
**Health informatics — Electronic health
record — Definition, scope and context**

*Informatique de santé — Dossier de santé informatisé — Définitions,
domaine et contexte*

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Foreword

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Introduction

This Technical Report was prepared in order to establish a set of categories of, and definitions for, electronic health records in order to describe the scope of application of the family of EHR standards currently programmed for development by ISO.

The primary purpose of ISO's family of EHR standards is to maximize interoperability between electronic records and systems that are specifically intended to be shareable, irrespective of the technologies they use and the platforms on which they reside.

However, a variety of health information systems may include features and functionality that could be characterized as belonging to an EHR system. Similarly, many health information systems may produce output in the form of EHR extracts or entries, as described in ISO/TS 18308, irrespective of whether their primary purpose or application is as a shareable EHR.

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Health informatics — Electronic health record — Definition, scope and context

1 Scope

This Technical Report describes a pragmatic classification of electronic health records, provides simple definitions for the main categories of EHR and provides supporting descriptions of the characteristics of electronic health records and record systems.

2 Terms and definitions

For the purpose of this document, the following terms and definitions apply.

2.1

archetype

⟨descriptive⟩ model of a clinical or other domain-specific concept which defines the structure and business rules of the concept

NOTE Archetypes may define simple compound concepts such as “blood pressure” or “address”, or more complex compound concepts such as “family history” or “microbiology result”. They are not used to define atomic concepts such as anatomical terms. Archetypes use terms which may be derived from external terminologies to identify archetype components.

[Beale:2003^[11]]

2.2

archetype

⟨technical⟩ computable expression of a domain-level concept in the form of structured constraint statements, based on some reference information model

NOTE 1 Archetypes are one-to-one with domain concepts, which can themselves have interior complexity.

NOTE 2 Archetypes all have the same formalism but can be either part of a standardized/shared ontology (i.e. definitional) or only used locally or regionally (i.e. not considered definitional).

[Beale:2003^[11]]

2.3

architecture

that set of design artefacts or descriptive representations that are relevant for describing an object such that it can be produced to requirements (quality) as well as maintained over the period of its useful life (change)

[Zachman:1996^[24]]

2.4

client

individual who is a subject of care

NOTE The terms “client” and “patient” are synonymous but the usage of one or other of these terms tends to differ between different groups of health professionals. Clinicians working in a hospital setting and medical practitioners in most settings tend to use the term “patient” whereas allied health professionals tend to use the term “client”.

2.5
clinical data repository
CDR

data store that holds and manages clinical data collected from service encounters at point of service locations (e.g. hospitals, clinics)

NOTE 1 Adapted from Infoway:2003^[13].

NOTE 2 Data from a CDR can be fed to the EHR for that subject of care; in that sense the CDR is recognized as a source system for the EHR.

NOTE 3 A CDR complies with the definition of a basic-generic EHR but not with the more specialized definition of an Integrated Care EHR (ICEHR).

2.6
clinician

health professional who delivers health services directly to a patient/client

NOTE Adapted from ISO/TS 18308^[3].

2.7
COMPOSITION

sub-class of RECORD_COMPONENT in the EN13606 Reference Model that contains the set of RECORD_COMPONENTS composed (authored) during one user's clinical session or record interaction, for committal within one HER

[ENV 13606-1^[6]]

2.8
computer processable information

information which can be programmatically created, stored, manipulated, and retrieved in an electronic computer

2.9
consumer

individual who may become a subject of care

2.10
electronic health record for integrated care
ICEHR

repository of information regarding the health status of a subject of care, in computer processable form, stored and transmitted securely and accessible by multiple authorized users, having a standardized or commonly agreed logical information model that is independent of EHR systems and whose primary purpose is the support of continuing, efficient and quality integrated health care

NOTE It contains information which is retrospective, concurrent and prospective.

2.11
electronic health record
EHR

(basic generic form) repository of information regarding the health status of a subject of care, in computer processable form

NOTE The definition of the EHR for integrated care in 2.10 is considered to be the primary definition of an electronic health record. The definition of a basic-generic EHR is given only for completeness and to acknowledge that there are still currently many variants of the EHR in health information systems which do not comply with the main (ICEHR) EHR definition (e.g. a CDR complies with the basic-generic EHR definition but not with the ICEHR definition).

2.12 electronic health record architecture EHRA

generic structural components from which all EHRs are built, defined in terms of an information model

[ISO/TS 18308^[3]]

NOTE A more descriptive informal definition of an EHRA is that of a model of the generic features necessary in any electronic healthcare record in order that the record may be communicable, complete, a useful and effective ethico-legal record of care and may retain integrity across systems, countries and time. The architecture does not prescribe or dictate what anyone stores in their healthcare records. Nor does it prescribe or dictate how any electronic healthcare record system is implemented. It places no restrictions on the types of data which can appear in the record, including those that have no counterpart in paper records. Details like “field sizes”, coming from the world of physical databases, are not relevant to the electronic healthcare record architecture.

[EU-CEN:1997^[12]]

2.13 EHR extract

unit of communication of all or part of the EHR which is itself attestable and which consists of one or more EHR compositions

NOTE Adapted from ISO/TS 18308^[3].

2.14 EHR node

physical location where EHRs are stored and maintained

2.15 EHR system

⟨components⟩ set of components that form the mechanism by which electronic health records are created, used, stored and retrieved including people, data, rules and procedures, processing and storage devices, and communication and support facilities

NOTE 1 Adapted from IOM:1991^[14].

NOTE 2 The original IOM definition referred to a “CPR System” (Computer-based Patient Record System) and used the term “patient records” rather than “electronic health records”.

