In: Advances in Medicine and Biology. Volume 82
Editor: Leon V. Berhardt

ISBN: 978-1-63463-312-3

Chapter 3

A Model of Information System for Healthcare: Global Vision and Integrated Data Flows

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Abstract

The information system is an essential instrument for the performance of a health system, since it makes it possible to record, process and consult huge amounts of data, guaranteeing their availability for several uses which go from healthcare provision to system management, stewardship and financing. Hence the healthcare information system is composed of elements of several kinds, like clinical, clinical-administrative and management applications, among others.

The existing literature on health information management studies these different applications, but does not offer a global vision of the healthcare information system as a whole entity. This chapter adopts this global point of view and describes the structure and data flows within the information system, showing through several examples how the data generated during a medical consultation can be used for the patient's healthcare, the management of the used resources, the invoicing of the delivered service, and in the long term for results assessment, strategic planning, clinical research or education.

As a consequence, the making of a healthcare information system requires a clear definition of data recording and analysis processes, and of the information exchange flows among the different applications. These chapter examines the fundamental requirements that arise: the use of master databases for the unambiguous identification of patients, professionals, facilities and resources; the adoption of organizational, semantic and technological standards; the implementation of mechanisms for information security management; the ability of adapting to changes in the needs of the health system; the availability of a basic technological infrastructure; and the existence of a specific legal framework.

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This theoretical treatment is finally backed up by the presentation of several national and supranational electronic health projects that are currently in development in Spain, the European Union and the United States of America. They all meet, at least partially, the requirements and features shown in this chapter, supporting the concept of the healthcare information system as a whole integrated entity presented by the authors and confirming their premises.

1. Introduction

1.1. Health Systems: Concept, Functions and Structure

The World Health Organization (WHO) defines the health system as “all organizations, people and actions whose primary intent is to promote, restore or maintain health” [1]. During the European Ministerial Conference on Health Systems organized by WHO and held in Tallinn (Estonia) in 2008, the next basic functions of a health system were defined [2]: the *delivery of health services* to individuals and to populations; the *creation and management of resources*, which includes professionals, facilities, infrastructures, technologies and knowledge of the health system; the *stewardship* of the system, which comprises, among others, a specific legal framework, health policies and strategies, and the monitoring and assessment of the health system performance; and the *financing* of the health system itself, based on an efficient resource allocation according to population needs and the performance on every area, providing healthcare services that solve these needs while ensuring the sustainability of the whole system.

Therefore, the final goal of a health system is providing healthcare, both individual –patients– and collective –population–, in order to prevent or solve health problems. Around this primary function several others are established, which are essential for the improvement and continuity of healthcare despite their instrumental nature. All these functions are common to every health system, regardless of characteristics like dimension or public or private ownership.

From a structural point of view, everything explained above means that a health system needs the following elements:

- A staff composed of professionals from several disciplines, clinicians as much as technicians or administrative assistants.
- Facilities for the development of the health system activities, both healthcare and management.
- Material resources for their use during healthcare or health system management.
- An organization that provides the units, work procedures and supporting actions necessary for the health professionals to perform their job: healthcare organization and management, human resources administration, economic-financial management, logistics and supplies, and facilities maintenance, among others.
- An information system for the registration, control and support of the health system activity.
- A communications infrastructure for the information exchange within the health system network.

- A senior management team who is in charge of the health system strategic planning and management control.

Furthermore, a health system involves or collaborates with several public and private entities, among which the following ones must be pointed out:

- Central or federal government and regional or local authorities. These are responsible for the health system regulation through the passing of a specific legal framework and the control of its observation. In public health systems they hold the competency to finance healthcare provision, as well.
- Healthcare services, conceived as organizations responsible for the management of a determined healthcare network, geographically delimited, with a clearly defined service catalog, staff and a set of facilities –own or external– which provide healthcare to a segment of population.
- Hospital, which perform specialized and urgent healthcare activities.
- Primary care centers, which represent a basic first healthcare level.
- Extrahospitalary emergency services.
- Pharmacies, which supply medicines and health products.
- Convalescent centers, for support in patients' recovery.
- Health professionals acting as external providers to the health system, thus not being part of its staff.
- Public health services, whose goal is monitoring the health status of the citizens from a collective point of view.
- Insurance companies, mutual societies and other entities which finance healthcare.
- Schools for the education and training of doctors, nurses and other health professionals.
- Research centers, which develop new diagnostic techniques and therapies.
- Professional associations and colleges.
- Foundations and learned societies.
- Stakeholders, such as patients' associations.
- Pharmaceutical and other health technologies industry.

1.2. Information Management within a Health System

A *health system* is a complex organization whose goal is securing healthcare provision and improving the citizen's health status. One of the most important elements of this organization is the *healthcare information system*, composed of a set of information flows which allow data exchange among the different entities and units that constitute the health system.

The management of this information includes every organization process: from the execution of a determined healthcare event, which may be as simple and usual as a consultation at the doctor's office or as complex as a transplant, to every process of resources management and results assessment. The execution of these processes implies the use of one or several applications for data registration or exchange, with clinical, administrative or management purposes, among others.

The existing literature on health information management has dealt profusely with each one of these applications, always using the term "health/healthcare information system" as a reference to any of them [3,4,5,6,7,8], and examining several of their main requirements, such as data quality, interoperability or information security [3,4,9,10]. However, the authors have not found any significant works describing the whole set of health information data flows and applications used within a health system, even though it is a core element for the performance of the functions describe above.

1.3. Objectives and Contents of the Chapter

This chapter intends to provide the reader with an analysis of the healthcare information system from a global point of view, as an integrated entity that stores and processes all the information necessary for the health system to perform its main functions. To this end, this chapter describes the different components or applications of the information system and their different purposes: clinical, clinical-administrative, planning and management, and public health.

