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Health digital state and Smart EHR systems

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ABSTRACT

Background: The digital transformation is a technological revolution that now penetrates all aspects of society, including health and care systems. To digitalize business processes in health and care, new concepts and innovative solutions are needed. *Health* is a self-evident concept yet, at the same time, it is extremely elusive because no precise definition of it has been provided. Digitizing the health of individuals to enable data analytics methods to support healthcare professionals is an important objective in the digitalization of decision making processes. This article introduces the "health digital state" (HDS) as a digital equivalent to the "health" concept. The HDS shapes the knowledge that underpins the decisions of healthcare professionals when diagnosing and establishing treatment. The article also introduces the Smart EHR system, an infrastructure platform for EHRs designed to assist healthcare professionals in making decisions using the HDS.
Method: 1. We begin by analyzing the possibility of quantifying health in order to digitize it. 2. We hypothesize that at the time of diagnosis specific mental representations of the patient's health are formed in the minds of healthcare professionals. We call these "induced health states" (IHSs). 3. With the help of a Smart EHR system, IHSs can be captured and digitized as "digitized induced health states" (DIHSs). 4. Smart EHR can use existing DIHSs to obtain a patient's HDS. 5. We consider HDS to be a digital equivalent of the concept of health that can be used in the digitalization of diagnostic and treatment processes.
Results: For each individual, Smart EHR uses a Virtual Health Record (VHR) to generate an intelligent agent that acts as an avatar for the individual's health. It interacts with healthcare professionals, providing information on any aspect of an individual's health, proactively offering solutions, and helping them diagnose and decide on the right treatment.

1. Introduction

Making the most of digital technology opportunities based on IT and AI will have profound consequences in terms of changing mindsets and skills in society [1]. To better govern the rapid and inevitable digitalization of the world we live in, explicit actions are needed to leverage digital technologies by digitizing, as comprehensively and accurately as possible, real-world entities, and improving or innovate business processes in the context of digitized entities. As a consequence of digital transformations, parallel *virtual worlds*[1] will emerge that should also be governed. These are populated by digital entities evolving in digital ecosystems enabled by complex digital infrastructures. In such worlds, new resources can be discovered that have a positive impact on our lives. We therefore contend that *the contamination of the real world with digital technologies allows us to accurately transfer various aspects of this world into a virtual world and generate long-term solutions to numerous unresolved issues. These solutions will ultimately enrich and expand the universe of our knowledge and our possibilities for acting in the real world* [2].

Medical care and actions taken to guarantee optimal well-being are a permanent presence in our society. They constitute a collective process that our society has created and manages to provide prevention and care services, both medical and social, aimed at improving our health and well-being. The services provided are typically offered through systems of health and care comprising health and social organizations (hospitals, laboratories, physician offices, communities, as well as social institutions and groups), healthcare professionals (primary care physicians such as GPs or pediatricians, hospitalists, medical specialists, etc.), and social agents (such as AHPs – Allied Health Professionals in Scotland [3]).

The new situation created by the COVID-19 pandemic has strengthened the opinion already expressed by specialists in recent

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[1] We understand the *virtual world* as a persistent, shared, simulated, and immersive space on the Internet, created with and supported by computer networks and other digital enablers. It is a completely digital "space" populated by avatars of users who communicate and interact with each other and with other digital entities in this space, as well as with real-world physical entities, in accordance with a shared understanding of this world.

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List of abbreviations

CHDS	Current Health Digital State
DHE	Digital Health Ecosystem
DIHS	Digitized Induced Health State
HER	Electronic Health Record
EHR-S	EHR System
GP	General Practitioner
HDS	Health Digital State
HIS	Hospital Information System
HSP	Health Synthetic Profile
HIS	Induced Health State
NHS	National Health Service
VHR	Virtual Health Record

decades that we should return to patient-centered medicine. The solution should be to emphasize the role of prevention and ensure a uniform and massive distribution of high quality health services throughout the territory. However, to replace the current cost-centered paradigm with a patient-centered one, innovative health and care use cases should be identified and promoted, especially with respect to continuity of care. As always when innovative changes are needed in a business, the role played by digitalization is essential. This is also true in the field of health and care where new technologies are expected to be employed successfully. This article proposes the possible use of IT and AI for the increasing digitalization of business processes in health and care systems.

New challenging targets for health and care systems[2] have imposed paradigm shifts in the way health and care can be provided. From cure to health prevention, from a focus on disease to a focus on the well-being of individuals, from hospital-centered systems to more community-based and integrated care structures, and from service fragmentation to service coordination and integration are just some examples of such paradigm shifts. Putting people and patients at the center of care delivery, supporting patient empowerment, and making health and care systems more efficient, safer, and cheaper are other recent paradigms. For all of these, we need to fundamentally rethink and accordingly design our health and care systems. The path followed in the industry and several other areas of human society is the intensive use of IT and AI for digital transformation. Social and healthcare services are areas of well-being in which digitalization could provide excellent opportunities.

In numerous countries, digitalization is an integral part of government policy in the health and care sector and is geared towards the generous provision of quality services [41]. National strategies have been proposed worldwide for the digitalization of healthcare and social services, the reorganization of tasks, and the adaptation of healthcare organizations to new scenarios [45]. However, the digital transformation into health and well-being also requires new concepts and paradigms, considerable innovation in the core business processes of healthcare, and changes in our lifestyle and habits [4]. Last but by no means least, the very way we deal with our health also needs to be reviewed. But how can we digitally transform health and care systems without digitizing the health concept itself? This article aims to address exactly this challenge. It proposes new concepts in the virtual world and a new IT product for health and care systems to support innovative business use cases based on these concepts. A method for digitalizing processes in health and care systems is also presented.

[2] The term "health and care systems" implies a broader notion than "health systems" or "healthcare systems" as it encompasses health and social care [32].

1.1. On digitization of the health concept

Health is a concept that has no directly operable definition. Although our minds may try to correlate as accurately as possible the various structural and behavioral aspects of an individual's health, we cannot use the concept of health for practical purposes. The health concept is a *noumenon*,[3] an object of purely intellectual intuition or an abstract object not sensed or perceived, and is thus difficult to handle. However, working with this concept is fundamental for our survival.

In [5] Margolis and Laurent argue for the possibility of coherently combining two dominant frameworks in contemporary philosophy. They consider the concepts to be either mental representations resulting from observations of facts present in the real world, or abstract objects that exist even in the absence of facts that enable them to be known. In fact, as presented in Ref. [2], the two approaches to health coexist in the minds of healthcare professionals as observations and are the basis for any assessment of a patient's health.

We can roughly define *health* as an overall state of well-being encompassing physical, mental, social, emotional, and spiritual health. The method healthcare professionals employ to obtain findings on the patient's health is to capture personal characteristics and observable manifestations of the patient's health, as well as evidence-based reports such as measurements of vital signs, laboratory data, imaging results, device measurements, and so on. These qualitative and quantitative observations are utilized to infer the patient's health status and then provide diagnoses and treatments. To then go beyond direct observations and arrive at abstract concepts using quantitative terms (for example, to answer questions such as "how sick/healthy is the patient?", "how much should I worry about the patient's health?"), the healthcare professional makes use of experience, knowledge, and reasoning. She/he classifies the observed facts into concepts and then filters and correlates them to synthesize a personal evaluation of the patient's health, even if it is a vague, abstract concept. This process is essentially cognitive and intimately linked to the creativity of the human mind. In our approach, the digitization of the concept of health requires us to transfer into the virtual world the conflict between the concrete nature of observations based on evidence and our definition of digital health and to resolve this with the help of healthcare professionals.

A digital version of health thus facilitates the digitalization of health and care processes. It can be used as a measure for comparing the health at different times in an individual's life or the health of individuals in a community.

We propose to capture in the virtual world what is happening in the real world using a three step procedure:

1. Gather in a digital format all significant observations on the individual's health made by healthcare professionals over time, including observations on her/his living environment and lifestyle;
2. Contextualize all these observations, which means establishing their interrelations according to a digitalized conceptual model of health and well-being;
3. Analytically process all this data to reconstruct aspects of reality in the virtual world that are relevant to the health of the individual. This will create a holistic picture of their health that can then be successfully employed to support diagnostic and therapy activities. We call this picture the Health Digital State (HDS).

To achieve this, we need a digital environment in which digitized health entities can be created, recorded, and processed. We propose to use the EHR-S infrastructure of health systems that already exists in many countries, only this time in a smarter version.

[3] In the Kantian philosophy, *noumenon* is a "thing-in-itself" which cannot be known directly, but only inferred from the nature of experience. It is the opposite of a phenomenon.

1.2. Electronic Health Record

In recent decades, a new IT player has entered health systems: the Electronic Health Record (EHR). During the COVID-19 pandemic, EHR software has proven to be one of the most effective ways to combat inefficiencies in health and care systems, the low productivity of healthcare professionals, and reduce the number of medical errors [42]. It needs special attention as its usefulness is closely related to the efficiency of territorial health assistance which relies on the perfect integration and cooperation of all health information systems [6,7].

An EHR is a systematized collection of authoritative documents in a digital format that record information on an individual's health and wellness as it is generated by various players in the health and care systems when health-related events take place in the individual's life [8]. The EHR aims to provide physicians and other healthcare professionals with comprehensive data on the health of their patients: demographics, medical history, allergies, medication, immunizations, laboratory test results, radiology images, measurements of vital signs, diagnoses, care plans, treatment costs, and personal statistics such as weight or blood pressure. It also contains documents on health events in patients' lives, all structured in a manner that allows for easy identification. Depending on the user's needs, it provides different ways of navigating seamlessly between data and clinical documents. The functionality of an EHR can also be directed to patients who are interested in knowing more about their health. It is now considered an indispensable tool for improving the quality of care and limiting costs in primary, secondary, and tertiary care.

In contrast to Electronic Medical Records[4] (EMR), an EHR is usually an inter-organizational artifact that contains longitudinal records with information on all significant health events that have taken place during the individual's life since birth and can be shared by many healthcare organizations and professionals. It is critically important for health and care system governance to recognize that the EHR has an integrative vocation [6] when it operates within the context of a National or Regional Health and Social Services system (NHS) [9]. This requires the EHR to be interoperable with other IT sub-systems and software applications as well as being able to integrate data from other clinical information systems or databases.

To work with EHRs in a country or region, an EHR System (EHR-S) should be deployed. This is a distributed software platform that enables communication between EHRs and other peripheral health applications with data repositories that contain documents regarding the health of individuals in that country or region and allows authorized healthcare professionals to share or exchange information [10]. The role of an EHR-S infrastructure is to facilitate the collection of electronically signed health-related documents in standard formats from EHRs and other peripheral applications and to render the information contained in them accessible through online reporting. Such an infrastructure has the following principal features:

- Management of documents: collection, registration, storage, and retrieval of documents in an electronic format.
- Notification of newly stored documents to all stakeholders who subscribe to access them.
- Monitoring and managing access to sensitive information according to well-defined policies committed to protecting the privacy and security of patients' health information.

EHR-S has the potential to provide healthcare professionals with the ability to accelerate and improve their diagnostic capabilities by better managing information. It helps to filter, sort, and organize vast amounts of health documents collected in data warehouses so that information about patients' health problems is readily accessible to those interested in them. A greater and more seamless flow of information created by EHRs within a digital EHR-S encompasses and leverages digital progress and helps to transform the way care is delivered.

Currently, EHR-Ss are implemented in most advanced countries (USA, Canada, EU countries, and many others). Where countries differ is in the degree of nationwide adoption and the available functions [11–14]. The EHR market is expected to grow significantly in the coming years. This growth is due to the increasing demand for centralized and efficient electronic health systems and the overcoming of a conservative mentality regarding the use and importance of EHR [44].

As mentioned previously, the vehicles for information exchange in such an EHR-S are health-related documents in an electronic format (usually XML-based). This approach takes account of several characteristics of the healthcare domain, such as an emphasis on the legal status of the health-related documents and the responsibility of the health organization and/or professionals that issue them to ensure their conservation. Health documents also have another important function: they determine the legal, civil, and criminal liability of the signatory subject. The documents handled by an EHR-S infrastructure may be in a minimum core set: patient demographics, physician prescriptions, patient condition, medication lists, patient summaries, discharge summaries, radiology and laboratory reports, and diagnostic test results. Added to this an extended range of additional clinical documents could be used: control visit reports, care/treatment plans, multi-dimensional evaluation reports, drug deliveries, or the outcomes of additional functions of clinical decision support: clinical guidelines, clinical reminders, drug reminders, drug allergy alerts, drug-drug interactions, drug dosing, and so on.

Health documents are ongoing entities with a "static" content that reflects a momentary aspect of a patient's health. They can be structured or unstructured. The former has a well-defined structure that is compliant with a data model. It follows a controlled vocabulary and a consistent ordering of component elements. The information it contains can be easily stored in databases and processed by computer programs. Usually, structured documents result from a standardization process that defines their syntax and semantics and renders them interoperable. Unstructured documents contain data that is not organized in a predefined manner or does not have a predefined data model; therefore the information they contain is difficult to extract for storage in relational databases. This is why unstructured documents are stored and managed in their entirety and the data contained in them can be only viewed by users and processed offline. However, as shown in Ref. [43], when trained algorithms are utilized to extract them, data from EHR unstructured documents are often more accurate for diagnosing and treating diseases than structured documents.

In current EHR systems, it is difficult to extract information about the evolution of the patient's health and her/his history of contacts with NHS facilities from single health documents. Furthermore, the system does not help healthcare professionals to reconstruct the history of a patient's health condition. To do this, a healthcare professional must "browse" several documents. Consequently, health documents are primarily used "post-event" when the care process is already underway or even completed. This explains why a document-oriented EHR is generally used to control the costs of the services the NHS provides to its citizens by keeping them as low as possible, rather than giving priority to providing a more accurate view of the patient's state of health. Working with such an EHR, the healthcare professional must build a vision of the patient's health by themselves from excerpts read in the available health documents. Thus, current EHRs provide only a partial picture of the potential functionality of a true patient-oriented EHR, which prevents healthcare professionals from obtaining a complete and holistic view of patient health.

[4] The Electronic Medical Record (EMR) is a standalone application that provides systematic documentation of patients' medical history for a limited time period and within the exclusive jurisdiction of one particular healthcare provider.

How could IT systems help the healthcare professional manage the dual aspect of the health concept? We argue that to participate as a partner of healthcare professionals in health care processes, a computer-based system should be able to intelligently construct an overview of relevant information on the patient's health similar to those the healthcare professional builds in her/his mind. This overview should be based on real data extracted from health documents that the system should analyze and validate in terms of their diachronicity, integrate, and then provide a holistic outcome to the healthcare professional.

How could digital services infer valuable judgments about patients' health from observations in digital format? We argue that it is first necessary to develop a conceptual model that contains all the concepts of interest for health and care-related activities. The instances of concepts that manifest in the real-world activities we want to digitalize should then be represented as accurately as possible as digital objects. To construct such objects from simple health observations and their aggregates, and to obtain health assessments that are as accurate as possible, we propose Smart EHR, an evolution of the current EHR-Ss. In our approach, the core component of the Smart EHR is the Virtual Health Record (VHR), an intelligent platform described in Ref. [6,7].

The remainder of the article is organized as follows. Section 2 introduces the two main objectives of our article: HDS, a new concept that digitizes the vague concept of an individual's health, and the Smart EHR, an innovative, distributed platform that integrates EHRs and other health care applications and devices. The section also presents an innovative business use case that better highlights the use of the concept of digital health in the Smart EHR system. Section 3 is dedicated to the Smart EHR infrastructure. It presents the functionality, architecture, and services of a Smart EHR-based digital ecosystem and introduces the Virtual Health Record. To digitize real-world entities and situations in the virtual world, instances of these concepts must be digitally represented. Section 4 introduces a conceptual model of the healthcare domain. The model is only partial as it was identified from the analysis of a single use case. Using these modeled concepts, in Section 5 we introduce the HDS concept. Section 6 presents several hints for designing and implementing the VHR. Central to this section is an algorithm for HDS computation. Section 7 offers concluding remarks and hints for future research.