2.16 EHR system

⟨system⟩ system for recording, retrieving and manipulating information in electronic health records

NOTE 1 Adapted from ENV 13606-1^[6].

NOTE 2 This definition is identical to the original CEN definition except that the original term “electronic health care record” has been abbreviated to “electronic health record” to be consistent with the terminology used throughout this Technical Report.

2.17 encounter

contact in the course of which health activities are delivered to a subject of care in her or his presence, and her or his health record is accessed or managed

NOTE 1 Adapted from EN 13940-1^[8].

NOTE 2 This definition is identical to the original CEN definition except that the original term “health care” has been abbreviated to “health” to be consistent with the terminology used throughout this Technical Report.

2.18

functional interoperability

ability of two or more systems to exchange information

2.19

health

state of complete physical, mental and social well-being and not merely the absence of disease or infirmity

[WHO:1948^[23]]

2.20

health condition

alterations or attributes of the health status of an individual which may lead to distress, interference with daily activities, or contact with health services; it may be a disease (acute or chronic), disorder, injury or trauma, or reflect other health-related states such as pregnancy, aging, stress, congenital anomaly or genetic disposition

[WHO:1948^[23]]

2.21

health organization

organisation involved in the direct provision of health activities

NOTE 1 Adapted from ENV 13940-1^[8].

NOTE 2 This definition is identical to the original CEN definition except that the original term "health care" has been abbreviated to "health" to be consistent with the terminology used throughout this Technical report.

2.22

health problem

health condition that results in some disability, pain and/or activity limitation

2.23

health professional

person who is authorized by a recognized body to be qualified to perform certain health duties

NOTE 1 Adapted from ISO/TS 17090-1^[2].

NOTE 2 The defined term is often named "healthcare professional". A convention has been adopted in this Technical Report whereby the term "healthcare" is abbreviated to "health" when used in an adjectival form. When used in a noun form, the word "care" is retained but as a separate word (e.g. delivery of health care).

2.24

health provider

health professional or health organization involved in the direct provision of health activities

NOTE 1 Adapted from ENV 13940-1^[8].

NOTE 2 This definition is identical to the original CEN definition except that the original term "health care" has been abbreviated to "health" to be consistent with the terminology used throughout this Technical Report.

2.25

health record

repository of information regarding the health of a subject of care

NOTE Adapted from ENV 13940-1^[8].

2.26

health status

individual's current state of physical, mental and social well-being

2.27**information service**

ability of a system to provide a defined set of output information based on a defined set of input information

[EN 12967-1 to 3^[7]]

2.28**integrated care EHR****ICEHR**

See 2.10

2.29**logical information model**

information model that specifies the structures and relationships between information but is independent of any particular technology or implementation environment

NOTE Information models are commonly classified from high-level abstract models through to concrete technology implementation models. The ISO Health Informatics Profiling Framework (ISO/TR 17119^[1]) defines three levels of specificity for information models and other artefacts viz conceptual, logical and physical. Logical information models provide detailed specifications for components of the model (e.g. container, section and link classes in a UML object model of an EHR) and the relationships between the components, without any technological constraints. A logical information model is therefore independent of any particular implementation technology. A physical information model on the other hand, includes technological constraints to enable the building of a particular implementation of the logical model (e.g. an EHR system built for a particular hardware and software platform).

2.30**patient
client**

individual who is a subject of care

NOTE 1 Adapted from ISO/TS 18308^[3].

NOTE 2 The terms “patient” and “client” are synonymous but the usage of one or other of these terms tends to differ between different groups of health professionals. Clinicians working in a hospital setting and medical practitioners in most settings tend to use the term “patient” whereas allied health professionals tend to use the term “client”.

2.31**semantic interoperability**

ability for information shared by systems to be understood at the level of formally defined domain concepts

NOTE Adapted from ISO/TS 18308^[3].

2.32**service**

number of processes, involving an organization in the provision of specific objectives

[EN 12967-1 to 3^[7]]

NOTE See also 2.27.

2.33**shareable EHR**

EHR with a commonly agreed logical information model

NOTE 1 The shareable EHR *per se* is an artefact between a basic-generic EHR and the Integrated Care EHR (ICEHR) which is a specialization of the shareable EHR. The shareable EHR is probably of little use without the additional clinical characteristics that are necessary for its effective use in an integrated care setting.

NOTE 2 Whilst the ICEHR is the target for interoperability of patient health information and optimal patient care, it is of note that the large majority of EHRs in use at present are not even shareable let alone have the additional characteristics

required to comply with the definition of an Integrated Care EHR. A definition of a basic-generic EHR has therefore been included to acknowledge this current reality.

**2.34
standard**

document, established by consensus and approved by a recognized body, which provides, for common and repeated use, rules, guidelines or characteristics for activities or their results, aimed at the achievement of the optimum degree of order in a given context

[ISO/IEC Guide 2^[4]]

**2.35
subject of care**

one or more persons scheduled to receive, receiving or having received a health service

[ISO/TS 18308^[3]]

NOTE 1 The terms “patient” and “client” are synonymous with subject of care in a health record context and are commonly used instead of the more formal term “subject of care”.

NOTE 2 The term “consumer” is also often used as a synonym in this context. However, it is of note that a consumer may not necessarily be a subject of care since it can be argued that it is possible for a consumer to have a health record without ever having received a health care service.

**2.36
template**

directly, locally usable data creation/validation artefact that is semantically a constraint/choice of archetypes and which will often correspond to a whole form or screen

[Beale:2003^[11]]

NOTE Templates in general have a one-to-many relationship with underlying concepts, each of which is described by an archetype.