This approach is complemented with the description of the data flows that must exist among the different healthcare information system applications. These flows are first examined through an example centered on an outpatient, and later expanded with the study of other functions, such as public health, strategic planning, clinical research or education, among others.

Afterwards, this chapter focuses on the most important requirements for the making, maintenance and evolution of a healthcare information system, always ensuring data quality through the availability of complete and reliable information and the traceability of every healthcare-related process, while protecting the patients' privacy. Concepts like information architecture, application interoperability, information security, system scalability or legal framework, among others, are then introduced and discussed.

Finally, this theoretical treatment is illustrated with the presentation of four use cases concerning the construction of healthcare information systems: the eHealth project of Navarre (Spain), that provides a regional perspective; the Spanish National Health System Electronic Health Record project; the European Union cross-border interoperability initiatives; and the promotion of eHealth in the United States of America, as a mean to guarantee the availability and exchange of clinical information within their national territories.

2. The Healthcare Information System

2.1. The Healthcare Information System Components

The fact that the health system has several basic functions implies that it has different needs concerning information and therefore health data have also different uses, consequently linked to the performance of these functions. In other words, the scheme of a healthcare information system is part and direct consequence of the health system, which places healthcare once again in the center of the functioning model [11,12]. This means that the information system conception must begin with the healthcare processes, around which the remaining processes, regarding resource management, health system stewardship and financing, must be implemented. The latter ones must adapt to the way the healthcare must be delivered, and not otherwise.

Healthcare can be synthesized in the meeting of a patient with one or more health professionals at a determined place, during which several resources are used. This event requires the attendance of the patient and the availability of the doctor, the facility where the meeting is taking place and the resources used during the consultation. As a consequence, a healthcare information system is based on four pillars [13]:

- A database containing the *population* assigned to the health system. The concept *population* includes not only the patients who are receiving cares, but also the rest of the citizens who may potentially need this healthcare. In this way this database can be used for strategic planning purposes, since it makes it possible to estimate the expectable health demand in the mid and long terms.
- A database containing the health systems *professionals*, both clinicians and supporting or management staff.
- A database containing the *facilities* in which healthcare takes place: hospitals, primary care centers, departments, doctors’ offices, exploration rooms, operating rooms, etc.
- A catalog containing the *medicines, health products, electromedical equipment and other services and material resources* that may be used.

The unique identification of all these people and elements makes it possible to generate the information necessary to prepare and record properly every healthcare event. Thus, the traceability and continuity of every individual healthcare process can be guaranteed, and so can the use of these data for healthcare, stewardship and logistics management purposes. This information is distributed within a healthcare information system that includes the following types of applications (see Table I) [14]:

- *Clinical-administrative* applications, for the coordination of healthcare processes, health professionals, facilities and other health system resources which are necessary for providing healthcare.
- *Clinical* applications, for the management of the information concerning the individual healthcare process of a determined patient.
- *Planning and management* applications, for the health system strategic management, resource allocation, management control and objective achievement assessment.
- *Public health* applications, which receive data from different information sources in order to assess and protect the collective health status of the citizens.

Table I. Main applications within a healthcare information system

Clinical-administrative	• Appointment and schedule management • Patient admittance • Hospital information system (HIS) • Primary care information system (PCIS)
Clinical	• Electronic health record • Computerized physician order entry • Nursing care • Departments: laboratories, pathology, medical imaging, etc. • Electronic prescription.
Planning and management	• Logistics and storage management • Maintenance • Economic-financial management • Human resources • Balanced scorecard and performance assessment
Public health	• Epidemiologic surveillance • Disease records • Vaccination records
Knowledge management	• Support to clinical decision taking • Support to planning and management • Research • Education

Source: compiled by authors.

- *Knowledge management* applications, which allow the health system to use the collected data for research purposes, learning from experience –errors included– [15] and improving every corporate process, both healthcare and management ones.

2.2. The Individual's Healthcare Process: Planning and Preparing an Outpatient's Consultation

Taking a healthcare event as a starting point, the different data flows among the components of the healthcare information system can be studied. To begin with, this meeting must have been previously agreed on –unless it is an emergency case– through the scheduling of an appointment, which means there must be some work schedules that make it possible to assure the availability of the doctor, the facility and the material resources used during the consultation.

These schedules must identify all the people and elements involved, using the four basic databases previously explained and also a service catalog that specifies in detail the *healthcare service portfolio* of the health system. In this way, the schedule also stores the additional information necessary to define properly every healthcare event, such as the patient type –outpatient, inpatient or emergency room–, the event type –consultation, exploration, diagnostic test, treatment–, the need for specific resources –anesthesia, special equipment–, and the assigned priority or the financial backer.

Moreover, these data allow the clinical departments to split the schedule in several time slots which can be used to plan and coordinate the healthcare performance. For instance, a doctor can take care of outpatients during the first two hours of the working day, monitor inpatients for the next three hours and spend the rest taking care of patients admitted at the emergency room.

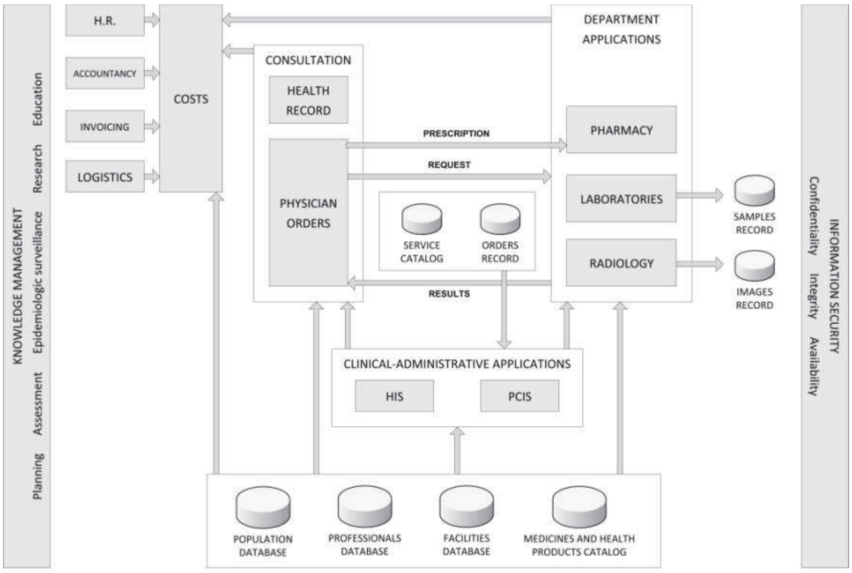
2.3. The Individual's Healthcare Process: The Outpatient's Consultation at the Doctor's Office

