

NHS

# ELECTRONIC HEALTH RECORD

SYSTEM

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# TABLE OF CONTENTS

## 1. STARTING POINT

## 2. NATIONAL HEALTH SYSTEM ELECTRONIC HEALTH RECORDS

- 2.1. Justification for the Project
- 2.2. Objectives
- 2.3. Functional Design
- 2.4. Security Strategy
- 2.5. Technology Strategy

## 3. STRATEGIC PRINCIPLES

- 3.1. Utility for Professionals and Citizens
- 3.2. Protecting People's Privacy

## 4. METHODOLOGY AND DEVELOPMENT PHASES

- 4.2. Professional Consensus Phase
- 4.3 Institutional Consensus Phase

## 5. ACTIONS TO CONSOLIDATE THE HCDSNS SYSTEM

- 5.1. Technical Interoperability. The NHS's Standards Policy
- 5.2. Semantic Interoperability. Semantic Services in the NHS
- 5.3. Pilot Study of the HCDSNS System and Implementation
- 5.4. Institutional Support. Resources Invested

## 6. CONCLUSIONS

ANNEX. Web Application

BIBLIOGRAPHY

# 1. Starting Point

The implementation of information and communications technologies by regional authority health services over the last few years has provided users and professionals with systems and applications that have facilitated access for both to quality information on individuals' health placed at the service of increasingly improved healthcare. Today all regional authorities without exception are equipped with electronic (or digital) health (or medical) record (EHR) systems in primary healthcare at the final stages of almost complete implementation. The level of implementation is much lower in specialised healthcare, although not below the levels corresponding to other developed countries<sup>1</sup>. These systems incorporate magnificent functionalities that contribute to increasing the effectiveness, efficiency and security of the healthcare process. However, they were not conceived to offer information when the patient has to be attended beyond the geographic scope within which the information was generated.

According to the results of the latest Health Barometer (data for 2008), 10% of the 7,125 citizens surveyed needed to go to a public health centre when they were outside their regional authority of residence<sup>2</sup>. On the basis of this piece of data, we can estimate that the number of citizens who seek medical care at NHS centres outside the regional authority where they normally live could exceed 4.6 million people a year.

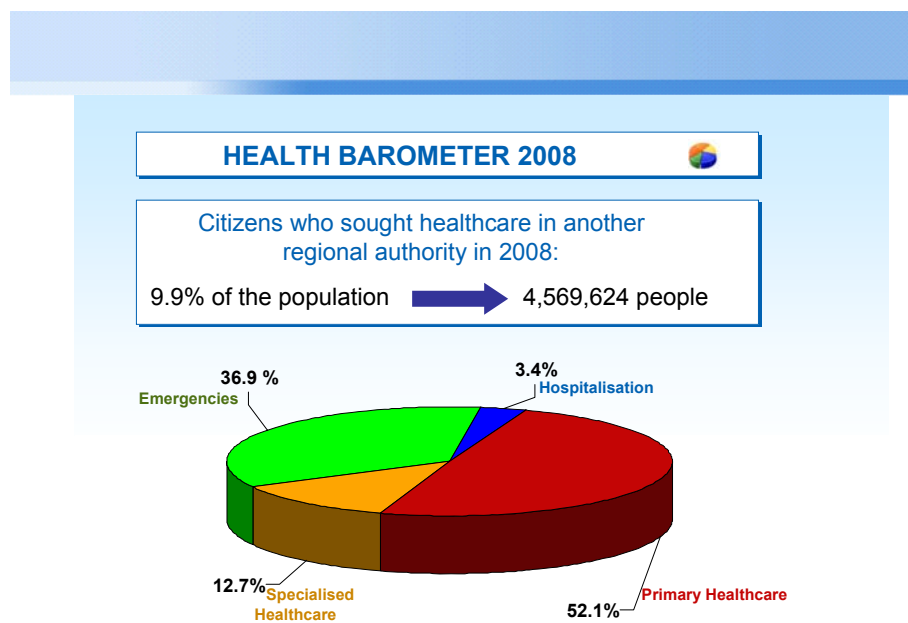


Figure 1. Health Barometer 2008

There can be no doubt that our society is evolving into an increasingly globalised world in which citizens travel ever more frequently for family, work or leisure reasons. This phenomenon means that many citizens use web services like banking transactions, travel bookings, purchases over the Internet, etc. on almost a daily basis. However, the offering of interactive services provided to users in web environments continues to be scarce.

In a health service like the Spanish health service, in which management competencies are highly decentralised and devolved to the regional health services, the use of robust coordination and cohesion mechanisms are more necessary than in any other model. The health record computerisation process is an outstanding example of this. Over the last decade, all the regional health services have made a great effort to achieve the almost complete implementation of electronic health records (EHR). These systems offer functionalities that provide great advantages to the service such as quicker, more secure healthcare for patients and higher margins of efficiency than their predecessor, hard copy health records. Nevertheless, access to such information has been restricted to the regional authority in question and, when patients have to be attended outside the region's geographical boundaries, the information is not accessible to either NHS professionals or to the citizens themselves.

In this regard, Article 56 of Law 16/2003 of 28 May on the Cohesion and Quality of the National Health System (*Ley 16/2003, de 28 de mayo, de Cohesión y Calidad del Sistema Nacional de Salud*)<sup>3</sup> grants the Ministry of Health and Consumer Affairs, which is now the Ministry of Health and Social Policy (MSPS - *Ministerio de Sanidad y Política Social*), the mandate to coordinate the electronic interchange mechanisms for clinical and individual health information in order to allow access to both users and professionals under conditions that are strictly necessary to ensure the quality of healthcare and the information's confidentiality and integrity.

Furthermore, the third additional provision of Law 41/2002 of 14 November, the Basic Law Governing Patient Autonomy<sup>4</sup> (*Ley 41/2002, de 14 de noviembre, Básica Reguladora de la Autonomía del Paciente*) sets forth that, "*The Ministry of Health and Consumer Affairs in coordination with and with the collaboration of the regional authorities holding competencies on the matter shall promote, with the participation of all stakeholders and in keeping with the evolution and availability of technical resources, the diversity of systems and the kinds of health records, the implementation*

*of a system of compatibility to make its use possible by Spain's healthcare centres that care for the same patient in order to avoid those receiving treatment at different centres from being submitted to unnecessary repetitions of examinations and procedures".*

After making this diagnosis of the situation, the Ministry of Health and Social Policy (MSPS), taking into consideration the needs identified, the legitimate interests of the stakeholders and in keeping with the legal mandate, decided to tackle the National Health System Electronic Health Records Project (HCDSNS) in 2006 to provide a realistic response within a reasonable deadline to the need thus identified. The HCDSNS system should therefore be considered as one of the cohesion instruments of the Spanish National Health System.

## 2. NHS Electronic Health Records

### 2.1. Justification for the Project.

The HCDSNS system forms part of a set of projects known as Online Health (*Sanidad en Línea*) laid down in strategy 11 of the National Health System Quality Plan aimed at making a contribution to generalising the use of new technologies in the health service to improve healthcare for patients and citizens.

This project, whose outline was defined in the first half of 2006, is based on four essential elements:

- **Healthcare reasons.** Citizens travel outside their regional authority of origin and, when they require healthcare, it is necessary that their health data – at least the most relevant data – are made available to the professionals that have to provide them with care.
- **Patient and user Rights.** Articles 3.2, 3.3 and 40.16 of Law 14/1986 the General Healthcare Law<sup>5</sup> (*Ley 14/1986 General de Sanidad*) as well as Article 23 of Law 16/2003 on the Cohesion and Quality of the NHS (*Ley 16/2003 de Cohesión y Calidad del SNS*) set forth the right of citizens to receive quality healthcare under conditions of effective equality. In order to comply with this mandate, essential information has to be made available.
- **Professionals' needs and responsibilities.** The NHS's healthcare professionals are obliged to provide healthcare to all citizens seeking it at NHS centres. Hence, it is the responsibility of the respective administrations making up the NHS to coordinate and provide the necessary elements that would allow such resources to be placed at the disposal of healthcare professionals, so as to guarantee the best possible healthcare.
- **Legal mandate.** Both Law 16/2003 on the Cohesion and Quality of the NHS as well as the Third Additional Provision of Law 41/2002 on Patient Autonomy set forth that the Ministry of Health and Social Policy is responsible for setting up the systems to ensure that any information on a single patient that may exist in different health services can be accessed.

Within this context, two different scenarios can be envisaged in which the public health service has to respond with coordinated solutions:

*Scenario 1: A citizen is in Spain but temporarily outside his/her regional authority of residence and requires healthcare at an NHS centre or service. The professionals that have to provide him/her with healthcare need to access the records containing his/her essential health data in order to provide quality healthcare.*

In this scenario, the Ministry of Health and Social Policy (MSPS), taking a pragmatic approach to the problem, considered it feasible to tackle this need in the short to medium-term (two to four years) with the agreement of all the regional authorities by means of the HCDSNS system to place at the disposal of professionals and citizens access to the relevant data sets that have been drawn up for almost two decades in digital format, such as clinical reports.

*Scenario 2: A citizen definitively changes his/her place of residence from one regional authority to another. Hence, transferring all his/her electronic health records to his/her new regional authority of residence is necessary in order to allow his/her health problems to be monitored with all the already existing information.*

In order to provide a response to this latter scenario, actions involving greater functional and technical complexity need to be tackled. These actions therefore require longer execution timescales and greater resources given that their scope includes interoperability at all levels and the entire contents of the regional authorities' electronic health records. This is an ambitious long-term project that has been called the Full Interoperability Project (*Proyecto de Gran Interoperabilidad*) by the MSPS.