3 Definition of Electronic Health Record

3.1 Definitional approach

Previous attempts to develop a definition for the Electronic Health Record (EHR) have foundered due to the difficulty of encapsulating all of the many and varied facets of the EHR in a single comprehensive definition.

The approach taken in this Technical Report is to make a clear distinction between the content of the EHR and its form or structure. This is achieved by first defining the EHR in terms of its structure (i.e. as a container). This definition (called the “basic-generic EHR”) is intentionally concise and generic to ensure the broadest applicability to the widest range of existing and future users of EHRs and EHR systems. Such a definition shall also be able to support legislative and access control requirements that apply to all “forms” of EHR.

The basic-generic EHR definition is supplemented by a more detailed and specialized definition to cover two of the most essential characteristics of the EHR not covered by the basic-generic definition. These are the ability to share patient health information between authorized users of the EHR and the primary role of the EHR in supporting continuing, efficient and quality integrated health care. There are of course many other important characteristics of the EHR dependent on the scope and context of care, which will not be explicitly expressed in a single supplementary definition. It would be possible to develop a whole series of formal definitions to capture all of the nuances of different care contexts. However, the approach taken in this Technical Report is to keep the number of formal definitions of EHR types to an essential minimum and to demonstrate the inclusiveness of these definitions through explanatory text and examples.

Figure 1 illustrates the specialization of the basic-generic EHR into two broad categories of shareable and non-shareable EHRs. A definition for a shareable EHR is given in Clause 2 but it is not included as a core definition in this Technical Report since the shareable EHR by itself is probably of little use without the additional clinical characteristics that are necessary for its use in an integrated care setting. This is called an integrated care EHR (ICEHR) and is shown in Figure 1 as a specialization of the shareable EHR.

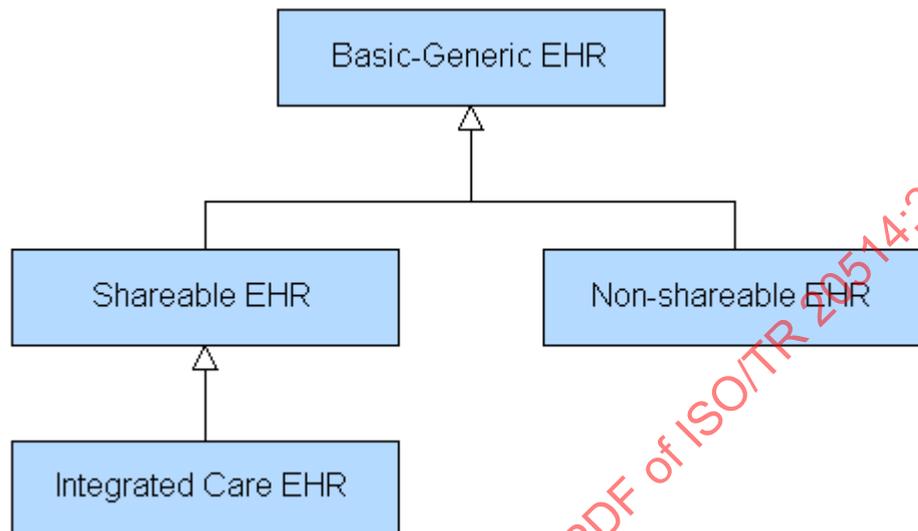


Figure 1 — Specialization of the basic-generic EHR

NOTE Figure 1 uses the conventions of object-oriented UML (Unified Modelling Language) diagrams. The unfilled arrows represent a generalization/specialization relationship that can be thought of as an “is a kind of” relationship. Thus a shareable EHR is a specialization of the more general basic-generic EHR (i.e. a shareable EHR is a kind of basic-generic EHR). Similarly, an Integrated Care EHR is a specialization of (is a kind of) shareable EHR.

It shall be emphasized that a clear distinction needs to be made between the EHR and an EHR system and that this Technical Report is primarily concerned with the former. Many of the characteristics often assigned to the EHR in fact pertain to EHR systems rather than to the record itself. This is discussed in Clause 6.

3.2 The key role of interoperability

From the viewpoint of standardization, the single most important characteristic of the EHR is the ability to share EHR information between different authorized users. In technical terms, this requires interoperability of information in the EHR and interoperability of EHR systems that exchange and share this information.

There are two main levels of shareability or interoperability of information:

- a) **functional interoperability:** the ability of two or more systems to exchange information (so that it is human readable by the receiver);
- b) **semantic interoperability:** the ability for information shared by systems to be understood at the level of formally defined domain concepts (so that information is computer processable by the receiving system).

Note that semantic interoperability is not an all-or-nothing concept. The degree of semantic interoperability depends on the level of agreement on terminology and the content of archetypes and templates used by the sender and receiver of information.

Semantic interoperability is necessary for automatic computer processing to underpin the real value-added EHR clinical applications such as intelligent decision support and care planning.

One of the key requirements for shareability of the EHR is to break the nexus between the EHR and the EHR system (i.e. the EHR should conform to an information model independent of both the physical database schema used for local storage and the applications which create, maintain and retrieve EHRs). This EHR information model should be independent of any particular implementation technology (i.e. it should be a logical information model). Technology independence is also essential to make the EHR “future proof” to enable the possibility of lifetime EHRs.