When the outpatient arrives at the doctor's office, the latter collects all the necessary information through the clinical interview, the patient's exploration and the access to his/her health record in order to check the data stored before the consultation. Once the doctor comes with a diagnosis, he/she adds the new data to the patient's health record, and may request a diagnostic test, a consultation with another clinician, prescribe a treatment or all of the above.

The diagnostic test or consultation request implies that the doctor must access the physician order application that manages the request process, the intervention of new clinicians and departments, and usually the scheduling of a new appointment before the performance of these procedures. This means that new work schedules must be used, as so must the applications of the departments in charge of performing the physician order and generating the corresponding results, like laboratories, pathology or medical imaging services.

On the other hand, the prescription of a pharmacologic treatment requires the participation of the pharmacy and the delivery and administration of a medicine or another health product, thus using new departmental applications.

After the performance of these physician orders, a new consultation is held in order to assess the patient's health status and make new decisions concerning their health.



HIS: Hospital Information System; PCIS: Primary Care Information System.
Source: compiled by authors.

Figure 1. Information flows during an outpatient's medical consultation process.

2.4. The Individual's Healthcare Process: Summarizing the Data Flows Concerning the Outpatient

The new consultation marks the closure of an individual's healthcare cycle, during which the following data flow has taken place (see Figure 1):

1. The clinical-administrative application of work schedule management sets the first appointment. The basic data are the people involved, the date and time, the location and the type of healthcare service that has been scheduled. Hence, the scheduling of an appointment requires the use of population, professionals and facilities databases, as well as a catalog with the healthcare services portfolio of the health system.
2. During the consultation, the doctor accesses the patient's health record to consult their previous clinical data and add the ones generated as a result of the meeting. This requires the doctor's authentication and the patient's identification. The former makes it possible to confirm the doctor's authorization regarding information access, as well as recording who has added the new data; and the latter is necessary to locate and supply the patient's information. This means that the health record application must use both the population and the professionals databases.
3. While requesting the diagnostic tests or consultations, the doctor uses the physician order application in order to select these actions. The items that must be identified are the patient, the doctor and the requested procedure, thus accessing once again the population and professionals databases and the catalog with the healthcare services portfolio. In addition to this, it is essential to assign an identification code to the requested procedure itself, which allows the system to link it to the patient, the doctor and the results obtained after its performance. These data, among others, must be registered in an *orders record* that identifies every requested procedure and guarantees its traceability.
4. A diagnostic test may require the taking of blood or tissue samples, which means every sample must be identified. As a consequence, a *samples record* must be maintained in order to link every sample to the corresponding patient, test and results. In the case of medical imaging tests, sample taking is not necessary but visual information must be stored, which means that there must be an *images record*. Besides, the performance of all these procedures may require the use of special materials or equipment, and usually the scheduling of an appointment.
5. A pharmacologic prescription causes the doctor to access the physician order application, this time identifying the patient, the doctor him/herself and the prescribed medicine –thus accessing the *medicine and health products catalog*–, and establishing the conditions for its supply and administration. When the patient arrives to the pharmacy, the pharmacist who delivers the medicine and the facility itself must also be identified. This means that the population, professionals and facilities databases are used again.
6. The cycle ends with the scheduling of a new appointment for a second consultation, during which the doctor accesses once more the health record and the physician order applications –this time in order to consult the results of the requested procedures–, which use the population and professionals databases and the orders record.

As it can be noticed above, clinical-administrative applications participate in the organization of the workflow, using three of the master databases previously explained, as well as the service catalog and the orders record. The clinical applications exchange information with each other, and receive several data from the clinical-administrative applications and from several databases and records, some of which are new in the process.

In a parallel and transparent way to the healthcare event, both types of applications contribute to the record of the health system activity, which allows the organization to perform a cost analysis based on the involved professionals, the performed procedures, the administered treatments, and the material resources and facilities used during the process. This also makes it possible to execute the corresponding invoicing process [16], which implies the participation of new applications such as human resources management, accountancy or logistics, among others.

2.5. Similarities to Other Individual Healthcare Processes

Though this use case refers to an outpatient's medical consultation, the cycle is conceptually similar for other types of patient or healthcare events, such as the following:

- Regarding inpatients, several processes like bed allocation are added, as well as some modifications in the appointment scheduling for consultations and diagnostic tests. Basically, this appointment does not require to be agreed on with the patient and is usually scheduled on time slots reserved for inpatient healthcare. Besides, the pharmacologic treatments are supplied by the hospital pharmacy and administered by the nursing staff.
- The patients admitted at the emergency room may require faster response times according to the severity of their status, but their management is practically identical to the case of inpatients or outpatients.
- The performance of a surgical intervention means that the patient must be object of several specific procedures, such a pre-operatory evaluation and preparation –which implies their admittance at the hospital– and a recovering phase after the intervention. The planning of the surgical activity –through an operating room schedule– is one of the most transcendent processes at a hospital, given the high cost of the used resources. These particular features are added to the cycle but do not cause any conceptual change.
- Another special case is the patient's derivation to an external professional or department, a circumstance that does not cause any important modifications in the process, either. In fact, this situation requires that these external providers are identified as rigorously as any member or resource belonging to the health system, so as to guarantee the integrity and traceability of the healthcare process.