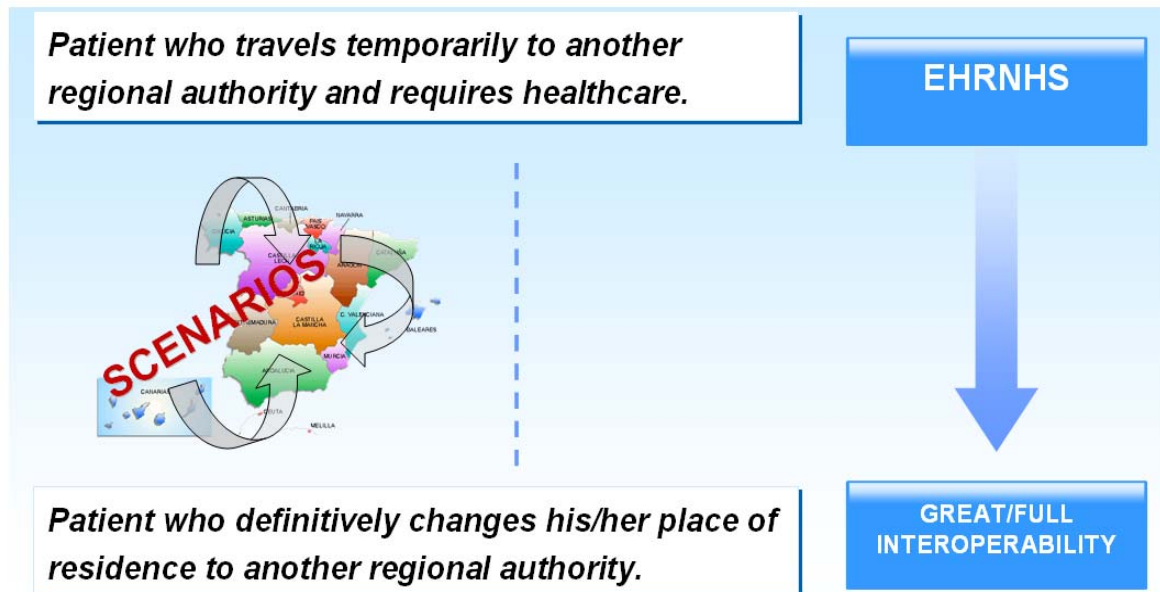


Figure: 2. Possible scenarios.

The HCDSNS system has been designed to provide a response to the first of the two scenarios described above. Nevertheless, regarding both its functional design as well as the adoption of solutions to make it feasible, full interoperability in the long-term has not been forgotten, so as to ensure both have synergies right from the start and that they both develop along the same lines.

The project's definition was tackled with the wide-ranging participation of the different stakeholders involved, including institutions and groups like providers and recipients of the solutions put forward, such as:

- Regional health authorities and health services, as the bodies holding responsibility for the provision of services, the management of resources and the processing of health centres' clinical information.
- Citizens, users and patients, as the final beneficiaries of the information made available and as the holders of rights over their own clinical information, as well as users of a group of functionalities aimed at them.
- Professional groups of the different functional areas and services at all healthcare levels.

- The Ministry of Health and Social Policy (MSPS), which holds responsibility for coordinating the services and ensuring citizens' individual rights are guaranteed throughout the country under equal conditions.

## 2.2 Objectives

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The following were defined as the project's general objectives:

- To guarantee citizens' electronic access to their own health data and to the health data of those they represent that are available in digital format at any of the health services that make up the NHS, as long as they comply with the minimum security requirements laid down to protect their own data against illegal intrusion by those who have not been duly authorised to access such data.
- To ensure the healthcare professionals duly authorised by each health service for such a function can access specific personal health data sets generated by a regional authority other than the one requiring the information, as long as the user or patient seeks the professional's healthcare services at a public NHS health centre.
- To provide the NHS with a secure access system that guarantees citizens the confidentiality of their personal health data.
- The HCDSNS system should be dynamic and simple as regards access and be at the service of citizens and professionals.

## 2.3 Functional Design.

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The strategic approach put forward in the functional design of the HCDSNS system does not include access for professionals and citizens to all the existing contents in the health records held by the regional authorities, but only to those data sets that are relevant from a clinical standpoint, as they summarise the essence of a citizen's health records.

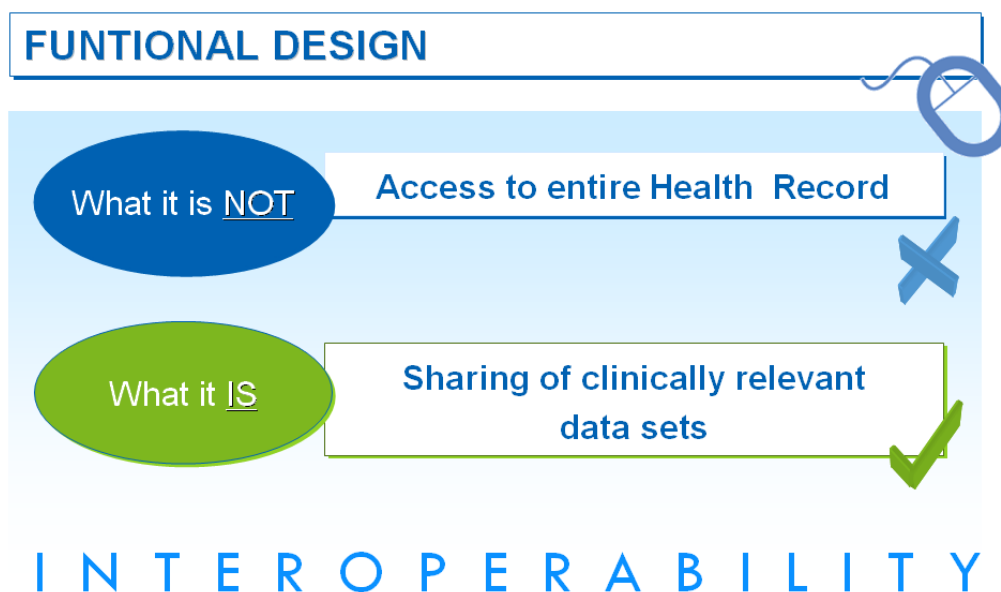


Figure: 3. Functional Design of the HCDSNS

With this aim in mind, the electronic documents containing truly relevant data as support information to the healthcare provided to a citizen seeking healthcare were defined. Such data sets include:

- Patient Summaries, known in Spain as *Historia Clínica Resumida* (HCR).
- Primary Healthcare Reports
- Emergency Room Reports
- Discharge Reports
- External Surgery Reports
- Nursing Care Reports
- Laboratory Test Results Reports
- Imaging Test Results Reports
- Results of other Diagnostic Tests

All these electronic documents are clinical reports to be found in patient health records, irrespective of the health record model each regional authority may have defined. They describe the details of the different healthcare episodes of each patient's medical biography, and the target recipients of most of the data are the patients themselves, who have until now received them on hard copy.

The only exception to this rule is the patient summary, a newly created data set on the basis of this system's implementation and primarily meant to be used by healthcare professionals. The patient summary's utility consists of offering all the essential information needed by a professional as briefly as possible when he/she has to attend a patient for the very first time. It therefore contains very little data on the patient's medical background (for example, allergies) because its main aim is to provide current data (active clinical problems or medication used at the moment). For this reason, it should be updated automatically whenever any of the data types included in it undergoes any kind of change in the full health record from which the patient summary is drawn. The patient summary is therefore more a transversal data set than a longitudinal data set or, in other words, an updated snapshot of the patient and not a video of his/her entire life.

## **2.4 Security Strategy.**

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This system's security strategy provides an exact response to the strategic principles set out in Section 3: wide-ranging *accessibility and protection of privacy*.

Security therefore plays an overriding role – given the system's criticality and the nature of the personal data processed by it – because such data require the highest level of protection set forth in the Organic Law on the Protection of Personal Data<sup>6</sup> (*Ley Orgánica de Protección de Datos de Carácter Personal*) and the Royal Decree that develops it<sup>7</sup>.

The security strategy is based on introducing some control measures prior to access that go beyond those required by the aforementioned pieces of legislation (recognised electronic signature and the assignment of professionals to different groups), but without establishing filters that are so strict they would impede legitimate access. Subsequent control mechanisms were especially reinforced (access by citizens themselves to the audit trails that concern them and the setting up of systematic access monitoring systems by the system's Board of Administrators).

## **2.5 Technology Strategy**

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The definition of this new system was drawn up from a highly pragmatic standpoint.

Starting off from existing systems at each regional authority, an information interchange layer was established through a service-oriented architecture (SOA) to make data transmission possible among the different systems implemented by the different NHS players without, however, conditioning the solutions that had already been adopted by the regional authorities or any they could adopt in the future.

The system's architecture is based on the Ministry of Health and Social Policy's central switching point and on the technology standards defined by a work group comprised of representatives from all the regional authorities within the framework of the HCDSNS project.

## 3. Strategic Principles

From our standpoint, it is essential to keep two values in balance at the highest level when dealing with a system of these characteristics and objectives: on the one hand, the availability of information for citizens and the professionals who have to provide them with healthcare and, on the other, the protection of citizens' privacy, represented in this case by their health data. Hence, no professional that has to act to the benefit of a citizen's health should encounter any obstacle to accessing the data he or she may need to exercise his/her function, but nobody without the legitimacy to do so should be able to access such data. The former arises from the principle of benefit and the latter from the principle of autonomy. Obviously, neither of them should override the other and both should be equally upheld at the highest possible level.

As information becomes increasingly accessible to a greater number of people from a wider geographical scope, the means of protection aimed at guaranteeing the maximum level of security possible should be increased. Nonetheless, protection systems cannot be so stringent that they end up impeding the provision of healthcare or caring for a person's life in some cases.

Naturally enough, the security measures needed by a system in which data are stored in a local server which only allows access to professionals performing their activity in the physical area of a centre do not have the same scope as the measures required to offer the same guarantees in a system providing much wider access to a large number of professionals acting from a variety of geographically distant centres, including those located in other regional authorities.

Combining this principle with the effective utility of the system's functionalities for professionals and citizens has made it necessary to design a work plan comprised of series of actions aimed at deploying and integrating realistic solutions within the structure and healthcare context of our National Health System based on these two principles which cannot be waived.

### 3.1. Utility for Professionals and Citizens.

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Two groups of available functionalities were described as a result of the needs analysis conducted for professionals and citizens, who are the system's direct users.

For professionals: Access a patient's health data sets and images, limiting access to:

- a) Strictly healthcare-related uses only when the patient seeks healthcare from a professional outside his/her regional authority of residence.
- b) Group-associated access permission, so that each one of the two healthcare groups defined in this system – physicians and nurses – can only access the contents needed to perform their functions.

