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A Virtual Health Record-based EHR System

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***Abstract*— EHR 2.0 is an evolution of current Electronic Health Records (EHR) which provides an intelligent support for all healthcare providers and patients in the National Health System with the benefit of improving the quality of care and increasing patient involvement in the health care and prevention process. At the center of the EHR 2.0 the paper puts the Virtual Health Record (VHR), an intelligent resource in network that contains all the digital information available about the patient health. How the main services of the VHR were derived from the analysis of some innovative healthcare scenarios is presented.**

Keywords— Electronic Health Record; Virtual Health Record; functional model; business scenario; system operation; web service

I. INTRODUCTION

One of the major objectives of the Smart Health 2.0 Project [8] was to implement EHR 2.0, a second generation Electronic Health Record (EHR), in the Sicily Region.

An EHR is a longitudinal (lifelong) electronic record of patient health information generated by patients' encounters with caregivers in any care delivery setting. To implement an EHR for all citizens in a jurisdictional area as a region, an EHR System (EHR-S) should be provided. It is a software platform able to manage records in digital format, each record containing a systematic collection of information on the patient's health which can be shared between all regional health information systems. The creation of an interoperable EHR-S has become mandatory for all Italian regions.

A traditional EHR (we called it EHR 1.0) is the point of aggregation and sharing of health documents related to the patient, generated by the various players in the healthcare system. EHR 1.0 was justified by the need for collaboration among various health professionals involved in caring for an individual through a shared repository of medical documents associated with the patient.

Overcoming the limitations of EHR 1.0, we conceived EHR 2.0 as an evolution of EHR 1.0 that aims to innovate the processes of health care, research, education and governance for raising the quality of services and improving the health and social wellbeing of citizens. It should be a decision supporting tool that provides a smart solution based on discrete, authoritative, clinical data (such as laboratory results, vital sign measurements, qualitative observations, images, and signals) found in clinical documents concerning the health of the patient and related to "operational health-related areas" such as: continuity of care, health care, health governance and personnel training, and support for scientific and epidemiological research.

To meet the complex demands of evidence-based and patient-centric medicine, an only document management tool as EHR 1.0 is insufficient. To support the new health paradigms, software applications that manage smaller, but significant, fragments of the content of documents are needed. Moreover, these applications should be able to aggregate atomic data into more complex data structures using predefined or *ad-hoc* created formats.

Section II introduces the method we used to analyze health-related processes, identify the EHR 2.0 innovative functions, develop the functional requirements document, and finally identify the EHR 2.0 services.

At the center of our EHR 2.0 we put the Virtual Health Record (VHR), an internet platform which provides social and health services useful for health professionals to care a patient. In our approach the VHR should be able to: a) collect data from the NHS environment, b) integrate them with the existing ones, c) notify the integration events to all those interested in this individual, d) aggregate the integrated data in new combinations of data according to the needs of healthcare professionals, e) launch and monitor process instances to support the individual's care process, and f) present this data in various formats [4][5].

By accessing with suitable rights the VHR of a patient any interested party can obtain necessary data and services to improve the patient's health. The following scenarios can be available:

1. To determine the disease or condition that explains the patient's symptoms and signs, a care provider can look for information in the VHR during the diagnosis process. Information from the VHR can be obtained regarding medical guidelines related to the health issue with suggestions for treatment and then focus attention only on the details of the care plan. The care giver can also receive notifications about significant events during the course of patient care.
2. A health care manager can view requests for a specific drug or health service and monitor the related costs.
3. With the help of the VHR demographic analysts can complete their study of morbidity regarding the incidence and prevalence of a disease during a certain period and/or in a geographical area.
4. A patient can view the trend of his/her vital signs measured by healthcare providers (i.e. blood, urine) in recent months, be remained of a scheduled check or when to take a prescribed medication.

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Section III introduces the VHR with its structure, functions, and services.

Section IV presents the ongoing implementation of the first prototype of the EHR 2.0 in Sicily.