The record and processing of all these data is essential for optimizing the management of the different health system resources, from the health professionals to the equipment or facilities used. Good information management makes it possible to know, down to the last detail, the availability of each one of these resources at the moment of planning the healthcare activity, as well as avoid procedures which are redundant or not compatible with the patient's condition.

Considering the potential risks associated to this, the high cost of the health system resources and the huge demand for clinical care, the healthcare information system reveals itself as a key instrument when it comes to increasing the quality, efficiency and safety of healthcare [15].

2.6. Other Data Flows Inside the Healthcare Information System

As mentioned above, the main use of clinical information has healthcare purposes, but the previous example has shown how these data must also be used for the management of the involved resources and the planning of every particular healthcare event. When this information is large-scale processed, analyzing the global data, these management and planning activities can be applied to the strategic management of the health system. Furthermore, the potential uses of these data include the *healthcare quality control*, the support of *clinical and epidemiologic research*, the *education and training* of health professionals, or even their presentation as *evidence with full legal validity* in court [16,17,18,19,20].

2.7. Public and Occupational Health

In *public health* environments, as explained above, the goal is to manage every health problem that can affect citizens in a collective way, detecting such problems and planning and applying the corresponding preventive or corrective measures. This includes a great diversity of actions, like the prevalence and incidence studies regarding determined diseases –e.g., AIDS or the most frequent cancer types–, child or seasonal –like influenza– vaccination campaigns, or the surveillance of risk situations or facilities. For these purposes, huge amounts of information are collected and processed, from both health-related sources –for instance, clinical diagnosis or vaccination records– and non-health-related ones –e.g., population census, health polls or meteorological data– [21,22].

A special case of collective health management is *occupational health*, focused on the management of occupational diseases. This environment exceeds the borders of the health system, since several external entities must participate in it, such as social security, companies, occupational hazard prevention organisms, mutual insurance companies or labor authorities, among others. This means that new information sources and data flows are created and must be added to the healthcare information system [23].

2.8. Strategic Health Planning and Management

Regarding *strategic management*, health system executives need information that allows them to establish realistic goals and assess periodically their achievement degree, as well as allocating and managing corporate resources. These data are extracted from the following sources:

- The clinical and clinical-administrative applications [24], which provide a global view of the personalized healthcare processes.
- The public health applications, which add the analysis of health problems from a collective point of view.
- The population databases, which show the general characteristics of the citizens whose healthcare needs must be taken care of by the health system, facilitating the short-term planning. Besides, these databases make it possible to calculate demographic projections and estimate the evolution of these needs in the mid or long term [16,25].
- The planning and management applications, which provide data about resources utilization and costs.

For these data to be useful during the assessment of the strategic goals achievement, the information must be synthesized in the form of indicators which are calculated using the data supplied by every hierarchical level and department of the health system. This means that the corporate strategic goals must be transformed into specific objectives for every unit through a disaggregation process, and the data generated from the activity of every unit must produce the system achievement indicators through an aggregation process. At the end of this chain there is a balance scorecard that allows the health system executives to know quickly the fulfillment degree of every strategic goal and the performance assessment of every unit, as well as perform comparative analysis of units, centers or periods [16,26,27,28].

However, a very important requirement of these data flows is that they must be transparent to the health professionals, i.e., the latter must record and use the information necessary to perform their healthcare duties, without dedicating any extra effort to collect the data which their superiors need but do not add any value to their healthcare activities. This is achieved by guaranteeing that the design of clinical and clinical-administrative applications includes among their features the automatic processing of healthcare-provision-related data, so as to generate the indicators needed by the health system senior management.

Thus, the data are introduced in the healthcare information system just once, and though this registration is initially performed with healthcare purposes, once they are stored and processed these data can be used for the remaining health system functions. In other words, the information for the system management must flow from the operational applications as a consequence of its purely healthcare-related use, and not as an extra feature of them [24].

This requirement was very hard to meet with paper-based health records, but the use of Information Technology (IT) has made it possible to overcome this barrier and provide non-clinical users with these data. This includes not only the health system executives, but also the financial backers, administrative assistants, clinical researchers, professors or auditors. Conceptually, the problem is defining which information must be accessible, by whom an under what conditions [29].

2.9. Clinical Research and Medical Education

Clinical research is essential for the development of new diagnostic techniques and therapies, in order to improve the healthcare performance. Logically, research projects need access to clinical data stored in the healthcare information system, so as to detect problems and events of potential interest for the development of new projects, to identify patient groups suitable for the execution of clinical trials, or to assess the results of the field tests to which the experimental procedures have been subjected. This process can be performed in a prospective or retrospective way, and several entities such as universities, research centers or pharmaceutical companies can participate on it.

Finally, the *education and training* of health professionals is essential not only to improve the healthcare quality, but to guarantee its continuity as well. This includes health sciences students and professionals with a degree who need to update their professional knowledge and skills. Once again, several entities not directly related to healthcare provision intervene in the process, like universities or libraries.

2.10. Protecting the Patients' Privacy

All these uses of clinical information must take into account the respect and protection of the patients' privacy, which may require the *anonymization* of their data at the moment of their recollection [30,31]. This process consists of the elimination or masking of every data whose hiding keeps their owner from being identified [32,33].

An example of this is the case of scientific research within the European Union (EU), where the processing and the free movement of personal data are regulated by the Directive 95/46/EC. The article 13 of this regulation establishes the possibility of restricting by a legislative measure the citizen's access rights –i.e., the possibility of legally suppressing the requirement of the citizen's permission previous to the treatment of their data–, when this information is to be used *"solely for purposes of scientific research"* and it is guaranteed that there is *"clearly no risk of breaching the privacy of the data subject"*.