All the documents that comprise electronic health records, apart from the patient summary, are documents that describe specific episodes and have an author responsible for their contents. For this reason, their format is closed so as not to allow any modifications to be made to their original contents. The system displays the reports' contents as an image that can be read and printed. However, such reports cannot be edited, nor can their contents be partially or totally copied or downloaded onto storage devices.

In the case of patient summaries, they should be automatically generated from the full electronic health record and it should be possible to partially or totally consolidate their contents into the electronic health record generated by the professional providing healthcare, thereby making the inclusion of the relevant data easier. The patient summary in the regional authority of origin will continue being the same and will only reflect the changes made to the original health record in the patient's own regional authority. There can therefore be as many patient summaries as regional authorities that have opened an electronic health record for a single patient.

For citizens. *The system offers three types of functionalities for citizens:*

**a) Access to personal data sets concerning their health**

Citizens are given access to each and every one of the reports that make up their electronic health records, which are kept by each of the regional authorities where they were generated.

All citizens included in the user registry (Individual Health Card database in his/her region) who have a recognised electronic signature (or electronic identity card – e-DNI), may access any electronic documents that are available through the website made available by their health service, as well as print them out or download them onto local storage devices. From a legal standpoint, people's entitlement to accessing their own health data was already sketched out in Article 61 of the General Health Law of 1986, which was repealed. Over the following years, it was consolidated by jurisprudence and finally explicitly confirmed by Article 18.1 of the Law on Patient Autonomy, which sets forth the entitlement of access to entire health records, with the only two constraints being third-party confidentiality rights and the rights of the professionals that take part in drawing up such health records. The HCDSNS system therefore does no more than facilitate electronic access to extracts or parts of health records, many of which are already in the hands of patients themselves on hard copy, without prejudice to the entitlement of obtaining a copy of their health records.

***b) Access trails to a citizen's data sets***

By means of this system, citizens can monitor details of the instances of access to their own data sets from this system, so they can verify their legitimacy. Citizens will thus be provided with information concerning the moment at which access was established, as well as the health service, health centre and department from which each instance of access was performed, along with details of the electronic documents accessed.

Each time a citizen makes use of this functionality, he/she will be acting as an external auditor of the system, thereby adding another element to those making up the system's security strategy regarding subsequent controls mentioned above, in addition to the mechanisms implemented prior to access.

By means of this functionality, compliance with the provisions set forth in Royal Decree 1720/2007 of 21 December approving the Regulations developing Organic Law 15/1999 of December 13 on the Protection of Personal Data is reinforced, Article 96 of which sets forth that, "as from an intermediate level (of security), information systems and data processing and storage facilities shall be subjected to an internal and an external audit at least once every two years to verify compliance with this Article".



***c) Hiding any data sets that should not be seen professionals other than those that normally treat the patient***

The recognition of a citizen's capacity to limit access to part of his/her health data to some professionals has aroused controversy, in as much as it is not an entitlement explicitly recognised in either Spanish data protection or health legislation.

Nevertheless, it should not be forgotten that this entitlement has always been exercised in healthcare practice in our public and private health systems. The information contained in hard copy health records provided by the patient continues to be the most frequent system by means of which professionals obtain the patient's data from a centre other than the one in which treatment is being carried out. Whether or not to show such documents is the patient's prerogative. It therefore does not seem pertinent that the implementation of a new automated system should now place constraints on capacities that the health system has already been granting to patients for decades.

Beyond our health system but within our most immediate context, section III.3.b of the document issued by the Article 29 Working Party of the European Union on the Processing of Personal Data relating to Health in Electronic Health Records, which is not binding, recommends that electronic health record systems should grant this power to citizens<sup>8</sup>.

This issue came up in the debates held by the HCDSNS project's work groups, in which professionals, managers, citizens, legal experts and bioethicists took part. However, agreement on the inclusion of this functionality in the system's design was finally reached, recognising that patients, fully exercising their autonomy, could take on the responsibility corresponding to them regarding the results of the healthcare received. The references and arguments which lie behind this decision were set out in detail in another publication concerning the HCDSNS project<sup>9</sup>.

It is important to highlight that the data a citizen chooses to hide will, under no circumstances, be deleted from the file and that the decision of hiding such data may be subsequently reversed by the user at any time.

At the same time, systems like the HCDSNS system, which make use of the resources current technology has to offer, allow a trace of the decisions taken by the different

players that take part in the processing of the information to be left behind, thereby making the auditing of such decisions possible.

The HCDSNS system additionally makes several safeguards available when this capacity granted to the patient is exercised.

- Firstly, before the hide document command is executed, the system always warns the citizen of the negative consequences this could have on him/her by conditioning the decision-making process of the professional who has to make the diagnosis or recommend treatment without having all the available information at hand.
- Secondly, whenever a professional from another regional authority has to access a patient's health records, he/she will be informed of the existence of hidden information (without specifying what kind of information it is), so that, if knowing all the information were so important in the specific clinical context, the patient may understand the convenience of revealing the non-visible contents after having been duly informed.
- Lastly, given that the patient's capacity to decide is a necessary prerequisite for exercising his/her autonomy, if the professional declares a patient is incapable of deciding on the basis of a clinical interview, the system would allow access to initially hidden information, despite the patient's previous decision, in an emergency situation requiring urgent attention. An audit trail indicating both circumstances would then be left behind.

### **3.2. Protecting People's Privacy**

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As has been mentioned above, this system's security strategy is essential as it has to provide a response to the protection of particularly sensitive data regarding people's health, the processing of which requires the use of high-level security measures, as set forth by the Data Protection Law and Royal Decree 1720/2007 approving the Regulations that develop it.

In addition to the security requirement laid down by prevailing legislation and given the nature of the information to be handled, the National Health System's services are equipped with security mechanisms which guarantee the following through the use of cryptographic and public-key techniques:

- The identity of previously authorised people;
- The authenticity of the players that claim they are acting on their behalf;
- A non-repudiation guarantee, thereby avoiding non-recognition by the parties when performing a transaction in the system;
- The privacy of the information to be interchanged, so that it is not disclosed to third parties either intentionally or accidentally;
- The integrity of the information, ensuring that it has not been manipulated at any point during the communication process (either intentionally or accidentally).

## 4. Methodology and Development Phases

A methodology aimed at reaching maximum consensus among the main players was applied to all the work leading up to the execution of the HCDSNS project. Firstly, it was deemed essential to identify the needs of the healthcare professionals that would eventually use the system and, of course, the points of view of the regional health authorities in Spain. The regional authority health services will be responsible for offering their citizens these services, which are linked to the provision of healthcare in the exercise of their competencies and which do not cease to exist when a citizen crosses the geographical boundaries of the regional authority where he/she resides. In this regard, all the agreements reached can rely on the backing of all Spanish regional authorities and autonomous cities.

The execution of the different tasks to be performed from the system's definition right up to its implementation was structured around two phases:

- Professional Consensus Phase
- Institutional Consensus Phase

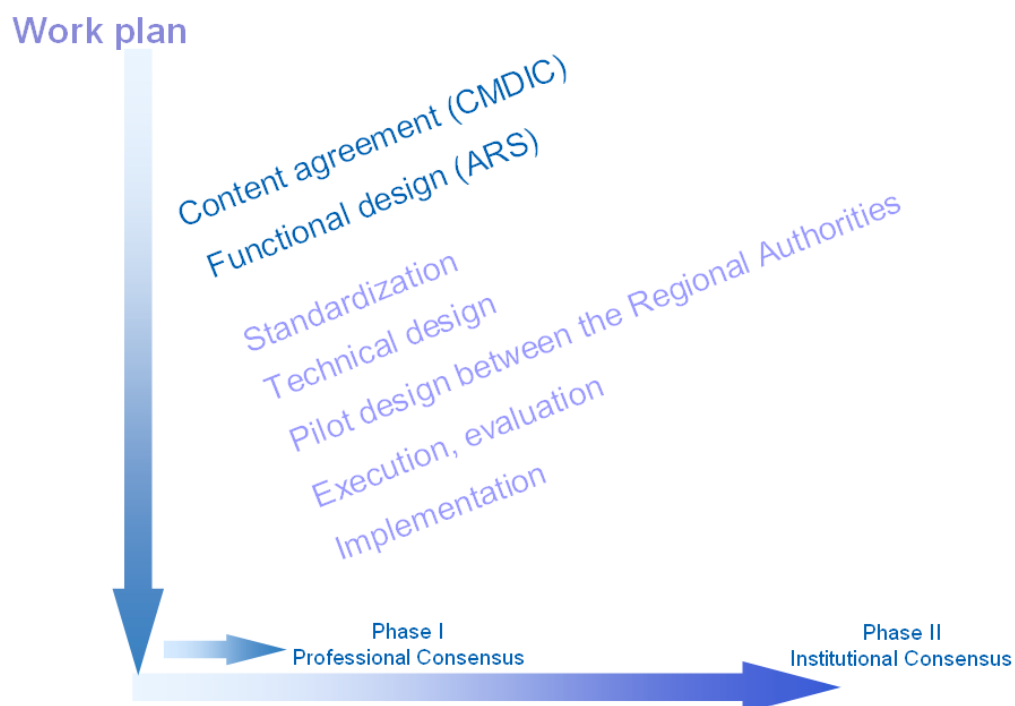


Figure 4. Evolution of the HCDSNS project work plan

#### 4.1. Professional Consensus Phase

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As no kind of explicit agreement or standard to define and unify the contents of clinical documents as regards the HCDSNS system had existed to date within the NHS's healthcare context, it seemed necessary to make an effort to arrive at a consensus on their contents from the standpoint of healthcare professionals. The only exception to this was the discharge report, whose contents were regulated by means of a Ministerial Order in 1984<sup>10</sup>, though even in this case the time that had elapsed since its publication suggested the convenience of reviewing and updating it. Hence, it was necessary to first deal with the standardisation of the minimum contents each of these clinical reports should offer.

The project's management team felt that the system's definition and that of its contents could only be managed with the participation of the professionals that generate and have to use the clinical information these reports contain, as well as that of professional experts in the management of healthcare centres, clinical documentation experts and the citizens themselves.