II. FUNCTIONAL ANALYSIS OF HEALTHCARE PROCESSES

We used as a reference the National Guidelines on the EHR of the Italian Health Ministry [2].

A. Method

To define the functional requirements of the EHR 2.0 and identify the VHR services, we used the following steps:

1. We started by identifying the major business processes in the National Health System (NHS) that are closely related to health and social wellbeing of citizens. First, we classified NHS activities according to the objectives of the stakeholders in the following three areas of functions:
   - *Medical staff functions*. They are related to the needs of care providers, aiming to help them during the various stages of care (from anamnesis and analysis of clinical conditions to the diagnosis definition, and treatment and medication prescriptions);

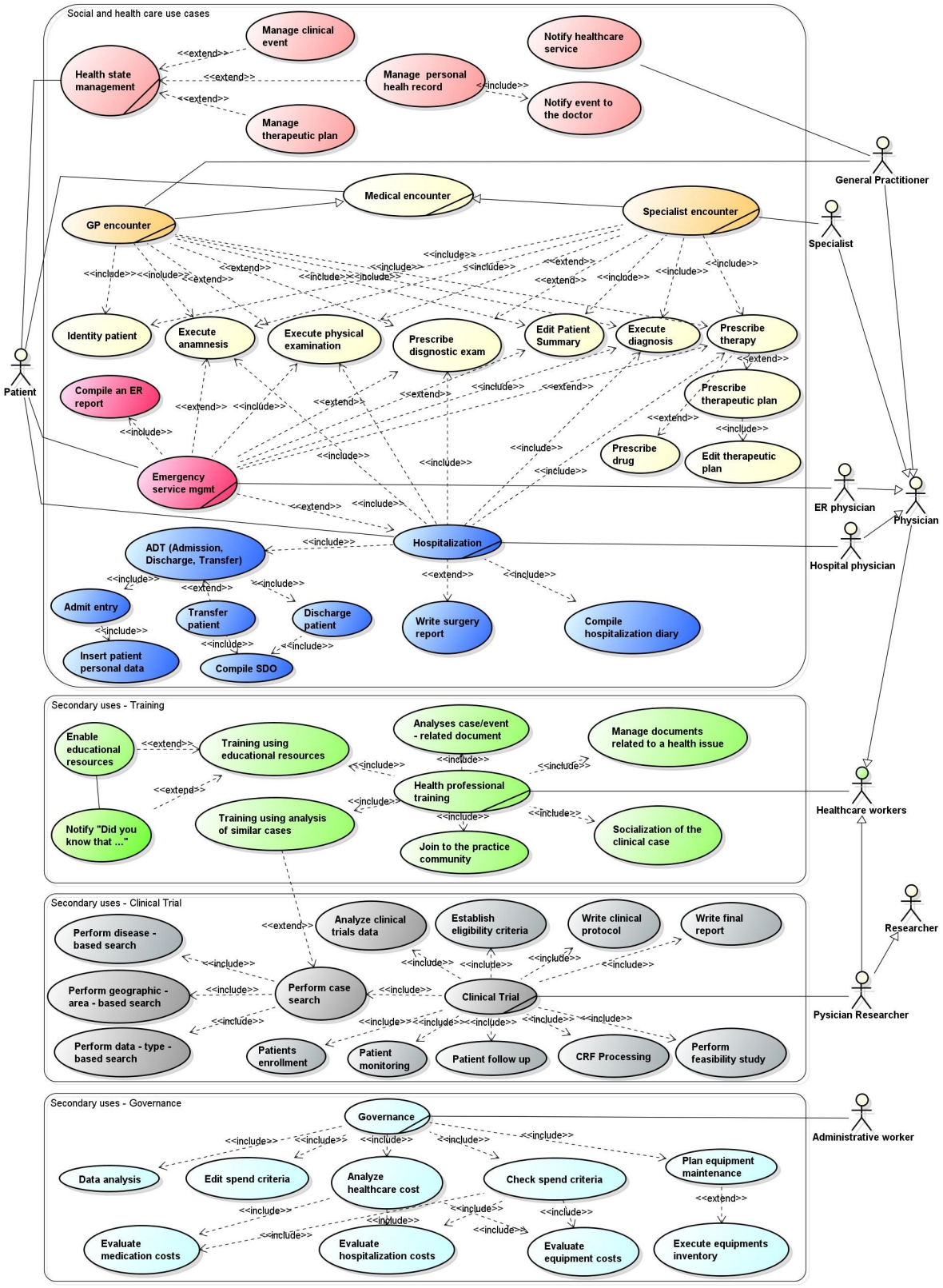


Fig. 1. Use case diagram of NHS business processes.

- *Patient functions*. They are related to the need to provide patients with tools that aid them to better understand the clinical events in which they are involved and play an active role in their own care;
- *Secondary use functions*. They go beyond the needs directly related to the healthcare process that basically involve care providers and patients, and address open issues of the national/regional health system: health governance, or clinical and epidemiological research.

For each area we identified some health-related, business processes in the NHS involving patients as *actors* and health professional or organizations as *agents*. The business use-case diagram in Fig. 1 describes the business processes we considered important to be analyzed.

2. For each health-related process in these areas, we chose a representative, successful scenario and described it as it is currently performed. They are actually frequently encountered instances of business processes in the NHS.
3. From the analysis of the representative scenarios, by generalization, we derived their business use-cases that describe how the NHS services are at present involved in social and health care processes. We called them *as-is use cases*, because they are currently used in NHS environments without the EHR 2.0.
4. For each identified *as-is* use case an alternative *visionary use case* was proposed. It describes how the same scenario is modified when the EHR 2.0 supports care processes.