In other words, inside the EU the use of the patients' health information for clinical research without their permission is legally backed, as long as these data have been properly anonymized.

3. The Making of the Healthcare Information System: Primary Requirements and Key Points

As it can be noticed, the healthcare information system is a complex entity, whose making and maintenance must meet, among others, the requirements and key points shown on Table II. Their final aim is to guarantee the *quality of the information* stored in the system. This concept includes several characteristics [14,17,19,34,35]:

- *Complete and reliable information*. In order to be useful, the information must be composed not only by true data, but also by all the necessary ones [16,36,37].
- *Balanced detail level while presenting the data to the user*. The information to be used must be detailed enough to be useful, but it must also be shown in amounts small enough to be manageable [11,20]. This balance depends on the situation, so the data presentation must be adaptable to the particular needs at that moment. For instance, a doctor needs to access basic data such as the patient's problem list,

diagnosis, allergies or active medication. The showing of an excessive amount of information might keep the doctor from identifying these essential data, and so might the display of redundant, non-relevant or too old information. This does not mean that these data must not be available, but they must be accessible only on the doctor's demand, thus avoiding confusion and inefficiency.

- *Opportunity, accessibility and pertinence*. The necessary information must be available in due time and form [11,20], according to the criteria that must be applied to every particular situation and given that this access is completely justified.
- *Traceability*. The information management must allow the audit of every step in healthcare and management processes, including the record and use of the data themselves [16,32]. Thus the actions taken can be known and the people responsible for them can be identified, as well as other people and items involved. The traceability of information is a critical requirement to every health systems, since it makes possible to integrate all the patients' clinical data, to protect their confidentiality, to guarantee the correct invoicing of the delivered healthcare services, and to reassure the validity of the health information as evidence in court.

According to the objectives of this chapter, the authors will discuss in this section the most important requirements and key points derived from this definition of quality information. They are information architecture, interoperability, principle of data uniqueness, information security, basic technological infrastructure and legal framework, and can be related to each other in some cases.

3.1. Information Architecture

The need for guaranteeing data quality makes it crucial to have a set of rigorous information architecture procedures. This concept comprises data structure, classification and analysis, in a way that it is possible to store, to consult and to process them [19,20,34,38,39]. This requires:

- *A detailed design of the databases* which must store the information, specifying clearly the nature and structure of their contents.
- *The identification of the different information sources involved*, according to the data that are required in every process.
- *The definition of the information flows* that make possible the data collection, record, consult and analysis at any point of the information system in which they may be needed.

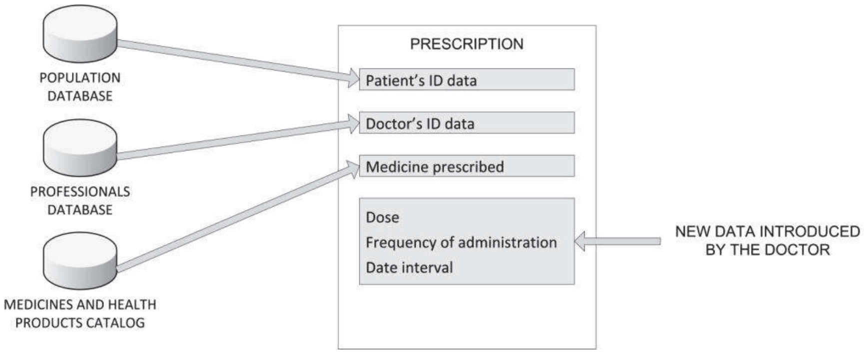
Figure 2 shows an example of information architecture procedure, concerning the prescription process.

Information architecture is the first step in the making of the healthcare information system. It is an organizational task that requires a deep knowledge of every health system process, both healthcare and management-related, as well as the legacy applications. This is essential in order to ensure the usefulness of clinical data not only for healthcare but also for other purposes [35,40,41].

3.2. Interoperability

One of the most important difficulties in the making of the healthcare information system comes from the great amount and heterogeneity of its components and of the data it manages [12,19]. The existence of different entities within the health system, with the addition of several external agents in some cases, means that there are different applications based on different work procedures and supported by different technological platforms. This leads directly to the *interoperability* requirement, so the data are available and can be exchanged for the performance of any healthcare information system function that needs them [34,42]. In a simpler way, interoperability can be defined as the capability of "speaking the same language". In addition to the obvious benefits related to application integration, some studies dealing with integrated vs. non-integrated applications also show an increase in patient safety and a reduction of costs [15,43].

For the different applications to be interoperable, it is necessary to adopt standards that make it possible to normalize both data and work procedures [15,21,34,44]. This standardization must be applied in a balanced way [13], because undernormalization makes interoperability more difficult but overnormalization decreases organizational processes flexibility, which penalizes the adaptation of healthcare to the specific circumstances of every patient or to new needs of the health system. Moreover, standardization must be applied on different levels [12,45]:



Source: compiled by authors.

Figure 2. Information architecture in the prescription process.

- *Organizational*, making every work procedure involved in the data management compatible to each other, so the data exchange is viable and effective. A key point about this level is the existence of master databases, starting with population, professionals, facilities and resources databases. The unique identification of all these people and elements allows the information system to index and link properly the stored information which is distributed in the different applications [46,47], ensure that the data exchange is performed according to what was requested, and also guarantee the traceability of healthcare and management processes.