In order to achieve semantic interoperability of EHR information, there are four prerequisites, with the first two of these also being required for functional interoperability:

- a) **a standardized EHR reference model**, i.e. the EHR information architecture, between the sender (or sharer) and receiver of the information;
- b) **standardized service interface models** to provide interoperability between the EHR service and other services such as demographics, terminology, access control and security services in a comprehensive clinical information system;
- c) **a standardized set of domain-specific concept models**, i.e. archetypes and templates for clinical, demographic and other domain-specific concepts;
- d) **standardized terminologies** that underpin the archetypes. Note that this does not mean that there needs to be a single standardized terminology for each health domain, but rather, terminologies used should be associated with controlled vocabularies.

The sharing of patient EHR information between different EHR systems and different health organizations will almost certainly take place in a distributed processing environment. ISO 10746, covers the reference model for open distributed processing (RM/ODP) and describes distributed systems in terms of five “viewpoints” (subdivisions of the specification of a complete system) which are the Enterprise, Information, Computational, Engineering and Technology viewpoints. The RM/ODP also describes the key concept of “separation of responsibilities” between different components/services in a complete distributed system. Each service in the system has its own set of responsibilities, independent of the other services, but linked by service interfaces. This is called the “system of systems” paradigm.

Using this approach, the EHR is but one of many services (although central to the focus of this Technical Report) in a comprehensive health information system. Examples of other services are demographics, terminology, access control and security. These and many other services are shown diagrammatically in Figure 2. Each service can be represented by a reference model which specifies the information semantics of the service (the RM/ODP information viewpoint) and a service model which specifies the interface between that service and other services via an API (Application Programming Interface) definition.

More detailed information on this important subject is contained in ISO 10746, EN 12967 and *open EHR:2003*.

3.3 The basic–generic EHR

3.3.1 Definition

See 2.11.

3.3.2 The basic-generic EHR in context

3.3.2.1 Applicability of definition

This definition makes no assumptions about the health system of any country or region. It also makes no assumptions about the type or granularity of information in the record. More specifically, the definition is broadly applicable to all health sectors, professional health disciplines and methods of health delivery.

3.3.2.2 Name of the EHR

It has been noted that in regard to the term “Electronic Health Record”, the word “Computerized” or “Digital” may be preferable to “Electronic” since the record itself is usually stored in digital form on a magnetic disc or other medium such as magnetic tape, “smart card”, or CD-ROM, none of which is strictly electronic, except that the hardware that processes them (and therefore the record) uses electronic circuits. However, this is a rather pedantic view and the term “Electronic Health Record” and its abbreviation “EHR” are now so well established internationally that a further name change would cause unnecessary confusion.

3.3.2.3 Source of definition

The definition is essentially a concatenation of the CEN definitions of a “healthcare record” (“a repository of information regarding the health of a subject of care”) and the EHR (“a healthcare record in computer readable format”) (see ENV 13606-1), with one important change. The phrase “computer readable” in the CEN definition has been changed to “computer processable” which encapsulates readability but extends this to include the notion that information in the EHR must be amenable to programmatic manipulation and therefore to automatic processing.

3.3.2.4 Subject of care

The term “subject of care” is used synonymously with “patient” and “client” throughout this Technical Report, depending on the context in which these terms are used. The term “consumer” is also commonly used in place of subject of care and in most cases this is a valid use. However, it should be noted that in a strict sense, a consumer may not necessarily be a subject of care since it can be argued that it is possible for a consumer to have a health record without ever having received a health care service.

“Subject of care” usually refers to a single individual. However, the definition in Clause 2, which is taken from ISO/TS 18308, allows for the subject of care to be “one or more persons”. This broader definition has been adopted to satisfy the needs of jurisdictions in which there may be a requirement for the EHR to include more than one person as the subject of the EHR (e.g. certain indigenous and cultural groups where it is customary to keep information and make health decisions at the family or other group level).

It may be tempting to abbreviate the term “subject of care” to “subject”. Whilst this may be acceptable in some contexts, it should be used with care since a “subject” in an EHR may be the “subject of information” rather than the “subject of care” (e.g. details of the patient’s mother in the family history section of the health record); “subject” is only used in this Technical Report where the context and meaning are very clear.

3.4 The non-shareable EHR

The non-shareable EHR will not be formally defined in this Technical Report since it is essentially a “definition by exclusion”. However, the characteristics of a non-shareable EHR are discussed briefly below.

As noted in 3.2, the single most important characteristic of the EHR from a standards viewpoint and also one of the greatest potential benefits of the EHR is the ability to share EHR information. At present, almost all EHRs are based on proprietary information models within EHR systems, with little or no interoperability between EHR systems and little or no ability to share EHR information beyond the immediate boundary of a single health organization. In fact, it is often impossible to share EHR information between different disciplines within a single organization (e.g. between doctors and nurses) or between different applications within a single clinical information system (e.g. a non-integrated decision support or care planning application is unable to access the EHR which is bound to the “EHR application”). Non-shareable EHRs are nearly always tightly bound to both the EHR system software and also to a particular database product. This is the case with the large majority of EHRs implemented in all areas of health at present.

The difference between a non-shareable EHR and a shareable EHR is analogous to the difference between a stand-alone desktop PC and a networked PC where the latter adds enormous benefits in terms of locating, retrieving and exchanging information using the Internet, an intranet, email, workgroup collaboration tools, etc.

3.5 The shareable EHR

The sharing of EHR information can take place at three different levels:

- a) **level 1:** between different clinical disciplines or other users, all of whom may be using the same application, requiring different or *ad hoc* organisation of EHRs;
- b) **level 2:** between different applications at a single EHR node (i.e. at a particular location where the EHR is stored and maintained);
- c) **level 3:** across different EHR nodes (i.e. across different EHR locations and/or different EHR systems).

