D modeling, simulators and stereoscopy – with a variety of structured mechanisms for interaction between professors and students.

After analyzing ten years of experience, the North Carolina Institute for Public Health (Horney, 2005) laid out ten guidelines with which to design, develop and offer training courses and modules. They are as follows:

— The courses must be compatible with participants' professional responsibilities

— The courses must be adapted to the profile of the target public

— The courses must be aligned with the needs defined by the target public

— The courses must be based on appropriate cognitive learning levels

— Reusable learning objects should be used

— The courses must be well-organized and aesthetically attractive

— The courses must make technical support available to instructors and students

— There must be a formal process of expectation management, to understand and fulfill the expectations of students and instructors

— There should be continual feedback between instructors and students

— The courses offered and their content must be subject to an ongoing process of evaluation, improvement and updating

The integration of DL resources in the educational process has produced positive results and it appears that these learning modes will be further developed and consolidated in coming years. Everything indicates that in some countries –the ones that have advanced the most in this area, such as Brazil– graduate and post-graduate teaching will be offered in a hybrid system in the future. Such a system will combine classroom-based education with the DL modality, thereby increasing the flexibility of a student's educational process. Similarly, we will no doubt witness robust growth in open universities, where people can engage in study regardless of their previous degree (Giusta, 2003).

DL in healthcare will be enhanced through the use of advanced resources. The literature shows that employment of such advanced resources as virtual simulators, organic modeling, stereoscopy and animation will provide a great deal of added value to the teaching-learning process. 3D modeling of organic structures makes it possible to dynamically simulate physiological, pathological and anatomical objects, presenting anatomical objects with animation, sound and video resources.

Web or video conferencing

The innovative aspects that technology brings to web conferencing relate not only to content, but also to the learning dynamics, where the feeling of belonging to a virtual community plays an important role.

Learning is enhanced when the group of people taking part understands the importance of innovative practices and incorporates them into its activity. As a model of collaborative learning, it is the group that acts as an interlocutor in video conferences, proposing its own identity that is built up in the work practices community. This same group is reinforced through mechanisms of esteem for and acceptance of new care practices. It feels like part of a virtual community, participating with others in different work experiences and modalities. This creates the groundwork for the consolidation of skills that are so important for changing the care practices learned by the groups.

In 2006 the UNC SLMS Task Force Evaluation (Puskin, 2010) looked at four web conferencing software applications that are learning-oriented[58]. The task force identified their strong points and also their weak points by considering different issues: the cost-benefit ratio, the existence of basic interactivity tools, flexibility for tailoring or adapting the application to the client, the existence of a moderator, content libraries, enhancing audio resources (for example, an open microphone during sessions), and the existence of tools for connection diagnosis.

The study concluded that virtual classrooms must have at least the following features in order to enhance the teaching-learning process:

— Integrated audio and video conferences

— Integrated text chatting – public and private

— Feedback tools – polls, yes/no, hand raising, applauding

— Shared applications

— Interactive blackboard

— Web browsing (internet navigation)

— Closed rooms, to reduce distraction and noise from elsewhere

— Online research and tests

In short, in order to meet its objectives, web conferencing must be carried out with the use of voice, video, data and graphic resources, all within an environment that is specifically structured for group learning.

One telehealth project that we deem especially noteworthy is that of Alberta, Canada (Klein, 2005). In Alberta, web conferences are considered very useful in overcoming the distance barrier. Conferences involving a small number of doctors are particularly valued because they help create a positive learning environment (Birden, 2005). In this region of Canada, web conferences have become a common tool that complements traditional teaching, as it opens up educational opportunities that would otherwise be impossible due to limitations on time, movement and costs.

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[58] Adobe Breeze 5; Saba Centra 7.5; Elluminate 6.5; HorizonWimba 4.2.

Various studies on educational video conferences indicate that social processes have an influence on the relationship between the means of communication and the effectiveness of the group in terms of learning[59].

The possibility of creating groups of students based on affinity and common interests that develop during the course produces beneficial results from the learning standpoint. This is true to the extent that the course provides possibilities for the continual exchange of experiences as it unfolds.

The technological structure needed for web conferencing is quite simple, calling for only a modest investment in some models. For example, units that receive web conferences need only a conventional microcomputer equipped with a multimedia kit (zoom boxes, microphone and web cams) and an internet connection with a minimum speed of 128 Kbps. The site where the web conferences are generated must have web conference software with the same number of access points as expected connection points, along with a microcomputer with a multimedia kit and high resolution web cams. More complex models can be equipped with specific devices for videoconferences that require a bandwidth of over 386 Kbps.

DI in the training of Brazilian healthcare professionals

In Brazil, the Ministry of Health has supported the production of didactic material within the Unified Health System (SUS) through two initiatives: the Telehealth Program and the Open University System (UNASUS).

The Brazilian Telehealth Program uses IT to support professionals working on teams devoted to family health. The healthcare centers are connected via internet to university staff that offer support for local decision making in the form of "pedagogical" second opinions. The difference between these and traditional second opinions lies in their educational potential. Professionals learn from the service and are able to have their questions addressed through the use of frequent questions/answers lists based on evidence. By the end of 2010, 789 municipalities had a total of 1,011 telehealth points connected to ten Telehealth Core Groups – benefiting 2,796 family health teams.

The second initiative was the creation of the UNASUS, by virtue of Decree 7,385 of December 8, 2010 (Santos, 2010). The UNASUS attends to the ongoing training and education needs of SUS employees working in the area of health, offering distance postgraduate and university extension courses to professionals.

The UNASUS system is comprised of the following elements:

— UNASUS network: network of public institutions of higher education that have been authorized by the Ministry of Education to offer distance learning, acting in harmony with the Ministry of Health to ensure well-coordinated actions.

— Common Educational Resources in the field of health (Acervo UNASUS): public collection of educational materials, technologies and experiences, gathered in a collaborative fashion, that can be accessed freely on the internet.

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[59] Brazilian Ministry of Health. Open University - Telehealth Program)
http://portal.universidadeabertadosus.org.br/?q=node/3

— Arouca Platform: national database integrated into the nation-wide information system of the Unified Health System, which contains the historical registry of SUS workers, their qualifications and their professional experience.

The UNASUS had been in existence for almost two years (2008) before the signing of Decree 7,385 – as an activity of the Healthcare Education Management Department. During that pilot stage, the initiative offered as many as 26,500 seats in specialized family health courses.

The UNASUS provides healthcare workers access to certified educational activities throughout the country. These activities recognize and value their previous knowledge, and their schedules and learning styles can be tailored to the professional. The number of seats are the result of agreements and cooperation terms that the Ministry of Health has arranged with nationally renowned public universities and the Health Departments of the different states. There are a number of large scale educational activities currently in progress. A total of 7,380 professionals have already started the courses, with the remaining seats to be filled during 2011.

In four years, the UNASUS will have trained more family health specialists than the total number of such specialists available at this time. Moreover, since only 20% of the seats will be occupied by persons already working as doctors, the program will train, with the remaining 80% of the seats available, new graduates that wish to do their specialized training in family and community medicine.

The UNASUS has created a virtuous cycle by connecting with the National Telehealth Program and the University Telemedicine Network (*Red Universitaria de Telemedicina*, or RUTE). This makes it possible –by means of video conferences– to connect family health teams with specialists that work at the universities. The latter can provide diagnosis support and educational second opinions while implementing ongoing and permanent educational processes. The Telehealth points in universities and hospitals are spaces devoted to educational activities. Professional groups interested in certain medical specialties –called "Telehealth Core Groups"– have supported the courses by developing educational content. The educational resource management strategies used by UNASUS have given greater visibility and sustainability to the content production of the Telehealth Core Groups, and have served as an educational platform that contributes to recognition of the activities they carry out.

The structure of distance courses at the UNASUS

The UNASUS follows the guidelines listed below when organizing its educational activities:

— Knowledge is understood as a public good, something that should circulate without restrictions and be freely adapted to different contexts. Accordingly, all UNASUS production must be accessible over the internet from open access repositories.
— Educational activities are learning-focused, which involves the use of active methodologies. Such methodologies set forth problems and encourage the search for solutions to the challenges that each student must face in reality.
— The management of these activities is a network-based process that operates in a decentralized manner, in order to foster the cooperative construction of methods, knowledge and tools for health learning.
— Continuing education is understood as lifelong, on-the-job learning, where learning and teaching are integrated into the daily activities of organizations.

— Training activities follow an open university format, in which students are free to choose their own learning opportunities, and to set the pace and choose the style of their studies.

— The technologies implemented follow open national and international patterns, thus ensuring that the educational resources produced will be able to be reused.

— Learning opportunities are continually evaluated in view of national, regional and local health needs, to ensure the quality and pertinence of those opportunities.

— The location of educational actions is determined through three-way agreements with states and municipalities.

The continuing training and education actions are structured as module-based training programs, with the corresponding certificates being recognized by the group of participating educational institutions. The UNASUS has led to a high level of cooperation between these institutions, which have exchanged educational technologies/methodologies and have made use of the resources produced by the others.

Use of animation and 3D modeling

The Health Technology Center at the Minas Gerais University School of Medicine (CETES) uses additional resources such as videos, graphic animation and 3D organic modeling in its distance courses.

The CETES chose 3D organic modeling and graphic animation to structure the distance courses they were planning for healthcare professionals because such resources make it possible to incorporate sophisticated technology and content production that offers high added value and didactic potential. 3D modeling of organic structures allows for the construction of virtual learning objects that are presented in sound-enhanced videos. Such objects are capable of dynamically simulating physiological, pathological and anatomic events, thus facilitating the understanding of the countless situations that can occur in the healthcare context.

The option of processing the 3D anatomic images –using Maya 3D software– recreates human anatomy in the same texture, scale and proportion as actual models. This offers public healthcare professionals educational materials of high didactic value. Moreover, these materials are relatively fast to produce.

The program used for 3D modeling of the muscular system has a control level of at least 20 maps at 2048 x 2048 pixels of resolution. The male and female human anatomy collection covers all organic systems. The models have quadrilaterals and edge loops (a modeling technique capable of accurately representing muscular structure and of producing images with a surface free of deformations). The models are prepared for video, simulating camera close-ups inside the human body, focusing on particular areas of the organs. The system works with high-quality images, so the transmitted content is as close to anatomical and functional reality as it can be – obviously an important feature in medicine.

Installing a content production laboratory is a complex process, given that the production of virtual learning objects requires the addition of specialized technology, human resources and infrastructure to an institution's traditional structure. This has certainly been the experience at CETES. The process involves not only the purchase of a 3D modeling program, it also requires the proper hardware infrastructure (computers with monitors and specific features, servers, image setters, editing

and video conferencing suites, lighting, etc.), as well as software for integrating the video, graphic animation and content production resources.

When considering the installation of 3D organ modeling and graphic animation, it is important to define the teaching platform to be used in distance courses, as well as to identify the particular institutional needs of the university offering those resources. The Universidad Federal de Minas Gerais (UFMG, or Minas Gerais Federal University), for example, opted for a free distance learning platform (the Moodle Course Management System) that can be tailored to the client, enabling different technological resources to be incorporated depending on client needs.

Another basic issue in the preparation of distance courses concerns the choice of methodological-pedagogical design. The staff responsible for developing the project will have to receive training in how to produce contents within the chosen pedagogical model. The model chosen will determine the way skills are taught, proficiencies are generated and performance standards are defined, among other tasks.

Finally, forming a team for DL content production entails the hiring of multi-skilled personnel. For example, at the DL department of the UFMG's Telehealth Core Group, in addition to the professors specialized in the subject matter of each course, one professional trained in fine arts and another trained in cinema were also hired. These two individuals were hired for the production of animation and virtual 3D modeling objects. There were also technicians to help with the production and editing of videos, and with the handling of the Moodle platform.

The complexity of incorporating modeling resources into DL is found mostly in the content production center, due to the particularities of the hardware involved (equipment with large storage capacity and stereoscopy resources), more than in the area of software, which is basically 3D modeling and stereoscopy programs.

For students enrolled in such courses, the most important requirement is having sufficient broadband access, so that videos can be downloaded and used repeatedly, without interruptions or other difficulties.

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Chapter XIV

Information systems for planning and overseeing the management of health services and systems

Javier Carnicero
David Rojas

Summary

For health service professionals to be able to do their job with the desired quality standards, the necessary human, material and financial resources must be available to them when needed. To this end, health service managers must perform a wide array of management tasks, such as setting targets and planning strategies, organizing resource allocation and the application of procedures, and verifying whether or not objectives are achieved.

A vital element in proper management is the availability of information, so that managers can find out the status of each area quickly and accurately, detecting possible deviations with regard to the objectives set and introducing the necessary corrections. Also, it is indispensable to find out, at the end of each period, the results obtained during that time, since these results form the starting point of the following period and must be consulted in order to set new objectives and strategies.

Electronic health systems are an important instrument for managers, because they contain the data related to health promotion, disease prevention and care delivery activities, all of which reflect the institution's performance. So, although the primary value of such systems is operational, they can also be very useful in the sphere of management. In addition, electronic health systems can export information to population-based information systems, which makes it possible to evaluate the impact of the health services on the population.

Introduction

The primary objective of health services is to provide the services necessary to protect or improve the health of both patients and the population in general. This makes the work of health professionals the most important activity taking place in these organizations, but there is also research, which is essential for the progress of medicine and other health sciences, and teaching, which is vital for the training of new professionals. These three main lines of action are where the work of every clinician –and by extension the activity of the health service– takes place.

The effective performance of these activities depends partly on a fourth line of action, the management of the health service, a very complex task due to both the nature of health services and the

dimensions of such institutions. As complex as it is, management activity can be divided into four basic functions:

— Planning, in order to define objectives and strategies.

— Organizing, in order to apply the measures that will make it possible to achieve the objectives.

— Overseeing, in order to verify the adequacy of such measures and correct them, when necessary.

— Using information, a necessary tool throughout the process.

Another very important factor in successful management is the capacity of the management teams, who must have the abilities needed to govern the decision-making process appropriately, to create a working environment conducive to achieving the objectives, and to exercise continuous leadership in the application of the measures designed to attain such objectives.

The purpose of this chapter is to review the contribution that electronic health systems can make as support for the functions of planning and overseeing the management of health services and systems. A succinct description is given of the different functions within management. This is followed by a discussion of the application of Information Technology (IT) to health services, and of the usefulness of IT tools in defining objectives, allocating resources and overseeing management.

Planning in health services

The first step of the management process should be strategic analysis, as this makes it possible to define the mission, vision and values and to define the goals that the health service wishes to attain in a given period. The management function to which this task corresponds is planning, the result of which should be a corporate strategic plan that describes the following aspects in detail:

— The present situation at the time the plan is drawn up.

— The objectives proposed, and the reasons for them.

— The strategies that will be applied, conceived as a set of general guidelines that help define the specific actions needed to reach the objectives.

— The specific operational actions that make up these strategies, clearly establishing the roles and responsibilities of each and every member of the organization.

— The allocation of budget and necessary resources to ensure that these actions can be carried out effectively.

One of the fundamental design requirements for the strategic plan is that a vertical and descending format be used, as this approach allows for application at every level of the organization. To put it another way, the plan's formulation should begin at the highest level of the organization and then be propagated through every other level, "translating" and adapting every objective, strategy, action and resource allocation to the various areas. This way, the corporate strategic plan is divided gradually and orderly into several specific plans distributed throughout the different levels, which has the effect of facilitating application and helping achieve specific objectives. The sum of all these plans and objectives enables the general targets to be obtained, a joint responsibility that is shared by –although not equally distributed among– all members of the organization. Despite this vertical vision of the planning function, the entire process should include feedback mechanisms, as everyone is expected to participate in it.

In Spain, the functioning of the regional health services is based on the pluriannual health plans drawn up by the regional Ministries of Health. Such plans lay down the main targets and the health services themselves then decide on the strategy to be used to meet the objectives of the health plan, by means of documents such as strategic plans, lines of strategy and steering plans. With either an annual or a pluriannual timeline, all of these plans are put into practice through management plans, contract programs, management contracts/agreements, etc. All of these terms refer to the system used by Spain's autonomous communities to specify the year's targets, budget, priorities, procedures for evaluating achievement and the incentives offered, if any. Generally speaking, management contracts are used throughout the primary care level but their use in specialized care is more uneven.

Defining objectives

When this model is used to implement the strategic plan, the objectives of a health service or system must be clearly established at every level of the organization: upper-level management, health zones and areas, health centers, clinical services, etc. The professionals who work at each level must know exactly what is expected of them. Table XIV.1 shows various examples of strategic target policies.

Table XIV.1. Strategic targets (Source: compiled by authors).		
Strategy	**Objectives**	
	General	**Specific**
Care quality	Improved clinical results	Survival rates
		Relapse rates
	Improved accessibility	Waiting times
		Geographical catchment areas
		Alternative hospitalization modalities
	Equity	Waiting list priority criteria
System sustainability	Improved efficiency	Average waiting times
		Average stay at hospital
		Remuneration linked to productivity
		Control of expenditure
		Return on investment
		Priority in cutbacks in case of economic crisis
Research	Higher number of projects	Publications
		Prizes
		Patents
Teaching	Post-graduate training, ongoing training	Specialist training according to demand
		Training courses, training visits in other institutions

For example, an ongoing strategy of all health services is to improve the quality of the care provided. This strategy takes concrete form in general and specific objectives such as increasing the rate of survival of cancer patients; diminishing the adverse effects caused by the treatment of certain diseases; quantifying the quality level perceived by patients and reducing the number of complaints and legal disputes, among others.

Another common strategy is system sustainability, which is based, among other questions, on improving the efficiency of the health system. This translates into measures such as the reduction of certain services to adapt them to real demand, the simplification of organizational procedures, the implementation of measures to avoid redundant diagnostic tests, etc. Improving efficiency takes on particular importance in situations of economic crisis, since budget restrictions put the equilibrium

between system sustainability and care quality at risk. It is important to highlight that "efficiency" is a relative term and therefore does not necessarily consist of reducing the amount of resources used, but rather of making better use of the resources used. For example, closing a hospital wing entails reducing the number of beds and therefore brings an undeniable savings, but it also clearly undermines the quality of the care provided. An alternative might be to close the wing and set up a major outpatient surgery program, which may not bring effective savings but will mean a more efficient use of resources. Implementing an e-prescribing system eliminates the patient visits that have no added value, which are the appointments made only to renew prescriptions for treatments being received. Eliminating these visits allows doctors to devote that time to appointments with much greater clinical value.

In any case, the formulation of objectives must be based on forecasts, that is, on the analysis of the historical information regarding the parameters directly related to each objective and of the resources available to reach the objective. Such analysis must be done in order to make a realistic estimate of the objectives that can be set. In the case of care quality, indicators such as death rates, nosocomial infections, complaints and legal disputes, average hospital stay, the number of successive consultations by a patient, or the case-mix may be used. To improve efficiency, attention must be paid to costs per DRG, budget deviations, percentages of occupation of the different areas (surgery, outpatient care, etc.), average hospital stay, number of appointments per professional, number of explorations per X-ray modality, among others. Some indicators, such as average hospital stay, are useful in both cases.

To apply the strategic plan at all levels, a health service or system must have specific management bodies that carry out this function, and there must also be persons who assume this responsibility in every level and component of the institution: management teams, department heads, supervisors, quality technicians, etc. These bodies and persons must lead the process of dividing the general objectives into specific objectives for each area, they must be directly involved in attaining these objectives and in evaluating the degree of achievement. For the process of defining objectives to fulfill its primary function –which is none other than to allow the members of the organization to know what is expected of them– it must meet the following requisites:

— Clarity:
  o Objectives need to be synthesized, and there should be the lowest possible number of them, in order to enhance their value as management instruments.
  o Objectives need to be weighed, clearly establishing the priorities and weights accorded to them.
  o Simple language needs to be used to describe the tasks and responsibilities. For example, "create a guide" is better than "collaborate in the preparation of a guide".
  o The allocated budget needs to be detailed, to facilitate calculation of the cost-efficiency of the actions.
  o Requisites and limitations need to be defined: deadlines, resources not available, working methods to be followed, etc.
  o Incentives for reaching objectives need to be specified.
— Use of achievement indicators:
  o Measurement criteria must be classified in terms of quantity, quality, time and cost.
  o Quantification should be used whenever possible: indices, rates, parameters, etc.
  o The formulas used to compute these indicators must be specified, along with the exact meaning of each data item used.
— Objectives must be realistic, depending on the present situation, on the predictions made, on the resources available and taking into consideration the unexpected events that may arise during the period in which these objectives remain valid.

— Continuity over time, as this allows progress to be measured periodically along the way by means of checkpoints, to encourage ongoing improvement and capitalize on the motivating effect this can have.

— Posing the objectives as a challenge, making it clear that achieving them truly is challenging and using this as a motivating factor.

— Consistence with the corporate policies of the system, department or functional unit.

— Express, formal comprehension and acceptance by the professionals affected.

Once the objectives have been defined, the organizing function consists of allocating the necessary resources and assigning responsibilities in achieving the objectives.

Overseeing management in health services

The function of management oversight encompasses various concepts and tasks that together make it a clearly ongoing activity:

— Verification of the correct implementation of the strategies and actions designed for attaining the objectives set.

— Evaluation of the effectiveness of these strategies and actions, detecting any possible deviations.

— Introduction of the corrections necessary to remedy these deviations, so that the results match or surpass the objectives set.