5. From an analysis of the visionary use cases, we found the system operations; these are the key interactions between *agents* of the health information system (not only health professionals, but also patients as active participants in their caring process) and the EHR 2.0, the software system that automatically processes the data and provides computerized services to agents. For an analyst who has to identify the software system functionalities, the *system operations* indicate entry points in the EHR 2.0 functionality.
6. The system operations are made explicit to obtain the document of functional requirements for the EHR 2.0.
7. From the functional requirements identified for the EHR 2.0 the services of the VHR were then derived.

This procedure is explained by examples hereinafter.

TABLE 1. 'Medical encounter' without EHR 2.0 *(as-is version)*

Use case	Medical encounter
Actors	Patient (main actor); GP (or a medical specialist)
Event flow	**1.** Patient goes to her/his GP to get health advice or treatment for a symptom or condition. **2.** Patient illustrates the reason for the visit. **3.** The GP visits the patient and records her/his observations in the EMR. **4.** The GP analyzes observations that the patient brought with her/him and also records them in the EMR. **5.** The GP analyzes/compares all relevant observations found in the EMR to identify the patient's health issue. **6.** The GP formulates a diagnosis and treatment, and includes them in the EMR. **7.** The GP generates the needed prescription documents. **8.** Patient receives the prescriptions and goes home.

B. Business processes analysis in the healthcare system

The healthcare activities in the NHS are true business processes aimed to care or study patients' health issues. In these processes the *actor* is the patient who 'triggers' the process and is always the process beneficiary. Such processes can be modeled as business use case diagrams.

From an analysis of NHS activities we identified the following use cases related to the patient's healthcare and a possible use of the EHR 2.0: medical encounter, emergency, hospitalization, patient empowerment, and medicine dispensation. With respect to secondary uses of the EHR, the analysis identified use cases for: e-governance, e-learning,