2. Objectives

Technological progress makes it possible to improve healthcare and ensure the widespread adoption of healthy lifestyles by offering intelligent services that monitor citizens' health and help them to manage their lifestyles. In addition to in-depth medical knowledge, such services utilize digitized information on aspects of citizens' health and the context in which they live. Currently, however, there is no digital, holistic overview of health that could allow data analytics investigations to quantify the current "health" of each individual, reconstruct the history of her/his "health evolution", and provide her/him with forecasts regarding their future health. Such an overview could also provide accurate and representative data for clinical research and demographic studies on population health and well-being.

Digitizing the health of individuals and using the results to assist healthcare professionals in the diagnosis and treatment of health conditions is an important objective in the digitalization of health and care activities. To achieve this aim, we introduce the "health digital state" (HDS) as a digital equivalent to the "health" concept that can be successfully used in the digital transformation of health and care systems. This concept is inspired by the possibility of shaping the knowledge underlying the decisions of healthcare professionals using advances in IT and AI.

The article presents a method for digitizing the concept of health by processing the existing information in EHRs with the help of several dedicated services. HDS entities can be used by EHRs to improve their performance when providing intelligent support to healthcare professionals making decisions about diagnosis and treatment.

To explain the concept of HDS and its use in an advanced EHR system, the article introduces a business use case that is extremely common in current medicine: the encounter between a patient and a healthcare professional caused by the worsening of the patient's health. This use case is proposed in an innovative version that is possible under the use of Smart EHR, an EHR system that employs an intelligent infrastructure based on a VHR. The workflow of this use case is presented in a narrative description in Fig. 1. Section 5.1 focuses on its embedded software (or system) use case.

To introduce and justify the HDS concept, we need to refer to concepts widely employed in the health care domain. We selected these from the description of this use case. Several other concepts can be identified in the countless innovative business use cases Smart EHR provides for healthcare and well-being.

The article focuses on the operational and cultural changes in the use of the HDS concept and an intelligent infrastructure based on an EHR system that utilizes the HDS concept to improve business processes in health and care systems through digitalization.

3. The Smart EHR system

From an analysis of several innovative, patient-centered business use cases in health and care systems (one of which is presented in Fig. 1 and Section 4.1), we found that the EHRs could be real protagonists in patient care only if they were able to follow the approach of the healthcare professional to the patient's care by reconstructing the patient's medical history and creating a holistic view of their health. Such an EHR could propose better solutions for the diagnosis and treatment of her/his patients and learn from both successful solutions and solutions rejected by healthcare professionals.

To achieve these goals, an EHR should perform four types of complex tasks:

1. Management of health events in the individual's life using discrete data extracted from structured and unstructured health documents that describe these events. An EHR should extract and integrate all health-relevant information contained in each electronic document[5] which is received from data sources in the system and associate it with the meta-data of the corresponding health event. In this way, the EHR will be populated by episodes of care containing information about all health-relevant events that have taken place in the individual's life and the services of the health and care systems that have either triggered or responded to these events;
2. Proactive dispatching of significant notifications to all interested parties according to their profile and the patient's privacy consent. This is not only for events relevant to the patient's health but also for situations in the patient's daily life that might put her/his safety at risk;
3. Creation of virtual environments (actually health digital ecosystems [2]) for context-aware digital services [15]. This is achieved by emulating real world health-related entities and activities in the virtual world through digitization and digitalization, respectively, according to the health-related needs of the individual. Advanced analytics like data mining and deep learning are needed;
4. Contamination of the virtual world with relevant and accurate information about real-world events, entities and activities should be followed by the reverse process: exposing the virtual world to the real world. In this process,techniques of predictive and prescriptive

[5] Documents can be structured and unstructured. In the case of unstructured documents, there are many well-established techniques of information extraction (text and concept mining, image recognition, natural language processing, etc.) that enable them to be converted into something that can be reasoned with.

Business use case short description: *Encounter between a patient and a healthcare professional with the aid of a Smart EHR system.*

Trigger event: *worsening of the patient's health.*

Actors: *the patient*

Agents: *the healthcare professional (in the role of a physician) and the Smart EHR system (mainly its VHR).*

Workflow:

1. At first, the healthcare professional attempts to understand the current situation with respect to the patient's health and assess the aspects of the patient's health she/he considers important for diagnosis. After being informed about the symptoms that bother the patient, she/he decides to conduct several assessments of the patient's health. Health assessments may be measurements obtained of the patient's vital signs or manifestations of the patient's situation that can be perceived during the encounter, or they may result from the patient's medical history. If some of this information is already recorded in Smart EHR, the healthcare professional may ask the system to provide it. If this information is missing in Smart EHR or is not sufficient, the healthcare professional needs new observations that may result from a more careful physical examination of the patient's condition or new measurements of certain aspects of the patient's health. The results can be direct observations derived from the interpretation of diagnostic reports of laboratory tests and described in numbers, text, graphics, or media (for instance, images), or more complex observations resulting from the physician's reasoning regarding the psycho-physical situation of the patient. After validating and classifying these observations with the Smart EHR aid, the healthcare professional accesses the system to record them in its VHR. The VHR integrates the new observations with previous ones.
2. The healthcare professional uses all the information gathered to identify the most appropriate health concepts useful for the diagnosis. These concepts emerge from inferences and logical judgments applied to a set of information obtained by the doctor through the selection and filtering of those existing in Smart EHR. This information is, in fact, a personal "overview" of the patient's health that the healthcare professional gradually builds in her/his mind. We call this an *Induced Health State* (HIS) because this mental representation is first suggested and then gradually reinforced by the factual observations on which the patient's health assessment is based. An IHS is a personal view of a healthcare professional, the result of a cognitive process aimed at acquiring new knowledge through the use of perception, experience, and thought to understand the patient's health issues and classify them in well-known categories of concepts. According to the representational theory of mind, an IHS may be viewed as an intermediary between the healthcare professional and the external world that allows her/him to experience reality.

   We consider IHSs essential in our tentative of raising the intelligence level of the support Smart EHR provides to healthcare professionals. Indeed, an IHS is the result of selecting the most relevant observations that allow healthcare professionals to derive the best explanation for the patient's condition. The success of such selections depends on the skills of the professionals and the hints that Smart EHR should offer them. To this end, Smart EHR should learn from every successful or unsuccessful selection and use this knowledge to assist healthcare professionals in future selection processes.
3. The IHS should be objectified by the healthcare professional, with the assistance of the Smart EHR, as a cluster of structured and interrelated information that will be explicitly recorded in the VHR. We call the set of information that is a digital version of the IHS the *Digitized Induced Health State* (DIHS). DIHSs should be saved by the healthcare professional in the VHR as an outcome of her/his encounter with the patient.
4. With the proactive assistance of the Smart EHR, the healthcare professional delivers her/his most plausible diagnosis. VHR associates it causally with the DIHS as a certification of the healthcare professional's decision and a confirmation of her/his reasoning.
5. With the proactive assistance of the Smart EHR, the healthcare professional delivers her/his consequent treatment. VHR associates it causally with the DIHS as a certification of the healthcare professional's decision and a confirmation of her/his reasoning.
6. At the doctor's request, Smart EHR can provide a digitized version of the patient's health. This involves intelligently assembling the authorized assessments and diagnoses of the patient's physical, mental, emotional, and social status as found in the DIHSs of the most recent clinical events. These assessments are based on biometric and environmental measurements made by wearable devices and environmental sensors, as well as authoritative quantitative and qualitative observations formulated using standardized, interoperable indicators during various encounters between the healthcare professionals and the patient. The VHR should identify as many semantic relationships as possible between these DIHSs to ultimately compose the *Health Digital State* (HDS), which provides a single updated view of the individual's health. This should be as holistic as possible and without internal conflicts. This concept abstracts the digital representation of all the knowledge healthcare professionals possess at a given moment on the actual health status of the patient. It can be of great help in healthcare, clinical trials, and demographic studies.
7. At the request of the healthcare professional, Smart EHR can monitor the patient's health to validate the correct diagnosis and treatment. Throughout the process VHR notifies all interested parties of health events that may contradict the validity of the decisions made by the healthcare professional.

Fig. 1. "Encounter with the Smart EHR support" – A business use case in narrative format.

analysis of the large amount of data available help the EHR to discover resources and solutions in the virtual world with beneficial effects on the real world.

The Smart EHR specifications resulted from the analysis of the innovative use cases we identified by leveraging on the advances in IT and AI. Based on these specifications, the Smart EHR architecture was designed as an infrastructural platform to intelligently support healthcare processes, adapting them better to the real needs of patients.

3.1. Smart EHR functionality

Smart EHR manages an impressive collection of information regarding the health of numerous individuals. All information regarding the same individual is included in a unique *Personal Record*. We use the term *Virtual Health Record* (VHR) to refer the core component of a Smart

EHR that creates and manages the Personal Records of individuals in the (national/regional) jurisdiction of the EHR [6,7]. VHR is based on the **availability of discrete data** on the patient's health. This data is extracted from health documents[6] or messages sent by local health applications (for instance, EMRs, legacy EHRs, or HISs) to the VHR. VHR uses this data to obtain aggregate information about the individual's health status, medical history, and care or treatment she/he is receiving.

The VHR-provided services far exceed the functionality of current EHRs [7]. The following is a partial list:

- VHR functions are much more useful, powerful, and flexible than the functions of current EHRs because the business domain of the VHR is richer in concepts and semantic relationships.
- VHR has more to do with care processes than the simple management of clinical documents. It can help physicians obtain a holistic picture of the patient's health and on this basis propose diagnosis and treatments more appropriate and accurate with respect to the patient's condition.
- By using data analytics techniques, the VHR can answer complex queries related to the patient's health status or medical history, accommodate any multi-criteria decision-support logic for compliance with evidence-based best practices, or evaluate and incorporate any authoritative assertion concerning changes in citizens' health status.
- Moreover, its proactive behavior means that the VHR provides more than a consistent, comprehensive source of data; it is also a trusted partner in a collaborative environment for all participants who jointly support integrated and patient-centric care processes. VHR can successfully support the various workflows of healthcare professionals that involve evidence-based decisions, as well as a substantial diversity of quality management and outcome reporting services.
- With its longitudinal repository, the VHR collects not only objective facts and phenomena that form the basis of any assessment of the individual's health but also the subjective assessments of healthcare professionals.
- To promote innovative scenarios in health and care systems [15], the VHR is able to synthesize from its collection of information and knowledge a digital surrogate of the individual's actual health. We called it *digital health state* (see Section 3.7). Using it, the VHR can help physicians make more accurate and complete assessments of the actual health of an individual, and provide intelligent support for medical decisions.

Fig. 2 presents the overall architecture of a Smart EHR system using a layered style.

As indicated in the figure, several kinds of entities interact with the Smart EHR:

- hospital information systems (HIS) and healthcare applications utilized by healthcare professionals, hospitals, and laboratories can communicate with the VHR by sending messages containing clinical documents or information requests. They can also receive response messages and notifications with information on the health of patients;
- patients' living environments can send information to and be notified by VHR. With the increasing availability of ambient sensors and IoT devices in medicine, it becomes feasible to remotely monitor patients, collect real-time measurements of their vital signs and environmental factors and perform analytics to assess patients' health conditions and identify potential diseases, critical health conditions, or threats to health from the environment.
- mobile applications (m-health) extend the coverage and quality of healthcare to anyone, anytime, and anywhere by providing additional, up-to-date information about patients. A special case of such an entity is the Personal Health Record (PHR), an online system used by patients for self-management of their medical records. The PHR mediates between patients and VHR, promotes transparency of information, and allows patients to be better informed and more responsible for their health care [16]. All this information should be verified and validated by a healthcare provider. Of course, if the VHR evaluates the condition of the patient as critical, it may issue specific alarms and notifications;
- users of different profiles and consequent access rights, for example patients and their relatives, can directly interact with the VHR by sending information queries and receiving reports.

The messages of all these VHR data sources represent significant health or care-related events in the real world that are captured by adapters, wrappers, and gateways as well as message queuing equipment. They are sent to a central point in the system where they are analyzed by an intelligent broker that dispatches the events to specific destinations according to the metadata or even content of the message.

To syntactically and semantically align with the standard data types supported by the VHR and other components of the Smart EHR system, the messages are "normalized" using message converters, translators, and "content enrichers". These normalized messages are used by the VHR to update its repositories with information on health events in the real world and to respond to these events if needed.

As outcomes of the Smart EHR system, the VHR:

- notifies occurrences of relevant events to all users interested in these events,
- commands devices that monitor or alert the patient, and
- answers queries that arrive from the VHR environment.

3.2. Software Architecture of the Smart EHR system

Fig. 3 presents a layered architecture of the Smart EHR software system. The layers are identified by their responsibility and the technologies they employ. Each layer consists of a set of components. In addition to the six horizontal layers, there are two cross-cutting, vertical components for management and security functions.

The first and second layers are horizontally partitioned by three categories of external entities that may interact with Smart EHR and consequently with VHR:

1. External health and care systems interact with the VHR using local applications as mediators in the first layer. The second layer of adapters and wrappers is needed to integrate these entities into the overall system.
2. RFID tags, sensors, or intelligent objects and devices in the first layer detect health and care-related events or changes in their environment and send corresponding signals or messages to the VHR. Actuators execute commands sent by the VHR to notify or change something in the environment. All these context devices are controlled by appropriate drivers and communicate in the form of input or output with the second layer using various protocols. The second layer focuses on functions that manage the devices of the first layer in order to integrate them into the overall system: identification and access control, remote inclusion/exclusion, locking/unlocking, activating/deactivating devices in the device network, enabling/disabling device features, monitoring device availability, and so on.
3. The first layer also allows users (patients, healthcare professionals, etc.) direct access to the Smart EHR. For this, the Smart EHR provides mobile apps, web-based front-ends, and portals to interact with users, as well as dashboards that offer insights into analytics and health event processing. Nowadays, patients are increasingly active

[6] A Health Information System (HIS) is a comprehensive, integrated information system that manages all aspects of a hospital's operation.