Based on this principle, different work groups comprised of professionals were set up. The background experience required for each group was set out on the basis of the contents to be defined, and citizens were included in the task of describing the system's functionalities. Once these backgrounds were defined, they were passed on to the relevant scientific associations and citizens' groups, so they could designate the appropriate people to take part. As a result, thirty-two scientific associations and citizens' groups appointed forty-five representatives and the Ministry of Health appointed fifteen professional experts in admissions, clinical documents and the management of centres to set up seven work groups.

All the work groups were coordinated by the Project Manager at the Ministry of Health and Social Policy and the work was performed through the discussion of successive drafts on a web-based work space until consensus was reached on a final draft. Highly structured face-to-face meetings were only held when they were deemed to be absolutely essential.

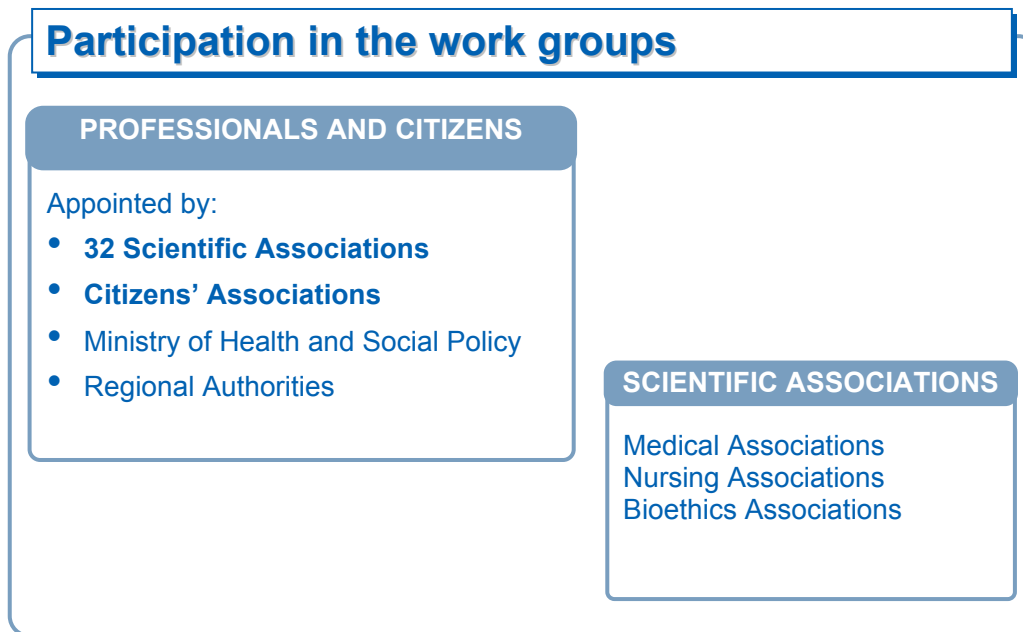


Figure: 5. HCDSNS work groups.

The consensus reached by the work groups concerning the contents of all the clinical reports that this system makes reference to was reflected in a consensus document entitled "Clinical Report Minimum Data Set" (CMDIC - *Conjunto Mínimo de Datos de Informes Clínicos*)<sup>11</sup>.

Similarly, consensus was reached regarding the security and functional requirements the system should meet, which were set out in a document entitled "System Requirements Analysis" (ARS - *Análisis de Requerimientos del Sistema*)<sup>12</sup>. This group was comprised of information and communications technology (ICT) professionals, as well as healthcare professionals with experience in healthcare management, admissions and clinical documentation, along with a citizens' representative, a legal expert on healthcare-related issues and a clinical bioethicist.

#### 4.2. Institutional Consensus Phase.

In this phase, two lines of action were performed in parallel:

- The validation by people holding institutional responsibility at all the regional authorities of all the professional agreements reached in the preceding phase, first through a group of institutional EHR experts, which then elevated its conclusions to the Information Systems Subcommittee and finally from there to the Interterritorial Council of the NHS. This latter body, at its meeting held on 10

October 2007, resolved to approve the design discussed previously, as well as the performance of pilot study in several regional authorities.

- Providing the NHS with the essential elements to guarantee the interoperability of the systems, based on the scope defined for the HCDSNS system. In order to make progress in this direction, new work groups were set up between the end of 2007 and the beginning of 2008, whose task consisted of drawing up proposals that would progressively lead to full EHR interoperability across the NHS, both at a technical as well as a semantic level, along with defining the necessary scenario and requirements to carry out the interchange piloting of the HCDSNS system:
  - The Standards and Technical Requirements Work Group (GERT - *Grupo de Trabajo de Estándares y Requerimientos Técnicos*), composed of experts having a technology background from each regional authority, reviewed the technical design of the National Health System Electronic Health Records system put forward by the MSPS and reached a consensus on a standards policy for the NHS for the coming years.
  - The HCDSNS Semantic Interoperability Advisory Group's (GAISHC - *Grupo Asesor de Interoperabilidad Semántica de la HCDSNS*) objective is to focus on lines of action in this field in order to resolve the problems of electronic health record semantic interoperability in the NHS, including support for linguistic diversity and placing priority in the short-term on any solutions required to ensure the patient summary's interoperability. Its members, appointed by the MSPS, are NHS technical experts having specific experience in this field.
  - HCDSNS Pilot Study Group of Regions (GCPHC - *Grupo de Comunidades para el Pilotaje de HCDSNS*). This group is comprised of the ten regional authorities that have stated their interest in taking an active part in this system's pilot study in real scenarios. The other regional authorities, which decided to act as observers of the piloting process, are provided with updated information on the evolution and results of the work carried out through the work space. They have also taken part in the face-to-face meetings held on a regular basis since the pilot study commenced.

## 5. Actions to Consolidate the HCDSNS System

At this point, there are two areas open to development and on which the efforts of the all the players involved are focused: technical and semantic interoperability and the development of the HCDSNS system's pilot study, with a view to its subsequent implementation across the NHS.

### 5.1. Technical Interoperability. The NHS's Standards Policy

The standards policy put forward by the Standards and Technical Requirements Work Group (GERT) for the HCDSNS system brings together a series of recommendations regarding:

- the data interchange format (XML);
- the formats of documents to be interchanged (PDF);
- the image format (DICOM);
- coding tables of the National Statistics Institute (INE) for regional authority, province, local authority, etc. codes;
- unique patient identification through the Personal Identification Code (CIP - *Código de Identificación Personal*) linked to the regional authority code, and the use of the NHS code of the NHS individual health card database is recommended;
- identification of professionals (national ID card number (DNI)/national alien registration number (NIE)/passport number) or professional association membership number;
- national alien registration number format;
- security certificates;
- interchange of clinical information (HL7 CDA level 1 for document headers). The decision not to adopt CDA levels 2 or 3 for the moment is linked to the current uncertainty about whether they could condition the model of reference. Thus, as no decision on this issue has yet been taken, the group preferred to wait and get to know about specific experiences demonstrating the compatibility of any CDA level with the existing model of reference, so as not to condition this choice beforehand.



This system's technology strategy is based on technological neutrality in order not to condition the decisions of the regional authority health services which have placed a wager on open standards, as defined in the European Interoperability Framework. The key lies in establishing a layer that would allow data transmission among the different systems that the players making up the NHS have decided to implement without it conditioning not only the solutions adopted and implemented, but also any others that may be decided upon in the future by each of the different health organisations exercising their competencies.

The technical architecture is based on a Ministry of Health and Social Policy central switching point and the technology standards defined within the project's framework.

The NHS central switching point is the piece of hardware and software infrastructure that facilitates the interchange of data (administrative and clinical) among the different National Health System players, including: regional authorities, mutual societies and others competent authorities.

It is a technology solution that makes the implementation of services like the HCDSNS system possible and allows Spain's current decentralised map of competencies to be conciliated with the ever more pressing need to provide the health service with continuity for a growing population of increasing mobility (work-related and personal) both in Spain as well as at a European level.

This switching point will likewise house the services that will enable information to be interchanged with other countries' systems concerning both the identification of patients as well as their patient summary and electronic prescriptions.

Communications between the different regional authorities and the Ministry of Health are established through the Health Service Intranet, a private communications network that provides access to these services solely to authorised parties for the transactions. It also guarantees the levels of security, availability and quality of service such services require due to their criticality.

The decision taken to implement a web service-oriented architecture (SOA) at the NHS central switching point has made it possible to incorporate the players in a progressive fashion without the need of unifying existing applications in the regional authorities, modifying basic software or integrating the systems of the different players involved<sup>13</sup>.

The NHS switching point is the nexus linking the different players involved. It implements the central switching point's security layer, verifying the authenticity of the players that connect to it, the validity of the certificates with which they identify themselves, the electronic signature of the messages received and the validity of the XML structure of any messages interchanged, subsequently making those XML messages available to the appropriate NHS service in keeping with the scheme illustrated in the figure below.

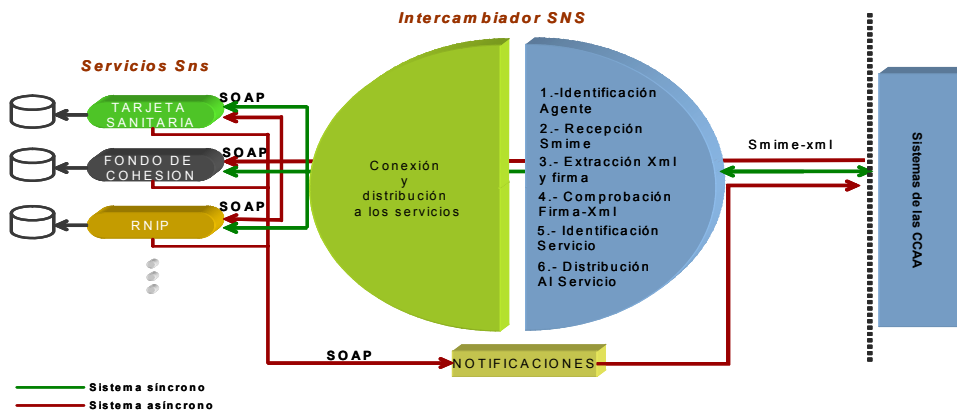


Figure: 6. Scheme showing the Ministry of Health and Social Policy's NHS switching point

On the basis of the NHS's services' needs, the switching point allows for the processing of both synchronous services (health record searches, etc.) as well as asynchronous services (notifications, changes of data, cancellations, etc.). The latter can be queued and their processing delayed for a time when the workload is lower.