TABLE 2. 'Medical encounter' with EHR 2.0 *(visionary version)*

Use case	Medical encounter with EHR 2.0	
Context	Real world	Digital world (EMR + EHR + VHR)
Actors	Patient (main actor); GP (or medical specialist)	EHR 2.0 System
Event flow	**1.** Patient goes to her/his GP to get health advice or treatment for a symptom or condition. **2.** The patient illustrates the reason for the visit. **3.** The GP examines the patient and updates her/his clinical application (EMR) with new data on the Patient's health state as they result from his/her observations. **4.** The GP, in order to have an accurate view on the Patient's health state, interacts with the EHR 2.0 and asks for existing information on the Patient's health state.	
		5. The EHR 2.0 System provides information on the Patient's health state using data from VHR.
	6. The GP asks the EHR 2.0 to provide an analysis of the Patient's clinical data to get a real time view of the trend of the vital signs of interest.	
		7. The EHR 2.0 System uses its tools to perform data analysis and provide the requested information.
	8. The GP updates her/his EMR with new data on the Patient's health state from her/his observations. EMR sends a message with this data to the EHR 2.0 System.	
		9. The EHR 2.0 System receives the message, parses it, extracts and interprets its information content and integrates the data in the Patient's VHR.
	10. The GP identifies the Patient's health issue and decides medication administration. With the help of the EMR, the GP generates a medication order; **10.** The GP's EMR sends the issued document to the EHR.	
		11. The EHR 2.0 System stores the document in the clinical document registry, extracts and integrates the information in the document in the Patient's VHR.
	12. The patient does not need to receive any printed recipe with the prescription and goes home;	

clinical trials, and medical research, which we do not report in this paper because of lack of space. The diagram in Fig. 1 provides an overall view of the studied business use cases.

C. *"As-is" use cases*

As an example of our analysis method, we report the use case model of the medical encounter. The concept of medical encounter may be of two types: encounter with a general practitioner (GP) and encounter with a medical specialist. They follow a very similar path. Our example describes the encounter between a doctor (GP or medical specialist) and a patient after a health problem. This event causes the inclusion of encounter-related data in the doctor's electronic medical record (EMR), a software application that allows caregivers to manage their patients.

Depending on the patient's specific condition, after a GP encounter can follow one/more encounters with specialists. Information resulting from these encounters may be used by the GP to obtain a clearer and complete perspective on the situation, necessary for an accurate diagnosis. Table 1 describes the event flow related to the *as-is version* of the 'medical encounter' business use case.

D. *"Visionary" use cases*

The EHR 2.0, with its ability to communicate with various NHS subsystems and applications, allows not only the sharing of the documents that other caregivers generate (functionality already provided by the EHR 1.0), but include some innovative aspects in the scenario, such as: (i) ability to process discrete data describing the patient's health state and provide information on previous, or in progress, episodes of care that are related to a health issue, (ii) notification to all those who previously subscribed, having the patient's consent, to receive information on the patient's clinical events, messages containing the event's relevant data, (iii) use of artificial intelligence tools to support the doctor decisions.

Table 2 shows how the event flow of the medical encounter use case changes with the adoption of an EHR 2.0. The last column shows the activities assigned to the EHR 2.0 to be performed in the digital world in support of the activities performed by the doctor in the real world.

E. *System operations*

System operations are identified from events that occur in the real world and force the virtual world of the EHR to react, doing something as a response. These events are stimuli or requests that the business environment composed of a "constellation" of clinical applications used by healthcare professionals and patients, addresses to the EHR to have a response. This response can be of various types. For example, any relevant event for the patient's health occurring in a clinical application in the EHR's jurisdictional domain (country or region) is recorded, processed, and the associated information is integrated in the EHR. Finally, a notification message is generated that will be automatically sent to all those who are interested in the patient's health state.

System operations are trigger events for the software use cases and serve to identify the functional requirements of the EHR 2.0. These operations are eligible to become EHR 2.0 functions and then VHR services.

Analyzing the use case shown in Table 2, we have identified the interactions between the GP's EMR and the EHR system. Three of these interactions are introduced as system operations in Table 3 where the first column presents the semantics of the operation, the second and third column, show the pre- and post- condition and the last column contains the corresponding service included in the VHR interface design.