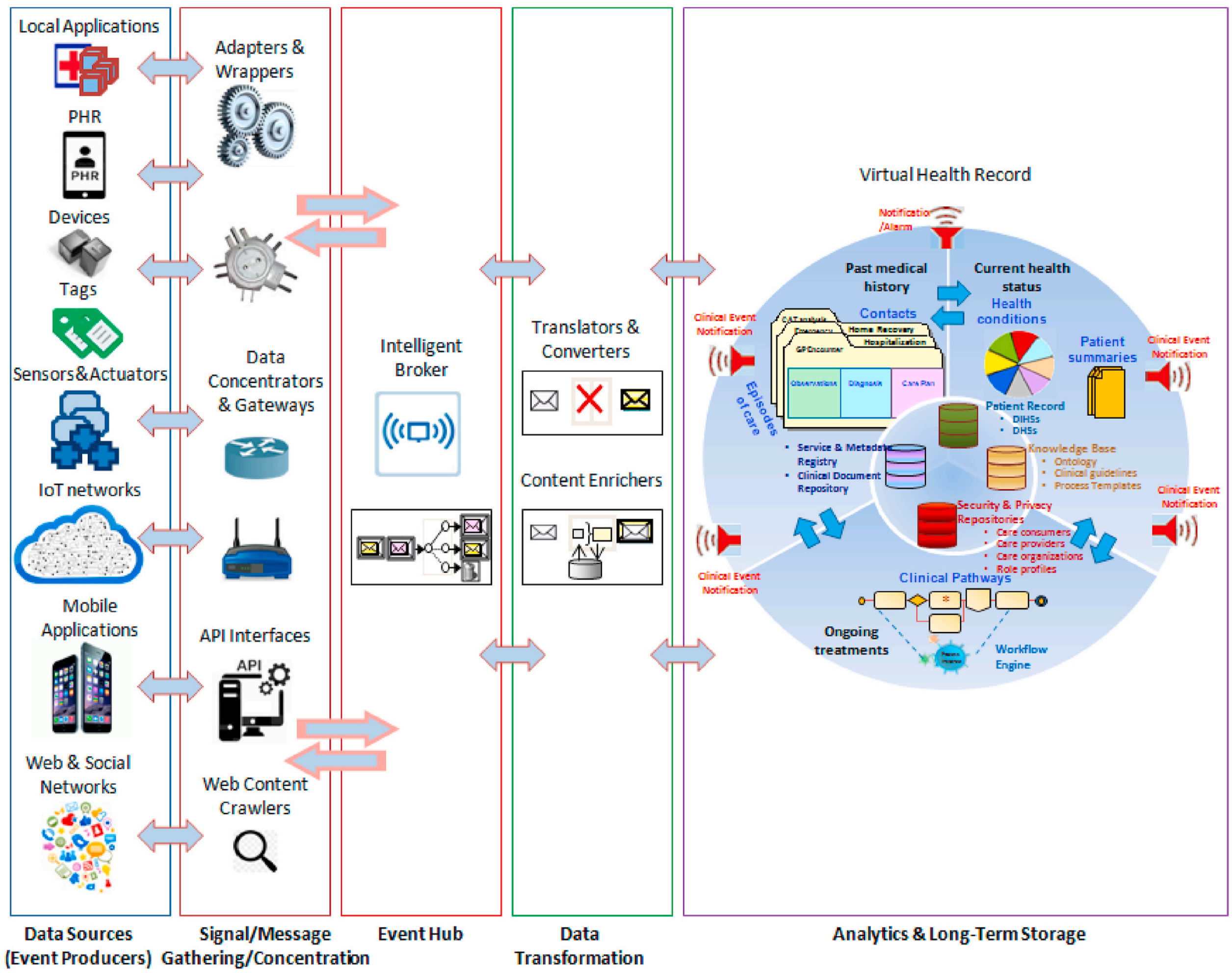

Fig. 2. The overall Smart EHR System Architecture.

online and are frequent users of social media for health purposes. Social networks could be valuable sources of data for VHR; however, the control and regulation of these sources of information is not always possible and the information obtained is not authoritative. A second layer is required for user authentication/authorization and the integration of user views.

The third layer, Data Communication & Integration, aggregates and dispatches messages. With its unified service interface, it is used by all three possibilities to access the VHR. It also distributes VHR notifications to all users. The main component of this layer is the Intelligent Broker, which is the central hub of the Smart EHR software system architecture. This can analyze, enrich, and combine messages arriving from different sources using potentially different communication protocols (HTTP/HTTPS, application-specific or message queuing protocols) and route them to other components.

The Context Management layer builds the context for each external event. This context consists of all relationships the event maintains with entities in the environment at the time at which the event occurred. The result is a digitized event.

The Virtual Health Record layer exposes the VHR services. A classification of these services in six categories is presented in Fig. 4 along with their corresponding VHR functions. Some of these services are basic, others are orchestrated. Service orchestration editors can be used to compose new, more complex services. It is also useful to note the existence of services regarding IHS handling. Additionally, a **generateHealthState** service is able to create an HDS. An algorithm to generate HDS is proposed in Fig. 9 and discussed in Section 6.2.

The VHR Knowledge Base layer is the storage environment for all types of data used by Smart EHR to meet user requirements. As Fig. 3 shows, it includes repositories for health-related facts (VHR Repository), clinical and administrative documents (Document Repository), a thesaurus of health-related concepts (Thesaurus&Questionnaire), and knowledge on best practices, including health practice patterns and clinical pathways (Clinical guidelines), manuals, policies, and so on. We will present these repositories in Section 6.1.

4. Modeling health concepts

In developing our conceptual model we adopted or adapted concepts from HL7 [17] and CONTSYS [18], two standards issued by international organizations: Health Level Seven International and the European Committee for Standardization, respectively. We have also introduced new concepts into our model, such as DIHS or HDS, which help us to model what we intuitively mean by health. The following presentation of the conceptual model, derived from the business use case in Fig. 1, is neither formal nor rigorous. Rather, it aims to describe the method the author employed to digitize instances of concepts in the field of health and well-being. The ultimate goal of this section is to provide a digitizable model of the concept of health.

4.1. Health concepts

We begin by introducing well-known health concepts such as

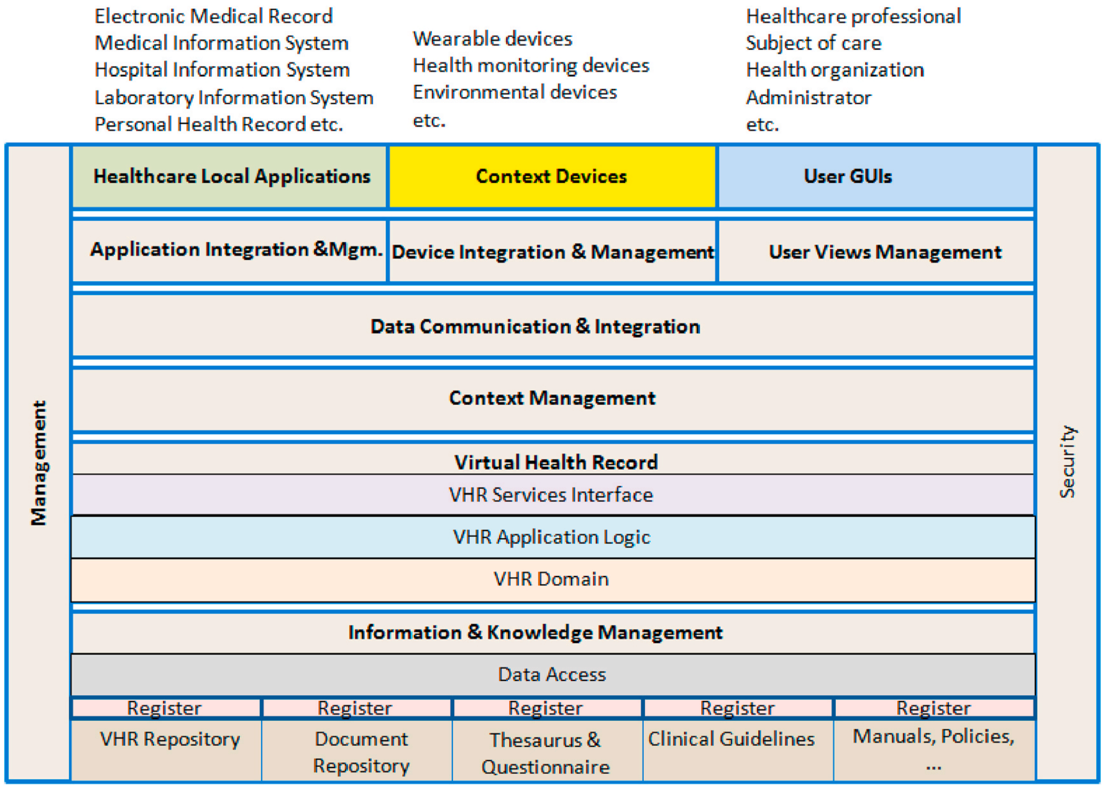

Fig. 3. Smart EHR software architecture.

observation, *health situation*, *health issue*, *episode of care* and *diagnosis*. They are closely related to each other, as seen in the simplified diagram in Fig. 5. Highlighting the semantic relationships between concepts will allow us to include the digital health in the conceptual model. For this, we will outline as far as possible the meaning of the concept of health through a series of abstractions to discover its possible digital equivalents.

Health manifests itself in a way that is partially observable. *Health observation* is the systematic process used to collect data about a patient's health situation. The same term, observation, is used to refer to the results of this process. Any instance of such an observation can be digitized as a value characterized by a type (observation type). The value can be either simple: a Boolean value (it may mean yes/no, true/false, present/absent, etc.), a simple number, a text of several words, or a compound value such as a complex data structure. It should be accompanied by metadata for its contextualization, as explained in Section 4.4.

We define a *health situation* as a set of circumstances relating to an individual's health that are perceived as worrisome by herself/himself or her/his caregivers at a given moment. This may involve the manifestation of negative or problematic symptoms such as pain or negative mood or it may result from objective or subjective observations made by healthcare professionals. In such cases, the patient usually takes note of her/his changed health situation, which manifests as a need for medical assistance. Addressing such a health situation as a *health issue* is an essential act undertaken by a healthcare professional who then initiates a care process related to that health issue.

The health issue is an important concept in the conceptual domain of health care which is also difficult to define precisely. In the ISO 13940:2016 documents [18,19], a health issue is defined as a "representation of an issue related to the health of a subject of care as identified by one or more healthcare actors". It may synthesize a certain deterioration of health that may be due, for example, to a disease or disorder. An immunization, a heart attack, a drug addiction, a health certificate, and injury are all health issues. Actions of preventive care for a person or community can also be considered health issues. Furthermore, a health issue also arises when the subject of care requests a preventive or therapeutic procedure after a loss of weight.

In our approach, the health issue is a conclusive observation provided by a healthcare professional at the end of a diagnosis process, an authoritative assessment of a health situation that does not always present a negative outcome but has risen to a level of concern. The health issue concept is both a useful classifier for various health situations/conditions of individuals and a structuring element for the knowledge we hold about their health. It may be expressed with a short textual description or synthesized as a label or code according to a standard medical classification system such as ICPC (International Classification of Primary Care) [20], SNOMED (Systematized NOmenclature of MEDicine) [21], LOINC (Logical Observation Identifiers Names and Codes) [22], or ICD (International Classification of Diseases) [23]. The health issue also appears as an effect in a logical cause-effect relationship with the observations that led to the diagnosis and as a cause in another such relationship with the care or treatment plans that resulted from the diagnosis.

We therefore consider all the healthcare activities and related services that healthcare professionals and healthcare facilities provide to a patient to address a health issue during various contacts the patient has from the onset of symptoms until the treatment is complete. We include all these events in an *episode of care*, another important concept that can be used to structure the life span of a patient from a medical point of view. If a health situation cannot be classified as a health issue, the healthcare professional responsible for the patient's care may request new investigations to deepen their knowledge of the health situation. New contacts dedicated to this health issue will then be included in the current episode of care. The same health issue may involve several episodes of care in the life of a patient.

After identifying the elements needed to decide on the health issue, the healthcare professional follows up with a *diagnosis*, which is a concept with multiple, context-dependent meanings [17]. The diagnosis is a clinical assessment of the health situation that occurs in an individual's life; in our approach it is a type of healthcare service. It

Type	VHR Services					
	Clinical Document Services	Personal Data Services	Clinical History Services	Health State Services	Ongoing Care Services	Secondary Use Functions
VHRServices	newDocument() editDocument() getTypedDocuments() getServiceDocuments() getLastServiceDocuments() getDocumentMetaData() createNewVersion() archiveDocument() extractInfoFromDocument()	newPatient() getPatientsList() getPatientInfo() editPatientInfo() getPatientFamiliarity() editPatientFamiliarity() getAllergies) editAllergies() getIntolerances() editIntolerances() getImmunizations() editImmunizations() getAdverseEvents() editAdverseevents() getAccessRights() editAccessRights() getPreferences89 editPreferences() newConsent() editConsent() addDevice() eliminateDevice()	getPatientSummaries() getHealthIssues() getEpisodes() getEvents() getEventServices () getLastEncounters() getLastCarePlans() getLastServices() getLastMedications() getTypedObservation() getTypedObservationHistory() getDiagnoses() getCarePlans() getCarePlanDetails() getTrend() getHealthIssueRisks() getInducedHealthStates() getHealthStates() getPatientSummaries()	getOpenEpisodes () newEpisode() editEpisode() closeEpisode() openEncounter() addServiceToEvent() getCurrentEventServices() getServiceDetails() addSimpleObservation () editSimpleObservation () newDignosis() editDiagnosis() setHealthIssue() editHealthIssue() newCarePlan() editCarePlan() getCrtMedicationList() checkMedication () analyzeMedication() newInducedHealthState() editInducedHealthState() newPatientSummary() editPatientSummary() generateHealthState() editHealthState()	getClinicalProtocol() editClinicalProtocol() newCarePlan () editCarePlan () editCarePlanWorkflow() addTaskToWorkflow () addConditionToWorkflow () activateCarePlan() suspendCarePlan () interruptCarePlan () traceCarePlan () checkMedication Allergy() notifyClinicalEvent() newInstructionsForPatient() traceImmunizations() analyzeInteraction()	exportDataForPHR() getPatientAnnotationList() getProviderAnnotationList() getPatientAnnotation () getProviderAnnotation() addPatientAnnotation () addProviderAnnotation () notifyEvent() configurateNotifications() anonymizeRecord() exportRecordDataSet() exportAnonymizedDataSet() checkVHR() dataAnalysisAndStatistics()
VHRFunctions	-search, versioning, archiving, a clinical documents; -content integration of clinical documents and/or messages that represent assessments, medical measurements, care plans, medication orders, clinical guidelines and protocols, standardized coding systems, etc.	-patient demographics mgmt.; -mgmt. of patient's (and/or family's) preferences directives, consents, and authorizations; -allergies, intolerances and adversereactions mgmt.; -immunizations mgmt.; -mgmt. of access rights profiling; -support for integration of devices.	-mgmt. of clinical events (encounters), episodes of care, health issues, diagnoses, and health states; -authored health states mgmt.; -intelligent support for identification of potential health issues and trends.	-mgmt. of healthcare services during patient encounters: laboratory results and reports, clinical measurements, medication lists; --generation of a complete map of indicators pertaining to the patient's current health; -generation of clinical views on the health state using either a health issue or a user concern expressed as a query; -generation of clinical synthesis such as digital health state or patient summary; -medication orders mgmt. including analysis of medication order efficiency, specific medication dosing and warnings, check of medication interaction and allergy risk; -intelligent support to medication specific dosing including proactive warnings; -intelligent and proactive support to prevention aspects. (present alerts for preventive services and wellness).	-intelligent support to customization of clinical guidelines and protocols for planning care; -care plan life cycle mgmt; -care plan workflow mgmt; -notification risk situations to all interested in the patient health; -care coordination and reporting; -generate, record and distribute patient-specific instructions; -medication administration mgmt.; -immunization administration mgmt.	-provide data for the patient health record (PHR); -enable commmication between patient and health provider; -electronic health record quality mgmt.; -support for population-based epidemiological investigations -support for monitoring notifications to health providers -anonymized data requests mgmt.; -support for e-governance and e-learning for caregivers: -provide anonymized data for clinical trials.

Fig. 4. Vhr services and functions.

assigns a name or a coded classification for the health issue.

The diagnosis outcome that includes the health issue documents the diagnosis service. This usually has a treatment service as a consequence. Using an evidence-based approach and clinical guidelines specific to the health issue identified, the care provider develops a care plan containing a set of activities and rules of conduct applicable in the case of the patient that, once completed, should eradicate the reason for the concern, or at least mitigate its consequences.

We can add several other aspects useful in determining the health issue concept and the diagnosis service:

1. The decision on the health issue is a result of the healthcare professional's know-how, experience, skills, role/position, as well available information on the patient's health situation and medical history. Any two healthcare professionals may have different interpretations and consequently different decisions on the health issue for the same health situation.
2. A diagnosed health issue may evolve during the care process as a consequence of the evolution of the disease process, changes in the observational context, more accurate knowledge of the patient and her/his health status, activation of care plans, or a need to adapt the health issue to some default encoding.
3. The medical history of a patient can be described not only as a sequence of clinical encounters but also as a network of health issues. In this network, the health issues are in various relationships with each other. Some of these are general such as chronological, generalization/specialization, causality, similarity, exclusion, while others are specific to some medical fields. The network not only provides a comprehensive description of the various health issues encountered during the patient's life, but also presents the evolution of the understanding of these issues by healthcare professionals. Finally, it allows professionals to reason and decide on the best care plan.
4. Assigning a name, label, or code to a health issue after a diagnosis process is nothing more than adding a new observation on the patient's health to all previous observations and constitutes a necessary step in the care process.