The shareable EHR used for levels 1 and 2 will contain mainly detailed information required for patient care within a single location and it will be created and maintained on a local EHR system as described in 6.3. However, it will also usually contain at least some health summary information such as a problem list, allergies, past medical history, family history, current medication, etc.

When level 3 sharing is achieved and the object of the EHR is to support the integrated care of patients across and between health enterprises, it is called an integrated care EHR (ICEHR).

3.6 The Integrated Care EHR (ICEHR)

3.6.1 General

Over the past decade there has been a marked trend towards integrated health delivery through multi-speciality and multi-disciplinary teams, often called "shared care" or "co-ordinated care". Integrated shared care is well suited to many chronic diseases such as diabetes, cardiovascular diseases, and respiratory diseases. It is also well suited to some episodic or periodic conditions such as ante-natal care and mental health problems.

Integrated care is usually planned and delivered over an extended period of time, particularly for the management of chronic diseases. This introduces the notion of a longitudinal record, with information recorded about past, present, and future events and plans. The Integrated Care EHR definition is based on these characteristics.

3.6.2 Definition

See 2.10.

3.6.3 ICEHR in context

3.6.3.1 Semantic interoperability

Effective integrated and shared care requires, at a minimum, timely and efficient shared personal health information (i.e. a shareable EHR, which implies at a minimum, functional interoperability). However, to obtain optimum information management for integrated health care, it is necessary to have semantic interoperability, through standardization of clinical and other domain concepts using terminologies, archetypes and templates. This requirement has not been included in the definition of the ICEHR since there is currently limited standardization of the components required for semantic interoperability. It is expected however, that substantial progress will be made over the next few years with the adoption of standardized terminologies and the rapid development and standardization of archetypes and templates.

3.6.3.2 Longitudinal

The term "longitudinal" has deliberately not been included in the definition of ICEHR due to differing views on what it really means (see 5.4). Nevertheless, the concept of an (extended) interval of time is implicit in the definition through the phrase "contains information which is retrospective, concurrent, and prospective".

3.6.3.3 Granularity

There is no mention in the definition of ICEHR of the type or granularity of information beyond the fact that it is “information regarding the health of a subject of care” and “its primary purpose is the support of continuing, efficient and quality integrated care”. It is likely that the majority of such information will be clinical but it will certainly contain some demographic information and may include administrative information such as appointment schedules, eligibility information etc. The granularity of the information will vary depending on the context of care (see Clause 5).

3.6.3.4 Standardized (or commonly agreed) logical information model

The ICEHR definition refers to “a standardized or commonly agreed logical information model”. This is the fundamental characteristic of a shareable EHR. A “standardized” logical information model, produced through the consensus standards development process of national and international standards development organizations such as ISO, CEN and HL7, is the preferred outcome to ensure widest interoperability. However, a “commonly agreed” logical information model, produced through a process of formal or informal agreement at the level of a group of users (e.g. a local or regional health authority), may be appropriate as an interim measure or in a jurisdiction where a formal standard is not thought to be desirable.

A logical information model specifies the structures and relationships between information but is independent of any particular technology or implementation environment. Thus, the ICEHR is “independent of (any particular) EHR systems” as stated in the definition. A physical model is a particular instantiation of a logical model for use in building a specific system or product. It is sometimes also called a design model or product model.

3.6.3.5 Persistence of information

The ICEHR definition does not explicitly mention persistence of information, although it is implied by the statement that it contains “information which is retrospective, concurrent and prospective”.

Information persistence is a fundamental characteristic of formal EHR models (i.e. EHR logical information models) which include semantics for information storage, version control, and rules regarding the modification and deletion of information in the EHR. This is a characteristic which distinguishes the EHR from the messaging paradigm (e.g. HL7 or Edifact messages) in which messages have no persistence (although the information in a message can clearly be stored in an EHR or other persistent artefact once it has been decoded by the receiver). It is generally agreed from a medico-legal viewpoint, that information recorded in an EHR should not be able to be deleted. Rather, errors in recorded information should be corrected by making a new version of the particular block of information (called a “Composition” in CEN EN13606 or a “Document” in the HL7 Clinical Document Architecture). This new corrected block of information is the default seen by a user but the old incorrect information can still be retrieved if necessary for medico-legal purposes.

Notwithstanding the above, there may be jurisdictions in which there is a requirement that particular erroneous information should be permanently deleted (e.g. at the request of the patient), despite other medico-legal difficulties that this may create. Many jurisdictions also specify a time (usually at least seven years and sometimes more than twenty years) after which the entire health record may be permanently deleted.

3.6.3.6 Completeness of information

It is often said that information in the EHR should be “complete” or that the ICEHR/longitudinal EHR should be a complete record of the subject’s health care. In practice, this will rarely, if ever, be true, particularly in the current era where a person’s total health needs are provided by many different clinicians and health organizations. Increasingly frequent travel and changes of abode also compound this problem. Furthermore, clinicians do not record a verbatim transcript of a health encounter but rather, only the salient history, observations, investigations, assessments, interventions and plans necessary for optimal management of a particular health problem or issue.

The ideal ICEHR will be comprehensive: it will be capable of representing and managing any kind of EHR information, and capable of integrating data from any number of EHR provider systems. In practice more limited forms of an EHR system may be developed for use in constrained clinical contexts. Practical

circumstances may limit the connectivity of one EHR system to other such systems. However, in principle each ICEHR will be as complete as local circumstances permit AND will itself be capable of contributing its data to other larger-scale ICEHR systems, respecting any access permissions that pertain to the EHR data.