Given its magnitude, this function must include the creation of an action plan to ensure the correct performance of these tasks. Therefore, management oversight blends both planning and oversight strictly speaking.

Stages of management oversight

The oversight function is divided into the following stages:

1. Specification of the procedures and standards that are to guide the work and action. As explained above, during the planning and organizing processes, objectives, strategies and actions are determined, clearly defining the goals, people in charge and resources to be used. These parameters are the basis of the management oversight function, since they determine the starting point and the boundaries of the sphere of action.

2. Definition of the measurement mechanisms, detection of deviations and communication to the oversight unit. In this stage all the data necessary to understand and evaluate internal and external events must be recorded; information must be consolidated in order to carry out a comparative analysis of the progress of actions; any anomaly detected during this analysis must be communicated to the decision-makers, with details as to its nature, possible causes and effects. In this stage it is absolutely necessary to have an information system.

3. Evaluation of the information according to the procedures and standards defined. The oversight process must be systematic, but not automatic, and it requires that any event detected be carefully assessed by a management team member. This manager must decide whether the deviations detected are likely to affect the ability to meet the objectives.

4. Application of corrective measures when necessary, putting the organization back on track for meeting its objectives. It should be noted that, due to the dimensions of health services and systems, quite a long time is needed to complete the application of these measures and therefore for their

"direction-changing" effects to become visible. One of the possible corrective measures is the redefinition of objectives (setting new ones more suited to reality).

It is easy to see that management oversight is a cyclical process, which requires a passive approach in the first three stages and an active approach in the last stage. It is precisely this last stage that allows management oversight to fulfill its mission, which is to lead the organization towards the attainment of its objectives. Therefore, the concept of oversight goes beyond mere knowledge about the situation, and also includes taking action on it. In other words, if there is no capacity or will to take action to correct an anomaly, having knowledge about it will be totally useless (along with the oversight function, by extension). Table XIV.2 shows an example of management oversight.

Table XIV.2. Example of management oversight (Source: compiled by authors).		
STAGE 1 – Specification of objectives and standards		
Objective	The average time in pre-op for non-emergency patients will be no longer than 2 days. Responsibility for reaching this objective lies with the department head. This objective must be met by May 30th.	
Conditions	Measurement criterion	Average time spent in pre-op
	Scope of application	Non-emergency patients
	Standard	2 days
	Person responsible	Department head
	Time available to meet objective	By 30 May.
STAGE 2 – Procedures		
Information System	The Hospital Information System (HIS) must record the date and time of admission (arranged in advanced) and the date and time of the intervention.	
STAGE 3 – Evaluation		
Comparison with the standard	Both the department head and the members of the hospital's management team must have direct access to the HIS statistics module, so they can check the progress of the indicator linked with this objective.	
STAGE 4 – Correction		
Corrective measures	The progress of the indicator is negative. The causes are investigated and it is found that two members of the anesthesiology department are unavailable, due to leave for health reasons and vacation time, respectively. It is agreed that the anesthesiology department will be reinforced with temporary staff.	

Electronic health systems in the management of health services

As stated above, three of the functions of health service management (planning, organizing and overseeing) are based in turn on a fourth function; information, which is the instrument for the entire process. Both setting objectives and overseeing their achievement are based on access to information generated through the care activity provided by clinical professionals, information from the population-based systems and information in public health and occupational health systems. In other words, just as the planning and organization functions must begin with the highest level of the institution and extend down throughout all the levels of the structure, there is also a certain return channel through which the data generated is sent back up to the management teams. So it is accurate to say that information needed for management flows out of the operational systems (NHS, 1998).

With the arrival of electronic health, the capacity of these systems to process and treat data has increased enormously and their application to management functions has become indispensable, since they allow real care demands to be known with a high degree of precision. In fact, it is precisely this feature that will play a vital role in the transformation of the traditional care delivery model, based on delivery itself, into another model that is based on demand and is thus more efficient[60] (Rojas, 2011). The current context of economic crisis, which has prompted intense debate about the sustainability of health systems, may be the trigger for such a change.

Planning and organizing

In the planning function, electronic health systems can provide information about the situation at the outset and its evolution in recent periods, facilitating realistic forecasting and the setting of attainable objectives. Such systems include:

— Population-based databases: patient master index, population census, etc. These sources can provide information about the general characteristics of the population attended by the health service: quantity, population pyramid, demographic projections, tourism or migratory flows, etc.

— Registries that inform about the care activity provided and its trends:

  o On illnesses: public health systems (notifiable diseases, tumor registries, institutional prevention programs, mortality, etc.), occupational health systems (work-related diseases), etc.

  o On activity: primary care data, hospital information systems, MBDS.

  o On resources: electronic prescription systems (use of medications and therapeutic products), departmental systems (material used), etc.

— Economic-administrative information systems: human resources, invoicing, accounting, stocks and supplies, etc. These provide data concerning the total costs of the activity carried out, which helps make budgetary previsions and allocate resources appropriately.

These data are used to design the health system or service's strategic plan, which is subsequently divided, in a progressive manner, into specific objectives and actions that are assigned to professionals at the various levels of the institution.

Management oversight: the Balanced Scorecard

At every level of the health service, the definition of the objectives and strategies or actions must be complemented by establishing criteria and standards with which to measure their degree of fulfillment, and of procedures for sending data and reporting deviations to all levels of the corresponding organizational structure.

In the case of management teams, the main oversight instrument is what is known as the Balanced Scorecard (BSC), which allows the organization's performance, in terms of achieving its objectives and implementing its strategies, to be measured. It is both a general concept, in that any type of organization can use a BSC, and also a specific concept, in that each organization must devise its own BSC. The fact that no two organizations are exactly alike means that no two BSC are exactly alike.

A BSC should help respond to the following management needs:

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[60] Hofdijk, Jacob. *Introduction to the Dutch patient-centered, value-based health reform*. I International Meeting "Electronic health in a global world: impact of Information Technology on health services". Spanish Health Informatics Society (SEIS) and the Economic Commission for Latin America and the Caribbean (ECLAC). Madrid, 22 February 2011.

— To quickly find out the degree of achievement of the institution's general targets.

— To coordinate the functional objectives (care provision, research, teaching) and the economic-financial objectives.

— To define corrective actions and evaluate the impact of those already applied.

For a BSC to be effective, it must meet the following requisites:

— It must present only the indispensable data, in a simple, brief and orderly manner:
   o Criteria and standards.
   o Indicators.
   o Comparison between the objectives set and achievement.

— It must show each manager the indicators corresponding to his/her level of responsibility in the institution's organizational structure. Ideally each level's indicators will be generated by aggregating the indicators of the level right below it.

— It must facilitate comparative analyses by standardizing the contents and the way they are presented.

These last two characteristics can be seen in Table XIV.3, which shows several examples of the use of electronic health systems as a source of information for the BSC of the different management levels.

Table XIV.3. Examples of indicators of the BSC at the different management levels of a health system. (Source: compiled by authors)	
Health system management structures	
Information System	**Data**
Population-based database	Citizens covered Population pyramid Demographic projections Public health information systems
HIS and departmental systems	Number and type of visits with specialists Number and type of surgical interventions Number and type of diagnostic tests Patients on waiting list for surgery, appointment or diagnostic test Average waiting times Average stay at hospital MBDS/DRG Patient safety and care quality indicators
EHR in primary care	Number of primary care appointments Number and type of patients referred to specialists Vaccine coverage Prevalence of chronic diseases Quality indicators (glycosylated hemoglobin/diabetic patients; cardiovascular risk indicators…)
Electronic prescribing	Quality indicators of the pharmaceutical benefits provided Cautionary and definitive treatment suspension Pharmaceutical expenditure
Economic-financial systems	Expenditures: human resources, medications, stocks and supplies, etc. Investments: infrastructure. Average costs of appointment, hospital stay, tests, surgery, DRG, etc.

(Table XIV.3 continued)

| Hospital management structures		Primary care management structures	
Information System	**Data**	**Information System**	**Data**
Patient master index	Patients attended	Patient database	Citizens included Number of patients attended
HIS	Number of appointments with specialists Number of surgeries Number of diagnostic tests Patients on waiting list Average waiting times Average stay at hospital MBDS/DRG Patient safety and care quality indicators	EHR in primary care	Number of appointments Number of patients referred to specialist Vaccine coverage Prevalence of chronic diseases Cardiovascular risk indicators Patient safety and care quality indicators
Economic-financial systems	Expenditures: human resources, medications, stocks and supplies, departments, etc. Investments: infrastructure. Average costs of appointment, hospital stay, tests, surgery, DRG, etc.	Electronic prescribing	Number of prescriptions Quality indicators of the pharmaceutical benefits Pharmaceutical expenditure
Radiology department at a hospital		**Primary care center**	
Information System	**Data**	**Information System**	**Data**
RIS	Number and type of explorations performed Number and type of radiological interventions Patients on waiting list Average waiting times Average exploration times Material employed Dosimetric data regarding the explorations Average cost per exploration	EHR in primary care	Number of appointments Number of patients referred to specialist Vaccine coverage Prevalence of chronic diseases Cardiovascular risk indicators Patient safety and care quality indicators Indicators about the pharmaceutical benefits Pharmaceutical expenditure

Perhaps the greatest contributions that these electronic health information systems can make to management oversight and to quality evaluation is the possibility of exporting information about the care provided to population-based information systems. The statistical exploitation of clinical information can be useful in analyzing the impact of healthcare on the population. So, for example, the degree of chronic patient monitoring can be evaluated by correlating the patient census (obtained from the diagnosis appearing in the MBDS of each patient's clinical record) to the treatment prescribed and the results obtained. The classic example is that of diabetic patients, for whom the number of prescriptions of antidiabetic drugs is correlated to the number of patients whose blood tests reveal a level of glycosylated hemoglobin determined in advance to be acceptable. Another classic example is that of patients with cardiovascular risk, for whom correlations are recorded in terms of lipid levels, blood pressure figures, prescription and dispensation of hypotensors, body mass index and smoking habits, among other indicators.

These examples make it quite easy to see the cycle of management planning and oversight. The planning starts with the data concerning the prevalence of an illness (diabetes) and the monitoring strategy is set according to the scientific evidence available. The objective of monitoring these patients with the glycosylated hemoglobin criterion is set and the acceptable levels are determined. The electronic

health systems (EHR, LIS and pharmacy benefits) then enable the performance of professionals (doctors and nurses), health centers and healthcare areas to be overseen. Based on this oversight, corrective measures can be chosen and implemented when necessary.

Another way that this information can be used is to analyze clinical practice variation, for example in the ordering of breast or prostate cancer surgeries or in the number of c-sections performed. The indicators of avoidable hospitalization and readmissions can also be studied thanks to electronic health systems (see Figure XIV.1).

Figure XIV.1. Application of operational systems to management planning and oversight.
(Source: Compiled by authors)
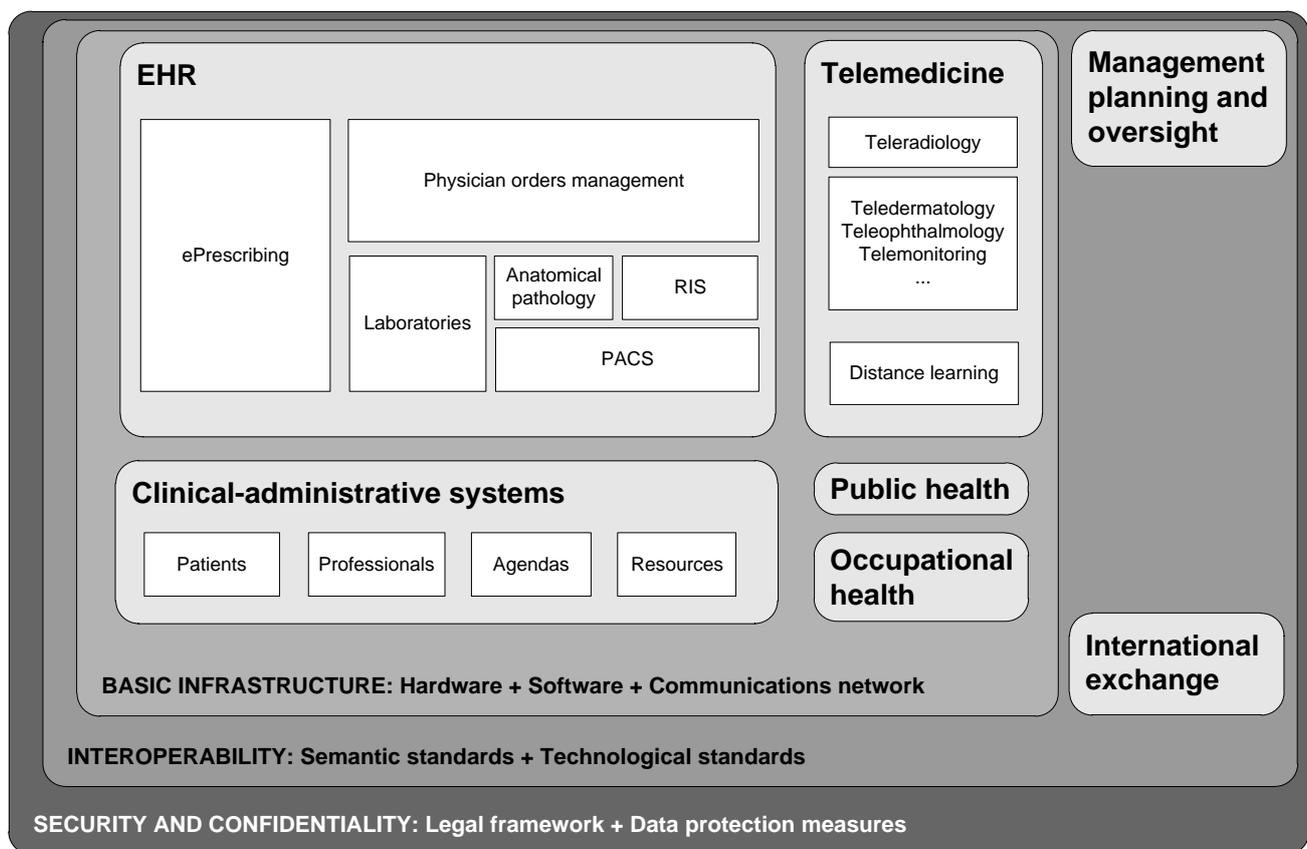
This closes the circle that links certain information systems to others. The population-based information systems are what make it possible to begin planning health services in the first place and they form the basis of public health systems. They are also the basis for patient identification, which is the first step taken by any form of healthcare and by all electronic health systems. Finally, one of the end-products of electronic health systems is their connection with population-based systems, which makes it possible to evaluate the care provided to the population.

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Chapter XV

Interoperability

Selene Indarte

Summary

Healthcare institutions face the challenge of creating computerized information systems that contribute to effective, efficient and citizen-focused management. Interoperability is an essential aspect of these systems, because it enables transversal and longitudinal communication throughout healthcare service structures, assuring the confidentiality and completeness of the exchanged information, along with timely access to that data. Interoperability is based on the adoption of a wide range of standards. Implementation of such systems poses a challenge for which we must be prepared, and it calls for a thorough understanding of the pre-requisites, the different types of standards and the different levels of interoperability. Only in this way will we be able to make the right decisions.

Introduction: Why is interoperability important?

Within healthcare institutions there are numerous information systems and the information housed in each of them is highly important for timely and appropriate healthcare, as well as for management at all levels of the organization. Furthermore, information is commonly fragmented into different, independent information systems – separate islands that allow only partial access to data that is useful and necessary in decision making. This situation leads to the loss of valuable opportunities due to access problems – even when the information exists. Such barriers can cause potential risks for patients, since medical decisions may be based on partial information.

It should be stressed here that this conceptualization of interoperability and standards should not be treated simply as a computing issue. Rather, it is a healthcare issue and its primary agents are the professionals who provide health services and the authorities responsible for healthcare.

In the multi-institutional context of health systems, the problem takes on even greater magnitude. All countries have private healthcare organizations offering different types of care that coexist with the public healthcare system – which itself may have different providers (ministry of health, municipalities, social security, etc.). Moreover, each of these comprises a varying number of hospitals, primary care centers, specialized outpatient services, etc. The exchange of information between them in an intra- and inter-institutional manner is necessary for daily activity. Every healthcare institution, financing organization, insurer, regulatory and other governmental agencies, university and other agents operating within the healthcare system are islands of information – where the exchange of information with the other agents is the exception, not the rule. This situation hinders coordination of policies and the carrying out of joint projects aimed at a comprehensive improvement in the population's health. This results in ineffective coordination of efforts, redundancy of processes, lower performance and increased

costs. The regulatory agencies and government in general have only a partial view, and it is late in coming, and they cannot effectively evaluate the execution of projects, nor their impact. This makes it difficult to plan new healthcare policies, adding further complication to governmental decision making.

Interoperability should be the rule, rather than the exception, at all levels. The correct configuration of intra- and inter-institutional information systems focused on the coordination of policies, plans and projects, computerization with appropriate IT and the application of standards are all basic requirements for attaining interoperability. This is the only way to overcome the current paradigm of healthcare systems based on informational islands, and to move towards a paradigm based on integrated networks of agents. This should be a goal set by the government as part of its attempt to optimize healthcare quality for the population. The ideal environment for developing this paradigm could come in the form of eGovernment initiatives.

We offer the following examples to give an idea of the potential of currently existing IT and standards:

— They can make real time indicators available, e.g., how many patients are presently in the national healthcare system.

— They can allow patients to receive an SMS when a vaccine is about to expire, and even indicate the vaccination center closest to each patient's current location.

— They can give citizens access to their health record from any location, at any time, in order to avoid overlapping paraclinical examinations or drug prescriptions.

Definitions

Interoperability

A number of definitions for interoperability can be found that add some nuances to the basic concept. From the technical viewpoint, the Institute of Electrical and Electronics Engineers defines it as "the ability of two or more systems or components to exchange information and to use the information that has been exchanged" (IEEE, 1990).

From the perspective of health IT, the Institute of Medicine of the National Academies (IOM) defines interoperability as "the ability of systems to work together, in general through the adoption of standards. Interoperability refers not only to the ability to exchange health information, but also to the need to understand the information that has been exchanged" (IOM, 2004).

The definition offered by the National Alliance for Health Information Technology (NAHIT) is also useful: "the ability of computerized information systems, software applications and networks to communicate, to exchange data accurately, effectively and consistently, and to use that exchanged information" (HIMSS, 2005).

In any case, the prevailing idea is clearly the need to assure the quality of healthcare information. This is based on one particular principle: one piece of data – one meaning. The application of this concept throughout information systems, without distinction between technological platform or operating system, greatly influences and has enormous value in health system planning. Interoperability must be regarded a basic attribute of information systems.

Standard

A standard is a group of guidelines concerning the essential requirements that a certain process, product or service must meet in order to meet quality objectives (Cañete, 2005). All of the definitions consulted in different fields and contexts share the concept of setting out obligatory requirements and the goal of assuring quality. Standards are the foundations of interoperability; it is not possible to build interoperable systems without them.

Types of interoperability

Moving beyond the generic definition, we should look at the different types of interoperability, given that their implementation has differential features:

— Syntactic or operative interoperability

— Semantic interoperability:

    o   Distributed processing

    o   Full

— Organizational or business interoperability

Standards focusing on communication provide data structures that determine a minimum semantic level (types, formats, codification, fields, sizes, etc.). They also provide some syntax for representing these structures in a format that can be communicated via IT. Although this minimum semantic level is necessary for sending and receiving the information, it does not guarantee the effective interpretation of the transmitted information. This basic kind of interoperability is called syntactic interoperability and it is important to remember that without syntactic interoperability, it is not possible to implement any other type of interoperability.

Once syntactic interoperability between two or more heterogeneous systems has been achieved, it is possible to take another step towards the correct interpretation and effective use of the exchanged information. This characteristic is called semantic interoperability. The final goal of any standardization process is always semantic interoperability, even if it takes a long time to get there.

Semantic interoperability, in turn, can be divided into two large classes: it is either of the distributed processing type or it is full. The difference between these classes has to do with the standards that are applied and how the systems are designed.

Full semantic interoperability means that the systems are capable of communicating with other systems and of correctly interpreting information from those other systems, even without having been designed to do so. This is possible thanks to the application of standards for the definition of concepts (content), and of logical rules that make it possible to make deductions from the information in the concepts. This means that systems can discover and analyze new information, even if those systems were not especially designed to do so. This automatic learning feature is very valuable in such areas as decision support, research, ongoing medical education, health promotion, etc.

On the other hand, distributed processing –which is much more common– means that the systems are implemented in order to comply with information communication and interpretation standards, and that they are not capable of carrying out logical deductions. Such systems rigidly implement a group of standards for the exchange of information, in which the information to be

exchanged is previously agreed upon, along with the format, protocol, etc. The name distributed processing refers to the fact that the information generated in the system is communicated to another system, which then processes that data in order to generate some type of worthwhile result. Frequently, changes in the messages exchanged will require software modifications – obviously an undesirable feature.

The third type is organizational or business interoperability. This kind of interoperability calls for specifying the business rules, the processes and the agents participating in them. In order to define the business rules, it is necessary to analyze different areas within an organization (emergencies, hospitalization, outpatients, laboratories, pharmacies, etc.), along with their needs, structure, responsibilities and products. This is the only way to reach a perspective of the entire institution, by means of formally defining its components, and the information generated and consumed. The same concept can be applied to the healthcare system as a large organization, with its components (agents), rules (laws), objectives (care, education, research, regulation) and the interdependencies among them.