Once the XML messages are received by the switching point, the NHS services perform the business processes corresponding to them (updating references, issuing reports, etc.)

The average number of messages interchanged through of the central switching point amounted to 400,000 a day at the end of 2008.

The integration architecture is star-shaped. In other words, access to the NHS services involves the switching point's mediation to gather the messages sent by the regions, authenticate the issuing region, validate the recognised signatures of any messages

received, extract the XML and then forward them to the appropriate health service to which they are addressed.

When implementing an SOA architecture and making different application services available through web services to different organisations, it becomes necessary to work on an appropriate method to govern them, so as to be in a position to reuse them and keep them under control and monitored at all times. When the number of web services grows, as is the case in this project, it is essential to use a tool that can manage and monitor their performance, as well as to provide them with the appropriate security levels in keeping with their use (control, availability, location and diagnosing problems).

The Ministry is currently in the process of implementing an enterprise services bus (ESB), a tool that would complete the SOA architecture's complex puzzle. This tool also manages to avoid point-to-point connections between the different applications, which are a major source of potential problems.

## **5.2. Semantic Interoperability. Semantic Services in the NHS**

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As Cimino, one of the main researchers in health informatics, stated in 1996, "one of the great challenges facing medical information is representing knowledge in a way that would allow it to be handled and used by information systems"<sup>14</sup>. This prediction made more than a decade ago has yet to be overcome.

Interoperability is not solely a technical issue, as there are many more factors that play a part in it. In systems that provide support to clinical information, the mere interchange of data between different applications is insufficient. If technical interoperability makes it possible to interchange data, semantic interoperability facilitates the interpretation of their meaning and the integration of such data into the systems they are destined to, along with their contextual information. In other words, it transmits us knowledge.

Semantic interoperability should also serve so that the languages used to represent the documents' contents are identified and interpreted in the same way by users having different languages or classifications. In order to achieve this, there is a common basic need among the different players taking part in the interchange of information to have available a single standardised terminology recognised by all the systems involved.

Hence, the NHS needs to provide itself with a whole set of semantic instruments which have to be made available to all the players that comprise it, including:

## ● Terminologies.

As has been mentioned above, one of the first tasks in semantic interoperability laid down for the HCDSNS project is to define, by means of professional consensus, a minimum data set with which clinical reports within the NHS should comply.

The use of standardised terminologies is established in this clinical report minimum data set (CMDIC), when dealing with free text, and the use of previously determined catalogues (implemented coding systems), which allow the data to be exploited and integrated, in addition to facilitating translation into different languages. Terminologies are therefore key elements, without which interoperability is only an unreachable theoretical concept.

Following the recommendations made by the HCDSNS Semantic Interoperability Advisory Group and bearing in mind the needs expressed by many regional authority health services, a decision was taken to initiate a new line of work aimed at making available to all NHS players the semantic services required to reach full interoperability as regards electronic health records. One of the first steps taken in this new line of work was to adopt a controlled standardised clinical terminology which would allow for the unequivocal automatic interpretation of the contents transmitted between systems in an accurate way and in different languages, thereby facilitating access to the relevant information for clinical decision-making. The terminology thus chosen was Snomed Clinical Terms ® (Snomed-CT), which is currently the most developed leading international clinical terminology and enjoys the most widespread recognition and use in the world.

The first step needed to turn this decision into reality was for Spain to join the International Health Terminology Standards Development Organisation (IHTSDO), an international non-profit consortium founded by nine countries which has acquired the intellectual property rights of Snomed-CT. Only countries duly recognised by the United Nations can form part of this organisation. Its main aim is to develop and promote the use of this standardised clinical nomenclature around the world to securely and efficiently support the interchange of information concerning people's health.

Spain's entry into this organisation as an ordinary member – which took place in 2008 with the resolution taken by its IHTSDO Management Board approving its membership – allows Spain to exercise an influence on the decision-making process concerning the evolution of this international tool. In addition, the Ministry of Health and Social Policy became the body that can officially distribute the international nucleus of Snomed-CT

free of charge, along with any Spanish extensions that may be developed, to both public and private organisations, as long as they are not used outside the borders of Spain.

The international nucleus of Snomed-CT currently being distributed through the MSPS website is bilingual in English and Spanish<sup>15</sup>. The part of this nucleus translated into Spanish is in Argentine Spanish, which means a preliminary task is needed of validating the terms into the Spanish used in Spain in order to obtain an extension that can be adopted as a terminology of reference. Such validation will be performed by several work groups under the Ministry of Health and Social Policy's coordination. Lastly, it will also be necessary to work alongside those regional authorities having co-official languages in order to translate the terminology into these languages and, thus, enrich the national extension with all the official languages of the Spanish state.

Within an environment marked by mobility like the one we find ourselves in, all of this will enable professionals to interpret the contents of citizens' health data independently of their place of origin and of the language in which such data is to be found.

- Archetypes

Archetypes are data models that seek to represent a part of reality. They go beyond clinical terminology and are "formal definitions of clinical concepts, such as a discharge report, a glucose test or a family history"<sup>16</sup>.

They allow us to formally represent the knowledge gathered in electronic health records<sup>17</sup> in a foreseeable evident way for clinicians.

As a matter of fact, the formal contents set out for the clinical report minimum data sets (CMDIC) are a preliminary approach to detailed clinical models based on formal representations comprised of archetypes and terminology.

- Templates

Templates establish a series of additional constraints to a static standardised model. They serve to represent a specific structural level and information contents with the aim of transmitting them in an orderly explicit way. In this regard, standardised models, like the one defined by HL7, may be used<sup>18</sup>.

- Model of reference

Selecting a model or models that can be adapted to the needs of the HCDSNS system is a priority objective in the roadmap set out for semantic interoperability. From our

standpoint, choosing a two-fold model in which the data and knowledge are represented independently, although closely linked, is advantageous among the different possible options. This allows the recording of objective data (that are fixed and stable over time) to be made independent of the representation of knowledge, which by definition is subject to the changes due to innovation as a continuous process that incorporates new knowledge. Any models of reference that do not function in this manner resolve the issue of transmitting data in a standard format well in the short-term, but they leave the question of representing knowledge unresolved when it changes, as they manage both aspects jointly.

The European ISO/CEN EN13606 standard<sup>19</sup> is an example of a two-fold model. The HCDSNS project management team has yet to put forward a choice in this regard, as it is closely monitoring the outcomes obtained by international groups through the practical use of this standard and HL7 CDA-3.

### **5.3. Pilot Study on the HCDSNS System and Implementation**

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In order to tackle the development of the pilot study put forward by the Interterritorial Council of the NHS, the so-called HCDSNS Pilot Study Group of Regions (GCPHC - *Grupo de Comunidades para el Pilotaje de HCDSNS*) was set up by the MSPS in February 2008.

Two phases (I and II) were defined, which the regional authorities could join in a progressive fashion. The only difference between these two phases resides in the moment to initiate the interchange of real information. Each regional authority has taken a decision as to which phase best suits it in order to be in a position to comply with the minimum requirements agreed upon for the pilot study.

Eight regional authorities decided to join Phase I, including: Andalusia, the Balearic Islands, Cantabria, Castilla y León, Catalonia, La Rioja, Murcia and Valencia. Castilla La Mancha and Extremadura will join in Phase II. These ten regional authorities make up the work group.

This group analysed the generic scenario (functional and geographical) put forward by the project's management for the pilot study, the technical requirements, the study's design, the computer application developed and provided by the MSPS, the laboratory

tests prior to the start-up of real information interchanges and the results assessment system.

The interchange phase of the pilot study began on 8 March 2009 with the participation of real professionals and citizens in the geographical scenarios delimited by two regional authorities, namely the Balearic Islands and the Valencia Region, which the rest of the regional authorities involved in the pilot study will progressively join. The analysis of these results, will allow for enhancements to be made prior the system's general implementation across the NHS.

On a geographical level, the minimum scope is comprised of a complete Health Area, which includes:

- A hospital centre of reference
- Health centres
- Physicians and nurses

As regards the choice of the specific scenario in each regional authority, the project's management recommended that the existence of a sufficiently active flow of healthcare activity provided across the participating regional authorities be taken into account.

Concerning the functionalities for professionals and citizens, all those defined for the system were included, apart from access through a representative due to the current difficulties involved in sharing such information in real-time.



Figure 7. Functional scope of the HCDSNS system's pilot study.

The transfer of functionalities to healthcare practice and the offer of services to citizens was done through the development of an application in a web environment that offers access to the different users of the HCDSNS system on the basis of the functionalities assigned to their different profiles in the system's definition, which were agreed upon by the consensus of professionals and citizens' representatives and validated by the different administrations holding responsibility for health management in the NHS.

Complying with the requirements defined in preceding phases, the MSPS developed a web application (see Annex) it provides to the regional authorities that wish to implement it in their systems. Nonetheless, the possibility of regional authorities wishing to develop a tailored application that complies with the requirements and functionalities approved and set out in the project's documentation remains open. In this regard, a method was defined to allow for the validation of any new applications that may be developed in this way to ensure compliance with the HCDSNS system's requirements.

Additionally, there is a methodology to assess that all the elements function properly in a production environment before a decision is taken on starting up the system in a regional authority with real data and people. This methodology was called Laboratory Testing (*Pruebas de Laboratorio*).



## Laboratory Testing

Testing is conducted on three different scenarios to represent all the system's functionalities:

- Access by the professionals of the regional authority undergoing the audit to the clinical information of a citizen who normally lives in another regional authority that requests healthcare.
- Access by professionals of other regional authorities to the information offered by the regional authority undergoing the audit about its citizens.
- Access by citizens of the regional authority undergoing the audit to their own clinical information to view it, hide it and track the instances of access that have been made to it from other regional authorities.

Successfully passing the laboratory testing is an essential prerequisite for the incorporation of regional authorities wishing to form part of the pilot study.