F. *EHR 2.0 functional requirements*

The HL7 standard proposes in the Electronic Health Record-System Functional Requirements Model (EHR-S FM) document [1] a classification of the EHR functions in several areas. Our research on the EHR 2.0 functional requirements was focused on four functional areas of particular importance for the Region of Sicily that practically match with the sections CP (Care Provision), CPS (Care Provision Support), POP (Public Health Support,) and AS (Administration Support) of the HL7 EHR-S Functional Requirements Model.

For only these sections, in [6] we identified a subset (about 40%) of the HL7 EHR-S requirements as necessary for the Region of Sicily. We also identified several requirements that are not covered by the HL7 standard functional model, but are important for our project Smart Health 2.0 [8].

III. VIRTUAL HEALTH RECORD

A. *The VHR Concept*

To allow close cooperation between patients, care providers, administrative staff, and health organizations, we propose VHR as the core of the EHR 2.0 platform. VHR is an entity that contains virtually all the knowledge we have on the health of each individual from the EHR jurisdictional area. It must have the ability to record clinical events relevant for the

TABLE 3. System operations for the 'medical encounter with the EHR 2.0 use case and their derived VHR services

System Operation Semantics	*Pre-condition*	*Post-condition*	*VHR Service*
Information request regarding the health state of the patient	Patient was selected Event was selected Observation type was selected	The requested values have been reported	**getObservation**(*ObservationType, criteria, period*, …)
View trends of some clinical parameters	Patient was selected Event was selected Observation type was selected Period was selected	The requested values have been reported	**getTrend(***ObservationType, criteria, period*,,…**)**
Updating message for the patient's EHR subsequent to a 'medical encounter' event		The EHR has acquired, recorded, interpreted the metadata of the message about the event, and has stored the documents attached to the message. The information contained in both the message and the attached documents have been integrated into the VHR.	**newEvent(**"ENCOUNTER", ..**)**

individual's health state, analyze and extract from them atomic data that are significant for the individual's health, and ensure a uniform, consistent, and intelligent management of these data, including their aggregation in semantically richer data structures. To assure this intelligent management each value of any data element in the VHR should be placed in its all-encompassing context, and structured according to several facets (or concerns) that this value exhibits to an external observer: a) *who* (i.e. the author, a health professional); b) *where* (i.e. the clinical ward); c) *what* (i.e. the measure unit and the normal range); d) *when* (i.e. the date of the data generation); e) *how* (i.e. medical devices used); f) *from* (i.e. a reference to the document where the data originates), and g) *why* (i.e. diagnosis). A clustered, semantically-networked data structure having the value at the center results.

The need to organize the available data about the individual's health as resources in a semantic network has led us to the concept of the Virtual Health Record viewed as a service provider entity that collects data from NHS clinical applications and medical devices, integrates the data collected with existing data (maintaining the overall consistency of the individual's record), notifies integration events to interested parties, launches and monitors process instances for supporting care processes, extracts compositions of integrated data, and presents all these data in various formats [5].

The main objectives of the VHR are two: (i) to provide services for information exchange with integrated health information systems; (ii) to maintain the coherence and consistency of internal information to provide at any time an accurate and consistent "instant picture" of the individual's current health state, and the history of his/her clinical events, and to allow monitoring of ongoing care processes.

B. VHR Structure

Knowledge inside the VHR is a complete and authoritative representation of the individual's current health state, medical history and ongoing care processes [8].