Semantic interoperability

As mentioned above, semantic interoperability is the primary objective, since it has a direct and visible impact on the work of healthcare professionals and on citizens, because this is the type of interoperability that allows exchanged information to be incorporated and used as if it had been generated by the receiving system. Semantic interoperability has two well-differentiated levels. The first is that of interoperability for visualization purposes while the second is interoperability for processing purposes.

Semantic interoperability for visualization purposes

Viewing information is one of the most common needs in health information systems. Information recorded in one information system must often be viewed in another, different system, e.g., when a laboratory system produces the results of a test that must be viewed in the electronic health record system. If the physician who ordered this test reads the value *260 mg/dl* on the screen without context, the data is worthless. On the other hand, if that doctor knows who the test was ordered for, the reason for the test, what it showed (if more than one result appears, he or she will want to know which results correspond to which order), when it was ordered, when the results became available, the reference values for each test ordered, etc., then the information takes on increasing value for decision making.

All of these details play a role in the proper comprehension of the information viewed, and therefore they correspond to the viewing aspect of semantic interoperability. To ensure the correct interpretation of information viewed on a system different from that in which it was generated, three basic aspects must be taken into account:

— The best way to display the information should be known.

— The way the user is accustomed to seeing the information should be known.

— The device used to view the information should be known.

The first point refers to the fact that the way of displaying the information depends on the content of same, i.e., that there is a different way of viewing each type of information. In turn, it may be that the same information can be viewed in different ways according to the context. Some information is better displayed as free text, while other data can be better viewed in the form of tables, bar graphs, etc.

The second point refers to the fact that the culture or customs at the location where the information is produced may be different from those of the location where the information is being viewed, and that this difference must be taken into consideration if the information viewed is to be correctly interpreted. Some examples might be the format used for writing blood pressure, the unit employed for taking temperature, etc.

The third point is becoming ever more important nowadays, given the many different devices being used, from smart phones and palm devices to tablet PCs, netbooks, notebooks, desktop computers, etc. Moreover, one can view information originating from different systems on each one. One of the most common challenges in this regard is the size of the screen, since one must be able to view all the information and its context (Van der Linden, 2009).

Semantic interoperability for processing

The automatic processing of information is one of the basic principles of computing, and it is one of the processes that offer the most added value to healthcare systems. There is a range of objectives for automatic information processing, including the following:

— Quality evaluation: accuracy and completeness of the information.

— Calculations: indicators (aggregation), averages, times and delays

— Search: patient information, related bibliographical sources, evidence.

— Derived information: analysis aimed at finding new information starting from currently available data.

— Support for decision making: rule verification, alarms, extrapolation of trends, prediction of probabilities based on recent history.

— Structuring: for processing, consolidation, communication, storage and analysis.

In order for information to be automatically processed, it must be suitably modeled by means of representational elements. Without entering into technical details, we can say that that these representational elements are those that make it possible to handle information about different concepts of reality within a computer system. This process, which happens constantly in nature, cannot be done by computers that, although equipped with large processing capacity, lack the ability to conceptualize and represent. The basic task of computer scientists is to take concepts from reality –their attributes and relations– and find a good way to represent them in information systems.

Now, imagine a system for recording information, and another system in which that information must be processed – where the first is a nursing record system in which blood pressure readings of hospitalized patients are entered, and the second is a monitoring system measuring variations in vital signs. Here, semantic interoperability for processing is absolutely necessary.

Syntactic interoperability, as mentioned above, is a prerequisite; it is the standard chosen for communication that provides a syntax and structure for the information and its context. At this point we find that the communication standards offer only transport mechanisms, but do not guarantee that the transmitted information is correct and complete.

The content of the messages between systems depends on the nurse or doctor entering correct information for the right patient, in the proper fields – and entering all the available information. It will

also depend on how the first system is set up, on its requirements, the design decisions and assumptions involved. For example, if the first system was designed in such a way that data is recorded at the time of measurement and the system automatically associates the date and time of the record with the date and time of the measurement, then in the event that just one piece of information is not entered at the time of measurement, there will be an error in the measurement times and in indicator and performance values.

The problem becomes much greater if we extend this example to an institution where hundreds of data items are being recorded at any given time, by dozens of people, in diverse information systems. In short, a communication standard cannot guarantee the arrival of correct and complete information, or that it can be semantically interpreted along with its context.

As with the internet, we can see the need to apply a group of standards that help solve the problems that communication standards alone cannot solve. The goal for this group of standards will be to assure that the semantics of the information entered in the first system is consistent with the semantics of the information received in the second system. In this way the second system will be able to process the information correctly. Looking back at the example of blood pressure readings, suppose that the systems use different measurement units. With semantic interoperability, one can verify that units measuring the same physical property (pressure) are being used, and to the extent that the units vary, the normal range scales must also be adapted.

Because there is often confusion regarding distributed processing and semantic interoperability, it is important to note that perfect semantic interoperability is full. The fact that two systems exchange information, such that one records the information and the other processes it, does not really mean that semantic interoperability has been achieved. It only means that a predefined protocol between the two systems has been implemented towards that end. In order to achieve perfect semantic interoperability, the systems must know the standards involved –syntactic as well as semantic– thus attaining effective communication and processing without the need to modify either system. They need not have been created for the purpose of intercommunication.

One of the most valuable functions of semantic interoperability is the discovery of information. If two systems comply with the same standards that allow for semantic interoperability, then one system can consult patient data contained in the other.

How can interoperability be attained?

Interoperability can be attained in the following ways: by planning healthcare service information systems in a comprehensive manner, from a systemic perspective, covering all possible situations; by putting computer system designs in line with the health system's and users' needs; and by conceiving of flexible, modular and scalable systems, since these will lead to sustainable information systems (Barnett, 1979; Van der Linden, 2009).

Information is constructed using data. In healthcare systems, data is recorded by healthcare personnel. It is essential to define how the data is to be recorded, in order that it may be processed and transformed into information. Such standardization in recording data is a necessary prior step for attaining interoperability (Para, 2009).

In order to arrive at such integrated networks, information systems must be created or adapted with the application of standards at three levels:

1. Systems level: individual systems must comply with a basic level of standardization covering data, codes, structures, relations and restrictions. Each system must have a well-defined objective (in terms of what information is processed, and how). This will make syntactic interoperability possible.

2. Networks level: standards covering communication protocols, interfaces, process definition, messages, security, etc. are applied at this level. Such networks can be set up according to affinity, e.g., one network for public health organizations and another for private entities, or one for connecting all of a country's emergency rooms, etc. Once syntactic interoperability has been achieved, distributed processing will be achieved at this level – an initial level of semantic interoperability.

3. Information and services infrastructure level: this level implies the interconnection of a number of networks that freely exchange information according to profiles, conventions, rules and well-defined security criteria. This is analogous to the network of networks concept comprising the internet. The other important point is that this infrastructure will provide services to all agents within the healthcare system, based on information that those agents enter into the networks, and the services that other governmental bodies provide. Some examples are the identification of people, of healthcare professionals, of social security entities, of police records, of town or city council records, etc. At this level, one click of the mouse provides access to all available information for use by the public, the government, institutions, physicians, etc. At this level, full semantic interoperability, as well as organizational interoperability, has been reached.

When the project of putting such alignments into practice is begun, we find that there is a wide variety of standards from which to choose. The first thing to remember is that there is no one standard that will meet all the needs related to the setting up of an interoperable system. A set of standards must be chosen, each of which meets the challenges at different levels. They are applied at these different levels, and their correct application is what achieves interoperability.

This point acquires even greater relevance when we realize that interoperability today is intra-institutional, inter-institutional, national and international. Current realities create the need for sharing information at all levels and between different areas and countries – all with the aim of assuring high quality healthcare for citizens[61]. This is why it is advisable to establish national and international policies that define the framework of interoperability in which to work (Spanish Ministry of Health, 2008; Brazilian Ministry of Health, 2010).

Without seeking to be exhaustive, an outline of standards that offers a general overview of the concepts analyzed above is set forth below. If we intend to set up a healthcare information system, the first thing we must standardize is the user registry. This ideally takes the form of a master index of patients/users/persons, which allows us to be certain about who our system users are. At times a standard national document is available, at other times a social security number or health card exists. This standardization must be dealt with by each country or community.

Then, using the same criteria, we must standardize the identification of healthcare centers, hospitals, clinics, outpatient centers, physician's offices, polyclinic networks, etc. This standardization also applies to the identification of the healthcare professionals working at those locations, such as doctors, nurses, technicians, and other healthcare professionals. This work must be done at the local or national level, as it involves an analysis of the healthcare practices in the system of reference.

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[61] epSOS Project: http://www.epsos.eu

Another area for standardization is the group of actions that are carried out within the system: appointments with doctors, surgeries, procedures, laboratory tests, radiological examinations – all the services offered to patients. Such standardization can be done at a local or national level, or can make use of international codes such as, for example, the LOINC (Logical Observation Identifiers Names and Codes) for laboratory tests, microbiology, radiology, etc.[62] The pharmaceuticals prescribed in the system (their active ingredients and commercial names) must also be standardized. Local and international solutions are also available for this task.

Finally, we must standardize medical terminology. In this area there are various systematized vocabularies or classifications that are applicable to different levels of healthcare:

— ICPC2 – an international health problem classification system used in primary care[63].

— ICD9 or ICD10 – the International Classification of Diseases, created for epidemiological and statistical purposes.

— SNOMED CT (Systematized Nomenclature of Medicine) – a controlled medical terminology based on contextual relations between concepts[64].

At another level of decision making is the selection of standards that will allow for communication between different systems. There is a variety of standards that can help at this level of management:

— HL7 messaging, like HL7 v2 and v3, which makes it possible to exchange messages concerning administrative and accounting issues, health data, etc.[65]

— DICOM, which allows for the exchange of digital medical images and their communication between systems[66].

— CEN/ISO 13606, which makes it possible to exchange digital health documents[67].

— CDA, another HL7 standard, which makes it possible to represent all kinds of health documents[68].

— OpenEHR, the benchmark open source model for health record systems[69].

Moving up one step, we can consider applying a communication model with a certain architecture, such as that of the IHE (Integrating Healthcare Enterprises), which lays out a group of profiles that help bring into line the use of standards for different healthcare activities, such as security and traceability[70].

In summary, it is important to emphasize that there are many standards, and that there are many levels of application that call for complementarity between those standards. They must be carefully chosen in order to set up a scalable and sustainable interoperability project.

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[62] LOINC Homepage: http://loinc.org/background

[63] ICPC2. International Classification of Primary Care. WONCA International Classification Committee. Available at: http://www.globalfamilydoctor.com/wicc/pagers/english.pdf

[64] ICD10 International Classification of Diseases: http://www.who.int/classifications/icd/en/

[65] HL7 Australia: http://www.hl7.org.au/HL7-V2-resources.htm, http://www.hl7.org.au/HL7-V3-resources.htm.

[66] National Electronic Manufacturers Association Homepage URL: http://medical.nema.org

[67] The European HCE CEN/ISO 13606 standard. Available at: http://www.en13606.org/the-ceniso-en13606-standard?format=pdf

[68] HL7 Homepage: http://www.hl7.org/implement/standards/index.cfm

[69] OpenEHR Homepage: http://openehr.org/home.html

[70] IHE homepage: http://www.ihe.net/

Conclusions

Interoperability is an attribute of computerized information systems, which are essential for the management of modern healthcare systems. Curiously, the proper application of interoperability makes it unnoticeable for the healthcare professionals using such systems, since it makes it possible for information to flow between different applications and systems. The benefits of designing interoperative systems are endless and undeniable, including the integration of patient information for effective decision making, the universal distribution of the information, the collection of statistics and indicators in real time, etc. Moreover, with interoperability, different applications and systems can be maintained in the information system without having to modify their structures.

Taking interoperability into consideration is vital when planning a health information system. Aligning information administration and management with the goals of the healthcare system and its users is the key to success.

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Chapter XVI

Principles of information security in healthcare settings

Óscar Blanco
David Rojas

Summary

Data about a person's health has always been considered strictly confidential, since during the care process patients may share with their doctors details about their personal life that they reveal to nobody else, and they do so with the confidence that the doctor will protect the secrecy of this information and, especially, with the hope that the information will be useful in improving or protecting their state of health. Therefore, clinical information must be *protected* and at the same time *available* to health professionals who need it, and many countries have adopted legislation to this effect, based always on the rights of citizens.

In addition to the legal framework, there are several technical standards that provide a series of guidelines and best practices in the area of information security management in an organization. Particularly important among them is ISO/IEC 27001:2005. The main advantage of this standard is the fact that it is based on the identification and evaluation of all the potential security risks, which makes it possible to plan and adopt specific measures to control them, within a suite of comprehensive and cyclical controls that are oriented towards ongoing improvement in the very management of information security. This standard can be applied to any professional sector, since it adapts to the particular features of each organization, such as, for example, the magnitude of a healthcare system and the complexity of care activity.

Introduction

Information is the foundation of all human activity. To a greater or lesser extent, all people work with data. For example, managers usually begin their workday by looking at their agenda to see what commitments they have scheduled, and sentinel physicians must know the boundaries of their area of surveillance and the hours that they will be on duty. Without this basic information, these individuals could not carry out their functions effectively. Moreover, there are occasions in which knowing or not knowing a certain piece of information can be a strategic advantage for some and detrimental to others. For example, industrial espionage helps a company gain access to the secrets of another company and thus reduce the latter's competitive edge. Therefore, access to information is necessary to carry out activities but it is also true that the information needs to be protected against inappropriate access.

In the past, information was a local element. It was something difficult to record, process, copy and transport, and thus no specific management was required. However, social and technological development over the last few decades has made it possible to generate, use, replicate and share large

quantities of information in a short period of time, so information is now exposed to new and numerous risks that can affect an organization's ability to reach its objectives. In other words, there has been a substantial change in the importance placed by companies and other bodies on information, which has become their primary strategic asset and as such requires appropriate management in terms of security.

With this as the point of departure, information security is usually defined as the sum of three basic concepts (Rojas, 2008):

— **Availability:** the information must be available when and where it is needed, regardless of when or where it was generated.

— **Integrity:** the information recorded must be accurate and complete, and it therefore must be protected from accidents and attacks. If the data is unreliable or incomplete, it is not useful[71].

— **Confidentiality:** access to information must be restricted, depending on the person who is trying to gain access and the pertinence of this access. In other words, it is important to establish who can access which type of data, and when and how they can do so.

The most important consequence of this definition is the existence of two requisites that conflict with one another: availability and confidentiality. Their presence creates a dilemma (MacDonald, 2001), since there is no solution that equally satisfies both needs. Any measure that facilitates the availability of data will necessarily penalize its confidentiality, and vice versa. Thus, a satisfactory information security solution must guarantee a reasonable balance between these extremes, and it must also be flexible enough to adapt to the particular circumstances of each situation without ever losing such balance. For example, the names of the filmmakers that have been chosen for an Academy Award are a very closely-guarded secret prior to the award ceremony, but immediately afterwards they are part of the public domain. In this case, the strict security measures at the beginning give way to the diametrically opposed extreme, with various publicity campaigns being launched to increment the box office receipts of the winning films.

In the health sector, the two requisites clearly converge, since the professionals caring for a patient need to have access to the data in the patient's clinical record in order to provide the best possible care, while at the same time this information is confidential and its consultation and modification require authorization by the patient. This is laid down in legal terms in the field of citizens' rights, which include the right to health and to privacy and make it obligatory for healthcare institutions to take the necessary measures to protect these rights.

It is easy to see that the progress made in IT has contributed greatly to the availability of information, as illustrated especially by the creation of communication networks, particularly the Internet. However, it is no less true that the great strides in IT have also led to the creation of very effective tools with which to safeguard information's confidentiality, such as access controls, activity registries and automatic alarm systems. This means that eHealth *per se* need not pose any threat to information security, quite the contrary in fact. To put it another way, there are now technological means capable of implementing any reasonable solution designed from the organizational perspective, which is where the crux of the problem lies and which is where the foundations of an information security plan must be built. These foundations can be described as follows:

— A well-defined corporate security strategy.

— A compromise being reached between the availability and the confidentiality of the data.

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[71] This is why some people believe that integrity is an element within availability, and thus define security as the sum of availability and confidentiality. The authors consider this distinction to be merely anecdotal, since the aim is always to guarantee the security of the information, which is the final sum of the factors in both cases.

— The use of IT as a tool for the application of the measures designed.

— Appropriate training for the individuals involved, both professionals and patients, that also contributes to their awareness of this issue's importance.

Legal framework and technical standards

The development of regulatory frameworks in the area of information security and data protection has taken different paths in different countries, although most share fundamental aspects, such as the following[72]:

— It is established that all people have an inalienable right to respect for their private life, as reflected in the highest-ranking laws of many countries, and in the European Union's Charter of Fundamental Rights.

— Specific regulations exist for the protection of personal data. Some of the most representative examples include: in Spain, Law 15/1999 on the Protection of Personal Data[73], generally known as LOPD; in Portugal, Law 67/98 on the Protection of Personal Data; in Chile, Law 19628 on the Protection of Private Life; in Argentina, Law 25.326 or the Habeas Data Law; and in the United States, the Privacy Act of 1974, which governs how personal data is processed by federal agencies and bodies[74].

— Personal data is classified into different levels according to its sensitivity, and the more sensitive the data to be protected, the more stringent the protective measures. Personal health data requires maximum levels of protection in all cases.

— In each country a supervisory authority is designated, and this body is responsible for overseeing, in accordance with the country's internal legal system, compliance with the principles of data protection. For example, in Spain there is the *Agencia Española de Protección de Datos* (AGPD), and in Mexico there is the *Instituto Federal de Acceso a la Información* (IFAI).

— There is always a duty to inform the citizen, who must explicitly express his or her consent for the collection, processing and transmission of data, after being informed of the purpose for which the data is being gathered.

— The access principle means that all citizens are entitled to know whether information concerning them is being processed, and also to request that such information be corrected or deleted.

Parallel to the legal mandates, there are voluntary working methods and best practice guidelines of a technical nature, which are laid down in international standards (Alamillo, 2008; Ortega, 2008). In the field of information security, the most relevant technical standard is ISO/IEC 27001:2005 (previously 17799:2005), which conceives of information as a crucial asset in organizations and sets forth the requisites and guidelines that must be followed to ensure that information security is effectively managed. This standard can be applied to any professional sector, not just healthcare, and it is updated periodically, incorporating improvements derived from the experience gained through its use in all sectors. There is also the possibility of an organization publicly demonstrating compliance with this

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[72] Some of these characteristics were laid down as early as the United National General Assembly Resolution 45/95, of 14 December 1990, *Guidelines for the regulation of computerized personal data files*.

[73] In Spain, there is also a law on patient autonomy and on rights and duties in the area of clinical information and documentation (*Ley 41/2002 básica reguladora de la autonomía del paciente y de derechos y obligaciones en materia de información y documentación clínica*). Article 7 of this law establishes that all patients have the right to privacy with regard to their health information, and it requires healthcare centers to adopt the measures necessary to guarantee this right.

[74] In the United States the *Health Information Technology for Economic and Clinical Health (HITECH)* Act was passed in 2009. This law calls for the general adoption of eHealth standards, with special emphasis on the need to reinforce the mechanisms that protect the confidentiality of patients' clinical data.

standard, by submitting to an audit performed by specialized external bodies, which issue a certificate to the organization in question if it is deemed to have passed the audit (Gómez, 2009).

The efficacy of management systems based on this standard has led to various public institutions, including the European Union and the Organization for Economic Cooperation and Development (OECD), using it as a reference in the formulation of new laws and recommendations[75]. In Spain these recommendations have been taken into account in the creation of the National Security Scheme[76], the aim of which is to generate citizen confidence through the adoption the measures needed to guarantee the security of their information in the sphere of e-Government.

Information management in health services

To fully understand the implications of information security in the healthcare setting, two of this setting's most outstanding characteristics should be recalled. The first is the magnitude of health services, which must be prepared to respond to a high demand for care. In most European countries, public sector health services have a legal obligation to provide universal coverage, and health expenditure represents a very significant part of the public administration's budget. For example, in 2008 the average national health expenditure by the EU-15 Member States was 9.5% of their respective Gross Domestic Product figures[77]. Another illustrative piece of information is that Britain's National Health Service (NHS) is one of the five largest work groups in the world (Carnicero, 2010).

The second characteristic that needs to be highlighted is the complex nature of care activity. Any clinical act, as trivial as it may seem, can involve a high number of professionals from different fields, and moreover, the professionals must work in a coordinated fashion. In addition, during the care process critical situations can arise that put the health or even the life of the patient at risk. To manage these needs appropriately, health services become large consumers and at the same time large generators of clinical information, since they must consult pre-existing data and also record the data generated during the care provided.

Health records and other sources of information in the health services

All of this data is stored in the patient's health record, which consists of a complete and well-structured record of all of that individual's clinical information. This makes it the most basic element of information for professionals and, by extension, the most fundamental instrument in the care process. However, it also has other applications, such as research, teaching, clinical management and care resource planning, and it is sometimes used in legal proceedings and in evaluating the quality of the care provided (Falagán, 2003). For all of these reasons, patient health records are the health services' most important source of information.

To guarantee the security of the information contained in health records, whether electronic or paper-based, several requirements must be met. One of the most important is the **data quality principle**, based on the unicity of data. This means that each datum is recorded only once and that a

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[75] COM(2001)298 final, *Network and Information Security: Proposal for a European Policy Approach*. Brussels, 6 June 2001. DSTI/ICCP/REG(2003)5/REV1, *Implementation plan for the OECD guidelines for the security of information systems and networks: Towards a culture of security*. 2 July 2003.