### **5.4. Institutional Support and Resources Invested**

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From the year the HCDSNS project commenced, funds have been made available by the administrations involved in the project. This funding is aimed at making possible the actions needed to facilitate semantic, technical and organisational interoperability among the different regional authorities.

Three sources of funding have been used since 2006: the Online Health (*Sanidad en Línea*) Programme, the Cohesion Funds (*Fondos de Cohesión*) aimed at funding Health Strategies pursuant to Law 16/2003 of 28 May on the Cohesion and Quality of the NHS, and the signing specific agreements to co-fund the pilot study's preliminary actions in conjunction with the regional authorities taking part in it.

The Online Health Programme, which formed part of the Avanza Plan 2006-2008, earmarked a total amount of € 252 million, of which € 141 million were funded by the Central Administration of the State (Ministry of Industry, Tourism and Trade - MITYC), through Red.es and the Ministry of Health and Social Policy (MSPS), and € 111 million were contributed by the regional authorities. These actions were aimed at implementing ICT in the health sector and, more specifically, at supporting the implementation of the EHR and e-Prescription systems each of the regional authorities

were already in the process of developing. Along with these, they were also meant to drive forward the integration of individual health card databases into one common system for the entire NHS. This phase of the Online Health Programme prioritised the creation of infrastructures at regional authority health centres to facilitate access by healthcare professionals to the clinical information available on the citizens they attend, along with the development of the NHS central switching point located in the Ministry of Health and Social Policy.

Once the Avanza Plan's deadlines had finalised and its objectives had been met, the Online Health Programme Phase II was initiated in order to further the objective of making access possible to citizens' health information from any point within the NHS. On this occasion, trilateral agreements were reached by means of which the parties agreed upon the objectives to be reached and the investments to be made concerning of the HCDSNS system's implementation. These agreements serve to guide the funding of any actions aimed at the HCDSNS system's fully functional implementation in each regional authority.

In this second phase of the Online Health Programme running from 2009 to 2012, the Central Administration of the State is allocating € 93,651,597, to which another € 8 million should be added for actions on the central switching point. This amounts to a total investment of € 101,651,597, of which the MSPS is providing a total € 46,643,947 (including actions on the central switching point).

By means of signing trilateral agreements among the MSPS, Red.es and the regional authorities, the actions that are to be co-funded through this financing plus any contributions made by the regional authority signing the agreement are determined. If all the regional authorities choose to sign such agreements, the total regional contribution would amount to just over € 93 million in addition to the contribution made the Central Administration of the State.

Since 2008, the HCDSNS system has been integrated into a financing line for information systems within the health strategies financed by Cohesion Funds. The MSPS earmarked a total of € 13,925,500 for 2008 and 2009. These funds were allocated to any actions carried out by the regional authorities aimed at implementing the functional and technical requirements laid down in the HCDSNS system's design, as well as to any actions geared at facilitating the generation of the electronic documents that make up this system.

Additionally, the MSPS proposed entering into an agreement in 2008 with each of the regional authorities taking part in the pilot study's first phase, whose objective would be to provide support to the actions needed at each regional authority to make the real interchange of data possible. Each regional authority allocated € 25,000 to performing such actions and the MSPS allocated € 200,000. Such agreements were finally entered into with seven regional authorities. Upon their expiry, five regional authorities had complied with all the requirements set forth therein, which finally amounted to an investment by the MSPS totalling € 1 million.

## 6. Conclusions

To sum up, we consider that the HCDSNS system responds to the needs of healthcare professionals who have to provide healthcare to patients during their trips, thus providing regional authorities with a tool that allows them to offer their citizens the essential information needed to be provided with healthcare when they travel. The system places emphasis on citizens' capacity to take decisions about how to manage their own clinical information within a National Health System in which all the players involved unanimously agree on the notion that citizens should be placed at very heart of the public health system.

# Annex

The web application designed by the MSPS to facilitate HCDSNS system users accessing the functionalities described above has two different displays:

- **Access for Professionals:** Each regional authority may integrate it into its own health service intranet.
- **Access for Citizens:** Access has to be gained through the website of the health service at which the citizen's health card is registered.

In both cases, user access is granted after the verification of the identity of the person trying to gain access (authentication) and that he/she appears in the registry of users, either as a professional or a citizen who is legitimated to make use of the system (authorisation). In either case, the responsibility of guaranteeing that each instance of access to the system meets the requirements lies with regional authority to which the system's user is linked, either as a healthcare professional or as a citizen who is duly registered in the regional authority in question.

## Access for Professionals

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### 1.1. Session Initiation

Once access is granted, the first step consists of informing the professional that he/she has accessed the HCDSNS system, the most relevant features of use and the functionalities offered by the system:

*Description of the system's purpose:*

"This space has been set up to place any clinical information that may be available at the disposal of National Health System professionals who have to provide care to a specific citizen from another regional authority."

*Essential prerequisites to be able to access the information:*

- "Being a healthcare professional duly authorised by the health service for which you provide services.
- Having obtained from your health service the permits and recognised electronic certification that guarantee the authenticity of who is gaining access.
- Having received a request for healthcare from the citizen whose data will be accessed, as an essential prerequisite to consider that the consent of the holder of such data has been granted, thus authorising you, as a healthcare professional who has undertaken the duty of keeping professional secrets, to access such citizen's personal data as you hold responsibility for providing him/her with healthcare."

*Information on the system's security:*

"The system will keep a trace of the identity of the people who access it and of the characteristics of the information queried. This trace will be audited on a periodic basis. Apart from the security elements implemented, anyone accessing information about the health of people without having duly obtained authorisation to do so or make any illegitimate use thereof will be held legally liable."

*Information for clinical use:*

"Bear in mind that the patient may have exercised his/her right to hide information and, should this be the case, an icon will appear indicating such a circumstance without specifying the kind of information concealed. In situations requiring immediate action without delay and in which the patient has lost his/her capacity to decide, you, as the professional providing him/her with healthcare, may view such information. A trace of such action will be recorded and the patient subsequently informed of such a fact. Under no other circumstances will such access be considered legitimate."

"Please remember that, in your capacity as a healthcare professional, you are not authorised to store the reports on any devices. You are solely authorised to view and print them."

## 1.2. Patient Identification

There are two systems to identify the patient: through the health card and manually (*Figure 8*).

If the patient has his/her health card at hand, the card can be read electronically and his/her identification details can be captured, so as to check any clinical information that may be available under his/her name.

Should the patient not have his/her health card at hand, he/she may be identified by entering into the system a combination of identification data provided by the patient. The existence of any available clinical information in his/her name will then be checked through the NHS switching point.

The screenshot shows the user interface of the HCD Sistema Nacional de Salud. At the top, there is a header with the Spanish flag, the text 'GOBIERNO DE ESPAÑA' and 'MINISTERIO DE SANIDAD Y POLÍTICA SOCIAL', the title 'HCD Sistema Nacional de Salud', and the version 'HCD SNS v8.0.1'. Below the header, the screen is divided into sections. The first section is 'Profesional' with a light blue background, containing a dropdown menu for the professional's name and the text 'Centro: Centro Msc - Madrid' and 'Servicio: U.37 Medicina intensiva'. The second section is 'Identificación del Paciente con Tarjeta' with a white background, containing a list of instructions: 'Lectura de los datos de identificación del paciente mediante banda magnética:' followed by '1. Seleccione el Servicio de Salud' and '2. Pase la tarjeta sanitaria del usuario por el lector'. To the right of these instructions is an image of a green 'TARJETA SANITARIA' with a white cross and the number '803454 LGTK5689701669902'. Below the instructions is a dropdown menu for 'Servicio de Salud' with the text 'Seleccione'. The third section is 'Identificación del Paciente de forma manual' with a white background, containing the instruction 'Para indentificar manualmente al paciente pulse el botón' and a button labeled 'Búsqueda Manual'.

*Figure 8. HCDSNS Application. View of the patient identification screen for professionals.*

From this moment on, all the information concerning the identification of the professional providing the healthcare and that of the patient being attended will remain on screen as the common header of the rest of the screens that may be accessed. Thus, any clinical information available will be related to the players involved in the consultation (*Figure 9*).



Figure 9. HCDSNS Application. Close-up of the common screen header for the professional profile.

### 1.3. Clinical information available

Once the patient has been identified, the screen first shows an index of references providing a summary of the health services which hold information on the patient, the date of the first report available in each one of them and whether there is any information at other regional authorities the system does not display to professionals due to a decision taken by the patient.

References on all the clinical reports available are then displayed, which are sorted by type of report (patient summary, primary healthcare reports, emergency room reports, hospital discharge reports and specialised external surgery reports) (Figure 10).



Figure 10. HCDSNS Application. View of screen used to retrieve patient information.



Diagnostic test reports (laboratory test reports, imaging test results, results of other diagnostic tests) do not initially appear on screen. In order to view them, the system is equipped with a double filter system through which it is possible to select the reports one wishes to retrieve by type (from among all those available in the system) and quantity (all, the last ten or a date range chosen by the user).

There is also the possibility of sorting the reports displayed to make the professional's search for information easier. The sorting may be done by any of the attributes that make up the label of each of the reports and in the order of priority chosen by the professional.

The professional can query any of the reports available on screen or print them out if necessary. When a report is opened, the system reminds the professional through an emerging note that states, "... in your capacity as a healthcare professional, you are not authorised to store the reports on any devices. You are solely authorised to view and print them".

All the reports are displayed in a closed format (PDF) to prevent their original contents from being modified. As was mentioned before, all the documents comprising the electronic health records, apart from the patient summary, are documents that describe specific episodes and have an author responsible for their contents.

In the case of patient summaries, it should be possible to either fully or partially consolidate their contents automatically into the electronic health record generated by the professional providing the healthcare, thereby making the inclusion of the relevant data easier.

#### 1.4. Access to hidden clinical information

From this same screen, professionals can access a view of information that a patient has decided to hide, as long as the circumstance defined for viewing such information in the system arise.

An access button has therefore been included in the top right-hand corner of the index of references, just above the information the system provides on the existence of hidden information (*Figure 11*).