3.6.3.7 Security and privacy

The ICEHR has two other important characteristics which introduce the important areas of security and privacy, considered in most jurisdictions to be essential for medico-legal integrity and community trust and acceptance of EHRs. These are:

- a) security of the information both when stored and transmitted;
- b) accessibility by multiple authorized users (and only by authorized users). This introduces the privacy/access control dimension to the EHR and allows for access by the subject of care (where appropriate and allowed by local laws and policies) and other authorized users (e.g. the subject's agent such as a parent of a child subject) as well as treating clinicians. Any system providing access to the ICEHR must conform to any consents and locally-applicable policies for such access.

NOTE Formal requirements or a specification of a) are not in the scope of this Technical Report. Such requirements or specifications are established locally or nationally.

3.7 Other common types of health records

3.7.1 General

There are a number of other terms commonly used to describe different types of health records in an electronic form. Although some of these terms have been formally defined by standards and other organizations, their usage has generally been inconsistent and variable across different countries and health sectors.

NOTE These terms are discussed here for completeness but will not be formally defined in this Technical Report.

3.7.2 Common types of health record

3.7.2.1 Electronic medical record (EMR)

The EMR could be considered as a special case of the EHR, restricted in scope to the medical domain or at least very much medically focused. It is a widely used term in North America and a number of other countries including Japan. The Japanese Association of Healthcare Information Systems (JAHIS) has defined a five-level hierarchy of the EMR (see JAHIS:1996^[15]):

- a) **Departmental EMR:** contains a patient's medical information entered by a single hospital department (e.g. pathology, radiology, pharmacy);
- b) **Inter-departmental EMR:** contains a patient's medical information from two or more hospital departments;
- c) **Hospital EMR:** contains all or most of a patient's clinical information from a particular hospital;
- d) **Inter-hospital EMR:** contains a patient's medical information from two or more hospitals;
- e) **Electronic healthcare record:** longitudinal collection of personal health information from all sources.

3.7.2.2 Electronic patient record (EPR)

The United Kingdom's National Health Service (NHS) defines the EPR as *an electronic record of periodic health care of a single individual, provided mainly by one institution* (NHS:1998^[16]). The NHS notes that the EPR typically relates to the health care provided by acute care hospitals or specialist units. This definition of

the EPR has gained quite widespread currency outside of the UK but its usage is still often inconsistent in many places.

3.7.2.3 Computerized patient record (CPR)

Also referred to as a computer-based patient record, the term computerized patient record is used mainly in the USA and seems to have a wide range of meanings which may encompass the EMR or EPR.

3.7.2.4 Electronic health care record (EHCR)

The EHCR is a term that was commonly used in Europe, including ENV 13606-1^[6]. It may be regarded as synonymous with the EHR and EHR is now rapidly replacing the term EHCR in Europe.

3.7.2.5 Electronic client record (ECR)

A special case of the EHR where the scope is defined by the non-medical health professional group utilizing the record within their health discipline (e.g. physiotherapist, chiropractor, social worker).

3.7.2.6 Virtual EHR

The virtual EHR is a loose concept which has been discussed for a number of years but there is no authoritative definition to date. It usually refers to an EHR which is assembled "on the fly" through a process of federation of two or more EHR nodes. This is further discussed in 6.3.

3.7.2.7 Personal health record (PHR)

This is an important entity and is discussed in 3.8.

3.7.2.8 Digital medical record (DMR)

Waegemann describes the DMR as "a web-based record maintained by a healthcare provider or health plan. The DMR can have the functionality of the EMR, EPR or EHR" (see Waegemann^[22]).

3.7.2.9 Clinical data repository (CDR)

A CDR is defined by Canada Health Infoway as "an operational data store that holds and manages clinical data collected from service encounters at point of service locations (e.g. hospitals, clinics). Data from a CDR can be fed to the EHR for that client, in that sense the CDR is recognized as a source system for the EHR." (Infoway:2003^[13]). A CDR is usually organized as a service-centric repository rather than patient-centric records and CDRs do not have the version control, privacy (particularly patient-controlled access) and other EHR medico-legal characteristics at an individual patient level. It should also be noted that notwithstanding the Infoway definition, many CDR products are in fact non-operational data warehouses designed for secondary processing.

3.7.2.10 Computerized medical record (CMR)

A CMR is defined by Waegemann as "a computerized record created by image scanning or optical character recognition (OCR) of a paper-based healthcare record" (see Waegemann^[22]).

3.7.2.11 Population health record

A population health record contains aggregated and usually de-identified data. It may be obtained directly from EHRs or created *de novo* from other electronic repositories. It is used for public health and other epidemiological purposes, research, health statistics, policy development and health service management.

3.7.2.12 Types of health records in review

The first eight of these variants clearly comply with the basic-generic EHR definition. A CDR may comply with the basic-generic EHR definition but CDRs are generally not considered to be patient-centric EHRs as is clear from the Canada Infoway definition.

The CMR might be considered to be partially compliant to the basic-generic EHR definition since scanned paper records can be indexed, retrieved and potentially searched within documents (if OCR has been done). However, a CMR is unlikely to have data structures to underpin any significant decision support or other applications requiring semantic interoperability.

The population health record does not comply with the ISO EHR definitions since it is not a health record, as defined in 2.20 “a repository of information regarding the health of a subject of care”. It is true that the definition of subject of care (see 2.29) makes provision for the subject to be “one or more persons”, but in most jurisdictions it will apply to a single individual only. Moreover, even if the subject of the EHR is two people or a family, this would not be regarded as a population as used by epidemiologists and other public health specialists.