[76] Executive Decree 3/2010, of 8 January, which regulates the National Security Scheme in the area of Electronic Administration.

[77] This figure includes private sector expenditure, although this sector's participation in the European market is minor.

single version of it is maintained, thus avoiding the risk of duplications or contradictions[78]. Equally important is the authorization and authentication of professionals who try to access information contained in a patient's clinical record. These processes are vital because they allow records of accesses to be kept and audits to be performed later, and also because they ensure that clinicians cannot later deny their actions (non-repudiation). These requisites are also applicable to health records of deceased patients, since the right to privacy is perpetual and therefore does not end upon the patient's death.

Finally, it is important to remember that health services often handle sources of information other than health records, and that these sources also need protection. For example, administrative departments may make use of the demographic and financial data of patients, professionals and suppliers. Generally this information is less sensitive than that contained in the health record, but some administrative data can have a certain clinical value. For example, the number of the room assigned to the patient allows deductions to be made regarding the floor the patient is on and with this information the specific medical service involved can be determined, which can give rise to some speculation about the health problem of that particular patient.

Current situation

Despite international consensus on the importance of citizens' right to privacy, studies have revealed major shortcomings in the healthcare sector's protection of this right. It is also apparent that in some cases information security is not among the organization's priorities nor is there sufficient awareness among professionals as to its importance (AGPD, 2010; Ponemon Institute, 2010; Wanless, 2007).

Key aspects of information security management

The application of ISO 27001 is based on the organization introducing an Information Security Management System (ISMS), which guides the organization in:

— Making a diagnosis of the initial situation: the information it possesses, how this information is used and the risks associated with such use, taking account of threats, vulnerabilities and impacts on its activity.

— Setting objectives and goals that increase the degree of confidence in information security and are appropriate with regard to the organization's initial situation.

— Designing and introducing a series of measures to meet the objectives set, while controlling levels of risk, preparing for possible emergencies and guaranteeing the continuity of activity.

— Planning, organizing and distributing the resources earmarked for security management, to make fulfillment of the objectives viable.

— Establishing processes and activities for the review, ongoing improvement and auditing of information management and processing, so as to evaluate the degree to which objectives are being met and to design the measures and corrections that should be applied.

— Integrating information security management with the rest of the organization's management processes.

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[78] The development of eHealth has given rise to the concept of shared or integrated health records, which allows all existing data - dispersed throughout different centers and services in the healthcare network - to be added to them and made available to any professional who needs such information. In this case, the data quality principle is a critical prerequisite.

One of the advantages of an ISMS is that the requisites and recommendations set forth in the standard serve as a framework for guidance. In addition, they are applied in accordance with the organization's specific parameters, such as size and activity. Similarly, an ISMS makes it possible to address –using a global approach– all the factors related to information security, with emphasis on organizational and human aspects and avoiding common biases and errors, such as devoting too much effort to purely technological questions (Gómez, 2009).

Application to the health sector

To implement an ISMS in a health service the following tasks must be carried out:

— A security policy must be defined, with a description of the general characteristics and objectives of the organization and its institutional commitments in the area of information security. This policy must be defined and approved by the upper-management bodies of the health service, since they are the ones responsible for guaranteeing the protection of the personal data used by the organization in its activity.

— A security committee must be created, to coordinate and approve the actions undertaken in the area of information security, and to ensure proper functioning of the ISMS. The following bodies must be represented on the committee:

  o The upper-management bodies of the health service and of the facilities belonging to it, as these are the bodies with the greatest responsibility in these institutions.

  o The admission and clinical documentation services, since these are the services in charge of managing the information related to patient health.

  o The IT services, as this is the department responsible for the maintenance of the computer and communications infrastructure used for recording and processing the information.

  o The administrative services, which do not use clinical data but do handle information related to staff and supplies that is necessary for the proper functioning of the health service[79].

— An inventory of assets must be created, listing all of the organization's assets in relation to information processing: data used, physical media, devices, computer applications, personnel, etc. These assets must be classified into different categories according to their characteristics and their importance to the organization must be assessed. In a health service, the most obvious examples of assets would be the files of clinical records, the computers used by clinicians, hardware servers, electronic health record applications, the master patient index, communications lines and even the organization's staff.

— A risk assessment must be performed, in which the threats to each asset are evaluated separately, along with the real impact that the materialization of such threat would have. Subsequently, acceptable limits must be established for each risk. In other words, the findings of the risk assessment help the organization understand and quantify the dangers to which each asset is exposed and they also help prioritize the application of security measures, starting with the assets that run the highest risk. For example, the files of clinical records are not exposed to the same risks as the database of providers or the schedule of shifts in a given ward, nor is the impact that an incident would have on the organization the same in all cases. The loss of information held in the clinical records could cause a reduction in the quality of care given to the patient, while the theft of such data would be a flagrant violation of his or her right to privacy. But in the case of the database of suppliers or the schedule of shifts, the loss or theft of information would cause short-lived operational difficulties in the organization, but in no case would it be a breach of data confidentiality, since this information is not especially sensitive.

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[79] These services are included for purposes of representation of all the parties involved, but given the focal point of this chapter, their role and the management of non-clinical information security will not be addressed in detail.

— A plan must be developed for the implementation of security measures aimed at risk containment, keeping risks within the previously-established limits: introduction of security controls, definition of action plans, etc.

— Roles and responsibilities must be defined for the application of the measures, keeping in mind that tasks can be assigned to practically any member of the organization.

— Sufficient resources must be allocated for the proper application of the measures.

— The controls and security measures must be implemented, as specified in the action plans that have been drawn up. These controls can be classified as follows:

  o *Access control*: assignment and revocation of user authorizations by which access can be gained to the organization's facilities or information systems. For example, this is where the user names of individuals authorized to use computer applications would be registered, removed or modified and where password management would take place. For this, the system users' roles and profiles must be previously defined. In other words, it must be decided not only *who can have access* but also exactly *what information* they can access and *what operations* they can perform with this data (Garbayo, 2003).

  o *Physical security*: measures by which physical access to certain areas is restricted and by which the maintenance of the physical infrastructure of the facilities is ensured. This group includes, for example, the installation of locks, the suitable conditioning of work areas, ensuring the redundancy of the power supply, etc.

  o *Logical security*: measures by which logical access to information assets is restricted and infrastructure capacity is managed. For example, logical security measures may include the installation of antivirus and firewall software, and guaranteeing the availability of space in the data storage systems.

  o *Backup copies*: the making of backup copies to minimize the risk of information loss in the case of accident or attack. It is also necessary to run periodic data recovery drills, to check that the backup process is taking place correctly.

  o *Security incidents*: the recording of information about any incidents affecting the assets, with a view to then studying and remedying them. For example, the time and date of the incident must be registered, along with the assets affected, the impact created, the specific measures applied to solve the problem, etc. A record of this type makes it possible to identify the most frequent incidents and take specific measures for their prevention.

— Efforts must be made to provide suitable training and increase the awareness of the organization's staff. This must cover absolutely all staff, not just the security committee or the individuals in charge of applying security measures and controls. The last link in the security chain is always the confidence placed in a person (Ortega, 2008).

— There must be an evaluation process followed by a series of actions, in order to measure the degree of effectiveness of the controls and to make the corrections and modifications considered necessary, to then begin the cycle once again.

In conclusion, an ISMS is extremely useful in designing and implementing an action plan based on detailed knowledge of the specific risks to information security, distinguishing among different assets, and also on decisions and actions that focus on the specific management of these risks. Also, the system is oriented towards ongoing improvement, since the cycle begins again after the evaluation of the results obtained, with the setting of new objectives and application of new measures. This makes the organization better able to adapt to new needs whenever they may arise.

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Chapter XVII

Managing electronic health projects

Renato Orellana

Summary

This chapter explains why eHealth projects must be understood as an intervention involving the organization's work practices and relations, and not only as the adoption of a technological system. Taking one perspective or the other can lead to success or failure in the implementation of such projects.

Secondly, the chapter identifies and describes the main factors underlying the failure to meet objectives, cost previsions and established deadlines. It points out that following a preventive approach allows the managers to identify the most common difficulties and thus prevent them, or manage them appropriately when they do arise.

Thirdly, the chapter gives visibility to the discipline of project management and shows how it can contribute to successful project implementation. Some general references on this topic are given, introducing readers to this discipline and allowing them to later deepen and expand their understanding.

And finally, the chapter offers some background about two perspectives that should be considered in order to manage eHealth projects in a professional manner. The first is based on management practices in the field of project engineering; the second is based on the implementation of technological solutions in health institutions.

Incorporating digital technology into health systems

Following Mair (2009) and as already stated in other chapters of this book, eHealth is the use of IT, including internet, to improve health and facilitate healthcare delivery. Digital technology can make valuable contributions to multiple dimensions, both in the area of clinical care and also in the handling of patient information, healthcare resource coordination and support for epidemiological analyses, to name just a few.

For this very reason, the implementation of eHealth projects brings changes to various aspects of the organization's functioning: a) in the processes used to provide health services; b) in the timeliness and quality of health information, and in the ways that such information is obtained, organized and retrieved, at both the individual and the population levels; c) in the analysis of information used to justify decisions about which healthcare benefits should be offered; d) in the medical technologies and equipment used for diagnosis, treatment and rehabilitation and for the integration of information, as well

as its use by patients; and e) in the communication and coordination methods used inside the health organization and with the users of the health services it provides.

This means that in order to successfully design and incorporate these changes, it is vital that experts in the field of digital technology work side-by-side with clinical professionals, epidemiologists, physicians and other health professionals such as nurses.

People whose everyday work activity is affected by these changes tend to experience them as a process of learning and experimentation, not simply as a modification in the way tasks are carried out. Therefore, eHealth projects should be understood as a situation of organizational change that is more closely related to management than to technical issues.

Undertaking e-Health projects

The literature indicates that there are various barriers that limit the use of eHealth solutions, and in fact in the United States it has been estimated that only 20% of doctors and 10% of hospitals use electronic health record (EHR) systems[80].

Two reasons are commonly cited to explain this situation. The first is of a technical nature and refers to the lack of interoperability between the systems available on the market, which limits the ability to share data between organizations and thus diminishes the solution's potential benefits[81]. The second reason, of a financial-administrative nature, refers to the cost of acquiring, maintaining and updating the system, and of providing training to personnel. This results in the use of EHR systems being limited mostly to large hospitals and those with greater financial resources[82].

Although the technical challenges related to the characteristics of the medical profession and of computer technology are certainly acknowledged, the analysis and evaluation of the problems commonly experienced in eHealth projects have led to growing consensus that such problems are mainly sociological, cultural and financial in origin.

Following reflection on how to achieve the desired results in the organizationally and technically complex context surrounding eHealth projects, several conclusions have been drawn. Success requires that robust methods be used to design the solutions required and to install them in the workplace, that an agreement between the participants be reached early on as to the meaning of success and as to when the evaluation of the level of success will take place[83]. These requisites point to the need to work with professionals specialized in the management of eHealth projects and to develop a strong commitment to success, in both health personnel and the organization's directors.

The foregoing illustrates why, despite the growing demands for the benefits of eHealth, there are still problems in executing budgets and respecting established deadlines, when it comes to new projects involving the development and implementation of IT (Parra, Sáenz and Nieto, 2007).

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[80] Jha AK. "A progress report on electronic health records in US hospitals" *Health Affairs* 2010.
[81] See the chapter on this subject.
[82] American Hospital Association. 2007. Continued Progress: Hospital Use of Information Technology.
[83] Health IT Success and Failure: Recommendations from Literature and an AMIA Workshop. *JAMIA* 2009; 16:291-299.

According to the literature, project managers use three general criteria to analyze the success or failure of projects; whether functional requirements are met, whether the project stays on budget and whether established delivery dates are respected[84].

The functional requirements determine the framework of agreement between the project manager and the individuals who will use the eHealth system in their work. By specifying them the expected capabilities of the system are established, and in so doing the standard for measuring the project's success is also established.

For example, one functional requirement in the area of patient admission could be the capability to automatically merge duplicate patient records; in relation to clinical records, one functional requirement could be the capability for online entry of nursing notes documenting patient evaluations, care activities, progress notes and discharge. Whether or not these requirements are met will be an element used in judging the project's success or failure.

In addition to these basic criteria for project evaluation, other factors can also be considered, such as the impact the project has on the organization, the variations in the value of the service provided to patients, the development of teamwork skills, the integration of different medical service areas, the opening of doors to new eHealth projects, among others.

Good project management requires that the evaluation criteria for measuring the project's success and impact be established at the beginning. These criteria must be formally agreed between the parties responsible for financing the project and those in charge of executing it. By doing so monitoring and control indicators are made available, making it easier to identify and foresee problem situations that may affect compliance.

Varying opinions exist regarding the aspects that must be observed and measured in order to assess the situation. In studies conducted from the perspective of project engineering[85] the risk factors typically pointed out are the following:

— Design failures. These occur when expected outputs (such as functional requirements, costs and deadlines) are not described with sufficient clarity, leading to differences in understanding among the project's participants regarding the scope and specificities of the products and goals that must be met.

— Decision-making failures. These arise when there is confusion about the distribution of responsibilities in the different processes and phases of the project's execution.

— Failures in project management mechanisms. These are present when documentation replaces the management of situations, especially as regards the identification and management of risks. To put it another way, identifying problems and presenting them to the participants is not the same as solving the problems.

— Supplier management failures. These are rooted in the lack of understanding between the customer and the supplier, which can give rise to a contract not suitably designed to respond to the situations that may arise during the project.

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84 Glaser J. More on management's role in IT project failure. Healthc Financ Manage 2005; 59:82–89.

85 See results of the study by Cave, T., D. Ingram and R. Stein (s/f), Improving the Success Rate of NHS IT Projects [online] http://www.bcs.org/content/conWebDoc/20341

Looking at it from a socio-technical perspective, the factors explaining variations in the percentage of failures include the following: a) the type of project; b) the number of working groups involved (for example, different medical specialties). The increasing complexity of the situation becomes apparent when we consider that each group of specialists may seek different functional requirements, which are each assigned different levels of priority. Such requirements can even be contradictory, in which case they must be negotiated. Therefore, as the variety of requirements increases, the complexity of the project also increases and this raises the likelihood of failure; c) the correct use of proven project management methodologies. This point refers to the fact that the project's success bears a close relation to the use of methodologies that effectively manage the project's technical and human complexity, beyond the use of partial tools such as time and budget controls; d) the support given to the project by organization's directors. This gives the project a greater capacity to deal with situations that might hinder its progress; and e) the number of end-users.

These considerations form the basis of a strategy that can be followed in the early stage of the incorporation of eHealth solutions. The strategy calls for the identification of projects with less complexity and greater likelihood of success, due to their having the following characteristics: a) the project adds infrastructure before incorporating new functionalities; b) there is only one working group as the client; c) management methodologies are used; d) the project has the support of the organization's directors; and e) it has a small number of end-users. By selecting such a project, success is more likely and this achievement will help overcome the lack of confidence that people often experience when their work routines change and when new tools with which they are not familiar must be used, sometimes even when they do not feel skilled enough to use them. By following this strategy the project management team will also have the opportunity to create relationships with the users of the technological solutions, thus generating favorable conditions for future projects of greater complexity. The strategy of selecting "quick gain" projects is intended to produce positive results in a short period of time, thus validating the use of eHealth solutions.

Mair, et al. (2009), after performing an extensive review of the literature on eHealth projects, identified the following factors[86] that affect the incorporation of IT into health systems.

— *Conditions prior to implementation.* The commitment of an organization to adopt and operate an eHealth system, and also the wider community's disposition to the project, are considered valuable facilitators of implementation. Similarly, to successfully implement the system it is important to have a thorough knowledge of the organization, its activities and its work processes.

Another factor deemed effective is the existence of a positive relationship between the different stakeholders that have an influence on the implementation of the project. This in turn points to the importance of thoroughly preparing the project and informing the organization's personnel about it and its benefits, as doing so will increase the professionals' collaboration and commitment.

— *Cost.* In general, limitations in financing are considered a factor that restricts the project's potential.

— *The need for and impact of validation and evaluation.* The confidence of directors, professionals and end-users is associated with the project's ability to demonstrate that: it has worked, it has improved the level of care quality, its implementation has been cost-effective, it can be used easily and efficiently. Any past experiences that have ended in failure will generate resistance to the intervention and will become barriers to its implementation.

— *Professional attitudes.* The responses of doctors and other health professionals are based on their perceptions concerning how the system will affect their work relationships and their ability to reach their professionals goals. Some studies conclude that the most fundamental condition for successful

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[86] It is important to note that there is no hierarchy among the factors.

implementation of a system is its acceptance by the doctors involved, since this will ensure the necessary leadership (Yarbrough and Smith, 2007).

— *Ease of use of the system.* Ease of use is a factor that contributes to successful implementation. The aspects considered in the evaluation of ease of use include: the interaction between users and the technology, compatibility with pre-existing systems, its reliability and it being a good fit with the work that has to be performed.

If packaged solutions are to be used, it is important to consider that for a single health service different alternatives may exist. A system that is well-designed for a given working method may not be a good fit with the totality of working practices in another institution, which may result in the system being "hard to use" in its original design.

— *Security, confidentiality and standards.* Systems must be secure for patients and professionals; for patients, security means appropriate levels of protection and availability, and that their personal data will not be accessed by unauthorized persons; for doctors, security consists of the systems installed not compromising their legal situation as a result of the transactions taking place therein, nor affecting their professional practice standards through errors in patient identification or in the data used to make clinical decisions.

— *Education and training.* Lack of skills and knowledge about the right way to use a technological system is a barrier to implementation. If people are unable to effectively use the new system they will feel resistance to it. Thus, the program for training the staff who will be using the system should be designed before the system is implemented. Educational activities must cover what the system does and does not do, highlighting the specific skills required and the professional abilities that allow the system's limitations to be overcome.

Finally, it is important to underline that in organizations with little experience in eHealth projects, a potential failure situation can arise from a lack of a system-wide perspective by those participating in the project, the result of the participants forgetting that the project is *organizational* in nature. This leads to a tendency to underestimate the relevance of interaction among persons, organizational routines and medical technologies, and the minimization of such interaction is always a mistake. The absence of a system-wide perspective can affect both computer experts and also health clinicians and directors.

For example, in the acquisition of electromedical equipment, in addition to assessing the contribution it will make to diagnosing and treating patients, the following must also be verified: a) compatibility between the desired equipment and the availability of suitable physical space in which to install it; b) computational/storage capacity in relation to the volume of data production; c) relationship between the precision of the data to be obtained and the experience/training of professionals who will use the data to make diagnoses; d) compatibility with other equipment used at that institution; and e) costs related to operation, maintenance, updating, licenses, etc.

Many of the mistakes made during technology acquisition processes have their origins in the asymmetry of the information between the purchaser and the seller in terms of the scope and the implications of such technology's incorporation into a health organization. It is a good idea to include biomedical engineering experts in such processes, so as to minimize risks and improve cost control.

Using project management methodologies

The absence of a systematic working methodology has been identified as one of the main factors leading to failure in the implementation of IT projects, both at the level of project engineering and in terms of

the implementation of new work practices in healthcare delivery. Not having an established framework with which to respond to conflict situations and facilitate decision-making increases the tendency to improvise. In a complex scenario such as the introduction of an eHealth project, satisfactory results cannot be achieved through common sense and ad-libbing.

The role of a project management methodology is to make it easier to appropriately structure the effort that must be made, ensuring mutual understanding of responsibilities and commitments by the organization's administrators, the end-users and the technical experts involved in each of the different stages of the project. This contributes to an accurate estimation of efforts and times required and to the creation of a structure with which to control intermediate milestones. Having a clearly specified project structure is also helpful in determining the effects that any changes in the project objectives will have, in terms of both costs and deadlines. Thus, using a project management methodology means there is a capacity to manage continuous adaptation.

The project management methodology must be considered a central axis that guides and gives meaning to the actions performed. There are many different project management methodologies. This chapter highlights the ones considered best practice standards.

The PRINCE2 methodology is used to manage all the projects undertaken by the British government. Another methodology, known as PMBOK (Project Management Body of Knowledge), was developed by the Project Management Institute and is an ANSI standard[87].

The difference between these two methodologies is that PMBOK offers a large corpus of information about proven practices in the field of project management, which project managers select according to the organization's needs and characteristics. In contrast, PRINCE2 lays down a series of steps that are more prescriptive, yet still flexible, that the project manager must follow during project development. Of course, the two methodologies have many aspects in common. Putting it another way, PMBOK *shows* project managers what they should do and PRINCE2 *tells* them what to do. These two methodologies constitute a standard in that they lay down verifiable practices the use of which demonstrates competence in project management. They are the most widely used standards around the world and they serve as guides for all kinds of projects, regardless of size or sector.

As a sample of their content, some elements of PMBOK are presented below. PMBOK was chosen basically because it comes closer to the international ISO standard.

Concern regarding the success of projects has also led to the formulation of methodologies in fields other than project engineering. In the area of health, the incorporation of new practices is related to the capacity to deliver effective healthcare services to the population. From this standpoint, eHealth systems represent a way to strengthen the practice of medicine. The analysis of various eHealth projects –examining especially the social processes that occur when new technologies are introduced into a work setting– has given rise to methodologies complementary to the ones mentioned above. In particular, we will discuss the theory known as the Normalization Process Model (May, 2006), the focal point of which is the operationalization of professional knowledge in health work. This model is being increasingly used by the British National Health Service in its eHealth projects.