The screenshot shows the HCDSNS application interface. At the top, there is a navigation bar with the text 'HCD SNS'. Below it, a main header reads 'Listado de Servicios de Salud con referencias'. To the right of this header is a button labeled 'Acceso a Ocultos', which is highlighted with a red arrow. Below the header is a table with three columns: 'Servicio de Salud', 'Fecha de primer documento', and 'Informes Ocultos'. The table contains three rows of data:

Servicio de Salud	Fecha de primer documento	Informes Ocultos
INGESA. Instituto Nacional de Gestión Sanitaria-CEUTA	02/12/2008	Si
RIOJASALUD. Servicio Riojano de Salud	13/05/2009	Si
Agència Valenciana de Salut	25/02/2009	No

Below the table, there is a red text warning: 'SI DESEA CONSULTAR LOS INFORMES SOBRE PRUEBAS DIAGNÓSTICAS UTILICE LOS FILTROS DEL FINAL DE LA PÁGINA'. Underneath this is a button labeled 'Ordenación'. Below the table is another section titled 'Informes Historia Clínica Resumida' with a table of clinical history reports. At the bottom, there is a section for 'Informe Clínico de Atención Primaria' with a table of primary care reports.

Figure 11. HCDSNS Application. View of the "Access hidden data" button.

Once a request to view hidden information is made, the system reminds the professional of the necessary conditions to view such information. Such conditions must be accepted by marking the box and then clicking on the "View Hidden Data" ("Acceso a Ocultos") button (Figure 12). Only then will the hidden reports be added to the set of reports that were previously displayed to the professional.

The screenshot shows a warning message box titled 'Atención'. The text inside the box reads: 'El paciente ha decidido ocultar parte de su información clínica. No obstante, en caso de que usted, haciendo uso de su criterio profesional, considere necesario actuar de forma indemorable y el paciente haya perdido su capacidad para decidir, puede ver la información oculta pulsando el botón. En ningún otro caso este acceso será lícito.' Below the text is a checkbox and a button labeled 'Ver ocultos'.

Figure 12. HCDSNS Application. Close-up of the "View hidden reports" notice.

In order to make it easier to locate such reports, they are identified with the hidden information icon. A flashing light appears on the upper part of the screen (like an emergency light) indicating to the professional that he/she is using the system in "emergency mode", that is to say, accessing information that was initially hidden by the patient.

The process to view hidden reports has been designed to guarantee the citizen's decision is respected under the terms laid down for the project, in addition to ensuring that professionals can view such data when the patient has lost his/her capacity to take decisions and the professional has to take immediate action without delay.

The system records a trace of any instances of access to such information, identifying them as such. Additionally, citizens are offered information on such instances of access, duly differentiating instances of access to hidden information within the record of accesses to their clinical information.

#### 1.5. Incident notification system

The application offers the possibility of sending *incident notifications*, which can only be detected by the system's users (Figure 13). These are integrated into the system as manual alerts, along with the automatic alerts which were present in previous versions. Such alerts identify possible failures and are managed by the application itself, which ensures they reach the system's administrators, who are responsible for resolving any such incidents.

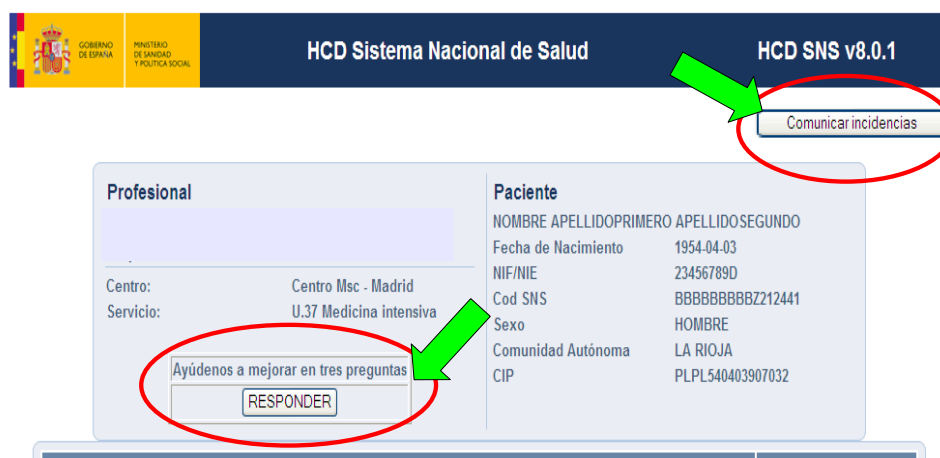


Figure 13. HCDSNS Application. Close-up of the "Incident Notification" and "Survey" buttons.

## 1.6. User Satisfaction Survey

Lastly, the system's users are provided with a brief survey aimed at gathering their opinion through three questions asking them to give an assessment (on a seven-point Likert-type scale) on the application's ease of use, the time taken to access the information available and the utility of information queried (*Figure 13*).

The results of the survey will contribute to an initial appraisal on the level of user satisfaction after using the system.

### **Access for Citizens**

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Citizens can access the system through the website their regional authority (their region of residence) have made available to enable access to the citizens' functionalities of the HCDSNS system.

Internet access allows citizens to make use of the functionalities that the HCDSNS system has placed at their disposal both from their place of residence, as well as on their trips to other regional authorities.

The guarantee of exclusive access to the system by authorised users is performed in this case through verifying whether the citizen wishing to access the system (from a regional authority website) has been duly registered in such regional authority's health card system. The citizen will then be requested to identify himself/herself through a recognised electronic signature or electronic national identity card (e-DNI). Only then, after verifying that the citizen is authorised to access the system from that access point and once his/her identity has been checked, will the initiation of a session be allowed.

### 1.1. Session Initiation

Once access has been granted, the first step consists of informing the citizen that he/she has accessed the HCDSNS system, the most relevant features of use and the functionalities offered by the system, including:

*Description of the system's purpose:*

"This webpage has been created to place at the disposal of citizens any information about their health that is available at any National Health System centre."

*Essential prerequisites to be able to access the information:*

"Access has to be gained through the health service at which the citizen's health card is registered. In order to gain access, an essential prerequisite consists of having obtained from that health service the relevant permits and electronic certification (signature) that guarantee that only you and the healthcare professionals that have to provide you with healthcare can access this information".

*The system's functionalities:*

"Through this webpage you can:

- Query, print out or save any existing clinical reports on you.
- Hide any clinical reports, which will not be displayed to the healthcare professionals that provide you with care. They will be aware that you have decided to protect certain information, although they will not be informed what kind of information it is. Should you find yourself in a situation requiring professional action without delay and you have lost your capacity to reverse your decision, the professional may view such information if he/she deems it necessary, of which you will be duly informed through the system.
- Query the instances of access that have been made to the clinical information."

*Information on the system's security:*

"The system will keep a trace of the identity of the people who access it and of the characteristics of the information queried. This trace will be audited on a periodic basis. In addition to the security elements implemented, anyone accessing this information without having duly obtained authorisation to do so or make any illegitimate use thereof will be held legally liable."

## 2.2. Options of Use.

The first screen displays a header containing the citizen's identification data. This header will form part of all the screens displayed thereafter (*Figure 14*).

After a brief welcome message to the HCDSNS system, two access options are made available to the functionalities:

- View instances of access made to your clinical data
- Obtain a copy of or hide your clinical reports

The screenshot shows the initial screen of the HCDSNS Application. At the top, there is a header with the Spanish Government logo and the text 'GOBIERNO DE ESPAÑA' and 'MINISTERIO DE SANIDAD Y POLÍTICA SOCIAL'. To the right of the header, it says 'HCD Sistema Nacional de Salud' and 'HCD SNS v8.0.1'. Below the header, there is a button labeled 'Comunicar incidencias'. The main content area is titled 'Identificación' and displays the following information: 'NOMBRE APELLIDOPRIMERO APELLIDOSEGUNDO', 'NIF/NIE: 23456789D', 'Comunidad Autónoma: LA RIOJA', and 'Código SNS: BBBB BBBBZ212441', 'CIP: PLPL540403907032'. Below this information, there is a survey question: 'Ayúdenos a mejorar en tres preguntas' with a 'RESPONDER' button. A welcome message follows: 'Bienvenido al Sistema de Historia Clínica Digital en el Sistema Nacional de Salud. Ha sido Vd. reconocido como usuario autorizado por MSC.' Below the welcome message, there is a section titled 'Elija una opción' with two buttons: 'CONOCER LOS ACCESOS REALIZADOS A SUS DATOS CLÍNICOS' and 'OBTENER COPIA U OCULTAR SUS INFORMES CLÍNICOS', both with 'Entrar' links. At the bottom, there is a 'Volver' button.

Figure 14. HCDSNS Application. Initial screen displayed in the citizens' profile.

A user satisfaction survey, similar to the one appearing in the professional profile, appears on this same screen, as well as the possibility of notifying any incidents that can only be identified by the system's users, which will be incorporated into the automatic alert identification, tracking and resolution process included in the application. The survey is offered to citizens on all the screens they may visit in order to make it easier for them to fill it in before they exit the application, irrespective of the place from which they may decide to do it.

## 2.3. Option 1: Access Monitoring

The next screen offers the possibility of viewing a specific number of instances of access through a time filter. The four options are: all the instances of access produced, the last ten instances of access or the instances of access made within a date range specified by the user.

The relevant information will then be displayed on each of the instances of access performed:

- Data concerning the instances of access about which information is provided:
  - Date and time in which access was produced
  - Health service and centre from which access was produced
  - Health service to which the health centre belongs from which access was produced
  
- Identification data on the report accessed:
  - Date the report queried was issued
  - Type of information accessed
  - Health centre that generated the report
  - Health service to which the health centre belongs from which the report was issued (*Figure 15*)

**Filtro temporal**

Todos

Solo los últimos diez

Rango de Fechas

Fecha inicio (dd/mm/aaaa):  Fecha fin (dd/mm/aaaa):

■ Acceso reclamado

Lista de accesos

Datos del acceso					Datos del informe			
Fecha acceso	Hora	Servicio	Centro	S. Salud	Fecha Informe	Tipo Informe	Centro	S. Salud
25/06/2009	11:34:22	U.900 Otras unidades asistenciales	COMPLEJO HOSPITALARIO SAN MILLÁN-SAN PEDRO DE LA RIOJA	<a href="#">RIOJASALUD. Servicio Riojano de Salud</a>	22/06/2009	Informe Clínico de Alta	HOSPITAL SAN PEDRO	RIOJASALUD. Servicio Riojano de Salud
25/06/2009	11:34:07	U.900 Otras unidades asistenciales	COMPLEJO HOSPITALARIO SAN MILLÁN-SAN PEDRO DE LA RIOJA	<a href="#">RIOJASALUD. Servicio Riojano de Salud</a>	09/01/2008	Informe Clínico de Alta	HOSPITAL DE LA CRUZ ROJA	INGESA. Instituto Nacional de Gestión Sanitaria-CEUTA

Figure 15. HCDSNS Application. Close-up of the information filters for citizens.