4.2. What does health mean?

In this section, we examine how the abstract concept of health has been defined over time and explore the utility of these definitions for its digitization.

In 1946, the World Health Organization (WHO) defined health as an overall "state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." [24] This well-known definition introduces the important idea that health is a state of being. Another important aspect of this definition is the multidimensionality of health as it is usually assessed in terms of l) absence of physical pain,

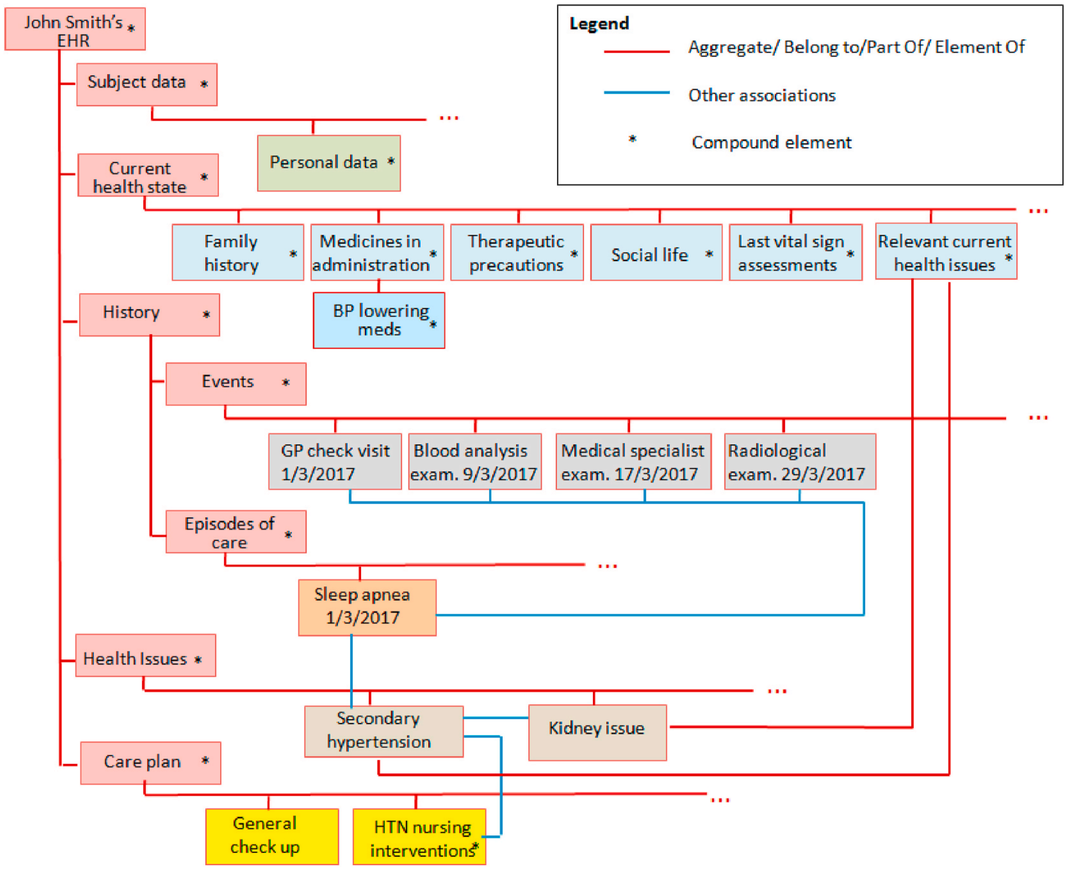

Fig. 5. Semantic relationships between instances of medical concepts in the Smart EHR.

physical disability, or worrying condition, 2) emotional well-being, and 3) satisfactory social integration. Newer medical health definitions go further and also emphasize the capacity to adapt to changing external and internal circumstances, and to self-manage.

Along similar lines, the MeSH definition of health refers to: "The state of the organism when it functions optimally without evidence of disease" [25]. In Ref. [18] a "*health state*" is described as "physical and mental functions, body structure, personal factors, activity, participation and environmental aspects as the composite health of a subject of care".

However, these definitions do not help us much because they simply describe health as an ideal state never fully achieved. Because we talk about health as either "good" or "poor", the concept of health is used even when the state of well-being is lacking.

Health status is another generic term referring to the quality of health of a person, group, or population as subjectively or objectively assessed by observers or measurements in a particular area, especially when compared to other areas. It is a holistic concept that is determined by more than the simple presence or absence of any disease. It is often summarized by general attributes such as life expectancy or self-assessed health status, and more broadly includes measures of normal functioning (activities of daily living), physical illness, and mental well-being [26].

A more pragmatic approach to achieving a digitizable model of health is to consider the evaluation of the *functional health status* as it is used in primary care. Following [27], functional health status is a measure of the mental, emotional, social, and physical well-being of patients and refers to their ability to independently perform activities of daily living. It can also be used to assess the severity of a person's disability. Functional health status is addressed to an individual in general and is not specific to a disease. The WHO adopted a similar approach when it introduced a vector of eight major skills: pain, affect, cognition, mobility, self-care, common activities (including household and work-related activities), and interpersonal relationships as a measure of the health of an individual [28]. This core vector can be expanded with other skills depending on the purpose.

Extending this latter approach, we can imagine our knowledge about the health of a human being as a "questionnaire" containing a huge list of questions representing health and wellbeing-related parameters that can be answered (quantified) with values. For each parameter two ranges, maximal and normal, are associated. The parameters refer to all aspects of the human body and psyche that can affect our health. It starts with genetic information and then continues with information about the health of the tissues of various organs, clinical or vital signs, and social behavior and living conditions, especially in terms of the environment in which the individual lives. Completing such a questionnaire with a value for each parameter represents an all-encompassing assessment of an individual's health. It can be considered a quantification of an instance of health. Based on this measure, qualitative assessments of health can be issued a posteriori depending on the subjective criteria we employ to evaluate health.

However, it is clearly impossible to complete such a questionnaire to describe a person's health due to the lack of values for most parameters. Moreover, to provide care and rehabilitation for all possible health situations and all cases of health problems, we must use a practically infinite number of relationships between health parameters and would require medical knowledge that does not yet exist.

But it is also clear that if we can evaluate as many parameters as possible in this questionnaire, we will get a better understanding of the individual's health. In any case, in assessing the health of a patient that a VHR could provide, even relatively few valued parameters can be of great help in supporting with new technologies the cognitive diagnostic process of health professionals.

In the following section, we introduce the induced health state as a model of how healthcare professionals represent the health of an individual in their minds. In our approach, this representation must be digitized to allow the system to understand the thinking of the healthcare professional and learn from her/his reasoning so that it can help her/him in similar situations. This step is useful for further introducing the digital health state, a concept that approximates our concept of intuitive health and has the advantage of being digitizable.

4.3. Induced health state

Mental representations[7] held by healthcare professionals regarding the patient's health are based on knowledge of health-related facts, such as perceived symptoms and clinical observations made at the time of the encounter with the patient and spontaneously associated with their medical knowledge. The information captured, even if it is limited, is the initial knowledge a healthcare professional uses during the encounter to shape in her/his mind a representation of the patient's health according to her/his medical expertise and experience. In this process, she/he selects from the small number of valued health parameters at their disposal those that are relevant for the analysis of the patient's current situation. Through specific cognitive structures, such as reasoning processes and thought patterns, the values of the selected parameters are correlated using well-known semantic relationships between the parameters and items of her/his professional knowledge. This facilitates the structuring and reorganizing of her/his knowledge according to the new information. The model we propose for the digitization of mental representations is based on a hierarchy of concepts from general to particular. In this hierarchy, the concepts of observations (i.e., facts) are at the base of the hierarchy, while towards the top are positioned more and more general concepts that have been identified through successive applications of reasoning operations of deduction and induction. We thus define the *induced health state* (IHS) as the mental representation of the healthcare professional resulting from interpreting facts that correlate with her/his medical knowledge. The IHS allows the medical professional to infer a diagnosis by reasoning. Because the healthcare professional continuously tries to adapt it to the patient's specific case, this representation may evolve during the encounter: the initial elements can change and new elements could be added. However, due to the narrow specialization of healthcare professionals or their lack of sufficient information, the IHS is limited to just a few facets of the multidimensional image of the patient's health. Moreover, it is partially subjective and sometimes even wrong.

We believe that VHR, as the only agent that possesses all the authoritative information about people's health, could help the healthcare professional refine her/his partial view of the patient's health by providing her/him with a holistic image, highlighting the possible internal contradictions of the IHS and proposing solutions for their elimination. For this, VHR should take possession of both the assessments of the healthcare professional and as much information as possible on her/his reasoning process. This is why we propose to involve healthcare professionals to deliberately transfer in digital format the information contained in their IHSs to the VHR. In our approach, digitization[8] of IHSs is a critical operation in which healthcare professionals should be primary and, ideally, convinced players. Without it, the digitalization[9] of complex processes such as diagnosis and treatment is impossible. It seems to be a difficult task to accomplish, but it is not. As we explain in the following sections, VHR can help provide healthcare professionals with necessary information and also guide them in transferring knowledge from their mental representations to the VHR.

4.4. Digitizing the induced health state

Let us assume that a healthcare professional who is going to assess the patient's health scrupulously records all new vital sign measurements and other (qualitative) observations made during the patient's encounter in the VHR. At the healthcare professional's request, VHR can use this information to complete a list of facts that contains information about medical events useful for assessing the patient's health. VHR begins the list by presenting brief information about immunizations, drug intolerance and interactions, possible allergies, medical equipment/devices used, patient and family preferences, as well as essential information about events in the patient's medical history that might be relevant to her/his current health situation. VHR further adds the latest measurements of vital signs, the most recent diagnoses with their codified health issues, currently administered drugs, recently concluded treatments, and the current status of workflows of the ongoing care plans.

This list can be displayed by the VHR and then verified and possibly edited by the healthcare professional. During editing, she/he can remove unnecessary items from the list and add others that are considered important for assessing the patient's current health.

When the list of facts is considered complete, the healthcare professional may decide to save it as a *digitized IHS* (DIHS) associated with the health event for which it was created (an Encounter event in our business use case).

Moreover, the healthcare professional may include in the list of facts any number of references to DIHSs previously created by herself/himself or other colleagues during contacts with the same patient that are considered useful in assessing the patient's health. The occurrence of such references is equivalent to including all the information found in the lists of facts of the referenced DIHSs. After each inclusion, VHR has to "clean" the DIHS, i.e., remove redundant information and highlight any contradictions in the resulting list. "Inclusion of the facts with the subsequent cleansing of the DIHS" is an automatic VHR function. It can also be executed on an *on-the-fly* composed list of facts at the explicit request of any healthcare professional who has the right of access to patient information.

VHR can also provide healthcare professionals with hints to help them search and retrieve useful information in its repository. For example, it could suggest previously recorded observations on the patient's health or even existing DIHSs as candidates to be included in the list of facts. To select these, VHR uses a built-in semantic rules engine that implements a dynamically adaptable rule-based control mechanism working in the semantically uniform Smart EHR ecosystem in which it

[7] A mental representation is a hypothetical cognitive structure debated in several fields of science and philosophy. In our approach, a mental representation is a model of the result of the internal, inherent processes of our mind in which we identify perceived entities from external reality, or even some imagined ones, that are integrated with already existing knowledge in order to explain their existence and behavior in the real world. Like any model, its usefulness should be validated in real situations.

[8] Digitization currently refers to the conversion of a version of analog/physical things such as paper documents, microfilm images, photographs, sounds, etc. In a digital format that can be used by a computing system with the goal of automating processes or workflows. In our case, digitization can also be the conversion of human mental representations in data structures.

[9] Digitalization is about enabling, improving, or transforming business processes by leveraging digital technologies and digitized information. It is not only a technical process (akin to digitization) but also an organizational and cultural one.

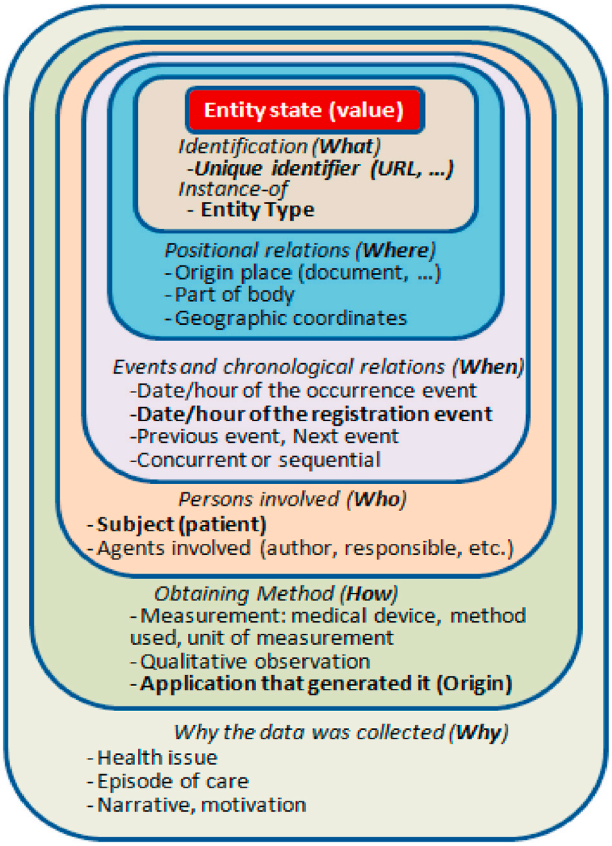

Fig. 6. Virtualization of a real world entity in a VHR implementation.

runs. As explained previously, the uniformity of the VHR environment results from conversions in a VHR-specific standard format of all messages and data streams received by the Smart EHR system and sent by heterogeneous entities such as HISs, applications, and peripherals connected to the Smart EHR system. The Intelligent Broker creates and maintains this uniformity.

Information regarding any real-world entity (thing, fact or event, person, etc.) that concerns the health of an individual, such as patient demographics, health service, medical observation, episode of care, significant environmental or health event, health provider, is collected as facts from the environment and *virtualized*[10] as a digitized entity in the VHR.

For virtualization, all relevant information about the entity should be included in its virtual representation, namely:

- the current state or value of the entity represented by its essential properties (primarily its type, i.e., the concept that applies to the entity);
- the context of the entity in the real world consisting of all significant semantic links between the entity and other entities. Fig. 5 hints at several semantic links between instances of medical concepts related to an individual known as John Smith in the Smart EHR;
- services that simulate in the digital ecosystem aspects of the entity's behavior in the real world.

Once virtualized, the real-world entity is transformed into an *item of knowledge,* namely a digital entity that can be located and manipulated as an independent object in the VHR Repository. This should include all the information the VHR needs to reason about this digital entity. Fig. 6 depicts how information gathered from the entity's real-world context enriches the basic information about the state of the entity and transforms it into an item of knowledge. In this case, the context consists of all the relevant, semantic links the entity has with other entities in the real world. It is essentially a *what-when-where-who-how-why* data structure where data elements such as a unique identifier, entity type, subject, author, times of occurrence/registration/virtualization, are compulsory properties inherent to any entity. They are used as metadata in the header of messages that transport the items of knowledge across the Smart EHR or facilitate the retrieval of items of knowledge in the VHR Repository. Depending on the entity type, other data elements that contextualize the entity state in Fig. 6 could be optional.