- *Semantic*, ensuring that the meaning of the exchanged data remains unaltered regardless of the process or application which is storing, transmitting or receiving them [48]. This implies the use of common codification for classifying information and normalized methods for data exchange. An example of codification is the use of terminologies like the *International Classification of Diseases* (ICD), the *Systematized Nomenclature of Medicine Clinical Terms* (SNOMED CT) or the *Logical Observation Identifiers Names and Codes* (LOINC) [12,49,50,51]. Concerning data exchange, the most used standards are HL7 (*Health Level 7*) for textual clinical information exchange [12,52], and DICOM (*Digital Imaging and COmmunication in Medicine*) for medical imaging exchange [42,53].
- *Technological*, allowing the different platforms that support every application to establish a connection for the data exchange.

3.3. Principle of Data Uniqueness

One of the main risks that the data exchange constitutes for information quality is the possibility of generating redundant data or, even worse, contradictory information. A healthcare information system composed of perfectly interoperable components must follow the *principle of data uniqueness*, which means every single data enters the system just once and it is stored and kept in only one application [54,55]. The remaining applications must request the data whenever they need it, but they must never store it permanently. This method avoids the possibility of replicated data records and has only one disadvantage, since the data would be inaccessible in case of application failure. However, it is better than the alternative method, which is based on storing a copy of every data in each application which may need it, and establish several mechanisms for the automatic update of every copy when a new value enters the healthcare information system.

3.4. Information Security

Another fundamental requirement of the healthcare information system is to protect the security of the stored data. This concept includes not only information confidentiality, but also its integrity and availability [55,56], which means that the healthcare information system must have the following features and mechanisms:

- *Confidentiality*: access level and authorizations definition, user management, access control and registration, user authentication, communication encryption and registration of the person responsible of every significant action on the system, such as data access, modification or elimination [32,57]. Thus, only authorized people can access the information, and they can do it just under the conditions established by such clearance.
- *Integrity*: backup procedures, as well as the protective measures against unauthorized access mentioned above. This protects the data from being corrupted or lost, which

may happen both accidentally and as a consequence of a deliberate attack, and allows the information system to recover the data if this corruption or loss actually happened [58].

- *Availability*: as mentioned above, the availability of the data requires every component of the healthcare information system to be interoperable with each other. Besides, there has to be a backup for every critical structural element, such as data processing centers, communication lines or system access points, so the data will remain available in case of infrastructure failure.

As it can be noticed, information security management requires the combination of several organizational, physical and technical measures [16]. The main difficulty here is maintaining a reasonable balance between confidentiality and availability requirements, two features in permanent collision given their nature [59]. The decisive factor which sets the prevalence of one or the other must be the urgency of every particular situation, putting availability first when time saving is critical –e.g., some cases at the emergency room– and confidentiality when it is not –for instance, an outpatient–.

3.5. Scalability

The healthcare information system must be scalable, i.e., capable of evolving and adapting itself to changes in the needs or the structure of the health system, like the performing of new healthcare proceedings, the opening of new facilities or the hiring of new staff. As a consequence, the components of the information system may need to be modified, or new ones may be added. This means new work procedures, new data sources and new applications. Though scalability is a concept different from interoperability, it depends strongly on the adoption of standards, since these establish the basic conditions which are necessary for the integration of new elements into the information system.

3.6. Basic Technological Infrastructure

From a transversal point of view, the health system senior management must take into account that the operation of the information system is based on an IT infrastructure which is composed of several elements itself, such as software applications, hardware equipment and a communications network, whose maintenance requires dedicated material and human resources, as well as a specific and formal budget. This entire infrastructure is directly linked to the healthcare information system, up to the point where it shares its interoperability, security and scalability requirements [60].

3.7. Legal Framework

Finally, every main function and feature of the healthcare information system must be backed by the corresponding legal framework, so the clinical information registration process is completely valid, and the different organisms and departments involved in the management of these data can establish collaboration agreements and work procedures for data exchange, with a proper legal support.

Table II. Primary requirements and key points of a healthcare information system

Information quality	• Complete and reliable • Appropriate detail level while presenting the data • Accessibility • Traceability
Information architecture	• Functional and structural design of databases • Identification of every data source • Definition of data flows
Interoperability	• Organizational: compatible work procedures • Semantic: use of terminologies • Technological: standardization
Principle of data uniqueness	• Just one entry in the system • Just one record, clearly located and identified • Delete after using when application is not the data host
Information security	• Confidentiality: protection against unauthorized access • Integrity: data recovery if necessary • Availability: interoperability and redundancy of critical elements
Other requirements	• Scalability • Interoperable, secure and scalable IT infrastructure • Legal framework

Source: compiled by authors.

4. Some Use Cases and Trends

Some governments are sponsoring huge electronic health (eHealth) projects in order to promote the exchange of clinical information within a health system or even among different systems. This chapter reviews briefly four of these projects currently in development in the Spanish region of Navarre, the Spanish National Health System, the European Union and the United States of America. As it will be clearly shown, the goals of every project take into account the requirements explained above.

4.1. Navarre: The eHealth Project of a Regional Healthcare Service

The project undertaken by the Spanish Chartered Community of Navarre began in the 1980s and continues in full swing to this day. The main actions undertaken as part of this project are the following [61]:

- 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 access this system from within their own clinical record application.
- Management of appointments for specialized care, available throughout the care network.
- Electronic prescribing, currently in the dissemination phase. At the moment of writing this chapter, the availability of this service is above 60%.
- Use of a corporate infrastructure for the communications network and for the application of security measures, to guarantee the confidentiality of patient information.

All these actions are in fact steps in the making of a regional healthcare information system, and they take into account several of the general requirements mentioned above, such as patient identification, interoperability, accessibility, data protection and scalability.