3.8 The personal health record (PHR)

The key features of the PHR are that it is under the control of the subject of care and that the information it contains is at least partly entered by the subject (consumer, patient).

There is a widespread misapprehension in the community, including among health professionals, that the PHR must be a completely different entity from the EHR if it is to meet the requirements of patients/consumers to create, enter, maintain and retrieve data in a form meaningful to them and to control their own health record. This is not correct. There is no reason why the PHR cannot have exactly the same record architecture (i.e. standard information model) as the health provider EHR and still meet all of the patient/consumer requirements listed above. In fact there is every reason to ensure that a standardized architecture is used for all forms of EHRs (but certainly the ICEHR), to enable sharing of information between them as and when appropriate, under the control of the patient/consumer.

The PHR can then be considered in at least four different forms:

- a) a self-contained EHR, maintained and controlled by the patient/consumer;
- b) the same as a) but maintained by a third party such as a web service provider;
- c) a component of an ICEHR maintained by a health provider (e.g. a GP) and controlled at least partially (i.e. the PHR component as a minimum) by the patient/consumer;
- d) the same as c) but maintained and controlled completely by the patient/consumer.

4 The EHR

4.1 Scope of the EHR¹⁾

There are currently two broadly different views of the scope of the EHR²⁾. The first of these views has been called the “Core EHR” whilst the second has been called the “Extended EHR”³⁾.

1) Some readers may prefer to think of this section as the “Boundaries of the EHR” since the scope also determines the EHR boundaries – i.e. what is permissible in the EHR and what is not.

2) These different views first emerged during review of a draft of ISO/TS 18308 in early 2002 and later in the development of the ISO/TC 215 EHR ad hoc Group report (Schloeffel & Jeselon:2002). The subject has since been taken up by the HL7 EHR SIG and debated on the SIG’s List Serv (EHR@lists.hl7.org) and at the October 2002 meeting of the HL7 EHR SIG in Baltimore, MD, USA.

No formal definition of the Core EHR or Extended EHR will be given in this Technical Report since these are informal artefacts used here to describe two different views on the scope of the EHR. Both the Core and Extended EHRs as described, comply with the ISO basic-generic definition of the EHR.

There may in fact be many more shades of variation in the fine detail of exactly what is in scope and what is out of scope within each of these two broad views. However, it is probably more fruitful to initially characterize and obtain consensus on the main features of just the Core EHR and Extended EHR views. Before doing this, it will be useful to reflect on the purposes of the EHR. The following section is taken from ISO/TS 18308:2004.

4.2 Purpose of the EHR

The *primary* purpose of the EHR is to provide a documented record of care that supports present and future care by the same or other clinicians. This documentation provides a means of communication among clinicians contributing to the patient's care. The primary beneficiaries are the patient and the clinician(s).

Any other purpose for which the health record is used may be considered secondary, as are any other beneficiaries. Much of the content of EHRs is currently defined by secondary users, as the information collected for primary purposes was insufficient for purposes such as billing, policy and planning, statistical analysis, accreditation, etc.

Secondary uses⁴⁾ of EHRs include:

- **medico-legal:** evidence of care provided, indication of compliance with legislation, reflection of the competence of clinicians;
- **quality management:** continuous quality improvement studies, utilization review, performance monitoring (peer review, clinical audit, outcomes analysis), benchmarking, accreditation;
- **education:** training of clinicians and other health professionals;
- **research:** development and evaluation of new diagnostic modalities, disease prevention measures and treatments, epidemiological studies, population health analysis;
- **public and population health:** access to quality information to enable the effective determination and management of real and potential public health risks;
- **policy development:** health statistics analysis, trends analysis, casemix analysis;
- **health service management:** resource allocation and management, cost management, reports and publications, marketing strategies, enterprise risk management;
- **billing/finance/reimbursement:** insurers, government agencies, funding bodies.

The EHR scope may include functions which support both primary and secondary purposes of the EHR. However, the Core EHR will be principally focused on the primary purpose whereas the Extended EHR is concerned with all of the secondary purposes as well as the primary purpose of the EHR.

4.3 The Core EHR⁵⁾

The key characteristics of the Core EHR view are that the EHR concerns a single subject of care, has as its primary purpose the support of present and future health care of the subject, and is principally concerned with

3) This view has been described as mainly North American whilst the Core EHR view has been described as the predominant view of EHR scope in Europe and Australia. Whilst this may be true as a broad generality, both views will undoubtedly have their adherents regardless of any geo-centricity.

4) The term "secondary uses" here is not intended to indicate that these are inherently less important than the primary use/purpose of the EHR. Some may prefer the term "derived uses" rather than secondary.

5) This section draws heavily from the ideas and writings of Thomas Beale, including the Health Information Standards Manifesto (Beale:2001^[9])

clinical information. The last of these three characteristics is the most significant in defining the difference between the Core EHR and Extended EHR views, as will become evident in 4.5.

The proponents of the Core EHR have adopted this view to facilitate standardization of the EHR and the attendant benefits that this can bring, of greater interoperability (particularly at the semantic level), portability, evolution and implementability. The Core EHR has a clear, limited scope enabling a manageable set of requirements to be specified and a manageable standardized model to be defined.

The scope of the Core EHR is essentially defined by the requirements for its record architecture, as specified in ISO/TS 18308^[3].

The Core EHR fits much more closely than the Extended EHR with the distributed systems or “system-of-systems” paradigm. This allows more modular health information systems to be built, ranging from a simple environment with just the EHR, a terminology service and some reference data, to a much bigger and more elaborate environment including many additional services such as decision support, workflow management, order management, patient administration, billing, scheduling, resource allocation, etc.