Generic "translation schemes" for each type of entity are available to the Intelligent Broker, which receives messages from the periphery of the Smart EHR system regarding real-world entities, translates the information they contain into appropriate knowledge items, and then sends these items to VHR and other Smart EHR components.

In the VHR Repository, we can also find *aggregates of knowledge*. These are data structures also contextualized as shown in Fig. 6 which are created not from a single value but from a collection of items and/or other aggregates of knowledge.[11] Their role is to emulate meaningful and identifiable collections of real-world entities in the virtual world.

A DIHS is such an aggregate of knowledge. It contains items and other aggregates of knowledge that make up the informational portfolio of a healthcare professional regarding an individual's health at the time of their encounter. For us, each DIHS is an objectification of the subjective view of a healthcare professional on the individual's health. In this respect, it is also a complex observation. It could also be a model mnemonic used to help the healthcare professional recall certain information.

Suppose we could access the DIHSs generated by all healthcare professionals who visited and treated the same individual in a given time period. This information, which comes from diverse sources, is all we know about the individual's health at that time. Assembling and correlating this information is thus equivalent to constructing a holistic image of that individual's health.

4.5. Diagnosis and treatment with DIHSs

Once saved, any DIHS can evolve. It may be modified or even archived as useless by the healthcare professional who created it according to the evolution of her/his mental representation of the patient's health. VHR should, of course, trace and record all changes in this evolution.

DIHSs that healthcare professionals use can be:

- stable when they are explicitly created and recorded by healthcare professionals to be available when confronted with other similar DIHSs, or
- temporary when they are provisionally created and used by their author and then canceled.

The transfer of knowledge to the VHR involves only stable DIHSs.

A diagnosis must identify the health issue that is the origin of the patient's poor health. Healthcare professionals make the diagnosis according to their knowledge of the patient's conditions, i.e., according to their IHSs. In our approach, IHS digitization also allows healthcare professionals to justify their decisions about the diagnosis and treatment they will take during the encounter with the patient, using a data

[10] To virtualize a real-world entity means to replicate it through the digitization of properties and behavior simulation in the virtual world.

[11] The use of items and aggregates of knowledge to populate an EHR is a solution similar to that of the resources and domain resources HL7 FHIR Foundation proposed as a new direction to improve the interoperability of health data [40].

structure recorded in the VHR and not ideas, findings, or intentions which cannot be proved.

In terms of cognitive processes, diagnosis is represented by an activity in which the health status of an individual is classified in a distinct category of diseases according to a standard system of medical classification. This classification then allows medical decisions on treatment and prognosis to be made according to that category.

The diagnosis, in the form of the outcome report of the diagnostic activity, should be retained as an observation in the VHR and related to the corresponding DIHS through a semantic causal association. That is, the diagnosis depends in part on the DIHS because many, if not all, elements of the IHS that have created the DIHS are, according to healthcare professionals, causal elements for diagnosis.

Deciding on a care plan for a poor health situation is the result of another cognitive process that usually represents the final step in the encounter of a healthcare professional with a patient. The process basically involves the application of medical guidelines and protocols for the already identified health issue, taking into account both the information gathered in the DIHS relative to the patient's particularities and the experience of healthcare professionals. VHR should also associate the care plan to the DIHS and create a second causal relationship between the diagnosis and the care plan. In this relationship, the causal factor is the diagnosis.

4.6. DIHS processing

Within the VHR, DIHSs play a central role in modeling the concept of health in order to digitize it. They exist in semantic relationships with each other and with other entities. We can thus imagine a network of several semantic relationships between instances of DIHS such as causality, aggregation, chronology, similarity, and refinement. We used a *Colored Semantic Network* to model this multitude of relationships between the DIHSs in the VHR. Such a network is a directed graph that has nodes labeled with DIHSs and edges that represent semantic relationships between DIHSs. Each type of relationship requires its edges to have a specific color.

Any DIHS is associated with the patient for whom it was created, the healthcare professional who generated it, and the clinical event during which it was generated. It is also associated with diagnosis and treatment. These associations give VHR the ability to select useful collections of DIHSs according to different criteria regarding the choice of patients, healthcare professionals, health issues, or types of treatment.

For example, consider a health issue D. Among all individuals represented in its repository, VHR can find those who in their lifetime experienced clinical events when they were diagnosed with D. Such a selection could be used as a data source for a regional D-disease registry: all persons in the region who have one or more DIHSs associated with a D diagnosis are candidates for inclusion in the registry.

The VHR should be able to process its DIHSs. Some of the DIHS-related VHR services are the following:

1. Detect and report potential redundancies and internal conflicts in an evolving DIHS and suggest corrections to the healthcare professional who edits it.
2. Selection of collections of DIHSs based on the equivalence, inclusion, or partial overlapping of their associated diagnosis and care plans.
3. Sort a set of DIHSs according to various criteria; for instance, the dates on which their corresponding clinical events occurred (chronological ordering).
4. Given two DIHSs, report the existence or absence of a relationship between them such as access to common information, use (one references the other), refinement, derivation, similarity, or contradiction.

To confirm or disconfirm a relationship R between two DIHSs, the VHR should first analyze their content and for each DIHS identify the following components:

- the set of simple observations in the facts list,
- the set of other DIHSs to which the DIHS refers,
- the associated diagnosis (e.g., health issue code), and
- the associated care plan.

The corresponding components of the two DIHSs should then be compared and the VHR should ultimately decide whether they are in the relationship R. For example, consider two DIHS: X and Y. They may be in certain dependency relationships, such as the following:

a. X and Y *depend indirectly* on each other. For example, X and Y share some simple observations (e.g., vital signs, symptoms reported by the patient or identified by the physician).
b. X *refers to/uses* Y. For example, the patient's general practitioner (GP), who previously generated Y, includes it in the list of facts of interest to X.
c. Diagnosis of X *refers to/uses* the diagnosis of Y.
d. The healthcare plan of X *includes* the healthcare plan of Y.
e. Y *is a refined version* of X. Y was generated by detailing X (X and Y probably have the same author).
f. Y *derives from* X. In this case, X and Y were generated by two different healthcare professionals. For example, X was generated by a GP. Under the GP's request, the patient was directed to a clinical specialist who generates a DIHS Y based on X (this fact is explicitly registered in Y).

4.7. The digital health state concept

What is missing in contemporary medicine is a holistic picture of the patient's health. The increasingly deeper specialization of healthcare professionals prevents them from having a holistic view. A comprehensive perspective on the patient's health is also difficult to obtain because, at the time of the encounters with patients, the information available to a healthcare professional about their health is inevitably limited. Often, it is not enough for her/him to make the diagnosis and then provide a care plan. In such a case, the healthcare professionals have to try to gain a better understanding of the patient's health by multiplying the clinical observations until the acquired knowledge is sufficient for diagnosis. However, even in this case, they cannot obtain a comprehensive picture of the patient's current health and health history at the time of encounter. We argue that only a longitudinal EHR (especially in the VHR-based version) can provide available information on all significant health events in patients' lives and can successfully support the work of healthcare professionals.

Another aspect relates to the subjectivity of the decisions made by healthcare professionals. A healthcare professional gradually forms a mental representation of a patient's health (we call it IHS) using existing observations recorded in the EHR. Another healthcare professional will build her/his mental representation of the same patient's health in the same way. It is likely that the two mental representations will differ. For instance, the IHS of a diabetes specialist is different from the IHS of a neurologist. As a result, the IHSs mentally constructed by healthcare professionals dealing with the same individual's health over the same period of time will differ, even if they are professionally correct representations of the same person's health. As a consequence, this is also true for the corresponding DIHSs.

The VHR in a Smart EHR contains all observations regarding an individual's health, including all DIHSs generated by the healthcare professionals who have taken care of the individual's health at different times in her/his life. This collection contains all documented, authoritative, attributable, persistent, and shared digitized information about the individual's health. This information is partly evidence-based and partly subjective. It has the advantage of providing us not only with a historical perspective but also a holistic view of the health of the individual. This view can be utilized by any healthcare professional who treats the individual. If she/he wants to know about the individual's health at one particular time or how it has changed over time, this is the collection of information in which she/he can find an answer. Due to the myriad specializations of healthcare professionals who have examined the health of the individual, this knowledge is multifaceted. Such facets[12] are "personal opinions" on the same problem: the individual's health. They are generally partially redundant and can sometimes even conflict because the professionals have different opinions, some of them are wrong, or the health of the individual has changed over time.

In order to intelligently participate in an individual's healthcare scenarios, the VHR should be able to obtain, possibly at the request of a healthcare professional, a new knowledge structure from the collection of all DIHSs that have been generated in a given period for that individual. After eliminating possible conflicts and redundancies, the new knowledge structure includes all significant information on the health of the individual. It consists of digitized observations (both simple, such as those obtained through perceptions or measurements using scientific instruments, and complex, for example, diagnostics) that describe the health of the individual in a factual manner. Of course, these observations are strongly related to each other as well as to other digitized entities. We call this data structure a *health digital state* (HDS). Any HDS is created and valid for a specified time period only.

With the support of the Smart EHR system, the explicit use of HDSs by healthcare professionals can accelerate the digital transformation in health and care systems. The following examples illustrate the advantages of using the HDS concept:

- At the request of the healthcare professional, the VHR can generate the *current health digital state* (CHDS) of an individual, which contains the latest assessments for each documented aspect of the individual's health. For this, the VHR selects the most recent DIHSs starting with a date specified by the healthcare professional. It extracts from this collection all the distinct observations contained in the DIHSs, which are then filtered to retain those which are the most recent. The observations obtained are classified in thematic chapters and subchapters according to authoritative medical classifications (SNOMED, ICD, etc.) and then displayed in separate tagged frames. The new CHDS can be saved in the VHR like any other observation ready for use in other DIHSs.
- From an individual's CHDS and with the aid of the Smart EHR, a GP can generate the *health synthetic profile* (HSP) of the patient, which is nothing more than a selection from the content of the CHDS. It is obtained by selecting significant slots of the CHDS according to a standard template. When the value of such a slot is missing in the HSP, the GP can include it after performing adequate measurements and/or qualitative assessments. Once created as a stable document, the HSP itself becomes an observation, ready to participate in the creation of other DIHSs.
- Smart EHR could provide, upon request, a series of chronologically sorted HDSs that cover a long period. Such a series represents the individual's *medical history* for that period. Based on such a history, predictive and prescriptive analytics can be applied.

The following Section 5 and Section 6 use the concepts introduced above to present several key aspects of the VHR conceptual domain modeling and design. They are useful to model the HDS concept.

5. Modeling the health digital state concept

5.1. Innovative use case for a healthcare encounter

To illustrate the VHR's ability to intelligently support the activities of a healthcare professional, we consider in more detail the business use case presented in Fig. 1 of a medical encounter between a healthcare professional and a patient who complains of symptoms attributable to a single disease. To simplify our presentation, we assume that the healthcare professional has the same goal as the patient: addressing the patient's concerns, fears, and so on to improve the patient's health status. We also ignored possible communicative barriers arising from cultural and even personality differences between the two people. Finally, we focus our description on the software use case of the interaction between the healthcare professional and Smart EHR, which is incorporated in the surrounding business use case. This software use case represents the core element of the digitalization of the business use case in Fig. 1.

While for the business use case the patient is the primary actor and the healthcare professional is an agent, the primary actor for the software use case is the healthcare professional who intensively operates the Smart EHR. For this, we will assume that she/he fully understands how to use the concepts of DIHS and HDS. A description of the main scenario in the software use case is presented in Fig. 7. To better explain the role of the VHR in the man-machine interaction during execution of the use case, the workflow description is structured in two columns: the left for the actions of the healthcare professional and the right for the actions of the VHR. In the followings, we explain the steps in the workflow.

(1) The healthcare professional begins by requesting Smart EHR to open the patient's personal record and then assist her/him in an Encounter session. (2) VHR responds by first creating a DIHS for this encounter with an empty list of facts, then initializes this DIHS with the patient's personal data, including critical health information, and displays the DIHS to be edited by the healthcare professional.

(3) Anamnesis. The patient is asked to explain the reason for requesting this encounter: specifically, the symptoms that concern her/him and changes in her/his health. (4) The healthcare professional asks the VHR for the patient's synthetic health profile where information about the patient's health peculiarities can be found. (5) VHR responds by providing the healthcare professional with the patient's synthetic health profile.

(6) After conducting a physical examination of the patient, which produces new observations, (7) the healthcare professional may repeatedly ask the VHR to visualize the patient's HDSs for different periods and/or diseases in order to better understand her/his medical history. For each request, VHR generates the requested HDS (8).

(9) If the information in the requested HDS is insufficient for diagnosis, the healthcare professional may repeatedly ask the VHR to include in the list of facts of the current DIHS: either (a) a new observation or (b) an observation already existing in the VHR Repository, or (c) a reference to an entire existing DIHS.

(10 a, b, c) For any request to include observations in the list of facts of the current DIHS, the VHR first verifies that the observations to be included do not already exist in the current list and do not conflict with the existing observations. If the result is positive, the observations are included in the current list of facts and the healthcare professional is notified.

(11) When the healthcare professional considers there is sufficient information to make a diagnostic decision, she/he requests Smart EHR to register the current DIHS as a stand-alone entity, as it is a sufficiently accurate translation of her/his mental representation of the current health status of the patient.

(12) The VHR records the current DIHS with the healthcare professional as the author and associates it with the event of the current encounter.

The healthcare professional can continue either by directly indicating as a diagnosis a health problem that best synthesizes the information from DIHS or, as the scenario in Fig. 7 suggests (13), requesting VHR assistance in identifying the health issue (14). VHR identifies the health issue from the comparative analysis of the current DIHS with previous DIHSs successfully associated with health issues and/or by

[12] On the role of such facets in human design activities, see Ref. [29].