4.2. Spain: The NHS Electronic Health Record System

In some countries, the data are so fragmented that there is not a fully integrated health system. This is the case in Spain, where the healthcare provision is managed by seventeen regional authorities, who have developed their own healthcare information systems in an independent way. In the last few years, the national government has promoted a project for the creation of a basic interoperability space, the National Health System Electronic Health Record (NHSEHR) [62,63,64]. The NHSEHR is based on:

- The unique identification of every citizen who is eligible for healthcare provision, every professional in the health system staff and every health system facility.
- The consensual definition of basic clinical data sets, using a normalized and coded language. This made possible the standardization of the following reports: discharge, outpatient, emergency room, primary care, nursing care, imaging test, lab test and other tests results. In addition, a summarized health record has been created that allows the clinician to access the patient’s basic clinical information. All these data sets have been designed by a work group participated by 32 professional and learned societies, and several patient and citizen associations. Furthermore, they have been legally backed by passing a specific regulation –Royal Decree 1093/2010–, according to which all regions must facilitate the clinical information requested by each other according to the agreed data formats. This regulation gives NHSEHR full legal validity.

- The citizens' access to their own personal health information. Every citizen can consult his/her data, know who has accessed them and disable the access to those data sets they wish to remain undisclosed. Before making this decision effective, the system informs the citizen about the potential negative consequences of this action, should this information be needed for future healthcare provision. As a cautionary measure, the health professional who uses the NHSEHR is informed about the existence of hidden data, and is able to access them if urgent healthcare is needed and the patient is incapacitated for confirming or revoking this decision.
- The adoption of open technological standards, which means that they are promoted by non-profit organizations, that any interested party may participate in their definition, that the access to the technical specification documents is public and free, and that there are no restrictions at all concerning their use.
- The implementation of a data protection policy regarding the access and use of the information, based on the utilization of a digital certificate or an electronic signature for the authentication of professionals and citizens.
- The availability of an own communications network, secured and with a high data transmission speed.

4.3. The European Union Projects: epSOS and eHGI

The EU has promoted the development of a pilot project which is conceptually similar to the Spanish NHSEHR, the *European Patient Smart Open Services* (epSOS, http://www.epsos.eu/). This project has two main action lines: the access to important medical data for patient treatment –patient summary– and the availability of an electronic prescription application [65]. Just like in the NHSEHR project, the basic data sets have been consensually defined and several semantic and technological standards have been adopted. However, the citizens' identification is delegated on every Member State, so there is no master population database. Concerning the legal framework related to data protection, the Directive 95/46/EC for the processing and the free movement of personal data is applied, though it is not a healthcare-specific regulation.

In 2011 the EU started a second project, the *eHealth Governance Initiative* (eHGI, http://www.ehgi.eu/), whose goal is supporting Member States on the implementation of electronic health interoperable services and infrastructures. The main action lines of eHGI can be summarized in four strategic goals:

- The governance of the citizens' unique electronic identification for e-Health services.
- Semantic and technical interoperability of healthcare information systems.
- Data protection.
- The development of several features, such as the summarized health record of every citizen –patient summary–, the interoperability of electronic prescription applications –thus giving continuity to the epSOS pilot– and the incorporation of every recommendation related to the sustainability of health systems.

The eHGI has a specific legal framework defined by the Directive 2011/24/EU, about the patients' right concerning cross-border healthcare. This regulation establishes the strategic guidelines on electronic health, with the aim of creating a network composed of all the national authorities and thus promoting the cooperation and collaboration among the Member States. The goals of this network are the making of directives which make possible the sharing of citizens' clinical information for healthcare and research purposes, the implementation of common methods for people identification and authentication, and the improvement of the quality, continuity, efficiency and accessibility of healthcare, with the subsequent economic and social benefits.

In this way, the EU is setting the foundations for not only the health interoperability within its territory, but also for a future health macrosystem supported by its own healthcare information system.

4.4. The United States of America: The promotion of the Electronic Health Record

In the USA, one of the most important issues of the Obama Administration is its proposal for Health Care Reform –often referred to as *Obamacare*–, whose goal is to bring *"affordable healthcare to all Americans"*. This reform has caused a controversial debate –both political and social– for several reasons, such as a disappointing previous reform promoted by the preceding Democratic administration, under the presidency of Bill Clinton; the necessary collaboration of the same insurance companies previously criticized by the federal government for *"leaving millions of Americans without coverage"*; and the citizens' confusion *"about the law and how and when it will affect them"* [66]. Although the *Patient Protection and Affordable Care Act* (ACA) has been passed, the Obama Administration has abandoned the implementation of several initiatives like the *Community Living Assistance Services and Supports* (CLASS) Act, a provision within the ACA that would have established a national, federally administered voluntary long-term care insurance program. It seems that this decision has been made as a consequence of *"fatal flaws in the program's basic design"* [67]. All these controversies have eclipsed the passing in 2009 of the *Health Information Technology for Economic and Clinical Health* (HITECH) Act, which encourages the massive implementation of the Electronic Health Record (EHR) as a means to improve the quality, safety and efficiency of healthcare. Though the political and professional consensus was remarkable this time, the ambition of the HITECH Act goals collides with the current situation, in which EHR is profusely used in most large healthcare organizations, but is barely implemented in small clinics and practices. In order to promote the adoption of EHR, the *Department of Health and Human Services* (DHHS) established a set of specific goals, being the following ones the most remarkable [68]:

- The creation of a patient master database.
- The big-scale implementation of extrahospitalary electronic prescription and computerized physician order entry applications.
- The addition of diagnostic test results to the EHR, in the form of structured data sets.
- The development of pilot projects focused on clinical decision support.
- The electronic clinical information exchange among providers and other entities authorized by the patient.