1. The *medical history* is a series of episodes of care, each caused by a medical issue, which occurred in the past. Each episode of care is composed of a series of contacts of the patient with health professional and organizations for certification, maintaining, or restoring his/her health. In the course of a contact health services are provided such as anamnesis, clinical observation, diagnosis, and treatment, prescription. Information on these services are contained in clinical documents that are captured and the contained data are integrated into the VHR as a large data structure: the individual's medical history.
2. The *current health state* is an aggregate of information that describes the current situation of the individual's health, resulting from the latest observations performed by

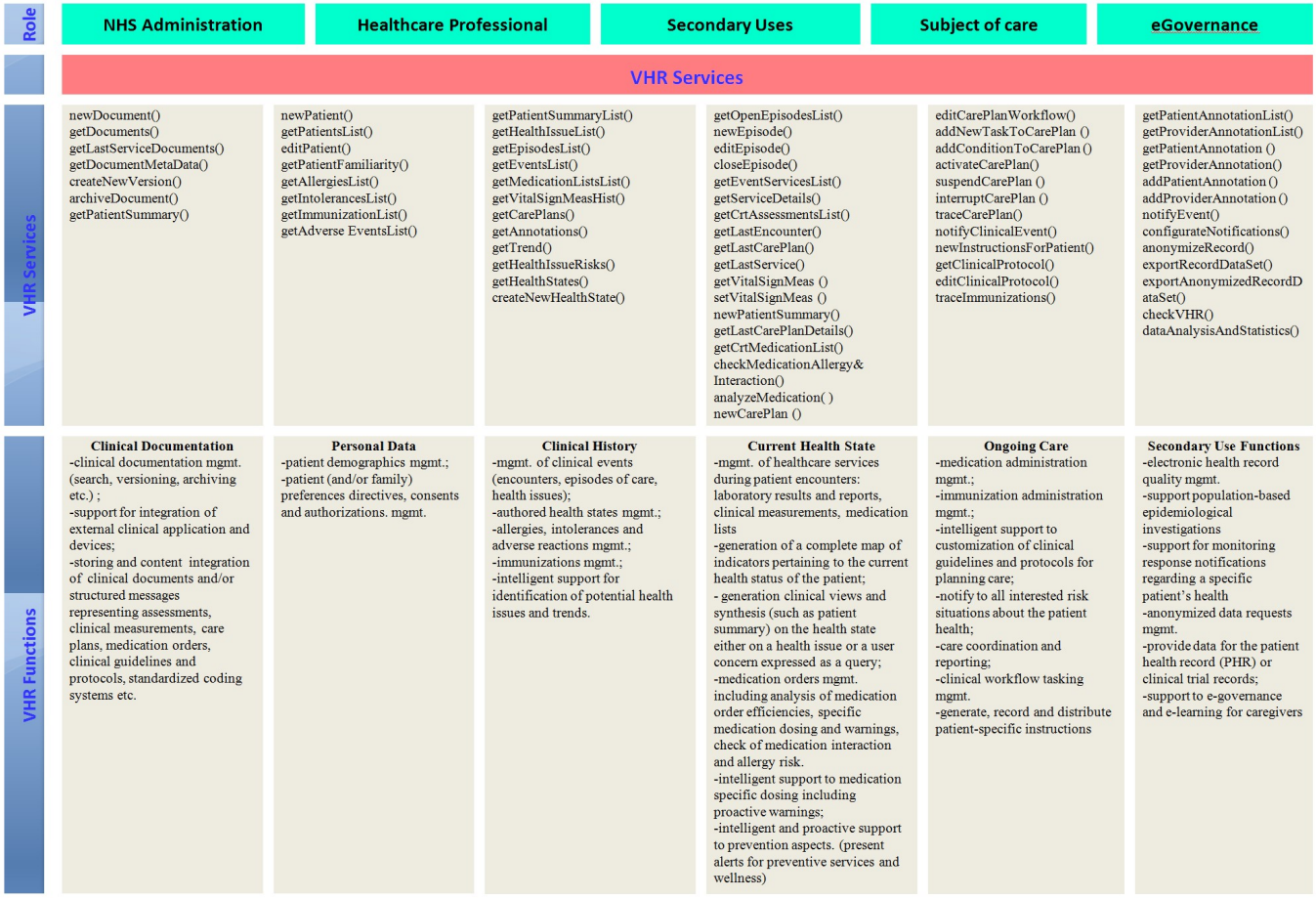


Fig. 2. VHR Functions and Services

The functions are classified into six functional modules: clinical documentation, personal data, clinical history, current health state, ongoing care, and secondary use functions. Each of these modules provides specialized services. For the sake of simplicity services are introduced only with their name.

caregivers. Information on these observations has been incorporated into clinical documents generated by clinical applications and sent as interoperable messages to the VHR.