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[87] American National Standards Institute ANSI/PMI 99-001-2004 complies with the ISO 10006 project management standard. More information at: http://marketplace.pmi.org/Pages/ProductDetail.aspx?GMProduct=00101095501

Afterwards we will highlight some of the main lessons that can benefit project management, as gleaned from reflections arising in project engineering and upon implementing new working practices in healthcare settings.

In contrast to these methodologies, it is often thought that tools for handling partial aspects of projects, such as critical path management (PERT, CPM), Gantt diagrams, etc. can adequately perform the project management function. Such thinking is based on the erroneous notion that controlling established steps is enough to lead a project. These partial approaches do not adequately absorb the complexity of an eHealth project, because they do not cover aspects associated with the various responsibilities of project users and developers, nor do they discuss how to handle changing expectations and their impact. Therefore, these tools can play only a formal role.

Lessons from the field of project engineering

A project management system is the set of tools, techniques, methodologies, resources and procedures used to manage a project. According to *A Guide to the Project Management Body of Knowledge (PMBOK)*, it is a set of processes and the corresponding control functions, which are combined and consolidated in a functional, unified whole. It is quite feasible to apply this project management capacity to eHealth projects.

Before starting the management phase of an eHealth project in an institution, it is important to link the vision and strategies of the institution to the strategies to be used in the implementation of the eHealth project. Mapping out such links shows how the incorporation of technology will help achieve the main objectives of the institution. The final product of this linking process is the identification of a portfolio of projects that will make it possible to move from the current (or base) scenario to the desired institutional scenario. In other words, eHealth projects form an integral part of the institutional project. Reaching consensus in the organization about these links is the foundation for obtaining support from the organization's directors for project execution.

Large or complex projects comprise various processes that are linked to one another and known as process groups. They are not necessarily sequential and in fact may be executed more than once during the project. This is because different aspects of the project (for example, human resources management and supply management) must perform these processes.

These processes can be described, in general terms, as follows:

— Studying feasibility

The aim of this process is to evaluate the necessity and viability of introducing an eHealth solution. The decision to go ahead with the eHealth solution must be based on it bringing added value to care provision processes and the study must define the most appropriate strategy for incorporating it.

The development of a problem-solving strategy is an opportunity to collaborate closely with the heads of the organizational area in which the project will be carried out, and to obtain their comprehension regarding the importance of the project and their commitment to participate in it. The commitment to participate begins by developing consensus concerning the technology's functional requirements. Having a formal end to this process is useful because it prevents additional requests for functional requirements being made throughout the entire project development phase, as people continue to come up with "good ideas" for the project. Each new requirement affects the planning, budget and delivery dates. The viability or feasibility study is the time to collect the information needed to make the decision to authorize the project.

— Defining a work plan

In this phase, detailed answers are given to the question of "how" the application defined in the previous phase is going to be constructed. The division of labor is established and a precise budget is drawn up. This entails arriving at a detailed design based on the functional requirements agreed with the system's end-users.

Depending on the organizational and technological complexity of the project, and the skills of the human resources available, a decision must be made as to whether the system will be developed internally or through external suppliers. The health IT industry has a great deal of technical expertise and experience in system installation. This in and of itself may justify a strategy of purchasing final services and discourage the construction and operation of computer systems with the organization's own resources.

— Organizing and executing

This is the time to assign tasks, responsibilities and the communication strategy for project participants (for example, between suppliers, staff with functional responsibilities and project managers). This correlation serves to coordinate the different processes and tasks, by reaching service agreements (what is to be done, in what time framework, what final outcomes are expected) among the different agents responsible for the action plan. When these issues have been organized, execution itself begins.

— Monitoring and controlling

In this stage the project's execution is measured and supervised regularly. Analyzing the progress reports and trends makes it possible to disseminate information about the accomplishments and to identify the discrepancies between expectations and reality. This feedback allows corrective measures to be put in place so as to be able to meet the project's objectives. It is also the basis for managing the project elements that have been contracted out and the relationship with suppliers and with end-users.

The differences between what is expected and what actually takes place can cause changes in the budget and the timeline. The acceptance of finished products will be formalized upon the basis of identified achievements. So it must be determined whether they comply with universally accepted quality standards, as defined when the functional requirements were established. Universal standards in quality have been created as a point of reference for good service, such as maximum waiting times for online consultation and the maximum time that a system may be down, with variations depending on the type of service involved. In addition, the methodology itself represents a standard regarding the actions that must be performed in order to carry out a project. As mentioned earlier, the PMBOK methodology provides standards that correspond to proven practices in the different spheres of project management.

The project's complexity will determine the range of domains that must be controlled in order to successfully manage it.

— Closing the project

In this phase, personnel with functional responsibilities must formally accept the results obtained.

The project may be unnecessarily prolonged and the complete transfer of responsibility for its operation hindered if there is not a formal process that thoroughly verifies that all the requirements have been met[88], and that the system works properly.

The processes described are connected to each other by the results they produce. Thus, the feasibility study will establish the scope and limits that must be considered while defining the work plan – which is subsequently executed and monitored and must continually adjust to the changes observed. Similarly, the tasks completed in the execution process will give rise to the closing process.

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[88] Especially important among them is the preparation of end-users for carrying out the operation.

The complexity of each eHealth project will be different, depending on the different dimensions, or domains, that must be managed and on how they interact. Identifying the various domains of the project will make it possible to evaluate their influence and relative importance in the achievement of results. These domains are set forth in the following table.

Table XVII.1. Project management domains (Source: Compiled by author)	
Area of knowledge	**Description**
Project Integration Management	This knowledge area includes the processes and activities needed to properly identify, combine, unify and coordinate the project's various elements. It considers the integration of the project's different technological elements and the impact of the individual projects on the rest of the projects or products (software packages, communications, medical equipment standards and regulations) and the use of standards such as interoperability. It involves the administration of different contractors. It also covers the integration of the different departments within the organization that are participating in the project.
Project Scope Management	These are the processes and activities needed to ensure that the project includes all the work required, and only the work required, to complete the project successfully.
Project Time Management	These are the processes and activities required to accomplish timely completion of the project.
Project Cost Management	These are the processes and activities involved in planning, estimating, budgeting and controlling costs so that the project can be completed within budget.
Project Quality Management	These are the processes and activities that determine quality policies, objectives and responsibilities so that the project will satisfy the needs for which it was undertaken.
Project Human Resource Management	These are the processes and activities needed to ensure the most effective use of the persons participating in the project.
Project Communications Management	These are the processes and activities that ensure the timely and appropriate generation and distribution of project information that is useful in decision-making in the subprojects of which it is comprised, and also the storage of such information.
Project Risk Management	These are the processes of identifying and handling the risk situations that the project faces.
Project Procurement Management	These are the processes required to purchase or acquire the products, services, and results needed from outside the organization in relation to the project.

Since many eHealth projects involve contracting with third-parties, below there is a presentation of the domains whose appropriate management will help prevent situations from arising among and with participants that may lead to delay or failure.

Integration

The management of integration is a very important factor, especially in projects of a certain magnitude. This area of knowledge is linked to the project components that must interact in a coordinated fashion in order to be successful.

When a company is contracted to take charge of integration management, its experience must be carefully evaluated. There are records of failures of large computer projects in the area of health insurance due to poor company selection. For example, there are documented failures caused by unresolved conflicts between companies and subcontractors, which end up going to court and affecting the project's management.

Integration management includes the coordination of changes that occur during the project, among all its components. Such changes are a significant source of potential conflicts.

Communications

Communications between the project managers and the different participating groups must be managed in order to maintain adhesion to the project. In particular, everyone must be informed of the decisions made, and also of the reasons for making them. For example, in a system for handling the clinical information of patients –in which different specialties intervene, each with different information needs– the ways to code and retrieve information must be known and ratified by the system's users. Good communications management ensures that all the parties involved are informed about the decisions made and their implications.

Procurement

Managing the procurement process becomes especially important in eHealth, where it is common to adopt highly complex packaged solutions, created by providers of services and computer products. Such solutions can seldom be developed by health institutions, because such institutions do not have the resources to do so nor is it their purpose to stay on the cutting edge of technology. Therefore, in complex processes it may be necessary to outsource the product or service required.

The most significant mistakes in the procurement process are made in the definition of the public tender. An incomplete definition exposes the contracting organization to increases in cost due to the appearance of new, unforeseen requirements, a situation which greatly complicates the administration of contractual performance and increases the risk of lawsuits.

Flaws in the definition of the public tender can take various forms, such as: a) no mention is made of the policy to be used for handling patient information, in terms of data security in data entry and in system access; b) the standards to be used, for example, regarding messaging, coding and interoperability, are not specified; c) the project's architecture, in terms of both technical and operational details, is not sufficiently defined; and d) the public tender does not have the consent of the organization's patients.

Procurement management is a source of protection for the organization that contracts services, in that it prevents fractures in the relationship between the contracting parties. It is important to highlight that when the relationship becomes litigious the greater costs are borne by the contracting party because, among other reasons, the suppliers tend to have more experience in this type of situation.

Depending on the complexity of the project many organizations create a Project Management Office (PMO). The function of a PMO can range from limited consulting services to the recommendation of policies and specific procedures for individual projects, and may even include a formal delegation of authority by the executive managers. In general, the project director will receive administrative support from the PMO.

The primary functions of a PMO are: a) structuring the project; b) verifying that established milestones are met in a timely and appropriate manner; c) anticipating the changes in the deadlines and timeframes established; d) identifying compliance with the responsibilities defined; and e) conducting follow-up meetings in which the state of progress and any necessary corrective actions are determined.

Lessons learned from the field of e-Health project implementation

Just as there are lessons to be learned from experience in the project engineering tradition, a body of knowledge, still under development, has also been generated from the analysis of experiences in incorporating digital technologies that modify the complex system of relationships between health professionals, administration, support services and patients).

Studying this process has led to the development of a theory called the Normalization Process Model (NPM)[89], which pertains to the implementation of complex interventions in healthcare. The analysis considers "normalization" to be the end point of the implementation process, defining it in terms of a stable set of practices that result in eHealth technologies becoming embedded in daily routines and sustained in practice.

The NPM consists of four constructs: a) interactional workability, which refers to aspects such as ease of use; b) relational integration, which pertains to confidence and responsibility (accountability); c) skill-set workability, which deals with issues such as training, workload, roles and responsibilities; d) contextual integration, which refers to organizational issues such as resource allocation.

The reason behind developing the NPM was to have an evidence-based conceptual model concerning the adoption of new technology by the health professionals of the National Health Service (NHS) in the UK.

According to the NPM[90] project success is linked to paying closer attention to: a) interactions comprising the patient/doctor (healthcare team) relationship; b) aspects related to the integration of the system in the work setting, such as confidence in the system's security and its effects on efficiency; c) existing work practices, their effect on roles and responsibilities and education and training needs; d) the participants' adhesion and commitment to the project; and e) the positive evaluation of new practices by the participants.

The implementation of a new system of practices with new technologies – and the new ways of working associated – is one of the main problems for health institution managers and clinicians. Successful implementation is that which ensures that eHealth technologies become a routine part of daily activities and, at the same time, that eHealth technologies are based on such activities[91]. This means that the very people who use the system are the ones who ensure it is used by others and who believe that this is the "right way" to do things in the organization.

The challenge of integrating eHealth services into the work patterns of professionals remains problematic, despite the rapid technological progress observed in professional, organizational and

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[89] See Appendix 1 NPM Definitions, SDO Project (08/1602/135) in Mair et al., 2009.
[90] http://www.normalizationprocess.org/
[91] For more on this point, see Finch, Mair and May, 2007; May et al., 2003a, and May et al., 2003b.

institutional terrain. It is thought that barriers to incorporation are rooted in the changes that it necessarily brings to the dynamics of roles, professional relationships and in how clinical activity is organized.

These considerations and the ones gleaned from surveys conducted on health professionals[92] have given rise to certain recommendations that, when followed, facilitate the process of implementing eHealth projects.

The first recommendation is to establish a three-way dialogue between designers, implementers and the professionals who will be the end-users, so as to appropriately relate the new practices to the existing practices and help end-users perform the tasks defined. Relationships of trust must be generated in order to be able to deal with the difficulties that arise upon operationalizing the system.

The second recommendation is to deliver a well-reasoned justification for introducing the eHealth system, in terms of the benefits it will bring to health professionals and patients. This is to generate acceptance of and willingness to use the system. There must be confidence that the system will have benefits for professionals and patients and such benefits should be easy to perceive.

Thirdly, a balance must be reached between necessary standardization and the needs of individuals. If such a balance is reached through consensus, there will be greater support by professionals for the system.

A fourth suggestion is to establish a long-term education system that covers awareness of the system's benefits and its limitations, and also how to obtain maximum benefits. This of course is in addition to instructions on how the system works.

Finally, a fifth recommendation is to clearly convey the security measures in place in terms of handling information and of operational continuity. Failures in eHealth systems can be a matter of life and death, as these systems are closely related to people's health. Doctors –aware of the risk factor of their profession– are understandably unwilling to tolerate failures in the system. They must be convinced that the system is secure. Since health data is considered highly sensitive, information security must be given even higher priority here than in other spheres.

Interest in identifying areas of potential difficulty in the implementation of eHealth projects has given rise to a multifaceted tool that can have considerable practical value. Foreseeing possible problem situations represents an opportunity to design and put into effect strategies to overcome or mitigate barriers to project realization[93].

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[92] See Mair et al. (2009), specifically Chapter 4, *Barriers and Facilitators to the Implementation of EHealth Services: The Perspective of Health Professionals.* SDO Project (08/1602/135).

[93] Mair et al. (2009), Appendix 29 WP4 Print-out of the e-HIT. SDO Project (08/1602/135).

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Chapter XVIII

Infrastructure and basic requirements of electronic health systems

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Summary

This chapter analyzes the various basic needs related to the implementation and maintenance of electronic health systems, with special focus on the infrastructure that supports these systems. This infrastructure comprises a number of elements that can be classified into three large groups: software, hardware and the communications network. Our examination of each of these groups will include descriptions of the different kinds of tools available (application and system software, hardware devices, etc). Attention will also be given to information system network architectures, where the role played by the data processing center, or DPC, is especially significant. Given its importance, the DPC must comply with a number of requirements, including various security measures and physical site preparations.

Finally, there will be a brief overview of several key issues, recommendations and best practices related to different specific aspects of managing the basic needs of electronic health systems. These include work teams, the adoption of standards and established work methods, alternatives to the traditional ways of managing projects and contracting services, infrastructure purchases and employee training.

To help readers grasp the content, an analogy is drawn between an information system and a house. Throughout the chapter, we will point out parallels between the components of both, so that the reader can extrapolate the needs described for one particularly technical environment to another that may be more familiar.

Introduction

In the world of Information Technology (IT), like other fields, it is necessary to combine a number of different elements so as to build instruments that enable specific tasks to be performed. This can lead to a certain amount of confusion for people who have limited knowledge in the area, making it difficult to clearly distinguish between one component and another.

The most important item among these instruments is the software, which is comprised of a group of computer programs. A computer program can be defined as an ordered and structured set of specific instructions that, when executed, make it possible to carry out one or more tasks on a computer (Stair, 2001). Software is thus the logical component of a computer – intangible yet essential for its functioning. Computer programs can be classified as follows:

— Application software: a kind of computer program expressly designed for performing specific tasks related to the activity of the user (word processors, spreadsheets, video and audio players, etc.). This is the type of software with which the user directly interacts. Such software encompasses the different electronic health systems.

— System software: a set of programs that are needed for controlling a computer. Such programs supervise interactive processes between a user and the computer, and between computer components – allowing for the proper execution of application software. Different types of system software include the following

  o *Operating system:* a program that manages the basic functioning of a computer, enabling the other applications to function with the computer hardware. The best known examples of operating systems are Microsoft Windows®, Mac OS® and Unix/Linux (Silberschatz, 2009).

  o *Database manager:* specific program (or set of programs) used for the structured recording, storage and processing of data, irrespective of the physical storage methods used and of the operating procedures of the applications that use this data.

  o *Utility software:* a program that carries out maintenance and control operations related to the status of the computer (installation of software updates, device configurations, etc.).

  o *Programming environment:* a specific tool (or set of tools) for writing computer programs through the use of programming languages, which themselves are artificial languages expressly created for encoding very specific instructions (Java, C#, etc.). J2EE® and .NET® are currently the most commonly used environments.

Software is an intangible element that requires a second, purely physical item to support its operation. This second item is a computer's hardware, a set of physical devices (microprocessor, memory, disk drives, monitor, keyboard, printer, etc.). The composition and features of these devices can vary according to the needs of the system.

In recent years, the need to work in a collaborative environment has led to the inclusion of a third item – the communications network. This network makes it possible to connect different computers and involves the addition of physical channels between the different points comprising that network. It also calls for the installation of specific software and hardware for managing communication. A communications network thus makes it possible to share information and resources between computers, forming what is known as a *computer network.*

It should be stressed that behind the creation and use of every computer application lies a human act. Thus, that application's effectiveness and efficiency in meeting a user's needs will depend on the quality with which it has been designed and built, along with its proper use and maintenance. In order to illustrate this fact, an analogy is drawn between a computer application and a house. This analogy will be used repeatedly throughout this chapter to make it easier to understand its content. Table XVIII.1 sets forth the different examples used.

| Table XVIII.1. House – computer application analogy (Source: Compiled by authors). ||
House	Computer application
Owner and residents	Users
General features: location, usable area, height, layout, number of rooms, orientation, elevator, parking space, etc.	Functional requirements defined by users
Built by owner / Purchased from a developer	Developed in-house / Contracted from a supplier
Blueprints and building specifications	Design (functional and technical specifications)
Cabin in the countryside	Isolated application
Housing developments and apartment buildings	Network applications
Services and essential supplies (electricity, water, gas, etc.)	Data network
Administrator of the association of neighbors in the same housing development.	Central server
Neighbors in the same housing development	Clients (user sites)
Materials	Source code and hardware equipment
Furniture and fittings	Data
Foundation and structure	System software (operating system, database manager, etc.)
Building styles (brick, stone, etc.)	Technological platform (programming environments, type of database manager, etc.)
Keys, alarm system, etc.	Security measures
Boiler room, control panels, etc.	DPC – data processing center
Legal and technical documents pertaining to the house	Regulations and standards, technical documents, user's manual, etc.
Technical inspections	Tests and audits
Labor	Work and maintenance teams

Architecture of a computer application

As with any kind of tool, a computer application must perform a function that meets the needs of the person using it. As such, the first thing that must be clearly defined before taking on this kind of project is the scope of the system, i.e., the set of functions it must have. These are commonly referred to as the user requirements. When a person wants to build a house or apartment, that person's needs as a resident or owner are the primary factors determining the features of that dwelling – its geographic location, is usable area, height, number of rooms, layout, orientation, the availability of an elevator or parking space, etc. Other highly important factors are the available time period and budget for construction. Finally, that person may choose to be in charge of building the house, or to purchase it from a professional builder or developer. With software, this coincides with deciding between developing the software in-house or contracting it out to a specialized software developer. Both methods can be acceptable, but the first requires a greater investment of the organization's resources.

In either case, once the application requirements have been determined, the design process begins. This process involves high-level descriptions of how each functional requirement is to be articulated, and what technological tools will be used for this. This design results in a set of functional and technical specifications commonly known as software architecture. Similar to the blueprints and building specifications of a housing unit, software architecture details the functioning model of the application, along with its structure, the technological platform to be used, the hardware needed, etc.

An important issue when designing an application is to distinguish whether it will function in isolation or in a network, i.e., if it must operate from a single point or from various (Hennessy, 2003). A very common example of an isolated application is a word processor. On the other hand, almost all electronic health applications operate in a network, allowing information to be shared by, and made

available to, all users. In other words, an isolated application is like a rural cabin, while an application functioning in a network is akin to a housing development or apartment building with common areas. Moreover, this comparison clearly illustrates the fact that an isolated application/cabin must meet the particular needs of a single user, while a network-based application/housing development must, as far as possible, meet the general needs of a group of users/neighbors – reconciling their particular needs. A data network is comparable to the network of services and basic supplies of a home (electricity, water, gas, etc.), to the point that its size depends on the required traffic/supply.

The fact that an application operates in a network greatly influences its software architecture and, in turn, the hardware and communications equipment with which the system will function. The first necessity is a logic element known as a server, which centralizes the different network management tasks and assures the proper functioning of the application at each node, called clients (in the house example, a server can be compared to the administrator of the association of neighbors in the same housing development, while the clients would be the neighbors themselves). Originally, the modest performance of communications networks made it necessary to limit the traffic flowing through them. This was done by installing one part of the computer application software in the server, and another part in the client. Technological progress since then means that it is currently possible to install the entire logic structure in the server, minimizing the software needed in each client. This has reached the point where such communications can be done simply with the browsing programs that have been factory-installed in computers for years. This new architecture is called a web client (or a light or thin client), while that described previously is usually called a server client (or fat or thick client). Both are network-based architectures, with each having its advantages and disadvantages. The web client greatly simplifies node maintenance tasks (such as application updates) since the software is centralized in the server. Its efficiency, however, is more sensitive to the amount of traffic on the network. There are also some pure, light client architectures that make it possible to use the application while storing all the information in the server, such that the hardware of the client requires nothing more than a simple replacement in the case of failure, with no security problems in the case of theft or loss.