Goal: addressing the patient's concerns, fears, etc. to improve her/his health status
Primary agent: Healthcare professional, a connoisseur of DIHS & HDS concepts
Precondition: VHR is activated with the healthcare professional's account
Post-condition: A triad composed of DIHS, diagnosis, and care plan is created and associated with the current Encounter clinical event
The workflow of the main scenario:

Legend
DIHS or Digitized IHS – digitization of an IHS
HDS – Health Digital State – a digital representation of the patient's health
IHS – Induced Health State – a mental representation of the patient's health

Healthcare professional (as a Physician)	Smart EHR (mainly VHR)
1. An instance of the patient's Personal VHR is created and assistance for an Encounter scenario session is requested from the Smart EHR.	
	2. A new current DIHS for this Encounter is generated. Patient's data and an empty list of facts are displayed.
3. **Anamnesis**. The patient is asked to explain the reason for the medical visit: the medically relevant complaints (symptoms) that worry her/him, what changes in her/him health have been perceived, and when they occurred. 4. The patient's synthetic health profile is requested from the VHR.	
	5. The patient's synthetic health profile containing demographics, a short medical history including family and personal diseases, allergy/intolerance and adverse reactions to drugs, immunizations, medications, medical equipment/devices, and patient and family preferences, is displayed in a structured and friendly format in a separate, tabbed window.
6. **Physical examination**. A preliminary physical examination is performed.	
7. A health digital state (HDS) of the patient is requested from the Smart EHR for a recent period and eventually for a given disease. Period and disease depend on the symptoms, when changes in health have occurred, and the results of the preliminary examination. *This request may be repeated several times for various periods or diseases until satisfactory HDSs are obtained.*	
	8. *For each request*: An HDS is generated for the given period and/or disease. In addition to the health information from the given period, critical health information is included in the HDS. The HDS is displayed in a structured and friendly format in a separate, tabbed window.
9. **Observation**. Three types of actions are carried out until the acquired observations are sufficient to deduce/confirm a diagnosis. *They may be repeated several times until a satisfactory amount of information is obtained.*	
a) A new observation of patient health is acquired. The Smart EHR is required to include this as a fact in the current DIHS.	10. *Do action*: a) The observation is verified among the other observations in the list of facts of the current DIHS to detect redundancies and conflicts; If a similar (as content) observation exists in the list of facts, exit; If conflicts exist, the healthcare professional is notified, and then exit; Otherwise, the observation is registered with the healthcare professional as the author and included in the list of facts of the current DIHS.
b) An observation that already exists in the VHR is selected because it is considered useful for the patient's current situation. The Smart EHR must include it as a fact in the current DIHS.	b) The selected observation is verified among the observations in the list of facts of the current DIHS to detect redundancies and conflicts; If a similar (as content) observation exists in the list of facts, exit; If conflicts exist, the healthcare professional is notified, and then exit; Otherwise, the observation is included in the list of facts of the current DIHS.
c) An existing DIHS is selected from the VHR because it is considered useful for the patient's current situation. The Smart EHR must include it as a fact in the current DIHS.	c) *For each Observation in the list of facts of the selected DIHS*: Observation is verified among the observations in the list of facts of the current DIHS to detect redundancies and conflicts; If similar (as content) observations exist in the list of facts, then make next Observation; If conflicts exist, the healthcare professional is notified, and then make next Observation; Observation is included in the list of facts of the current DIHS. The result of the action is notified.
11. Registration in the VHR of the current DIHS with its list of facts as a satisfactory emulation of the healthcare professional's mental representation of the patient's health (i.e., IHS) is requested	
	12. The current DIHS with its list of facts is registered as a stand-alone digital entity in the VHR with the healthcare professional who created it as the author.
13. **Diagnosis**. VHR is requested to obtain a list of possible diagnoses for the current DIHS	
	14. After an analysis of the current DIHS using the knowledge base, a list of possible health issues is produced and displayed in a structured and friendly format in a separate window.
15. Three types of actions are carried out until a diagnosis is included in the VHR. *They may be repeated several times until a final diagnosis is obtained.*	16. *Perform action*:
a) A health issue is selected from the list of possible diagnoses.	a) The diagnosis is registered as a stand-alone digital entity with the healthcare professional as the author and is associated with the current DIHS.
b) A new health issue is proposed to the VHR as a possible diagnosis.	b) An accuracy check of the diagnosis is performed using the knowledge base to detect possible conflicts. If conflicts between the diagnosis and the current DIHS information are found, the healthcare professional is notified, and then exit. The diagnosis is registered as a stand-alone digital entity with the healthcare professional as the author and associated with the current DIHS.
c) A new health issue is imposed as a diagnosis.	c) The diagnosis is registered as a stand-alone digital entity with the healthcare professional as the author and associated with the current DIHS.
17. Care plan. The aid of the Smart EHR is requested to obtain a list of the most appropriate medical guidelines for the identified diagnosis. *The action may be repeated several times until a satisfactory care plan is obtained.*	
	18. An analysis of the current DIHS and the associated diagnosis is performed using the knowledge base, a list of possible medical guidelines is produced and displayed in a structured and friendly format in a separate window.
19. Two types of actions are carried out until a care plan is decided. *These may be repeated several times until a satisfactory diagnosis is obtained.* a) A medical guideline is selected from the list of possible medical guidelines.	20. *Perform action:* a) An editing session is open for the selected guideline to build a new care plan tailored to the patient's health problems
b) The aid of the VHR is requested to create a care plan from scratch	b) A new care plan is generated and an editing session opened for this
21. The selected medical guideline is edited to obtain a care plan tailored to the patient.	22. For every editing action, a care plan accuracy check is performed using the knowledge base. A validation check is made to detect possible conflicts, namely allergy intolerance and adverse reactions or contraindications of prescribed medication. The validation results are notified.
23. The care plan is agreed upon.	24. The care plan is registered as a stand-alone digital entity with the healthcare professional as the author. It is associated with both the DIHS and the diagnosis. 25. The care plan is activated.
26. The Encounter session is closed.	27. An Encounter event is created. It is added to an Episode of Care for the same health issue. 28. From now on, the VHR will monitor the execution of the care plan and notify all healthcare professionals and also the patient of the significant health events that may occur.

Fig. 7. The software use case of the business use case in Fig. 1.

querying its knowledge base. Finally, VHR proposes valid alternatives for identifying the health problem that could underlie the diagnosis.

(15) The healthcare professional can repeatedly: (a) choose a health issue proposed by the VHR, (b) propose to the VHR a new health issue to check, or (c) impose a new health issue, regardless of the VHR hints. (16b) In case (b), the VHR checks with the help of its knowledge base whether the diagnosis proposed by the healthcare professional conflicts with information from DIHS or if it can be considered for further customization. If conflicts exist, the healthcare professional is informed about these (possibly accompanied by explanations), the diagnosis is not accepted, and a new cycle of assistance in establishing the best diagnosis is activated. When the healthcare professional has decided what the health issue is, she/he can ask that the diagnosis be recorded and associated with the current DIHS. (16) For each choice (a, b, c), if admitted, the VHR records the diagnosis as a stand-alone digital entity with the healthcare professional as the author and associates it with the current DIHS.

The healthcare professional can now draw up a care plan adapted to the patient. The purpose of such a plan is to provide a solution to the risks that arise from the health issue or at least to mitigate these. This goal is in itself a type of observation that describes a target situation: once executed as a care process, the plan should allow the patient to achieve a health status that meets the goal. To this end, (17) the healthcare professional may repeatedly request Smart EHR assistance until an appropriate care plan is identified that can be customized. (18) For each request, the VHR proposes valid alternatives to the care plan. For this, it builds a list of care plans from the comparative analysis of the current DIHS with similar previous DIHSs associated with successful care plans in its repository. VHR also interrogates its knowledge bases to identify medical guidelines advised in the case of the patient's health issue.

(19) At this point, the healthcare professional can (a) choose one of the care plans proposed by the VHR or (b) decide to create a new care plan from scratch. In both cases, the healthcare professional can ask Smart EHR for assistance in editing the plan. (20) VHR opens an editing session for the care plan.

(21) The healthcare professional modifies the care plan with different actions to adapt it to the patient's condition. (22) For each editing action, the VHR checks its validity to detect possible conflicts, such as allergy intolerance and adverse reactions or contraindications of the prescribed medication. The healthcare professional is then notified of the validation results.

(23) When the care plan is agreed, the healthcare professional asks the VHR to register it. (24) VHR creates a stand-alone digital entity with the healthcare professional as its author. The care plan is associated with the current DIHS and the diagnosis. (25) The Smart EHR creates a healthcare process instance according to the plan and activates it.

(26) The healthcare professional closes the Encounter session. (27) With the information from the current DIHS, VHR creates an Encounter event and adds it to the still open episode of care for the health issue associated with DIHS, if this episode exists. Otherwise, VHR initializes with this event a new episode of care for that health issue. (28) From now on, VHR will handle monitoring of the execution of the care plan and notify all healthcare professionals, as well as the patient herself/himself, about any relevant health events.

5.2. Modeling the problem domain

To define the HDS concept, we have to deal with two conceptual models: that of the health and care system, a system in the physical world aimed at citizens' health prevention and care, and that of the VHR digital ecosystem, which should ensure relevant situations that appear in the external health system are correctly reflected in the virtual world.

The objective of the first conceptual model is to ensure it aligns with the fundamental principles and basic functionality of the health and care system and that it provides an easy-to-understand interpretation of the system.

The objective for the second model is related to the design of the Smart EHR system: appropriate choice of software concepts and relationships that allow real-world situations occurring in the health and care system to be correctly reflected in the VHR virtual world. The implementation of this model should help healthcare professionals make well-informed decisions that lead to welcome interventions in the health and care system.

Concept mapping between the two conceptual models should exist, and, in the following section, we will try to evidence this mapping. To distinguish the Smart EHR system conceptual model - the model we used for implementing the VHR - from the conceptual model of the health and care system, we call the first one the *problem domain model*.

Fig. 8 introduces a UML class diagram that shows the part of the problem domain model that is of interest in this article. The classes in the diagram represent relevant health and care concepts in the conceptual domain of health and care systems. These concepts are involved in the Encounter use case introduced previously.

In the figure, we employed Peter Codd's method [30] to color the four class archetypes (Act, Role, Entity, and Participation) of the HL7 Version 3 [17].

The concepts and their corresponding classes in our problem domain model are now presented. We start with the Encounter concept in the health and care system, and its corresponding class Encounter. In our diagram, Encounter is a specialization of Contact that represents a more general concept abstracting all clinical events that connect an instance of Patient (a role of the entity Person) participating as a Subject (the subject of care) with an instance of HCProvider (a healthcare organization or professional) participating as a ResponsibleParty. Encounter inherits all relationships of Contact; for instance, it connects an instance of Patient with an instance of HCProfessional (a healthcare professional) which is a specialization of HCProvider. The use case in Fig. 7 is triggered by the occurrence of such an Encounter event.

During the execution of an Encounter scenario, several instances of HCActivity are performed. In our model, an HCActivity instance represents a service that a HCProvider, participating as a Performer, provides for the Subject. There are 7 subtypes of HCActivity: Hospitalization, ProcedureService, HealthStateAssessment, SubstanceAdministrationService, CarePlanning, PrescriptionService, and ObservationService.

Any healthcare service must be documented. For each instance of HCActivity, an instance of HCDocument (a healthcare document) participating as a Recorder is created, and the useful information contained within it is extracted as discrete data and stored in the VHR. HCDocument denotes the role an ElectronicDocument instance (for example, an HL7 CDA document) plays in an HCActivity. For example, an instance of ObservationService (this may be a measurement of vital signs) results in a medical report whose content will be recorded in the VHR as an instance of SimpleObservation, a specialization of the class Observation (clinical observation). A simple observation can be a qualitative evaluation ("weakened", "pale", "nervous", etc.) or quantitative measurement of a vital sign of a patient.

Diagnosis is a specialization of Observation concerning the HealthIssue (health issue) of a Patient participating as a HealthStateOwner in a Contact. Diagnosis is the result of a DiagnosisService (diagnosis service) and represents an assessment of the Subject's condition. It is a more complex observation resulting from the reasoning process of the HCProfessional. Diagnosis is associated with a HealthIssue and is ascertained by the HCProfessional participating as an AuthorOfDiagnosis.

To clarify the semantics of these concepts, our UML model utilizes attributed stereotypes for classes. The stereotype emphasizes the class archetype and its attributes add valuable information regarding the use of class instances. For example, the class Diagnosis inherits a stereotype « Act(OBS.VAL)» from the abstract class Observation. It is important to note that OBS in HL7 is one of the possible values of the classCode attribute of the Act class that expresses the specific nature of the Act. We attributed OBS with VAL to emphasize that the class is not an

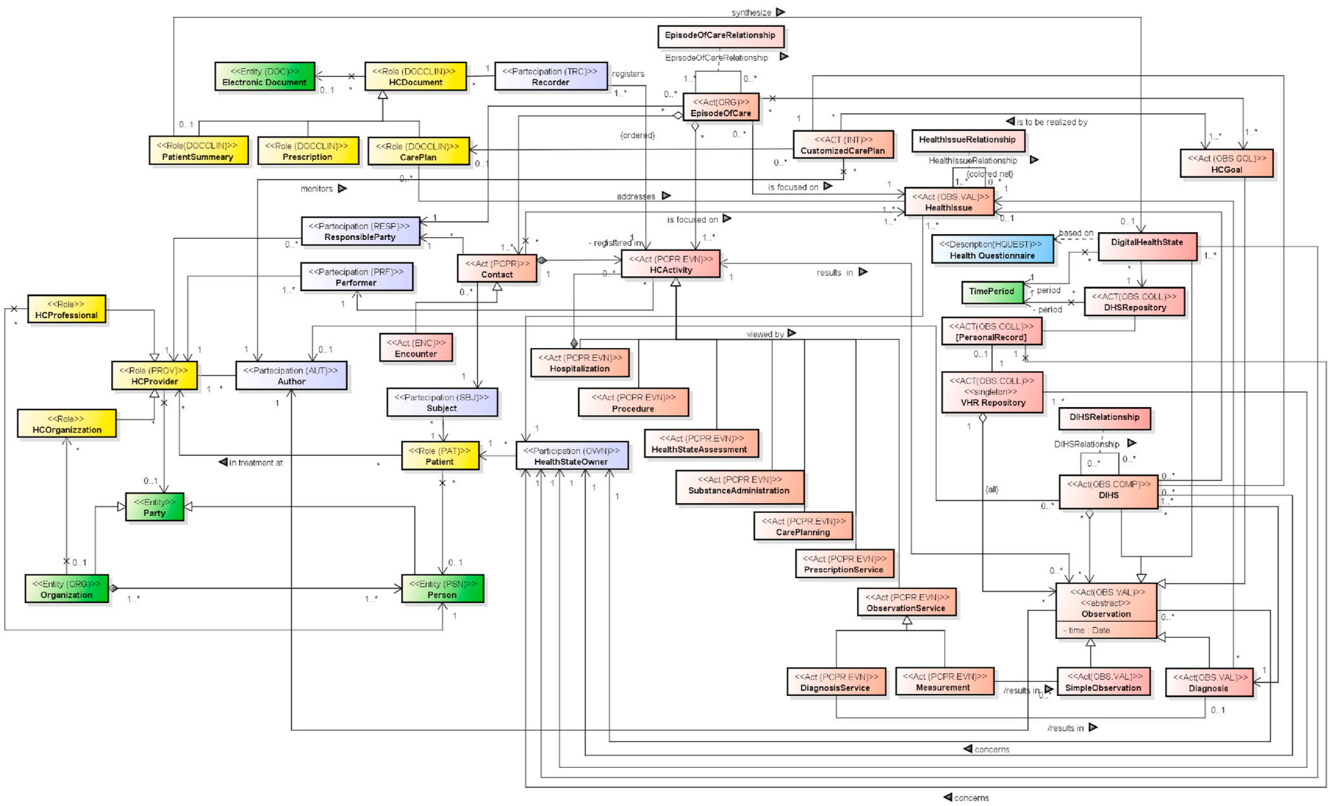

Fig. 8. The problem domain model.

- *Act* classes are *salmon pink* in color.
- *Role* classes are *pastel yellow* in color.
- *Entity* classes are *pastel green* in color.
- *Participation* classes are colored in *pastel blue* (Codd uses this color for Document classes. We prefer to color documents as roles and to use pastel blue for participation classes, i.e., those concepts that describe how an entity that plays a generic role participates in a specific act. They express the context of performing an act: who performed it, for whom it was performed, where it was performed, etc.).

observation activity (i.e., service) in one of its possible HL7 "moods" (Definition, Intent, Request, etc.) or one of its possible HL7 states (Registered, Preliminary, Final, Corrected, etc.) but the result of an already executed observation activity (VAL is equivalent to the result of an HL7 Observation with the EVN mood).

We considered the goal of any healthcare activity as a health situation that should occur at the end of the prescribed treatment. It cannot be verified in the current situation, but may be a fact later on. This is why HCGoal is a specialization of Observation and is related to a CustomizedCarePlan with a "to be realized" association.

An EpisodeOfCare includes a series of instances of Contact that treat the same instance of HealthIssue in a TimePeriod (time interval) from the onset of disease until the Subject's healing or death. The same instance of HealthIssue can be associated with more than one instance of EpisodeOfCare. For every instance of EpisodeOfCare, the associated instance of HealthIssue is unique. However, for an Encounter instance, links with multiple instances of HealthIssue can exist: due to eventual comorbidity, during a contact, the health care professional can diagnose the patient with more than one health issue.