3. The *ongoing care processes* are represented as care plans, that is, descriptions of clinical pathways able to manage the care process quality and use evidence-based practices.VHR can provide services that support the care plan development starting from authoritative clinical protocols and monitor the plan execution.

registration and integration of information on the health of all people in a given jurisdictional area. This information is generated by healthcare applications during encounters of patients with health care professionals and organizations. VHR is able to respond to queries on the current health state or medical history of any patient, adapt itself to better support decisions in the care process, or evaluate and incorporate authoritative information regarding changes of the patients' health state. To enhance the EHR-S characteristics with new functionalities, VHR incorporates a comprehensive and

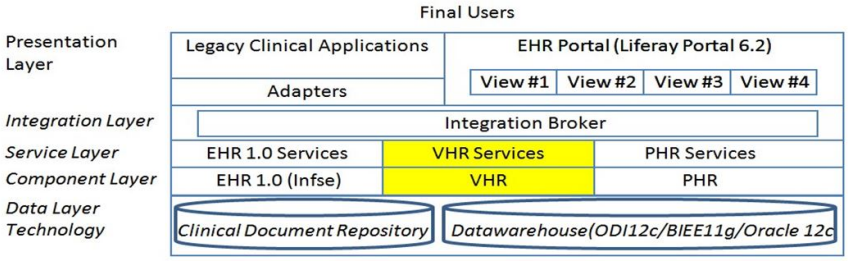


Fig.3 EHR-S 2.0 Software Architecture

Presentation layer : Clinical applications and the Smart Health portal.

Integration layer: Adapter provides a seamless flow of interoperable messages. It also assures to fill the technological gap legacy/ EHR 2.0 Integration Broker assures the centralization of the messages exchanged between the environment and the EHR 2.0.

Component layer: 1.*InFse*, a reusable EHR 1.0 that manages HL7 CDA clinical documents [9]; 2. *VHR*, the key component of the EHR-S 2.0 that exposes specialized, innovative services as we presented before; 3. *PHR*, the patient's Personal Health Record.

C. *VHR Functions and Services*

Fig.2 introduces the functional architecture of the VHR. The architecture components are modules that represent specialized views according to the roles of the main stakeholders. The VHR functions and basic services are structured in 6 categories. The modules share all VHS basic services. To implement the functionality of each module the VHR should be able to aggregate the shared basic services.

IV. EHR-S 2.0 Prototype Implementation

The ongoing Smart Health 2.0 project scheduled a first prototype implementation for this year. Fig. 3 shows the layered architecture of this EHR-S 2.0 prototype. The presentation layer includes the components in the EHR 2.0 environment used to interact with the EHR 2.0 platform. The integration layer reveals the integrative vocation of the EHR 2.0: it is able to connect to any clinical application, even a legacy one. [5]. The component layer is represented by three relatively independent main components: Infse, VHR, and PHR (Personal Health Record). The last one embodies the patient empowerment paradigm, another major research line in the project.

V. Conclusions

An EHR-S infrastructural platform should provide care to providers and other stakeholders with a comprehensive and unified view of the patient's health. Its functionality is also directed to the people who are interested in knowing more on their health state. It is not only a necessary tool to manage and support health care processes, but also an enabler to improve service quality and significant cost containment.

The paper proposes the VHR as the main component of such a system. VHR is a *networked agent* specialized in the coherent knowledge amount that allows it to propose itself as a valuable assistant for assuring the patients' welfare, too.

How the main services of the VHR were derived from the analysis of innovative healthcare scenarios is also presented.

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