Infrastructure

As explained in the introduction, a computer application is supported by three basic elements: software, hardware and communications.

Software

Here we must clearly distinguish between the source code –comprising the instructions that completely define the functioning (or business logic) of the computer program– and the data with which that program operates. In a house, the source code would correspond, along with the hardware, to the building materials (brick, plaster, paint, etc.), while the data would be the resident's furniture and appliances. Both can be changed, but it is more common, and easier, to replace the furniture than to change the structure of the home.

Separating the business logic from the data is the basis for layered programming. This has the advantage of dividing the development of the computer application into various independent levels. In this way, if a change is made, only the affected level or levels have to be modified, avoiding the need to revise the entire application. The most widely used model has three layers:

— Presentation or user layer: also known as the graphic interface, this is the layer that enables the user to communicate with the application and to consult or enter information into the system. Given its nature, the use of this layer must be as simple and intuitive as possible for the user. Thus, the appropriate design of the different windows is highly important.

— Business logic layer: this layer contains all the rules and instructions governing the operations of the application. It is responsible for receiving all user requests, retrieving and recording information and displaying the results. For this reason, the business logic layer must be located between the presentation and data layers.

— Data layer: this layer handles the storage of data according to a predefined structure, and manages access to that data, working from requests issued by the business logic layer. An important part of this layer is the database, which could informally be defined as a set of structured and interrelated files that store and classify all the data that an application uses during its operations. Of course, the more specific and detailed this classification is, the more complex the database structure will be. This will require more effort in order to use it, yet at the same time it will offer greater possibilities for use. Databases are so important that specific software has been developed for managing them. Together with the abovementioned operating systems, database managers are the most important types of system software. They are needed for the proper functioning of the applications of the hardware in which they are installed. This system software could be said to coincide with the foundation and structure of a home.

Finally, the source code as well as databases are conditioned, respectively, by the programming environment and database manager chosen for creating the application. Here one more analogy can be drawn, which likens this technological platform to the building styles in which houses are constructed (brick or stone façade, classic or modern aesthetic, etc.).

Hardware

Logically, hardware architecture is always conditioned by the architecture of the software it must support, to the extent that it repeats the distinction between servers and clients. Hardware clients include a wide range of equipment, including desktop computers, laptop computers, mobile devices, etc. A hardware server is a high-performance device, the features of which (processing capacity, robustness, etc.) always depend on the software that it hosts. For example, an application with one hundred simultaneous users requires a server with higher processing capacity than an application having only ten users. Moreover, an application that must run without interruption, such as an electronic health system, calls for a server that can handle such a heavy load of activity.

Although a server can host several applications, usually those that are the most important for an organization are each installed in a different server – known as a dedicated server. It is worth noting here that a database manager behaves like any other application and therefore needs its own dedicated server. It is also possible to increase the performance of a system through the installation of various servers for the same application, in such a way that the activity load is shared more or less equally between them (high performance cluster configuration) or in such a way that, should one of the servers fail, its tasks are assumed and continued by the others (high availability cluster configuration).

One interesting option when implementing these configurations is server virtualization, a process that allows for the creation of a number of logical servers with the same physical server. Such virtualization makes it possible to reduce the number of physical servers while making the best possible use of them (Singh, 2004).

Communications

Obviously, the functioning of network-based architectures relies on the availability of a communications infrastructure that makes it possible to establish the necessary connections between the

different nodes. This infrastructure is usually divided into two types, depending on whether it is located inside or outside an organization's facilities:

— Internal: each organizational center must have its own network based on guided media (cable or fiber optic), making it possible to connect the different work stations. This connection can, in turn, be one of two kinds – fixed or wireless, depending on whether the client connects directly via cable or through radio waves that communicate with an access point to the fixed network. It is evident, though, that a wireless connection does not eliminate the need for a cable network, except in the last segment of the client's part of the system.

— External: the connection between different centers of an organization requires physical communication channels. Due to their nature, such channels do not usually belong to the organization, but are contracted from telecommunications operators. This gives rise to what is known as a virtual private network, named as such because it offers the same services as an in-house network, although they are not completely the same, given that this network has been implemented making use of an outside infrastructure.

An organization's entire network infrastructure, comprised of the internal communications network and the group of private virtual networks, is known as an intranet.

In order to have a well-functioning network, an organization must draw up a communications plan that specifies its features in detail. For example, each network link must be sized according to the traffic it is to handle (keep in mind the comparison with a home's electricity supply or the plumbing and piping for water and gas). With critical connections, the network should have redundant links installed over physically independent paths whenever possible, in order to increase its resistance to failures. The plan should also include mechanisms for the expansion of this infrastructure, which will depend on the predictions regarding increase in demand (increase in users of the current centers, opening of new centers, etc.).

Data Processing Center (DPC)

Software, hardware and communications come together in an important way in what are known as data processing centers (DPC). A DPC brings together all the devices needed for the centralized management of a group of corporate computer applications (application servers, database servers, centralized data storage units, communications systems, etc.). It assures, to the extent possible, continual access for users. Physical protection of the equipment in this environment is essential, since it is of vital importance to an organization's operations. Accordingly, a DPC must have.

— Environmental conditioning measures: air conditioning and ventilation systems, fire protection system, adequate and redundant power supply (uninterruptible power source, or UPS), generator sets, etc.

— Security measures: physical control over access points, backup copy system, antivirus software and protection against unauthorized access through the data network (access registry, monitoring software, firewall, etc.). In a house, such measures could be compared to keys, alarm systems, etc.

The DPC is a highly important factor in the proper functioning of any organization's corporate information system, much in the same way as a machinery room (electricity and water controls, boilers, elevators, etc.) is for a building. For this reason, it is a good idea (although not habitually practiced) to have a backup DPC, one that allows the system to continue providing critical services should the main DPC fail. Such a backup DPC should be located at a reasonable distance from the main center. Given that it is only to be used occasionally, the infrastructure of this DPC should of course be less elaborate than the primary center. One interesting idea would be for public health services to reach an agreement with another governmental body for the cross-hosting of two backup DPCs. For example, a hospital

could host a backup DPC for civil protection services, and vice versa. Figure XVIII.1 shows an example of a corporate intranet, with all the elements described above.

Figure XVIII.1. General framework of an intranet hardware and communications infrastructure.
(Source: Compiled by authors)
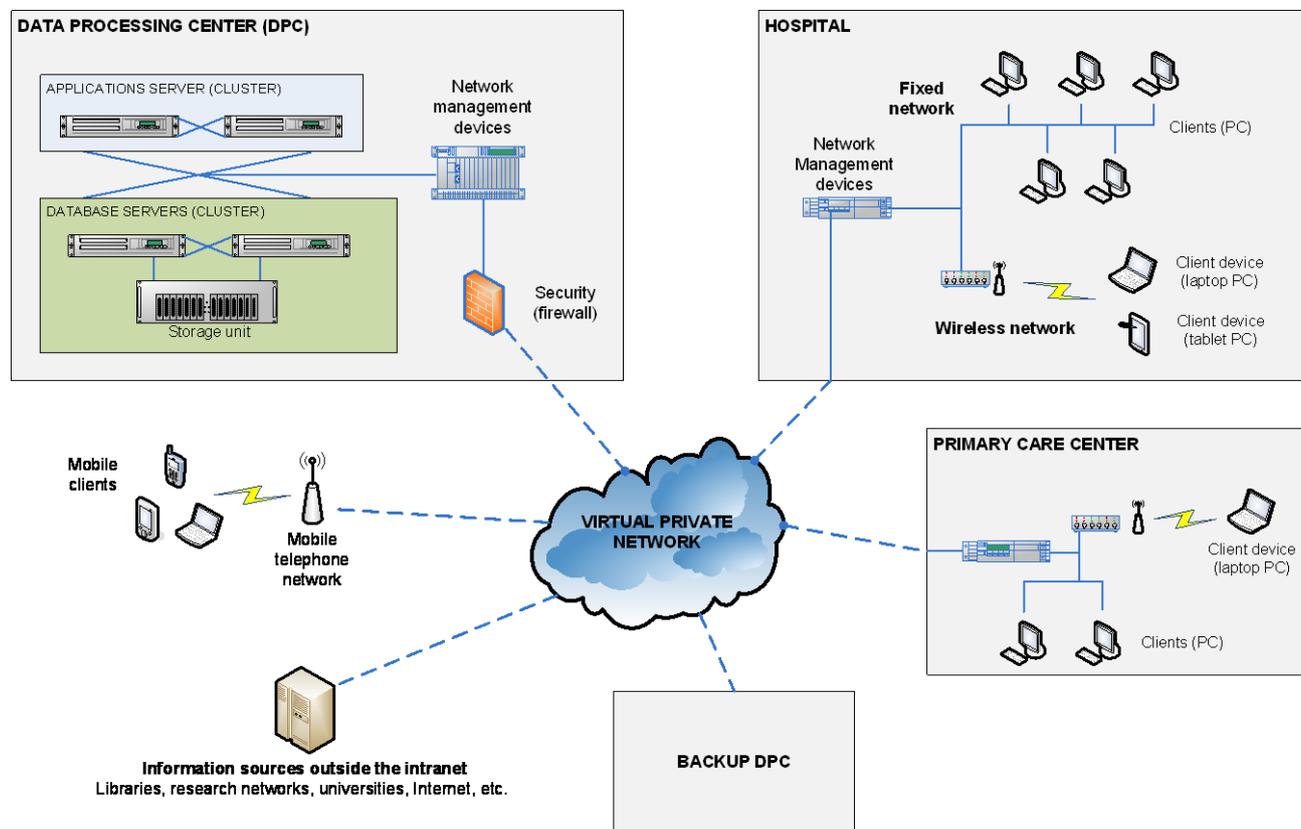
Key points, recommendations and best practices

As can be seen from the descriptions above, the creation of computer applications is quite a complex process that requires a certain amount of basic infrastructure, among other items. In the electronic health sector, this inherent complexity is augmented by the complexity of the health organizations themselves, given that their healthcare activities can often be critically important. The capacity of this system must be appropriately managed in order to assure that it meets the organization's present and future needs, and that this will continue into the future at a reasonable and affordable cost. Obviously, good resource management is the cornerstone for effectively managing a system's capacity. This section will look at a number of important points to consider when carrying out this type of project.

Work teams

The first area that is vital for success is the creation of stable work teams that include professionals of all profiles, assigning them clear roles and responsibilities:

— Clinicians, to provide project leadership, determine the requirements and specifications, carry out validation tests, and to monitor the use and growth of the systems.

— Technicians, to design the software (programmers and analysts), install the hardware (experts in IT and microcomputing infrastructure), and for the general deployment and maintenance of the system.

— Project managers, experts in the general coordination of projects, and especially of work teams.

— Executives**,** to make decisions.

— Professionals from outside the organization: suppliers (software development, hardware supply, assistance in implementation and deployment, support and maintenance, health technology, etc.).

These work teams can easily be extrapolated to the house analogy. The construction of a home involves the residents (clinicians), masons (technicians), architects (project managers), developers (executives) and different kinds of tradesmen (outside professionals).

Following standards and established work methods

Common and agreed-upon work methods must be established in order to meet the objectives that have been set, and comply with the prevailing legislation regarding healthcare, data protection, risk prevention, etc. Similar to the situation with a home, these projects are influenced by a number of laws involving the handling of legal documents and the performance of technical tests and inspections.

Going beyond simple compliance with the laws[94], which is of course not subject to debate, there are a number of voluntary standards for the application of best practices. All of these standards include various levels of compliance certification, making it easier to adapt them to the particular needs of the organization planning to implement them:

— The CMMI® (Capability Maturity Model Integration) stands out in the software development field. The CMMI® is a model for the implementation, evaluation and continual improvement of processes for the development, maintenance and operation of computer applications (Chrissis, 2011).

   However, with small and medium sized projects having demanding lead times, or ones that are applied to rapidly changing environments, traditional strategies for managing development projects have proven to be ineffective (Chin, 2004). One of today's most popular working frameworks for such cases is called agile software development, which has the goal of reducing software development lead times without affecting the quality of the final product. This method divides the project into a number of iterations, such that each takes its starting point from the results of the earlier, previously validated step, then adds a few new functions to the system. Each iteration should last only a short period (usually from one to four weeks) and be treated as if it were a development project in itself – thus including all strictly applied steps and tasks, including an analysis of requirements, design, programming, testing, project plan, documentation, validation, etc.

— The ITIL® (Information Technology Infrastructure Library) is a standard that can be followed for the comprehensive management of services based on computer technologies (Cartlidge, 2007). This method is especially useful for the management of information system operations and maintenance processes.

— DPCs have historically been managed without the use of standards, but in 2005 the American Telecommunications Industry Association (TIA) published the TIA-942 standard, which includes a section on the location of a DPC, the physical arrangement of its components, the wiring installation, reliability levels and a number of environmental requirements (ADC Telecommunications Inc., 2006).

Besides these environments, one must keep in mind the environment of the health technology. Such environments represent an important data source for electronic health systems but they also tend to pose greater problems in terms of standardization. It is highly important to verify the compatibility of radiological, electromedical, surgical, etc. equipment. Although there are no mandatory standards in the

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[94] The chapter on information security includes a section on the legal framework for information management in healthcare services.

sector, the HL7 is often used for the exchange of textual information, while the DICOM is employed for the recording of medical images.

Some alternatives to traditional management and contracting models

Healthcare services –whether public or private– almost exclusively use traditional forms of contracting that are based on a classic customer-supplier formula. Some electronic health projects, however, are considered to be in the area of R&D. When this is the case, collaboration frameworks can be formed between public and private entities in which both parties make investments. Moreover, these investments can be complemented with funds from public subsidy programs. In this type of set-up the healthcare service and IT companies share costs, risks and benefits, cutting down considerably on the competing interests that tend to characterize the traditional customer-supplier relation.

When dealing with electronic health systems of a general nature, one alternative to the traditional models of computer application development is cloud computing, which is based on the concept of Software as a Service, or SaaS. In cloud computing, a supplier offers comprehensive software management and maintenance services that allow the software to be accessed from any computer with an internet connection (Buyya, 2011). Here the supplier is entirely responsible for hosting the source code and data. One simple example of such a service includes public email servers (Gmail®, Hotmail®, Yahoo®, etc.) as well as blog servers (Blogspot®, Wordpress®, etc.). The main advantage of this model is lower costs, since it bypasses the need for specific infrastructure, with costs limited to consumption of the service (although some of these services are free, such as those mentioned above). The main disadvantages include the fact that data is stored at an external entity (with all that this situation implies for information security), and the impossibility of modifying the program code – something that could greatly restrict its use by healthcare services.

Planning infrastructure purchases

Given their vital importance for system functioning, IT infrastructure purchases must be well planned. This is even more important considering the large investment involved.

The first step is to clearly lay out the scope of the budget to be allocated to the IT section, keeping in mind that an organization's hardware, software and communications infrastructure is to be shared and is not for the exclusive use of technical services. People often think that an electronic health system is solely an issue for IT departments but in truth, it is the system's users who should have the most responsibility (and the greatest interest) in the creating, implementing and improving that system. This does not rule out the important participation of IT services as specialized consultants, who can help healthcare professionals find solutions to their needs. Keeping this premise in mind, it is logical for the IT services budget to include line items for the development, maintenance and growth of electronic health systems, given that IT technicians are their most appropriate managers.

It is also highly important to make sure that each system component is obtained from a specialized supplier, with independent contracting for each item if necessary. Purchasing an entire system from the same supplier may simplify the initial steps and procedures, but it can negatively affect the quality of the final results, given that almost no suppliers have expertise in all three facets (software, hardware and communications). In fact, a house is never built by a single professional. Rather, the work is divided among different specialized professionals: a mason will take care of the foundation and basic structure, a carpenter will handle the carpentry, a plumber will do the plumbing, a painter will put the finishing touches on the walls and ceilings, etc.

Also necessary is a detailed analysis of the performance features of the components offered by each supplier. This analysis should include the following:

— Verifying the compatibility of these components with the equipment already in use at the organization.

— Checking the projected useful life of the component, taking into consideration the component's expansion and growth possibilities. This is to ensure that it will continue to be useful for as long as is reasonably possible, and to confirm that the technological basis of components is up to date, in order to avoid the purchase of products that have been discontinued – or which will be soon, before they have been amortized.

— Evaluating the different contracting options, when more than one option is available. For example, certain devices may be leased, which offers certain advantages for replacement in case of failure or amortization.

— Clearly establishing the scope of the contracted services. In the case of software, for example, the product licensing terms should be made very clear, along with the ownership of the source code resulting from the software development, the terms covering user training, whether or not application upgrades are included, etc.

— Including support and maintenance services, clearly determining their scope and validity periods. If possible, renewal terms should be preestablished.

— Evaluating the level of dependence on a supplier which could influence these purchases. At times such dependence is inevitable, such as, for example, with the installation of system software.

Finally, those with decision making responsibilities should be particularly aware of some specific issues concerning the planning of IT infrastructures:

— Planning should always be oriented towards the medium term. In this way a balanced solution can be reached between two opposite risks. On the one hand, short-term decisions may lead to the saturation of existing resources that can slow down or stop the system (data storage capacity is a good example of this). On the other hand, long-term planning can lead to the mistake of purchasing an oversized infrastructure, one that may be expensive and then become antiquated before it has been completely amortized, since ongoing advances in base technology result in the rapid and progressive appearance of greater performance features and ever-lower prices. Medium-term planning can also include intermediate milestones that make it possible to evaluate compliance with the main objectives, detect deviation and apply any corrective measures that may be needed.

— All infrastructure has a finite useful life, so each year the plan must include a section to cover the replacement of amortized or antiquated equipment, or the expansion or adaptation of same in order to prolong its useful life (if that option is economically viable for the organization). In addition, before proceeding with the definitive removal of a device, all sensitive information it may contain must be deleted.

— The implementation of new systems –and upgrading of those already installed– calls for three different software and hardware infrastructures for each system. These are commonly referred to as environments, which comprise, at minimum, application servers and data groups:

  o *Development environment*, where different programming tasks are carried out for the construction of prototypes for new functions and applications. These tasks are done in a controlled manner that is isolated from the systems the users employ in their daily activities.

  o *Preproduction environment*, where groups of tests are carried out in order to verify the proper functioning of new software. For these tests to be effective, the environment must contain either real data or fictional data. In the case of the former, the same security measures as those applied in the production environment must be followed. If fictional data is used, there is no need to follow such security measures – but the data must be sufficiently similar to the

real data. In this way, the tests will produce meaningful results, and they will be carried out in a controlled way that does not interfere with users' daily activity or with any concurrent activity related to the development of new functions and applications.

o *Production or use environment*, which hosts the final system that users will work with, using real data only.

Processes that involve the migration of software between these environments (from development to preproduction to production) must be carefully planned and executed so as to minimize their impact on care activity, because they usually require system shutdown and rebooting.

Training

Just as in other professional sectors, the training of the organization's employees is a fundamental element of electronic health projects, especially considering the rapid progress in information technologies and the continual updating efforts that this entails. This training must include such diverse themes as project management methods, standards and even the laws under which healthcare institutions must operate. It is also useful to plan initial training as well as refresher courses. The first should be offered when the new systems are introduced, and also when new employees are hired. The second can be used to update employee knowledge as well as to teach them how to handle the new functions that may appear as the systems evolve.

With IT services personnel, we recommend planning two different training levels:

— Advanced training in frequently used features, such as basic systems administration, user management, dealing with minor incidents, etc.

— Basic training in infrequently used features, especially in tasks that require the participation of specialists from outside the organization, to permit adequate monitoring of the actions of these external specialists, which may include: administration of database managers, periodic maintenance reviews, changes due to progress in the software market, etc.

Another interesting idea is to occasionally organize basic cross-training activities. This would provide training in healthcare management to IT professionals, and training in IT management to healthcare professionals and health service managers. This can help narrow the gap that exists between the different professions, thereby strengthening their collaboration in electronic health projects. Some university study programs already include the possibility of doing a residency in medical informatics and university engineering departments frequently participate in projects related to electronic health. Such initiatives, however, usually lack continuity and there are rarely equivalent practices in programs aimed at professional development within the health services.

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Chapter XIX

A use case: The corporate electronic health project in the Chartered Community of Navarre

José Manuel Vázquez

Introduction

Previous chapters have examined the various specific electronic health systems and the relationships existing between them, emphasizing that they are not isolated entities but rather the elements of a single, macro information system. Therefore, the implementation of electronic health requires that great coordination and integration efforts be made while these elements are under development.

To illustrate the dimensions and complexity of an electronic health project, in terms of both resources and execution periods, this chapter describes the project undertaken by the public healthcare service in the region of Navarre, Spain, which began in the 1980s and continues to this day.

Scenario

Navarre is one of Spain's 17 autonomous communities. It has a population of approximately 620,000 inhabitants and an area of slightly over 10,000 square kilometers. The public body in charge of providing healthcare is the *Servicio Navarro de Salud - Osasunbidea* (Navarre Health Service), which in order to fulfill its mission has a care network comprised of the following:

— 1 hospital complex (consisting of 3 hospitals and 3 specialized ambulatory care facilities located on the same site)

— 2 hospitals

— 2 specialized ambulatory care facilities

— 57 health centers (primary care)

— 242 local health centers (primary care facilities that are smaller than health centers)

— 16 women's health centers

— 8 mental health centers

These healthcare facilities are distributed all over the territory, although most of the population is concentrated in the capital city –Pamplona, where about half of the region's inhabitants live– and in the areas of Tudela and Estella. The map appearing in Figure XIX.1 shows the location of the different care facilities, and also the density of the population in the various Basic Health Zones (administrative division used by Spain's regional health services). Greater population density is indicated by a darker shade.