All this information is complemented by information on the instances of access that may have come about regarding the reports the patient may have decided to hide. In this case, the record of instances of access is preceded by the icon identifying the existence of hidden information in the HCDSNS system.

As has already be explained in preceding sections, the system foresee the possibility of professionals accessing any information the patient may have decided to hide regarding any health reports comprising his/her electronic health records should the patient require healthcare outside his/her region of residence and the circumstances of the patient losing his/her capacity to decide and the necessity of a healthcare professional duly authorised by the regional authority in which the citizen finds himself/herself taking immediate action without delay come about.

In such a case, the professional has to leave evidence that the conditions allowing him/her to gain access to the information hidden by the patient have come about, leaving behind a trace of the instance of access that subsequently shows the citizen information concerning such access (*Figure 17*).

The possibility of filing a complaint about any of the instances of access produced to the citizen's clinical is also made available on this screen.

After selecting the instance of access about which the citizen wishes to file a complaint, he/she has to click on the information identifying the health service from which such access has been produced. A partially filled in form will be displayed (*Figure 16*) (the citizen's identification data and details of the report about which he/she wishes to file a complaint) and then the citizen only has to fill in the sections on his/her address (postal or electronic address) where he/she wishes the response to be sent and the section aimed at reflecting the reasons for the complaint.



RECLAMACIÓN SOBRE ACCESOS REALIZADOS A SUS DATOS CLÍNICOS

**Datos personales**  
 Nombre: NOMBRE  
 Apellidos: APELLIDOPRIMERO APELLIDOSEGUNDO  
 NIF: 23456789D

---

**Dirección de contacto para respuesta** Seleccione un tipo de dirección ▼

<p><b>Dirección postal</b></p> <p>Calle <input style="width: 80%;" type="text"/> nº <input style="width: 20%;" type="text"/> Piso <input style="width: 20%;" type="text"/></p> <p>CP <input style="width: 50%;" type="text"/></p> <p>Población <input style="width: 80%;" type="text"/></p> <p>Provincia <input style="width: 50%;" type="text"/></p> <p>Teléfono <input style="width: 50%;" type="text"/></p>	<p><b>Dirección de correo electrónico</b></p> <p>E-mail <input style="width: 90%;" type="text"/></p>
--	--

---

**Identificación del acceso sobre el que se reclama**

Comunidad autónoma desde la que se realizó el acceso: COMUNITAT VALENCIANA  
 Centro asistencial desde el que se realizó el acceso: GANDIA EL GRAU  
 Documento a que se accedió:

- Tipo de Documento: HISTORIA CLÍNICA RESUMIDA
- Fecha última actualización: 13/10/2009
- Número de historia: 4598395
- Código de referencia del documento: 26374

Fecha del acceso: 13/10/2009 12:59:19

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**Motivo de la reclamación**

Figure 16. HCDSNS Application. View of the complaints screen on instances of access made to a patient's clinical data.

Once the complaint is sent, an acknowledgement of receipt is provided to the citizen, which appears on screen in the upper margin of the complaint, and it is simultaneously sent to his/her e-mail address if he/she has chosen to receive the response to the complaint by e-mail. In either case, the citizen may print out the complaint, along with its corresponding acknowledgement of receipt.

From that moment on, the reference of the report about which a complaint has been filed will appear in green to differentiate it from the other reports and make it easier for the citizen to monitor his/her complaints (Figure 17).

11/06/2009 10:10:09	intensiva	Centro Msc - Madrid	<a href="#">MSC</a>	26/06/2008	de Atención Primaria	LA CRUZ ROJA	Gestión Sanitaria-CEUTA
10/06/2009 18:27:36	U.900 Otras unidades asistenciales	COMPLEJO HOSPITALARIO SAN MILLÁN-SAN PEDRO DE LA RIOJA	<a href="#">RIOJASALUD, Servicio Riojano de Salud</a>	13/06/2008	Informe Clínico de Urgencias	HOSPITAL DE LA CRUZ ROJA	INGESA, Instituto Nacional de Gestión Sanitaria-CEUTA
05/06/2009 13:25:20	U.37 Medicina intensiva	Centro Msc - Madrid	<a href="#">MSC</a>	07/10/2008	Informe de Cuidados de Enfermería	HOSPITAL DE LA CRUZ ROJA	INGESA, Instituto Nacional de Gestión Sanitaria-CEUTA
05/06/2009 12:48:43	U.37 Medicina intensiva	Centro Msc - Madrid	<a href="#">MSC</a>	09/01/2008	Informe Clínico de Alta	HOSPITAL DE LA CRUZ ROJA	INGESA, Instituto Nacional de Gestión Sanitaria-CEUTA
05/06/2009 12:30:44	U.37 Medicina intensiva	Centro Msc - Madrid	<a href="#">MSC</a>	26/06/2008	Informe Clínico de Atención Primaria	HOSPITAL DE LA CRUZ ROJA	INGESA, Instituto Nacional de Gestión Sanitaria-CEUTA
05/06/2009 09:51:42	U.37 Medicina intensiva	Centro Msc - Madrid	<a href="#">MSC</a>	27/03/2009	Informe de resultados de pruebas de Imagen	MUTUA DE CEUTA	INGESA, Instituto Nacional de Gestión Sanitaria-CEUTA
05/06/2009 09:38:13	U.37 Medicina intensiva	Centro Msc - Madrid	<a href="#">MSC</a>	26/06/2008	Informe Clínico de Atención Primaria	HOSPITAL DE LA CRUZ ROJA	INGESA, Instituto Nacional de Gestión Sanitaria-CEUTA
04/06/2009 15:40:06	U.37 Medicina intensiva	Centro Msc - Madrid	<a href="#">MSC</a>	26/06/2008	Informe Clínico de Atención Primaria	HOSPITAL DE LA CRUZ ROJA	INGESA, Instituto Nacional de Gestión Sanitaria-CEUTA
04/06/2009 10:48:37	U.37 Medicina intensiva	Centro Msc - Madrid	<a href="#">MSC</a>	27/03/2009	Informe de resultados de pruebas de	MUTUA DE CEUTA	INGESA, Instituto Nacional de Gestión Sanitaria-

Figure 17. HCDSNS Application. Close-up of record of instances of access made to patient information.

### 2.3. Option 2: Obtaining a Copy or Hiding Clinical Reports

Once this option has been accessed, a list is displayed under the citizen's identification details of the health services that have clinical information available under the citizen's name, along with the date of the first report available at each regional authority and whether there are any hidden reports in that regional authority.

The references of all the reports available which the citizen can access then appear below grouped together by type of report.

A text containing the instructions on how to hide reports and access the different kinds of reports that are not retrieved by default due to their size (laboratory test results, imaging test results and results of other diagnostic tests) has been placed as a header for this information

All the reports may be sorted on the basis of the different attributes that identify them to make searching for information easier. Time filters may likewise be applied to access a specific set of reports.

The system of filters works in the same way as has been explained for access to the system under the healthcare professional profile.

Any report can be viewed by clicking on the "Report" button located to the right of each of the report records. A new screen will then be displayed containing the report in PDF format, which can then be read, printed out or saved onto magnetic storage media (Figure 18).

DATOS DE LA INSTITUCIÓN EMISORA		DATOS DEL PACIENTE	
Denominación del Servicio		Nombre	Primer Apellido
Dirección del Centro: Dirección CP - Población Teléfono		Segundo Apellido	CIP
Persona de referencia	Teléfono	CIP Internacional	Código SNS
Cuidador principal	Teléfono	Fecha de Nacimiento: __/__/__	N° Historia ____/____
		Sexo:	
		NASSS:	
		DNI / Pasaporte / T. Residencia	
HISTORIA CLÍNICA RESUMIDA			
Fecha de creación: __/__/__		Fecha de actualización: __/__/__	
DATOS DE SALUD			
EL PACIENTE HA DECIDIDO EJERCER RESERVA SOBRE PARTE DE LA INFORMACIÓN		SI <input type="checkbox"/>	NO <input type="checkbox"/>
EXISTE ANOTACIÓN EN EL REGISTRO DE INSTRUCCIONES PREVIAS		SI <input type="checkbox"/>	NO <input type="checkbox"/>
ESTA INCLUIDO EN UN PROTOCOLO DE INVESTIGACIÓN		SI <input type="checkbox"/>	NO <input type="checkbox"/>
ALERGIAS			
VACUNACIONES			
LISTADO DE PROBLEMAS RESUELTOS			
PROBLEMAS ACTIVOS		DIAGNÓSTICOS ENFERMEROS ACTIVOS	
Fecha de Inicio	Problema		
__/__/__	_____		
__/__/__	_____		
__/__/__	_____		
TRATAMIENTO ACTIVO		RESULTADOS DE ENFERMERÍA	
RECOMENDACIONES			
_____			
_____			
FARMACOS	DOSES	Fecha de prescripción	
ALERTAS		OBSERVACIONES SUBJETIVAS DEL PROFESIONAL	

Figure 18. Example of the patient summary (Historia Clínica Resumida - HCR) contents structure.

Lastly, if the citizen decides to hide one of his/her clinical reports, he/she is informed of the healthcare consequences this decision may have by means of an emergent message containing the text below when the "Hide" box is ticked:

"You should bear in mind that hiding information from the professional that provides you with healthcare may have consequences on the quality of care you may receive if he/she does not have all the information about your health available."

The citizen then has to click on the "OK" button in order to hide the report. An emergent message then appears informing him/her that the operation has been correctly performed and a tick appears in the hidden report's box.

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