- The delivery, on the patients' request, of an electronic copy of their personal health information, including diagnostic-test results, problem list, medication lists, medication allergies, and for hospitals, discharge summary and procedures.
- The patients' timely electronic access to their own health information, including laboratory results, problem lists, medication lists and medication allergies.
- The provision of a summarized care record for patients referred or transitioned to another provider or setting.
- The reporting of clinical quality measures to the *Centers for Medicare and Medicaid Services* (CMS) or states.
- The submission of electronic immunization data to immunization records or applications.
- The submission of electronic data on syndromic surveillance and reportable laboratory results to public health agencies.
- The segmentation of population groups, generating lists of patients by specific conditions to use for quality improvement, reduction of inequalities, research or outreach.
- The protection of the privacy and security of patient data in the EHR. This goal was already established in 1996 with the passing of a specific regulation, the *Health Insurance Portability and Accountability Act* (HIPAA), according to which every data related to the health of an identified of identifiable individual must be protected against unauthorized access or use [16,33,58].

Table III. Main features of the four use cases analyzed in this chapter

Feature		Navarre	Spain	EU	USA
Functional	Patient identification	X	X	X	X
	Integrated hospital EHR	X			
	Primary care EHR	X	X		X
	Summarized EHR		X	X	X
	Medical imaging	X	X		X
	Medical orders and test results	X	X		X
	Appointment management	X			
	Electronic prescription	X		X	X
	Nursing care	X	X		
	Clinical decision support systems				X
	Collection of data for public health and management purposes				X
	Patient's access to clinical data		X	X	X
Technological	Standardization	X	X	X	X
	Securized communications network and data protection measures	X	X	X	X
Legal	Specific legal framework on eHealth	X	X	X	X
	Specific legal framework on privacy and data protection	X	X	X	X

Source: compiled by authors.

In spite of the fact that the American health system is quite different from the European public health systems, the HITECH Act promotes a national-scale interoperability project, thus sharing the goal of the regional project of Navarre, the Spanish NHSEHR and the European epSOS and eHGI. Table III collects the main features of these projects, thus facilitating the comparison between them.

4.5. The Patients' Access to Their Health Information

An experience already in development in some healthcare information systems is the patients' access to their own clinical data. It is a specific characteristic featured and legally backed in the three of the four use cases shown above (this feature is not available in Navarre yet). In Spain, the Article 18 of the 41/2002 Act establishes the patients' right to access their health information, regardless of whether it is recorded on a paper-based system or an electronic one. In the United States, the HIPPA includes a *Privacy Rule* which sets the basics of the process for the access provision, denial and documentation [69,70], and the HITECH Act encourages the DHHS to promote the patient's right to data access, especially in those healthcare institutions which are already using an electronic healthcare information system [71]. As for the European Union, the Directive 2011/24/EU remembers that the development of IT-based healthcare information system is a national competency of the Member States, but it encourages the patient's right to data access, which is by fact and by law applied in the NHSEHR and epSOS projects.

This feature appears to be destined to spread in a not so distant future, and even go one step further and allow the patient to record new data in the system, something already developed by several successful pilot experiences [36]. Furthermore, the strategic agenda of the different health systems has included for a few years the need for promoting self-care, as a way of adaptation to several demographic projections which show a progressive aging of the population and the subsequent increase in the prevalence of chronic diseases. This guideline has been remarked by some experts who also remind of the need for fulfilling basic requirements such as interoperability, confidentiality and patients' training [30,72,73,74,75], as well as a cultural change regarding the clinicians [69,76,77,78], whose attitude towards the patient has traditionally been characterized by paternalism, though the views of both patients and professionals concerning this new feature seem to be quite positive [37,79]. The impact studies performed up to date are inconclusive, for some of them show a decrease in frequentation [80] while others show an increase [81], the latter arguably due to an inadequate training of the patients.

Conclusion

The health system is a complex organization that requires an integrated management of its primary functions. Healthcare delivery is the most important, since it represents the corporate mission, but resource management, system stewardship and financing are also essential for the system to perform its activities. The development of these functions is based, among other requirements, on the data exchange within the organization, which implies the existence of a healthcare information system that stores, processes and provides the data which are necessary at any moment and at any point of the health system.

As a consequence, the information system has the same primary functions, and thus a structure and a complexity similar to those of the health system. Besides, given that healthcare provision is the main function, the information generated by the healthcare itself is the base for every management, stewardship and financing process which takes place within the health system. These functions are performed using several applications commonly referred to as “health/healthcare information systems” and analyzed separately, hence giving an inaccurate portrait of the complexity of health information management.

This chapter presents the healthcare information system as a whole, complex and integrated entity, inside which data are transmitted and processed from the very moment they are stored in it. Thus the information system contains huge amounts of complex data, which can be used for several different purposes. For this reason, it is essential that these data meet some quality criteria in order to ensure the system’s quality. This means that the information must be reliable, complete, accessible, properly structured and shown, as well as allow the system to trace any of the actions performed.

This information quality concept implies several requirements and key concepts, the following ones being the most prominent:

- Master databases for the unique identification of citizens, professionals, facilities and resources, among others inside the health system.
- Rigorous information architecture procedures which specify clearly the data sources and the data recording methods, as well as the data flows within the information system.
- Interoperable applications which make possible the data exchange inside the information system, through the adoption and use of organizational, semantic and technological standards.
- Mechanisms for the information security management, in order to ensure the data confidentiality, integrity and availability.

Moreover, this chapter states that the information system must be capable of adapting itself to changes in the needs of the health system; rely on an IT infrastructure composed of software applications, hardware equipment and a communications network; and have a specific legal framework which backs the management of all the requirements mentioned above.

The final confirmation of the contents and contributions of this chapter is given by large institutional projects for the making of electronic healthcare information systems, such as the ones currently being developed in Spain, the European Union and the United States of America. They take into account all the requirements and features shown in this chapter, as a means to ensure high-quality healthcare for every citizen. Each of them is properly backed by a specific legal framework, establishes the basics for information interoperability and security, and includes an upcoming need of health systems: the patients’ access to their own health information.

Acknowledgments

The authors wish to express their gratitude for the assistance of Ms. Pilar Carnicero, whose contributions have been essential in achieving the final result.

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