Communications network infrastructure

One of the project's primary requisites is the interconnection of all points on the care network. The Navarre Health Service is supported by a communications platform of the Regional Government of Navarre, which supports communications protocols of different bandwidths (10 Gigabit Ethernet, Gigabit Ethernet, Ethernet, WiMAX, Frame Relay and ADSL) using guided media (fiber optics and copper cabling) and unguided media (radio links), combining its own infrastructure with another that is rented from an operator. In this way, all the healthcare facilities are connected to the same network (with the exception of 22 local health centers located in areas with very little telecommunications coverage and which all together serve less than 1% of the population).

Figure XIX.1. Network of care facilities in the Navarre Health Service (Source: Compiled by author).
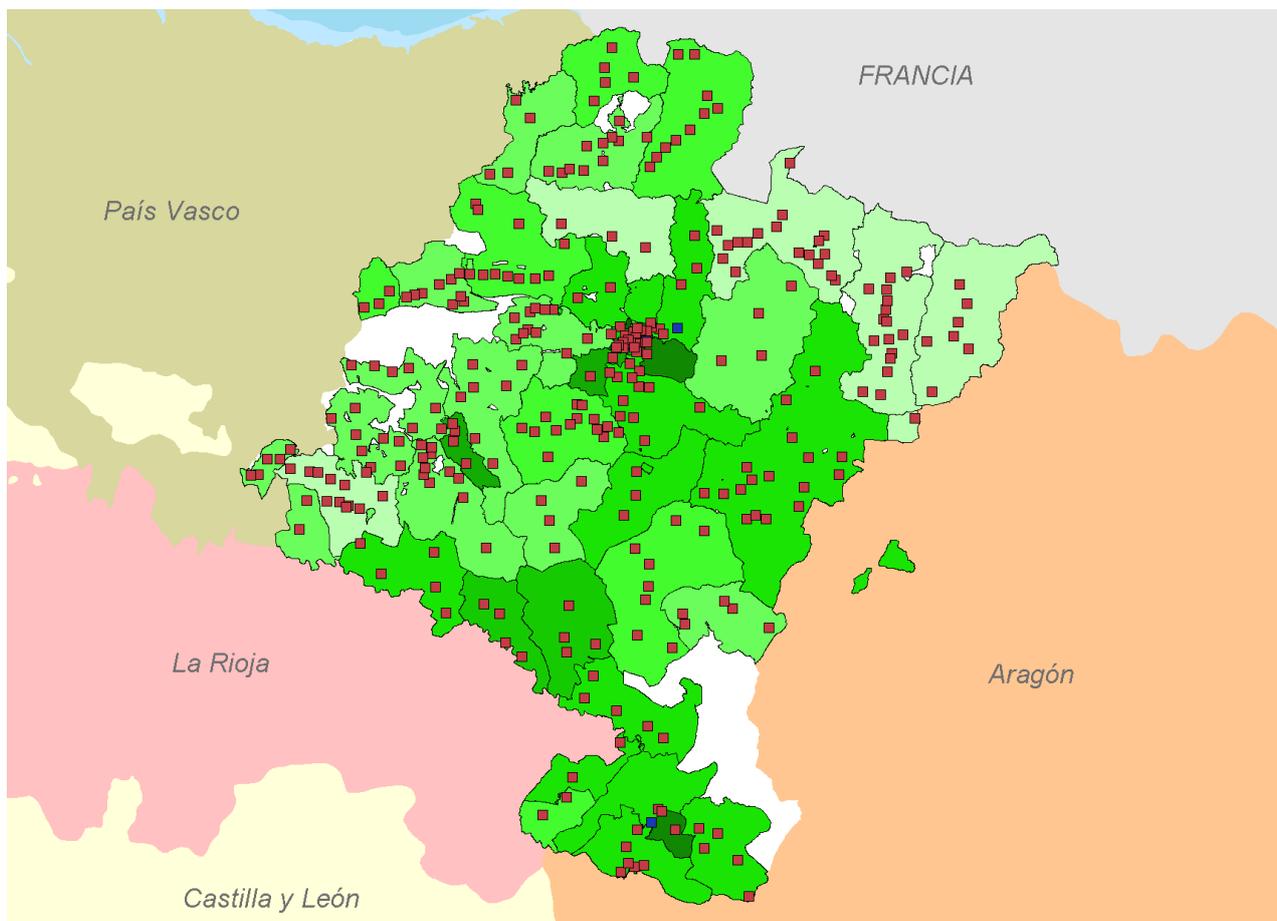
Health information systems

Early health information systems were developed and introduced as isolated information entities, in that they were custom-developed applications or were proprietary commercial applications, each one focused exclusively on its functional area (admissions, appointment management, pharmacy, laboratories, etc.) or on its geographical area (a particular hospital or service, etc.) This approach is indicative of the organizational scheme in use at the time: communication between different health professionals was very limited, to the point that paper-based health records were maintained separately by each different service, so it was difficult to conceive of a corporate computer system that would permit collaboration through networks.

Since then, the structure of health systems has changed significantly, with the appearance of the primary care level –and the need to coordinate this level with that of specialized care–, of multi-disciplinary units, of the outsourcing of some services, and of home hospital care. In this new arrangement it is important to be able to access all patient information quickly and easily. In addition, health technologies are advancing at such a rapid rate that it is difficult for health organizations to keep up (organizations generally dedicate only limited resources to the integration of these technologies into existing information systems, or to the systems themselves). In fact, at this time all diagnostic or therapeutic equipment necessarily includes a computer system or a communications interface so that, once it is functioning, it can interoperate with the other systems in the organization.

Patient identification

For the various health information systems to be interoperable, a system for positive patient identification is vital, since the single identifier used in such a system is the only data item that enables all of a person's information (both clinical and administrative) to be linked and accessible even if it is distributed throughout different points of the care network. For this reason it is crucial that the databases storing patient identifiers have high levels of data quality.

The processes that affect the quality of this information are the addition of new individuals to the network and modification of patient data, actions that can be carried out at any of the following points in the care network:

— The Admissions Service of a hospital, where the addition of new patients or modification of patient data is entered in the specialized care database, of which there is only one for the entire autonomous community. The identifier used is known as the Specialized Care Clinical Record Number.

— The Admissions Service of a primary care center, in which case the addition of new patients or modification of patient data is entered in the database of the Basic Health Zone. Navarre currently has 56 Basic Health Zones, so there are 56 different databases. The identifier used in this case is called the Basic Health Zone Clinical Record Number. It is important to point out that a patient can have only one identifier of this type active at any given time, since in the event of a change in residence all patient information is automatically sent from the original Basic Health Zone to the new one.

— The Health Card Office, in which case changes are entered in the Health Card database. The identifier assigned is known as the Personal Identification Code of Navarre (CIPNA).

To ensure the quality and consistency of the information contained in these different databases, a synchronization procedure was developed. The procedure is based on the fact that the Health Card database prevails over the others and that the CIPNA is used as the link between the different identifiers of the same patient. The addition of new patients or modification of patient data (with the exception of changes of address and of assigned doctor) are actually proposals that must be validated by the Health Card Office.

This *modus operandi* is the result of the fact that the quality of the information added to the database varies according to the point at which it is entered. In care facilities caring for patients takes highest priority, and the entry of data into the system is usually done quickly. It is therefore more likely for the data to contain errors. On the other hand, the Health Card Office does not perform any care activity but rather has the specific mission of maintaining the quality of the information contained in patient databases. For this reason, the Health Card database prevails over the others and propagates the

changes made in it to the others. Although individuals with no CIPNA do appear in the databases, it is a tiny percentage and this situation is mostly related to deceased persons or persons who have had minimal contact with the public health system of Navarre.

Moreover, the Health Card database is synchronized with its counterpart in the National Health System of Spain, so as to guarantee the correct identification of patients all over Spain.

The main difficulty encountered in implementing this procedure was the management of change, beginning with the need to assign data ownership to the organization's different units (i.e., deciding who is responsible for the governance of the different types of data). For example, the Health Card Office is responsible for the personal data of patients, with the exception of the patient's address and assigned doctor, which are the responsibility of the primary care services. Changes in organizational culture also had to occur at each point in the network:

— The Admissions Services at hospitals had to assume responsibility for assigning a Specialized Care Clinical Record Number to each newborn baby.

— The professionals working at primary care centers had to be made aware of the vital importance of correctly identifying patients, since these facilities are the most frequent initial point of contact between patients and the health system, a situation which has significant repercussions on the rest of the system.

— The Health Card Office, which was the unit in charge of the management of individuals entitled to healthcare by the Navarre Health Service, had to also assume responsibility for the management of all persons receiving care by this Service.

Electronic health records

During the care process, the traditional method of recording information regarding the actions taken has been to write it on printed forms, which along with other documents and objects such as X-ray plates, comprise what is known as the *patient clinical record*. This method makes it difficult for the clinical information to be available when and where it is needed, since it is not possible for various professionals to access it immediately and concurrently. Furthermore, the use of paper as a support and the way that such documentation is transported entail great risks in terms of confidentiality and security.

As a response to this situation, the Electronic Health Record (EHR) system for the Navarre Health Service was developed. It consists of three integrated components:

— The computerized clinical record application used in specialized care (HCI).

— The computerized clinical record application used in primary care (Atenea/OMI).

— The application used to manage nursing activity in specialized care (Irati).

The integration of these three applications makes it possible to access –from any of them– the patient information stored in the other two, regardless of the geographical location of the professional making the consultation. This consultation is possible, as explained above, thanks to the patient identification mechanisms based on the synchronization of the various databases. In fact, the HCI and Irati use the same identifier, the clinical record number used at the specialized care level.

The following are some of the functions available to professionals thanks to such integration:

— Requests for diagnostic support can easily be sent from primary to specialized care, and ordering physicians are automatically informed of the arrival of results as soon as they become available.

— There is a single registry of patient allergies, which is shared by the HCI and Irati.

— Medical orders made to the HCI are automatically entered into the Irati nursing care plan.

Although Irati is still in the expansion phase, 100% of the professionals of the Navarre Health Service and some the private centers associated with it have access to HCI and to Atenea/OMI, and most of them have received training in how to use them. As regards the degree of effective use, it varies from area to area. Practically 100% of the primary care services use Atenea/OMI, and the figure is the same for the nursing units that have Irati, so the use of paper in these settings is practically non-existent. However, in specialized care about 60% of clinicians directly enter hospital discharge information and information from appointments with specialists into the HCI, while in the remaining cases this information is entered by administrative staff following the dictations by clinicians. It should be noted that all of these reports are finally added to the HCI, and the percentage of professionals that personally enter the data into the system is on the rise, which demonstrates the added value of the HCI.

Despite these advances, paper is still widely used in hospitals, mainly for three reasons:

— There are some healthcare systems and equipment that are not yet integrated into the HCI, such as electrocardiograms, for example.

— There are some professionals who do not yet use eHealth systems.

— There is still a large amount of information stored on paper, in documentation generated before the EHR system was introduced (information dating from before 2000). To solve this problem these documents are in the process of being scanned and made accessible through an explorer integrated into the HCI. Currently, the clinical records available in scanned form are those of deceased patients and of patients who have not visited specialized care facilities in over four years. In the event that the latter require medical care, efforts are made to avoid the generation of new paper documentation, but if that is not possible, the new documentation is scanned. The scanning project does not bring about any reduction of physical storage space, since for legal reasons the paper documentation cannot be destroyed, but it does free up the resources previously needed for transportation.

Digital medical imaging

The incorporation of digital medical imaging systems leads to the phasing out of traditional X-ray plates, and this brings a radical change to the procedures used for performing and evaluating radiographic exams. This transformation is also one of the most significant factors in the development of electronic health records, since the use of digital images promotes the digitalization of a number of related elements: medical orders, appointments, reports, etc.

The digital medical imaging project was begun with several objectives in mind:

— To reduce risk to patients, by minimizing their exposure to radiation.

— To increase the availability and accessibility of diagnostic images.

— To eliminate the use of toxic material, such as developing fluids and the plates themselves.

— To reduce operational costs, by eliminating the need to print X-ray plates.

To this end, an RIS module was incorporated into the HCI. The RIS is in charge of sending the work lists to the PACS (Picture Archiving and Communication System), of receiving notification that X-ray exams have been performed, and of registering the reports associated with such exams. Requests for

exams can also be made by primary care professionals using the Atenea/OMI, since this system is linked to the HCI.

The architecture conceived for the storing of images is based on a series of departmental or local PACS (they may correspond either to one or more services or to one or more health facilities). Each of these PACS is sized according to previsions regarding the volume of images that will need to be stored (the intention is to give each PACS approximately two years of autonomy). Each PACS is connected to a series of modalities, to which it sends the work lists it receives from the RIS within the HCI. The studies stored in the departmental PACS are replicated, in real time, in a central PACS that in turn has a backup PACS located in a different data processing center (DPC). There are thus two levels of back-up security copies. When a professional wants to look at a study that is not stored in his or her local PACS, the request is forwarded to the central PACS, which sends the study to the professional who needs it.

At this point, the Health Areas of Estella and Tudela, the ambulatory facilities of Pamplona and one hospital specialized in trauma have stopped printing X-ray plates. Nor are any plates printed for use at the primary care level. It is expected that by the end of 2011 X-ray plates will no longer be printed in the public health system of Navarre. Also, efforts are underway to digitalize different types of images – other than radiological images– and convert them into DICOM format, so that they too can be incorporated into the PACS. The images being digitalized are the ones available in the HCI or other support media (network drives, computers, etc).

The introduction of digital medical imaging has been favorably received for several reasons:

— X-ray studies are available immediately after the exploration, from any point in the care network.
— There is no need for plates to be transported and thus there is no risk of their being lost or misplaced.
— Various professionals can access the digital medical image simultaneously.
— Less physical space is needed, since the storage of traditional plates is no longer necessary.

The main obstacles that have been encountered are the following:

— It is difficult to define a common catalog of services, which is indispensable if everyone works in the same network.
— Workflows necessarily experience changes, and they especially affect radiodiagnostic technicians.
— The connection between modalities is sometimes problematic because, despite the existence of a standard, *de facto* DICOM, not all companies who provide modalities to healthcare facilities apply it in exactly the same way.

Management of medical orders

There are only two possible points of voluntary initial contact between a patient and the Navarre Health Service: hospital emergency rooms or that citizen's primary care center. From that point on, the care process is guided by successive medical orders for diagnostic and therapeutic support procedures which are carried out by the different health professionals taking part in the process. The mechanism most frequently used to support this process is a request form or slip. The primary aim of this project was to eliminate, to the extent possible, the use of paper request slips and to streamline the processing of the information related to the different actions undertaken for a patient.

As explained above, the trigger that got this project moving was the introduction of digital medical imaging, which in turn promoted the computerization of medical orders for radiology exams. Just like the RIS, the electronic request system was developed as a module of the HCI, which made it necessary to define and maintain a common catalog of services for the entire organization. This catalog brings together the catalogs of the following service areas: Allergology, Digestive system, Cardiology, General Surgery, Pediatric Surgery, Genetics, Hematology and Hemotherapy, Internal Medicine, Nuclear Medicine, Pneumology, Neurophysiology, Obstetrics and Gynecology, Ophthalmology, Radiodiagnostics, Rehabilitation, the Sleep Unit and Urology.

One hundred percent of the medical orders for radiodiagnostic tests are now made using the electronic request procedure. Since the autumn of 2010, this function has also been available for primary care professionals using the Atenea/OMI, thanks to it being linked to the HCI.

As regards difficulties related to its implementation, the management of change must be mentioned once again:

— The definition of a catalog of services is a very time-consuming task that requires the leadership of a clinical professional to help consensus be reached among his or her colleagues, and also to provide guidance to the technical professionals who must implement the catalog.

— The elimination of the use of paper means that the information circuits are more rigid, since the transmission of data is practically immediate. For example, in the event that a mistake is detected in the medical order, it is no longer possible to simply tear it up and start over. The diagnostic service in question must also be notified, because it has already received the erroneous information and may have started working with it.

— The mechanisms used to remind professionals of the tasks pending are less explicit, since what used to be piles of request slips or plates or reports are now work lists appearing on a computer screen.

The following functions have been incorporated into the most recent versions of the electronic request module (which is currently in the consolidation phase):

— A request level has been created one rung above that of service provision. This new level makes it possible to group in a single request various orders that need to be sent to different specialties.

— A results management function has been created, with a view to facilitating the management of the patient's personal agenda: which diagnostic tests have been requested, which ones have already been performed, which of the corresponding reports have been issued, and which tests/results are still pending.

Upcoming versions will hopefully also be integrated with the appointment management module of the Navarre Health Service, to enable coordinated management of both the administrative and clinical information of each patient.

Procedure for scheduling appointments in specialized care

As discussed above, the care process is structured around various diagnostic and therapeutic support activities, the performance of which involves the use of request forms. In most cases, the requested medical acts require that an appointment be made in advance, but the scheduling of appointments is not among the duties of the ordering physician.

The Navarre Health Service has a corporate application for scheduling appointments in specialized care, to which all professionals have access, including those working in primary care. Several of the agendas within the application allow the appointment scheduling process to be performed by the primary care professional. This means that the patient can often leave the primary care center knowing the time and date of his or her appointment with the specialist, instead of having to wait to be informed of the appointment, when other administrative bodies have scheduled it. For this procedure to function effectively, the management structures of primary and specialized care must previously have reached an agreement regarding the volume of tests and visits with specialists, to serve as a point of reference in order to plan for and organize the available resources. One of the useful features of the appointment management system is that it helps evaluate the degree of compliance with these agreements.

E-prescribing

Navarre's e-prescribing project, known as Lamia, is one of the maximum expressions of interoperability, since it involves not just the systems of the organization itself but also the systems of various agents outside the system.

The project's objective is very simple: to replace the traditional paper prescription by an electronic prescription so that citizens can go to a dispensing pharmacy, identify themselves using their Individual Health Card and enable the pharmacist to dispense the appropriate treatment. The dispensation is recorded in the system and can be consulted by the prescribing doctor to verify patient adherence to the prescribed treatment.

In this system three basic components should be highlighted:

— The prescribing module, which was developed expressly for Lamia and will gradually replace the prescribing modules of Atenea/OMI and of HCI (in the latter, Lamia will be used for prescribing in specialized ambulatory care facilities and upon a patient's discharge from the hospital). Thus all the professionals working at the Navarre Health Service will be using the same prescribing system.

— The Lamia nucleus, which is in charge of unified management of prescriptions and dispensations. It is a single, centralized system for all of Navarre.

— The dispensation module implemented in the dispensing pharmacies. In most cases the module is integrated into the management software used by the pharmacy, but it can also be accessed directly.

E-prescribing is one of the most complex projects that can be taken on by a health service, not because of its technical difficulty but rather because of the large number of actors involved. On many occasions conflicts of interest will arise and great organizational effort is required to define competencies and responsibilities, such as data ownership.

The piloting of Lamia began in June of 2010 in one of Pamplona's Basic Health Zones. The zone serves about 20,000 citizens through two primary care centers and it has 20 dispensing pharmacies. Over this period minor functioning errors have been detected and the system is now ready to be extended to the rest of the region.

Information security

The information stored in an electronic health record is classified as high level information by the Spanish Law on Personal Data Protection (Ley Orgánica 15/1999 de Protección de Datos de Carácter Personal), and must therefore be protected with the strictest measures laid down by this law.

The data is held in servers hosted by DPCs equipped with physical security measures and communication between the different applications is encrypted. The only way to access the data is through these applications (which require positive user identification). Furthermore, records are kept of all access to the system (details such as who seeks access, what information is accessed, when, from where and what modifications are made to the data) and these records can be examined at any time.

In fact, the Navarre Health Service - Osasunbidea periodically performs audits of the access to the clinical information of three types of citizens:

— Patients with certain social relevance.

— Patients that have expressly requested an audit.

— Patients that have been randomly selected.

In addition, content that specifically addresses data protection and confidentiality has been included in all training sessions on the EHR tools.

Conclusions

When a health organization decides to take on a corporate electronic health project, it should be aware that such an undertaking involves the existence the various specific systems. Also, it must choose between developing completely new systems, or integrating the pre-existing ones, since such projects rarely start from scratch. Another possibility is to combine both options.

Whatever decision is made, the organization must ensure that various basic requirements are met, such as positive patient identification, the creation and maintenance of organization-wide service catalogs, the use of homogeneous formats and nomenclatures for documenting information, and the implementation of security measures to guarantee data confidentiality. The scope of such tasks goes well beyond the need to develop computer systems and it is often equally or even more difficult to achieve them, due to their markedly organizational nature.

Finally, it is important to underline that these projects:

— Tend to have long execution periods.

— Require the participation of personnel at all levels within the organization, especially of clinicians, who must assume a leadership role.

— Require a great deal of coordination, in order to guarantee the efficacy and interoperability of the resulting systems, and also to make project execution compatible with the organization's care activity.

— Must be part of a larger dynamic that facilitates ongoing evolution and improvement, so as to be able to continuously adapt as new needs arise with regard to patients, professionals and the organization.

Acknowledgements

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Glossary

10 Gigabit Ethernet. A version of the Ethernet standards, with a nominal data rate of 10 Gbits/s (10 billion bits per second).