It is likely that during the patient's life a multitude of health issues are diagnosed. The VHR thus has to relate various instances of health issues according to factual relationships such as previous/next, cause/effect, part-of, but also to known patterns of disease-disease relationships: biologic similarity, the similarity of symptoms, causality, comorbidity, and so on that are useful in enabling healthcare professionals to better understand the evolution of the patient's health and make medical prognoses. In our model, we described this aspect in an HL7-style by using the association class HealthIssueRelationship of which instances are binary "many-to-many" associations between health issues. We previously called this kind of data structure "a colored semantic network" . In this case, it is essentially a graph with nodes labeled with health issues and differently colored semantic relationships on the edges. It creates a superposition of the colored graphs of all various binary relationships between health issues where the similar nodes are the basis of this superposition.

As stated in Section 4.4, an instance of the class DIHS (Digital Induced Healthcare State) aggregates instances of the Observation class that are needed for a healthcare professional to make a diagnosis and build a care plan. Hence it is itself an observation, albeit a complex one. Consequently, Fig. 8 introduces a DIHS instance as an aggregation of several Observation instances which can be both SimpleObservation instances, resulting from an ObservationService (i.e., an observation activity), or instances of previously created DIHSs.

Moreover, according to Fig. 8, a DIHS instance is linked to five instances of the following classes:

1. Patient that participates as a HealthStateOwner;
2. HCProfessional, the creator of the DIHS participating as an Author;
3. HealthIssue, as the codification of the health situation the DIHS instance describes, is the essential component of Diagnosis. It is also one of the results of the Contact event.
4. Diagnosis that may contain more complete information than the simple identification of the health issue, this could be the DIHS rationale;

5. CustomizedCarePlan that is a result of the Contact event; it introduces an ad-hoc-created care plan, namely the method to evolve the current health status described by the DIHS to the HSGoal.

To better describe the semantics of the DIHS class we employed the stereotype « Act (OBS.COMP)» in its definition. According to the HL7 standard, the stereotype OBS is extended with the attribute COMP (compound) to indicate that the class represents a compound value obtained through selection, aggregation, and interpretation of several observations [17].

To model the complexity of relations between instances of DIHS, we chose an association-class DIHSRelationship that represents the colored semantic network of DIHSs that were introduced in Section 4.6.

5.3. Modeling the health digital state concept

We now introduce our solution for modeling the HDS concept in order to digitize the health concept with it. In defining the HDS, we used the "multifaceted" metaphor to describe how knowledge about patient health is structured in the VHR. This suggests there may be several "views" of healthcare professionals regarding the health of the same subject of care. These views are, as a rule, different because the healthcare professionals involved may have different specializations, the patient's health may change rapidly, and the opinions of each healthcare professional may change over time. Consequently, the views probably only partially overlap, even if they are based on the same facts.

We assumed that many useful and even unexpected aspects of the patient's health can emerge from the holistic view that results from the selective assembly of information that appears in patient's DIHSs found in the VHR. VHR builds an HDS from the totality of the most recent non-contradictory information found in the same patient's DIHS collection. If the resulting HDS does not provide sufficient coverage of the slots in the patient's ideal health questionnaire to provide a useful holistic view of their health, or if the knowledge included in the HDS is not sufficiently detailed for certain diagnostic situations, the knowledge in the HDS may be enriched by the healthcare professional with new observations. In this case, VHR can be helpful in suggesting what new information/knowledge is needed or in resolving any conflicts between the observations in the DIHSs. The resulting HDS is a valuable observation that approximates quite accurately to the actual health of the patient at a given time. Finally, an HDS can be used to create other HDSs.

In the use case presented in Section 5.1, the VHR is a software component embedded in the Smart EHR system that can interact as an intelligent agent in health and care use cases. To model situations and behaviors in the real world, it is appropriate to include the VHR in the model as a singleton class, which we call the VHRRepository. The instance of this class collects all information available on the health of individuals in the jurisdiction of the Smart EHR system. We call *Facts* this collection of information where we can primarily find observations. We call *Obs* the subset of all observations in the VHRRepository instance, i.e., *Obs* ⊂ *Facts*.

The collection *Facts* feeds the creation of all instances of the class [PersonalRecord]. Such an instance is a collection of health-related facts, primarily observations, regarding an individual.

The relation between the facts in VHRRepository and those in [PersonalRecord] can be formalized in a mathematical model as follows.

Let f_1, f_2, f_3 … be elements in *Facts* that we use to introduce a binary relationship "∼" on *Facts*.

Two facts are in the "∼" relationship if they belong to the same individual, i.e.,

$$f_1 \sim f_2 \stackrel{\text{def}}{=} \{f_1, f_2 \in \mathit{Facts} \mid f_1.\text{HealthStateOwner} = f_2.\text{HealthStateOwner}\}$$

It is evident that:

$f_1 \sim f_1$ (reflexivity)

$f_1 \sim f_2$ if and only if $f_2 \sim f_1$ (symmetry)

if $f_1 \sim f_2$ and $f_2 \sim f_3$ then $f_1 \sim f_3$ (transitivity)

Consequently, "∼" is an equivalence relation. *Facts/*∼ denotes the quotient set of *Facts* by ∼. It determines a partition of *Facts* in which each block is an equivalence class whose facts unequivocally concern the same HealthStateOwner *p*. Such an equivalence class is defined as:

$$[f] \stackrel{\text{def}}{=} \{x \in \mathit{Facts} \mid x \sim f\} \text{ where } f \in \mathit{Facts}$$

[PersonalRecord] is the class in our model whose instances are exactly these equivalence classes of *Facts/*∼. An instance of [PersonalRecord] is written as PR(*p*):[PersonalRecord] and is called the *personal VHR repository* of *p*.

Suppose that a healthcare professional opens a Smart EHR session for an individual *p*. Loaded in the running space of the VHR engine will be the facts only related to *p*, that is exactly the instance PR(*p*):[PersonalRecord].

We can obtain a similar structure of equivalence classes for the *Obs* set. For this, we define the following equivalence relation:

$$o_1 \sim o_2 \stackrel{\text{def}}{=} \{ o_1, o_2 \in \mathit{Obs} \mid o_1.\text{HealthStateOwner} = o_2.\text{HealthStateOwner} \}$$

Obs/∼ denotes the quotient set of equivalence classes of *Obs* by ∼. An equivalence class in *Obs/*∼ is defined as:

$$[o] \stackrel{\text{def}}{=} \{x \in \mathit{Obs} \mid x \sim o\} \text{ where } o \in \mathit{Obs}$$

Such an equivalence class, if associated with a HealthStateOwner *p*, contains all observations in *Obs* concerning *p*. For the same HealthStateOwner *p*, we have:

$$[o] \subset [f]$$

To create a new HDS for a specified patient *p* and a specified period T = [t_1, t_2], $t_2 > t_1$, the VHR should be able to complete as many of the questionnaire slots as possible using the latest observations extracted from the patient's [PersonalRecord], which were recorded during the period T.

Finally, we introduce an HDSRepository class representing temporary subsets of selected facts from [PersonalRecord] with the property that the facts were recorded in the VHR for a given *p* patient and in a given T period. VHR uses such selections to generate instances of HDS.

In the next section, we describe how an HDS could be generated. For this, we first describe the proposed architecture for VHR and then present an algorithm for generating HDSs within this architecture.

6. VHR design and implementation

6.1. VHR architecture

As shown by the layered architecture of Smart EHR in Fig. 3, the VHR occupies an entire layer. It is supported by appropriate technologies for enterprise integration (cloud computing technology, service-oriented and component-based architectures, Enterprise Service Bus, knowledge base, business intelligence, inference engines, etc.). Its own architecture is also multi-layered with three sub-layers: VHR Services Interface, VHR Application, and VHR Domain.

In the VHR Domain sub-layer, objects representing instances of the classes in the problem domain model are created and managed. Interactions between these objects are implemented in the VHR Application sub-layer according to the workflows of the use case scenarios we considered in our design. Finally, the VHR Service Interface sub-layer exposes services that are used by higher layers to access the VHR (Fig. 4).

The VHR layer uses the Information &Knowledge Management layer below as a data access layer, which in turn has two sub-layers. This layer can be implemented as a cloud storage, a central or distributed database, or a data warehouse with specialized data marts.

The upper sub-layer is a persistence layer that contains drivers to access the registries and repositories according to their chosen implementation.

The lower sub-layer contains several specialized registries used for information/knowledge discovery in corresponding repositories that hold information/knowledge about individuals and their health. Of these, VHR Repository and Thesaurus&Questionnaire are especially important for the objectives of this article and warrant a more detailed description in the following sections. VHR Repository is the registry/repository of all health-related facts regarding persons in the Smart EHR jurisdiction. PR(p): [PersonalRecord] is a selection from this repository that contains all information regarding the health of a single person *p*. Thesaurus&Questionnaire is a knowledge base plus a mechanism that acts as a template in feeding the lists of facts of HDSs.

The other registry/repository components are used by the VHR to access medical knowledge, clinical protocols, and data access policies that will be described elsewhere.

6.1.1. *VHR repository*

The VHR Repository contains the health-related data of individuals. Among these, a rich collection of three types of observations can be found: atomic observations, DIHSs, and HDSs. These observations are related to each other as well as to other entities in the VHR Repository, similar to that seen in Fig. 5. We focus on the observations in the VHR Repository that represent digitizations of real-world facts.

First, any observation has, as mandatory attributes, the date when the associated fact occurred in the real world and the date when the observation that derived from the fact was actually recorded in the VHR.

In our approach, an atomic observation is an *item of knowledge*, i.e., a strongly contextualized object. It is the digitization of a unique fact in the real world that is recorded in the VHR. It can be a simple observation resulting from facts such as subjective examinations, physical and laboratory measurements, or a diagnosis, namely a report that classifies and eventually details the patient's health issue. Any fact is related to an instance of a medical or well-being concept with its own properties. Its digitization as an observation item results in an object that has a type corresponding to the fact concept and attributes that reproduce as accurately as possible the essential properties of the fact. Any type of observation (namely any fact concept) is present in the Questionnaire with one or more of its codes that differentiate it from other types (i.e., concepts) and a textual description (e.g., "Blood pressure" or "Pain level" for simple observations, and "Palpitations" or "Stress fracture, right shoulder" for diagnostics). Any atomic observation always contains a value, as shown in Fig. 6. This can be a number, code, text, or Boolean value, and has a complete meaning only in the context of the relations of the fact with other entities in the real world.

In the VHR Repository, we can also find DIHSs. A DIHS is an *aggregate of knowledge* that contains a list of references to atomic observations and to other DIHSs and HDSs.

HDS is another kind of knowledge aggregate in the VHR Repository. This mainly contains a list of references to atomic observations, as well as contextualization information.

In both cases, the atomic observations referred to by the DIHSs and HDSs should be non-redundant (no two occurrences of the same atomic observation in the list of facts) and non-conflicting (two distinct atomic observations are in potential conflict if they are instances of the same concept but have different values in the period considered). "Clearing" a list of references to atomic observations means eliminating redundant atomic observations and retaining only the most recent observations from the set of conflicting observations.

6.1.2. *Thesaurus & Questionnaire*

To conceive the Treasure & Questionnaire, we were inspired by the idea introduced in Section 4.2 of describing an individual's health as a vast, seemingly infinite "questionnaire," specifically a list of questions about all the aspects of health and well-being that can be evaluated in some way. These aspects can be named with the help of evidence-based or quantifiable medical and well-being concepts.

To digitize an individual's health, we propose the Questionnaire, a structure composed of a list of slots to be filled with values representing answers to a series of questions, one slot for each question. Each question is related to an evidence-based or quantifiable medical or wellness concept. The question is answered by identifying in the VHR a documented instance of that concept. This should be an authoritative observation of a healthcare professional regarding the presence or absence of the concept in describing the current health of an individual, and, if applicable, the level of its presence. Once the observation is identified as a concept instance, the value included in the observation represents the answer to the question and will be copied to the corresponding slot in the Questionnaire. The answer may be found in the clinical history of the individual as a value of a recent observation regarding the concept concerned.

Therefore, to obtain a comprehensive digital picture of an individual's health status, the VHR should answer each question in the Questionnaire with a value that represents an assessment of the concept that corresponds to the question in accordance with the individual's health status at the desired time of digitization. This value can be Boolean (yes/no, positive/negative, or present/absent), numerical, or a text, but it is always contextualized in a complex data structure similar to that of Fig. 6. The slots in the Questionnaire are designed to accommodate such data structures.

It is impossible to find answers to all the questions in the questionnaire in the VHR Repository. Usually, only a small number of questions can obtain values that evaluate their corresponding concepts. These are the ones for which there are observations regarding the health aspect designated by the concept within the question, as they have been recorded in the VHR Repository by healthcare professionals over time. For all other questions (in fact the vast majority), the value of the answer is "undefined" and they do not participate in the digital assessment of the individual's health.

To identify and answer the questions, the VHR should have a mechanism that allows it to browse the questions using criteria based on the semantics of their associated concepts. Our proposal is to include a knowledge source in the Smart EHR system architecture that we call a Thesaurus. In a simplified version, this consists of several controlled vocabularies of medical and well-being concepts, complemented by attributes and semantic relationships between them. The main semantic relationship that helps us to structure this immense set of concepts is *is-a* or the *genus-species* relationship. It introduces several taxonomic hierarchies between concepts. Concepts with the broadest semantic extension (i.e., the set of instances to which the concept applies) such as "Pathological Conditions", "Pharmacology" or "Anatomy" are found at the top level of hierarchies in the Thesaurus. In our approach, other hierarchies with top-level concepts such as "Health Issue", "Healthcare Service", or "Observation" are important because these are the most frequently used in health assessment processes. Concept extensions are gradually reduced as we descend using specializations to lower levels of hierarchies. The terminal nodes in hierarchies contain concepts that can no longer be specialized such as "Restless Legs Syndrome", "Lubricant Eye Drops", "Hyperuricemia" or "Body Temperature". These are all quantifiable or can be evaluated with a "present/absent", value.

Hierarchies in our Thesaurus can partially overlap: the same concept can be found in more than one hierarchy.

The proposal for such a knowledge base in the Smart EHR is not fanciful. There are several examples of such thesauri in the health and well-being domain. Two of the most prestigious biomedical thesauri are now briefly presented.

The Medical Subject Headings (MeSH) thesaurus is a controlled and hierarchically-organized vocabulary [25]. It is used by the National Library of Medicine (NLM) to index articles from biomedical journals for the MEDLINE®/PubMED® database and bibliographic descriptions of books, documents, databases, and audiovisuals. MeSH can be also used as a thesaurus and enables users to browse medical terms and their synonyms.

The Unified Medical Language System (UMLS) is a collection of multiple controlled vocabularies in the biomedical sciences. Its objective is “to facilitate the development of computer systems that behave as if they understand the meaning of the language of biomedicine and health” [31]. UMLS provides a thesaurus that defines over one million biomedical concepts and comprises a network of semantic relationships between concepts. The most basic relationship in the UMLS semantic network is *is-a* which yields taxonomic hierarchies of biomedical concepts. The UMLS thesaurus integrates terms and codes from many vocabularies (including CPT, ICD-10-CM, LOINC, MeSH, RxNorm, and SNOMED CT), and includes hierarchies of terms with their definitions, attributes, and relationships.

For digitization purposes, the concepts are coded in all thesauri. For instance, UMLS uses a *Concept Unique Identifier* (CUI) for each biomedical concept that consists of a letter followed by 7 decimal digits.

The concepts that label the nodes in our Thesaurus hierarchies are also coded for easy search and retrieval in repositories, as well as for facilitating their semantic interpretation. Our coding is inspired by the MeSH codes. Any concept has an integer as its short code that uniquely identifies the concept among its siblings in a hierarchy. The full code of a concept consists of a letter followed by a sequence of integers separated by dots. The letter identifies the hierarchy to which the concept belongs. The sequence of integers represents the path taken in the tree of this hierarchy to reach the concept using the specialization relationship. Each integer in the sequence is the code of a concept in this path. The first integer in the sequence identifies a concept at the top level of the hierarchy while the last integer identifies the concept we want to encode. Any pair of successive integers in the sequence identifies two concepts on successive levels in the hierarchy, which are in a subsumption relationship. This way, from the full code of a concept, the VHR can at any time reconstruct the chain of concepts that leads from the top of a hierarchy to the concept in which it is interested. This is useful for reconstructing the semantics of concepts in a *genus–differentia* definition style.