Access control. The area of information security management that lays down the conditions for accessing data (who can access what data and how such access takes place) and the measures necessary to verify compliance with these conditions (mechanisms for the identification of users, access registers, audits, sanctions, etc.).

ADSL (Asymmetric Digital Subscriber Line). A kind of technology used for broadband Internet connection. Unlike a modem connection, it does not use the same band as the one used for the transmission of voice data, so it enables users to be connected to Internet and have a telephone conversation at the same time. It is called 'asymmetric' because the data download speed (from Internet to the subscriber's terminal) is considerably greater than the data upload speed (from the subscriber's terminal to Internet).

Agile software development. A project management method for the development of small or medium-sized computer applications, the aim of which is to reduce software development lead times without affecting the quality of the final product. It is based on the division of the project into various iterations.

Analytical phase. The set of tasks comprising the analysis, strictly-speaking, of a specimen in a clinical laboratory and which leads to results being obtained.

APIS (Anatomic Pathology Information System). An information system that supports the activity carried out by an anatomic pathology department.

Application software. A computer program expressly designed and developed to perform specific tasks related to the activity carried out by the user: word processors, spreadsheets, audio and video players, etc. Electronic health systems are an example of application software.

Archetype. A formal specification used for the creation of data structures and the validation of data input. Archetypes are used in the two-level modeling approach that characterizes OpenEHR, where the first level is based on information models constructed with time-invariant reference models, and the second level is based on restricted formal structures. This makes it possible to ensure that the data introduced in a system, in addition to complying with the reference model, also meet the conditions defined by the archetype.

ASTM (American Society for Testing and Materials). Organization for the development of technical standards applicable to the use of materials, products, systems and services. It has a specific section for medical services and devices.

Back-up DPC. A contingency DPC designed specifically to assume the tasks of the primary DPC in the event of its failure. Given the high cost of a DPC and the presumably temporary nature of the failure situation, the back-up DPC tends to have fewer features than the main one, enabling it to assume only the organization's most critical services, while the failure is being repaired.

Business Intelligence tools. Tools that enable knowledge creation and better decision-making through the storage, retrieval and analysis of the data generated by an organization.

Business layer. The software layer that contains all the rules and instructions governing the functioning of an application. This layer receives user requests, retrieves and records data, and presents results.

Care program. A list of the services that are going to be performed on a patient, indicating the date, time, place and any preparation instructions that may be necessary.

CDA (Clinical Document Architecture). A standard for structuring and encoding clinical documents, with the aim of guaranteeing their semantic interoperability in the exchange of clinical information between different systems. It is part of version 3 of the HL7 standard.

Client (software). A terminal or application employed by a user to connect to a remote service that is hosted by another computer, known as the server.

Client-server model. A type of client software in which a significant part of the business logic and the data necessary for the functioning of the remote service is hosted by the client itself, as well as by the server.

Clinical record. A set of documents that contain data, assessments and other types of information about the situation and clinical evolution of a patient throughout the care process. The clinical record, or health record, comprises documents – that may be either textual or graphic – about the episodes of health and illness experienced by that person, and about the healthcare processes carried out in relation to these episodes.

Cloud computing. A model for providing software services in which the provider fully assumes the management, maintenance and custody of a computer application and its datasets, which are accessible from any computer with an Internet connection.

CMMI® (Capability Maturity Model Integration). A model created for the implementation, evaluation and ongoing improvement of processes, for purposes of developing, maintaining and operating very large computer applications.

Computer-assisted prescription writing. A prescription method that uses paper to transmit the necessary information, but uses a computer application to generate the printed prescription.

Copper pair. Cable comprised of two copper wires, used to physically connect telephone equipment.

Data layer. The software layer that stores the data necessary for the functioning of an application, according to a predefined structure, and that manages data access according to instructions received from the business layer.

Data uniqueness principle. A basic principle for ensuring information quality, according to which each data item must be recorded only once and stored in only one place, in order to avoid the risk of inconsistencies. In the event that one of the organization's systems needs this data item, that system must request it from the system in charge of custody. For this to occur, the two systems must be interoperable.

Data Warehouse. Collection of data on a specific topic which allows for the efficient analysis and reporting of the data. The data stored is generated by the hospital's applications and the warehouse contains incremental information, which means that the information is never modified or eliminated. Instead, new data is simply added to the data already present.

Database manager. A specific software system used to manage the data structures necessary for the functioning of the computer applications.

Datamatrix. A system that ensures the traceability of pharmaceuticals, based on the codification or serialization of each product.

Departmental information system. A specific information system for managing the activity carried out by a particular clinical service, the use of which is limited to that service only. Examples of departmental systems include the LIS, the RIS and the APIS.

Development environment. The hardware and software infrastructure used for programming and building prototypes of computer applications, in a setting that is controlled and isolated from the real systems involved in the users' daily activities.

DICOM (Digital Imaging and Communication in Medicine). A communications standard to ensure interoperability among devices that generate and process medical images, including both modalities and diagnostic stations. It was initially promoted by the American College of Radiology and the National Electrical Manufacturers Association in 1985.

Digital certificate. An electronic document that certifies the association between an individual or entity and a public key. This certificate plays a vital role in asymmetric encryption systems, which are predicated on the use of paired keys: the first is a public key, which the entity that owns the paired keys makes available to any person who wishes to send encrypted messages to that entity; the second is a private key, which only the owning entity knows and which is needed to decode the message. The existence of a public key means that there must be a mechanism that guarantees that it belongs exclusively to the message's intended recipient. This mechanism is the digital certificate, which is provided to the entity by a certification authority. Thus, the digital certificate is not a mechanism to verify the identity of the intended recipient but rather the recipient's connection with its public key. The authenticity of the intended recipient as such is verified by the private key.

Digital pathology. An environment for managing information and images in the field of anatomic pathology, based on computer systems that integrate the data contained in digital slides and facilitate telediagnosis.

Digital signature. A cryptographic mechanism used in the authentication of electronic messages and documents, confirming the identity of their author and ensuring that the contents have not been altered during transmission.

DL (Distance Learning). A form of education that allows the generation and exchange of knowledge to take place between people even when they are not in the same place at the same time. In other words, it allows knowledge to be accessed by any person, at any time and in any place.

DLT (Digital Linear Tape). A type of magnetic tape originally developed by the Digital Equipment Corporation (now Hewlett-Packard). It has algorithms for compressing the data recorded.

DPC (Data Processing Center). A site especially prepared to house all the hardware, software and communications elements needed for the centralized management of a set of corporate computer applications (application servers, database servers, centralized storage units, communications systems etc.), guaranteeing, to the extent possible, continuity in access by users. Also called a data center.

Drug database. A structured record containing basic data (active ingredient, dose, pharmaceutical form, etc.) about the medicines and health products included in the catalog of benefits provided by a health organization.

Electronic health record (EHR). Longitudinal collection of electronic information about a person's health, where information about health is defined as information relevant to the health of an individual and the care given to him or her by any member of the health team. The EHR allows immediate access – by authorized users – to information about the health of a person or population, thus providing knowledge bases and support systems for decision-making aimed at enhancing the quality, security and efficiency of the care given to patients, with the fundamental objective of improving the efficiency of healthcare processes.

Electronic prescribing. A pharmacotherapy management method that practically does away with the use of paper, as it fully integrates all the information systems involved in the prescription process, which exchange the necessary data electronically.

Electronic signature. The storage of a digital signature mechanism in a physical medium, such as a chip embedded in a card.

epSOS (European Patient – Smart Open Services). A project undertaken by the European Union to promote cross-border interoperability of health information among the different member states. The aim of the project is to allow the exchange of data appearing in the Patient Summary and the ePrescribing system.

Ethernet. A family of communications standards used in local area networks.

EUCLIDES (European Clinical Laboratory Information Data Exchange Standard). A European open standard for the interoperability of different Laboratory Information Systems (LIS). It addresses three levels: the transmission of messages, syntax and semantics.

Frame Relay. A communication standard for voice and data networks, based on the formation of virtual circuits that enable a packet switching methodology to be used. It is commonly used in wide area networks (WAN) because of its simplicity and low cost, mainly in rural areas where is it not financially feasible to install the infrastructure necessary for more modern technologies (ADSL, optical fiber, etc.).

Gigabit Ethernet. A version of the Ethernet standards, with a nominal data rate of 1 Gbit/s (1 billion bits per second).

Granularity (of data). The relative scale or level of detail in a dataset.

Hardware architecture. The set of functional and technical specifications that describe the structural and operating model of a computer, describing the devices comprising it (microprocessor, memory, disk units, etc.), their integration with one another and also their interaction with the user.

High-availability cluster. The configuration of a set of servers in such a way that, in the event of failure by one of the servers, the rest of them can assume the services that it was handling. This means system functioning is not interrupted while the failure is being fixed. The services are returned to the original server once the situation is back to normal.

High-performance cluster. A configuration of a set of servers in such a way that all of them take on a part of the same services. This configuration is very useful for maximizing the efficiency of services with high computational demands, but it must be possible to divide these services into processes that can be executed in parallel.

HIS (Hospital Information System). An integrated information system designed to manage all the administrative matters directly related to the clinical activity taking place in a hospital: identification of patients and professionals, configuration of agendas, resource planning, etc.

HL7 (Health Level 7). A set of standards that seek interoperability between health systems, enabling the electronic exchange of clinical data. The term "health" makes reference to the field of application of these standards, while "level 7" refers to the highest level of the communications model called OSI (Open Systems Interconnection). The HL7 standards are developed by the global non-profit organization HL7 International.

ICD-9 (International Classification of Diseases, 9th version). Ninth version of the disease classification published by the World Health Organization covering the different diseases and their external causes, for statistical purposes. Although there is now a tenth version, ICD-9 is still used in many countries.

ICD-10 (International Classification of Diseases, 10th version). Tenth version of the World Health Organization's disease classification. See ICD-9.

ICPC-2 (International Classification of Primary Care). A standard for the terminology used at the primary care level. It includes the reason for the encounter, diagnosis and medical procedures used.

ICT (Information and Communication Technology). See IT.

IHE (Integrating the Healthcare Enterprise). An initiative to improve the level of integration between diagnostic devices and health information systems, through the coordinated use of DICOM and HL7 standards. It focuses on resolving differences of interpretation as to how these standards should be used. To this end, IHE identifies integration problems in the administration of processes, in work flows, in information access and in the infrastructure used; it selects standards to cover the integration needs detected; and it details how such standards should be implemented. IHE is a joint initiative of the Radiological Society of North America and the Healthcare Information and Management Systems Society, with the participation of many health organizations and technology vendors.

IHTSDO (International Health Terminology Standards Development Organization). An international non-profit organization dedicated to the development and promotion of the SNOMED CT standard, to ensure the efficient and secure exchange of clinical information.

Integration bus or engine. A software infrastructure that provides integration services between systems through standards-based messaging.

Interoperability. The ability of computerized information systems and software applications to work together, communicating with each other and sharing information in an accurate, effective and consistent manner, and also the capacity to understand and use the information received. Interoperability has three levels:

— The organizational level is based on using certain well-defined work procedures, which are the starting point for the development of the semantic and technological standards used for the exchange of clinical information.

— The semantic level is based on adopting standards for the use of a homogeneous terminology, so that all participating systems assign the same value and meaning to each exchanged data item.

— The syntactic level is based on adopting standards for the construction of messages that all the participating systems will be able to transmit and receive correctly, from a structural point of view, during the exchange of data.

Intranet. A network infrastructure used within an organization for its own information and operational systems. Although it is based on Internet technology, the concept is actually the opposite, in that it refers to the organization's internal network, and not the one used to exchange data with other bodies.

ISO 13606. A technical standard that seeks to achieve semantic interoperability in the exchange of information from electronic health records.

IT (Information Technology). The set of techniques, elements and devices used expressly to capture, record, process and transfer data. The concept of IT encompasses:

— Services based on the exchange of information: e-mail, forums, the media, the distribution of audiovisuals, social networks, electronic administration, electronic commerce, electronic health, on-line banking, search engines, etc.

— The telecommunications networks that support this exchange of information: landline and mobile telephony, Internet, corporate intranets, radio broadcasting, etc.

— The terminals used to access the various services: personal computers, telephones, television sets, audio and video players, radio devices, etc.

ITIL® (Information Technology Infrastructure Library). A standard for managing the processes related to the maintenance and operations of computer systems.

IUPAC (International Union of Pure and Applied Chemistry). An association of different national chemistry societies that has been given the task of developing standards for naming chemical substances and compounds.

J2EE® (Java 2 Platform, Enterprise Edition). A programming platform for developing and executing software applications, sometimes considered a *de facto* standard. The cost of licenses is very low or non-existent, as many implementations are distributed free-of-charge and there are a large number of open-code tools.

JPEG (Joint Photographic Experts Group). A method for compressing images, often used to record images in electronic format. This method involves certain losses, so it is not recommended for procedures that require high image quality.

Layer programming. A software development method that divides a computer application into various independent levels, so that, in the event of a change, only the level or levels affected must be changed and there is no need to review the entire application.

LIS (Laboratory Information System). The set of hardware and software tools that support the activity carried out by a clinical laboratory.

Logical security. The set of measures used to restrict logical access to assets related to information security (passwords, firewalls, antivirus, access registry, etc.), and to appropriately manage the capacity of these assets (security copy, availability of storage space for new data, etc.).

LOINC (Logical Observation Identifiers Names and Codes). A standard for identifying clinical laboratory observations and aggregating them to the electronic health record.

LTO (Linear Tape-Open). An open standard for recording data on magnetic tape, developed as an alternative to proprietary formats.

Medical order management module. An information system that centrally manages the processes related to the request for diagnostic support and the viewing of results. To do its job properly, it

must be integrated into the different information systems involved: electronic health records, professional and patient identification, configuration of agendas, departmental systems, etc.

Modality. The equipment used to generate medical images used for making clinical diagnoses. Although the term is traditionally associated with radiological equipment, any device capable of generating images, either still images or video sequences, is considered a modality.

.NET®. Programming platform for developing and executing software applications in Microsoft® environments, considered the direct competitor of J2EE®.

OMR service request form. A type of service request that contains information which is automatically extracted by an optical mark reader (OMR). It is currently the most widely-used method for requesting services in the Spanish health system.

OpenEHR. An open standard for recording clinical information and generating reports in an electronic health record environment. It is developed and maintained by the OpenEHR Foundation, a non-profit organization.

Operating system. A computer program that manages the basic functioning of a computer, allowing the other applications and utilities to function on the computer's hardware.

Optical fiber. A data transmission medium based on the sending of pulses of light along a very fine glass or plastic fiber. Since it is optical in nature, this system offers high transmission speeds and is very resistant to electromagnetic interference, in addition to other advantages. It is very commonly used in data networks, both in telephone infrastructures and in local area networks (LAN).

PACS (Picture Archiving and Communication System). A system used for managing medical images, from their capture and storage to subsequent distribution for the preparation of the pertinent diagnostic reports. The PACS must be connected to the different image source modalities, to the workstations used by the clinicians who prepare the reports and to the RIS, the system that centrally manages the activity carried out by the diagnostic imaging service.

PathLex. Unified lexicon for anatomic pathology. It is a joint initiative undertaken by IHE and HL7 to meet the terminology needs of information system developers, in order to fill the gaps not currently covered by other terminologies such as SNOMED-CT or ICD-O.

Patient master index. A single, up-to-date record of a patient's identification data (name, last name, date of birth, ID card number, address, etc.), grouped together under a unique identifier that distinguishes that patient from all others and also links the patient to his or her clinical data.

Personal health record. An electronic record of information about the health of an individual that adheres to the established standards of interoperability and can be extracted from various sources to be handled, shared and controlled by the individual.

Physical security. The set of measures put in place to restrict physical access to assets related to information security (locks, security checks, video surveillance, etc.), and to appropriately maintain these assets (air conditioning, redundant power supply, etc.).

Point-of-care (POC) testing system. A simple, portable testing system able to perform diagnostic tests quickly and easily, with no need to move the patient or rely on the clinical laboratory's specialized personnel.

Post-analytical phase. The last part of the clinical laboratory process, comprising the management of the results obtained (review, validation and sending to the ordering physician) and the storage of processed specimens.

Pre-analytical phase. The first part of the clinical laboratory process, comprising the test request, the collection of specimens and the processing of the specimens before analysis begins (transport, classification and distribution).

Preproduction environment. The hardware and software infrastructure used for testing the prototypes of computer applications, in a setting that is controlled and isolated from the real systems involved in the users' daily activities. For these tests to be meaningful, the data used must be of a similar nature to the real data.

Presentation layer or user layer. The software layer that enables the user to communicate with a software application or make queries or introduce information into the system. It is frequently called the graphic interface.

Production or use environment. The hardware and software infrastructure that hosts the real systems used regularly by the users.

Programming environment. A specific tool or set of tools with which to create computer applications through the use of programming languages.

RAID (Redundant Array of Independent Disks). A storage system based on the use of various disk units that distribute or replicate the data. Depending on the configuration applied, a RAID system can offer better resistance to failure, better performance or greater actual capacity than a single disk unit of the same nominal capacity.

RFID (Radio Frequency Identification). A system used for identifying elements, either persons or objects, by transmitting an identifying code over radio waves. This code resides in a tag attached to or carried by the element, and it is detected by a network of antennas.

RIS (Radiology Information System). An information system that supports the tasks related to the management of patient demand in a diagnostic imaging department: appointments for examinations, resource planning, management and recording of activity, diagnosis and reporting of the examinations performed, etc.

SAN (Storage Area Network). A storage method based on the distribution of data among network-connected devices, such as disks or servers. This method offers high transmission speed, because

it uses optical fiber and low-level access, meaning that it can transmit files at block-level instead of complete files.

Security copy. An information protection mechanism based on periodically copying the data necessary for system functioning, so that it can be restored in the case of accident or attack, thus minimizing the loss of information. Also called a back-up copy.

Security incident. An event affecting one or more assets related to the management of information security. The basic information regarding each incident must be duly recorded for subsequent analysis and study: the nature of the incident, cause, impact, assets affected, measures applied, time and date of event, person reporting the incident, person recording the incident, etc.

Server (software). A terminal or application that hosts a service and centralizes its management, and that the user accesses remotely from a client workstation.

Service. Any action that can be performed on a patient: diagnostic tests, treatment prescriptions, therapeutic procedures, consultations with doctors or nurses, surgical interventions, inter-professional consultations, etc.

Service request. The piece of paper traditionally used to request diagnostic tests or to refer patients to specialists.

SNOMED CT (Systematized Nomenclature of Medicine, Clinical Terms). A standard widely used as an interface terminology or controlled vocabulary, to ensure semantic interoperability among clinical information systems.

Software architecture. The set of functional and technical specifications that describe the operating model of a software application, its structure, the technological platform to be used, the hardware it needs, etc.

Standard. A set of guidelines that provide orientation about the requisites that any given process, product or service must meet in order to reach its quality objectives. In eHealth, as in any other setting in which information is shared, at least two types of standards must be used: *syntactic standards*, to ensure that the data exchange messages are structured in such a way that all the systems involved can transmit and receive them correctly; and *semantic standards*, to ensure that each data item is assigned the same value and meaning at every point of the care network, and that they are interpreted in the same way by all professionals. Therefore, it is accurate to say that standards are the foundations of interoperability, since without them it is not possible to build interoperable systems.

System software. A set of computer programs necessary for the control of the computer on which the user executes the application software, and by extension for the correct functioning of the application software. The system software is comprised of an operating system, a database manager, maintenance utilities, etc.

TC 251 WI 130.1.1. A standard that defines service request and report messages between information systems. It is developed and maintained by the European Committee for Standardization TC 251.

Telemedicine. Exchange of medical information from one place/site to another, by means of electronic communications, with the objective of improving the health status of an individual.

Terabyte. A storage unit equaling one trillion (10^{12}) bytes.

TIA-942. A technical standard applicable to data processing centers (DPC). It defines the conditions that must be met as regards their location, the physical arrangement of their components, the cabling, reliability levels and environmental requirements.

Traceability. The capacity of an organizational process to find out, at any given moment during that process, the history, current situation and expected actions regarding an information asset, whether a data item or a device. For this to be possible, certain preestablished organizational procedures must be used and they must be incorporated into the computer applications that support the electronic health systems.

UPS (Uninterruptible Power Supply). A battery-equipped device that provides electrical power to a system in the event of failure in the mains power supply, so that the system's operation is not interrupted, as long as the UPS battery does not run down. The UPS also protects equipment from voltage spikes or dips, and improves the quality of the alternating current supply by eliminating harmonics from the network.

Utility (software). A computer program that helps maintain and oversee the status of a computer's various hardware and software components.

Virtualization. Process by which it is possible to create various logical servers on a single physical server, reducing hardware requirements and making the most of available resources.

Web client. A type of client software that hosts only a minimal part or none of the business logic or data necessary for the functioning of the remote service.

Web server. Computer application that is always running, waiting for requests that users may make from their client workstation and sending them the resulting information.

WiMAX (Worldwide Interoperability for Microwave Access). A communications standard used to establish radio links. In ideal conditions it allows for communication at a distance of up to 50 miles and at speeds of up to 75 Mbps.

Worklist. A DICOM service by means of which the PACS sends each modality the list of patients with appointments for radiological examinations during a certain period of time.

Workstation (diagnostic radiology). The computer equipment used by the diagnostic imaging specialist to review and interpret the studies performed on the patient. It usually consists of a

personal computer equipped with high-resolution screens and a graphics card that enables these screens to work.

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