Each concept in the Thesaurus keeps track of all its occurrences in the hierarchies with a set of distinct full codes. Each full code identifies the semantic context of the concept: the hierarchy type and its position in the hierarchy.

Concepts are also associated with a list of their synonyms and textual definitions.

Finally, for any quantifiable concept, the range of its possible values and the sub-range of its normal values are also associated with the concept as attributes or metadata.

The Thesaurus hierarchical structure based on the subsumption relationship induces a structuring in groups or folders of the questions in the Questionnaire. Each question first belongs to a small subset of questions, which in turn is included in a larger one, which is then included in another larger one, and so on. An internal concept of a hierarchy determines a grouping in a folder of all terminal concepts it dominates in the hierarchy and consequently of their associated questions. The largest folders of questions are those determined by the top concepts in the Thesaurus. In this way we can identify a question from the Questionnaire using a path through folders similar to the path in the Thesaurus hierarchies that identify its terminal concept.

To summarize, the *Questionnaire* is a collection of numerous slots intended to selectively extract information from the VHR Repository using questions that correspond to the quantifiable concepts in the Thesaurus. The questions inherit the organization of their associated concepts and can be identified using the full codes of these concepts. Answering the questions in the Questionnaire involves the assessment of their corresponding, quantifiable concepts in the Thesaurus for the particular health status we want to digitize.

To implement the *Thesaurus,* we may begin by initializing it from some existing thesauri with as many concepts as possible, but it is evident that it cannot “a priori” contain all biomedical concepts. At a later stage, new concepts that designate concepts in human health and care assessment can be captured by the VHR from the documents it receives. The registry of the Thesaurus & Questionnaire repository should facilitate browsing and editing concepts. The editing policy should be judiciously chosen to allow only changes made by IT specialists after a verification procedure that involves a team of healthcare professionals. These changes should be shared with Smart EHR instances in other regions or countries.

Due to the vast size of the Questionnaire and because our available knowledge about an individual’s health is limited, the slots of only a small number of questions will be filled with information found in the VHR repository. The more information we have in the HDS list of facts, the more holistic our vision of the individual’s health will be for the selected period. For any HDS generation request, the Questionnaire can be used as a list of quantifiable concepts from the Thesaurus, which guides the selection of information from the VHR Repository in order to maximize the number of authoritative observations that participate in the digitization of the individual’s health status.

However, we expect that most slots will remain undefined or initialized with default values; therefore they will not participate in the HDS generation. Thus, when implementing the HDS generation service, it is preferable to avoid the use of a whole Questionnaire copy and keep in memory an HDS data structure of acceptable size by only preserving slots that are not empty.

In the next section, an algorithm that uses the above data structures for the generation of HDSs is introduced.

6.2. An algorithm for HDS generation

An HDS is generated from a collection of observations in the VHR Repository. These comprise atomic observations, DIHSs, and other HDSs, all of which belong to the same individual and have their registration date in a given period. The result is an aggregate of knowledge that contains non-redundant and non-conflicting atomic observations that were identified within the initial collection, including the semantic relationships between them and other digitized entities.

The algorithm for generating an HDS instance for a given individual *id* and a given period *t* is presented in Fig. 9. For algorithm description, a Java-style pseudo-code is used.

The HDS generation algorithm comprises the following steps:

1. Create the personal record *PersRec* of the individual;
2. Extract all observations from *PersRec* in *Obs*;
3. If *Obs* is not empty, identify all atomic observations in *Obs* (including those “hidden” in the DIHSs and HDSs existing in Obs) that were created in the period *t*, and collect them in a single list *AtomicObs*;
4. “Clean up” the list *AtomicObs* of redundant and conflicting observations;
5. Create a sorted map *Facts* using the *Questionnaire* as a data source for keys and with empty slots for values;
6. Embed the most recent observations from the cleaned list *AtomicObs* as values in *Facts*;
7. Generate HDS from *Facts* and deliver it.

Note for Step 4. To identify all atomic observations in a DIHS, including those which are “hidden”, we have to search for them in all the lists of references, including those of internal DIHSs and HDSs. A solution to this problem is to transform the DIHS list of references into a tree of references. The tree root is a reference to the DIHS itself. Its children are all references in the DIHS list. In the case of references to atomic observations, they are terminal nodes in the future tree. In the case of a reference to a DIHS or HDS, it becomes an inner node that is expanded with a sub-tree where the children are the references from its list. The operation is recursively repeated for each DIHS and HDS among the children until no reference to an un-expanded DIHS or HDS is found in

```
Algorithm Generate_HDS
Input:
id:UID -the unique identifier (UID) of an individual.
t:TimePeriod - the period for which the generated HDS is valid.
Output: hds:HDS – a sorted map representing the digital health state of the individual id in the period t.
Precondition:
An instance of VHR is active.
Sequence of actions:
/* A repository PersRec of the type id:[PersonalRecord] is created for the individual id */
PersRec := VHR.getPersonalRecord (id);
/* All observations issued during the period t are identified in PersRec and initialize a collection Obs. They
are atomic observations, as well as DIHSs or HDSs. */
Obs := PersRec.getObservations (t) ;
/* If Obs is empty, the HDS cannot be created */
if (Obs is empty) return null;
/* AtomicObs, a sorted set of atomic observations is created using a Comparator object chrono with a
compare function that compares the dates of any two observations in order to maintain chronological sorting
of the observations in AtomicObs */
AtomicObs := new AtomicObsSet(chrono) ;
/* Atomic observations are identified in Obs and included in AtomicObs if they are not already present */
AtomicObs.addAll (Obs.getAtomicObs());
/* Only the most recent atomic observations are kept. Conflicts are removed. */
Obs AtomicObs.cleanup();
/* Creation of a sorted map of facts (i.e., a sorted set of pairs (key, value) where key is a terminal concept and
value is an atomic observation in its corresponding slot in Questionnaire) */
Facts := new FactMap();
/* For each atomic observation o in AtomicObs, the code c of the corresponding concept in Questionnaire is
identified (if any) */
for (Observation o : AtomicObs ) {
    c:=o.getConceptCode();
    if (c==null) // the concept is not found in the Questionnaire
            /* the observation o is isolated to be analyzed later */
            VHR.putInQuarantine(o);
     else
            /* the pair (c, o) is added to the map Facts */
            Facts.put(c, o);
}
return new HDS(Facts) ;
end
```

Fig. 9. Algorithm for HDS generation.

the tree. Finding all the references that are terminal nodes in the tree is equivalent to finding all the atomic observations within the initial DIHS.

Note for Step 5. An HDS can be implemented as a sorted map that maps codes of concepts in the Questionnaire as *keys* to items of knowledge representing atomic observations as *values*.

Note for Step 7. An HDS is reduced to a simple list of pairs (concept, value) that quantitatively assess various aspects of the patient's health. Qualitative health assessments based on this quantitative assessment are also needed. They express likelihood estimates in non-numerical terms such as "good", "bad", "high", "medium", "low", or "negligible". A qualitative assessment according to a health risk scale can also be useful. The VHR should provide services for various types of qualitative assessments of an HDS. They may be provided at the request of healthcare professionals. For this, the VHR should use the semantic relationships that each concept in the list has with other concepts that are found in its medical knowledge base and combine the values in the HDS with rules and algorithms, according to predictive analytics techniques in order to classify the patient's health in some likelihood classes.

7. Conclusions

The absence of a powerful health information infrastructure weakens the ability of countries to provide planned care for their communities and cope with extreme events. There is also little doubt about the usefulness of having a digitized version of citizens' health, especially after the ravages of the recent pandemic in which the importance of demographic studies using data analytics methods, the only ones capable of monitoring the pandemic and modeling its evolution, was understood.

The COVID-19 pandemic revealed profound deficiencies in existing health and care systems in the vast majority of countries and exacerbated the adverse consequences of already known system deficiencies: difficulties of citizens in accessing affordable primary care providers they know and trust, inefficiency and lack of resilience of under-resourced services of the public health systems as well as lack of reserve capacity to handle pandemic crises [32,33].

It has become clear that only by completely rethinking our health and care systems can we ensure that they efficiently meet not only the everyday needs of citizens but also new trends in the health and well-being domain such as health promotion, disease prevention, and patient-centered care.

The main allies in this process of rethinking health and care systems are IT and AI. In recent years, a combination of the need for paradigm shifts in health and social care, the advancement of IT and AI technologies leading to new concepts, new ecosystems, and new models of organization in health and care systems, and innovative scenarios for the provision of health and care, have all strived to improve the quality and efficiency of health and care services.

Currently, national health and care systems in all countries are composed of disconnected sub-systems: systems of governance, hospitals, laboratories for analysis, research and pharmaceutical companies, medical device manufacturers, and so on are all sub-systems that are either disconnected or only partially connected with each other. To put the patient at the center of health and social public services, the entire health and care system should be integrated with interoperable information flows between and inside sub-systems. An EHR-S would naturally be the right infrastructure for this integration, especially if it exists in a "smart" version [7]. New health and social services should be provided, including the possibility of their unbounded orchestration to make interventions and care more precise, more efficient, less complex, less invasive, and cheaper [34].

Decision making is a complex activity in medicine that should be optimized with the help of IT and AI. It relies on the availability of comprehensive, authoritative, and reliable information on objective facts, access to medical knowledge, the correct interpretation of available information, and the inclusion of patient risk/benefit ratios. To improve decision-making processes, new technologies could be of immense help in all these aspects. Digitalizing decision-making activities can help prevent common situations in modern medicine where information is often insufficient, sometimes inaccurate, scarce or fragmented, unsystematically acquired, or obsolete. However, the digitalization of decision-making processes is probably the most challenging paradigm shift because it requires a radical change in the mentality of healthcare providers.

To promote the digital transformation in medicine and well-being through the large-scale digital integration of health and care systems and intelligent support of the decision-making process in medical practice, we propose the following:

1) the " health digital state " (HDS) as a new concept in the landscape of challenges arising from profound changes in health and care systems;
2) the Smart EHR system, an advanced and intelligent EHR-S, with an integrative vocation, capable of working with the HDS concept;
3) a method for digitalizing processes in health and care based on mirroring entities from the real world into the virtual world through digitization.

We define the HDS concept as an interoperable, holistic synthesis of all the available authoritative data concerning the individual's health, namely a comprehensive and multifaceted collection of digital information on her/his health. It can be created and managed by the VHR, the core component of the Smart EHR system, and used by healthcare professionals to identify, diagnose, prevent, and remedy patients' health issues. An instance of this concept is a virtual entity created by the VHR that acts as a health-oriented avatar or digital twin of an individual's health in the digital healthcare ecosystem [1,35,36]. Any healthcare professional who has access rights to the health information of the individual may interact with this avatar or, due to the avatar's proactive behavior, can be notified when significant health or environment change events occur in an individual's life.

The Smart EHR system is a distributed platform, specifically an EHR-S at a regional or national level, which provides social and health services useful for healthcare professionals in the provision of patient care. Its VHR encloses all available health information that has been captured either through medical software applications during citizens' contacts with healthcare professionals and organizations in care delivery settings or through medical devices. This information is highly structured according to several criteria: contacts, episodes of care, health issues, care providers, medical devices and equipment, organizations, personal and territorial jurisdictions, and dates of occurrence and/or recording events. Our approach to the Smart EHR system require it to work with discrete data extracted from structured and unstructured documents and adds two types of new objects:

1. Digital induced health state (DIHS) is the digitization of the patient's induced health state (IHS) which is a representation of the patient's health that the healthcare professional shapes in her/his mind at the time of the encounter with the patient;
2. Digital health (HDS) is a complex, multifaceted object obtained by the VHR from authoritative sources that contains all electronically documented information about an individual's health at a given time. In our approach, HDS is the digitization of the concept of health, a holistic and customized image of the well-being of each individual.

The widespread use of the HDS concept and a tool such as Smart EHR can make services in healthcare more efficient, improve procedures, and contribute to innovative methods of healthcare and well-being, as well as provide opportunities for research and development.

Our research can and should be continued in several directions.

The generation of HDS instances and use of the HDS concept should go beyond simply collecting within the Questionnaire all the existing observations in the VHR Repository according to the set of quantifiable concepts in the Thesaurus, as described by the algorithm in Fig. 9. Generating HDSs by simple combining observations, DIHS and HDS available in the VHR for a patient, should be refined by a complex "Merge" operation between all DIHSs of health professionals who have analyzed the patient's health in a given period. Data analytics and AI have the potential to transform health and care systems in numerous ways to achieve the systematic improvements in quality and cost reductions demanded by the paradigm shifts in health and care. Monitoring one's own health status, remote consultations (telemedicine), judgments of expert systems, learning from the clinical history of patients around the world, enabling treatment and health maintenance protocols with the aid of digital twins, and personalizing treatment based on an individual's genetic information are just some of the scientific and technological challenges that can be successfully addressed and solved with the help of HDS and Smart EHR.

An HDS-based avatar, created by the VHR for each individual, could evolve continuously, maintaining an accurate digital reflection of its owner's health and adapting in order to better interact with other species or digital organisms in digital health ecosystems (DHE) [15]. The virtual species in DHEs are virtual representations of existing software applications and hardware devices as well as other real-world entities. The health avatar can take decisions on its own according to its owner's beliefs, desires, and intentions (BDI) [39] and can proactively propose its own actions in the system.

Smart EHR should adopt all these innovative ways of extending conventional medicine. For example, it could provide services that allow its own informed interpretation of the individual's health status to be compared with the most recent list of facts and, focusing on the critical points, to propose variants of treatment plans.

Overcoming barriers to the acceptance and implementation of Smart EHRs is a complex process. All stakeholders from providers to government bodies should be convinced of the benefits of these innovative EHRs and the ways in which they make the delivery of healthcare more effective and efficient. Moreover, it is extremely likely that consumers of health and social care services, holders of detailed personal information about their own health recorded in the Smart EHR, and those who have become accustomed to the digital transformations that have taken place in other sectors such as e-commerce and mobility, will want health and care systems to follow the same path and be digitally transformed in the same way.

Smart EHR systems should become the backbone of national or regional health and care systems, and the supporting infrastructure of all medical and social services provided nationwide. They should facilitate document digitization according to USA and European standards that aim for interoperability by enhancing data extraction, collection, analysis, and harmonization. They should also facilitate the easy access of stakeholders to the system (e.g., by patient empowerment), complete feeding of the Smart EHR with information from public and private organizations, the strengthening of protection systems for safe consultation, the creation of apps to collect clinical and environmental data from individuals, and intelligent interaction with users.

Finally, the method employed in this article for digitalization of the Encounter business process could be improved and extended into a useful methodology for all those wishing to develop projects focusing on the digital transformation of health and care systems.

Declaration of competing interest

The author declares that he has no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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The author participated as a system and software architect at the LUMIR project in the Basilicata Region. This project aimed to design, develop, and deploy a regional EHR-S infrastructure of e-services for the regional health information system, through which it was able to interconnect with other regional EHR-Ss in Italy. Its infrastructure design was based on the Virtual Health Record concept. It was an attempt to provide a tool not only for controlling health costs, but also for better management of citizens' health by health professionals [37]. The project was conducted by the Italian National Research Council as a result of the enactment in this region of the GP's Network Pilot Program (RMMG), a program launched by the Italian Permanent National Board for e-Health [45].

The author also participated as a consultant in the Smart Health 2.0 project in the Sicily Region [38]. One of the major objectives of participating in this project was the design of a region-wide EHR-S of the second generation, also based on VHR.

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