The limited scope of the Core EHR and adoption of the system-of-systems approach also simplifies the development of EHR and other related health information standards. It means that the EHR standard does not have to try to be everything, but can rely on other standards to provide the services it requires. It also allows standards to be layered and released incrementally, making the overall standards approach much more manageable than it would be with a monolithic approach.

4.4 The Extended EHR

The Extended EHR view of the EHR includes not only clinical information but essentially the whole of what has been called the “Health Information Landscape” (see Beale:2001^[9]). It is a superset of the Core EHR. Conversely, the Core EHR should be seen as a true subset of the Extended EHR.

Examples of functions which are part of the Extended EHR but outside the scope of the Core EHR include:

- patient administration;
- scheduling;
- invoicing;
- decision support;
- access control and policy management;
- demographics;
- order management;
- guidelines;
- terminology;
- population health recording, querying and analysis;
- health professional service recording, querying and analysis;
- business operations recording, querying and analysis;
- resource allocation.

Each of these functions could form part of a comprehensive health information system. It should be noted that the ISO basic-generic EHR definition may include almost all ⁶⁾ of the Extended EHR types of information — provided they can be considered as “information regarding the health of a subject of care”. Thus, although the scope of the Core EHR has been defined as being predominantly limited to clinical information, the ISO basic-generic EHR definition and even the Integrated Care EHR do not prevent the inclusion of information related to patient administration, scheduling, invoicing, decision support, etc.

4.5 Comparative features of the Extended EHR and Core EHR

4.5.1 EHR systems functions

The distinction should be drawn between functions which are important for EHR systems in a “real world environment” and those which are important for standardization of the EHR. Good examples of the former are OLTP (On-Line Transaction Processing) and OLAP (On-Line Analytical Processing). These functions may be critical in a hospital or similar large scale EHR system but they will not form part of standards for the Core EHR record architecture. They will, however, be part of evolving standards for EHR systems. It is also important to recognize that these types of function may be just as relevant to Core EHR systems as to Extended EHR systems.

4.5.2 Information, knowledge and inference

Another perspective on the Core EHR/Extended EHR scope is their relationship to information and knowledge. Rector has described three classes of entities in the EHR environment:

- **knowledge:** statements that apply to all entities of a class⁷⁾; examples relevant to the EHR are terminology, clinical models (archetypes, templates), guidelines, drug reference data, etc.;
- **information:** statements about specific entities; examples are clinical, demographic, invoicing and scheduling data about particular individuals;
- **inference:** the use of knowledge to infer or deduce information about an individual (reasoning from the general to the particular); the primary example in health informatics is clinical decision support systems.

The Core EHR contains only information (i.e. facts about particular individuals). The Core EHR is not a knowledge system and is not, on its own, an inferencing system. The Extended EHR on the other hand may contain not only information but also knowledge. A comprehensive Extended EHR system will include components which are information systems, knowledge systems and inferencing systems.

Table 1 below provides a summary of the differences between the Core EHR and Extended EHR.

6) The exception to this would be population health information since this clearly does not constitute “information regarding the health of a *subject of care*”.

7) The definitions of knowledge and information used here are by Thomas Beale^[10].

Table 1 — Differences between the Core EHR and Extended EHR

Scope attribute	Core EHR	Extended EHR
Focus	principally clinical information	the whole health information landscape
Relationship to each other	subset of Extended EHR	superset of Core EHR
Relationship to purposes of the EHR	principally concerned with primary purpose (i.e. clinical care)	concerned with both primary and secondary purposes
Relationship to ISO/TS 18308 EHR requirements	defines the scope	many of the Extended EHR requirements beyond the scope of the ISO/TS 18308 EHR Reference Architecture
Modelling paradigm	small model which interfaces to many similar models for other services in a distributed systems environment	large model which defines the whole health information landscape
Approach for standardization	separate standard for Core EHR and each other service in the health information landscape (layered approach)	single multi-part standard for all services
Relationship to information and knowledge	contains only information	may contain information and knowledge

5 Context of the EHR

5.1 The EHR for different health paradigms

Differences in health paradigms or models will likely lead to major differences in EHR content. In “western” countries, the allopathic or “orthodox” medical model is the dominant health paradigm. However, there are also two other models of western health care, the social model and the psychological model. These models have different assumptions about the nature of illness and well-being and differences of approach to the maintenance of good health and the treatment of illness. They also often use different terms for the same health concept (e.g. “problems” in the medical model and “issues” in the social model). However, differences between western and non-western health models are generally greater than those between the three western models.

Oriental medicine (e.g. Chinese medicine) and Ayurvedic medicine, collectively often called “alternative” or “complementary” medicine in western countries, are fundamentally different from western orthodox medicine. This is particularly important in countries where patients/consumers seek health care from practitioners of more than one health model, sometimes for the same illness. The practitioners of these different health models not only use different terms for the same entity but sometimes also use the same term to express different concepts; e.g. the terms “inflammation” and “elevated calcium” have quite different meanings for western and some alternative/complementary practitioners.

A single EHR, across different health paradigms, could be very beneficial for the holistic care of patients seeking care from practitioners of different health models (more than 50 % of the population in many countries). However, it could also be potentially dangerous or even life-threatening for a patient unless different assumptions and different meanings for the same terms are recognized and dealt with in the EHR.

There is little if any experience as yet in using a single EHR across different health paradigms but there are techniques available in the evolving model-based EHR standards to assist in dealing with these difficulties.⁸⁾

8) The use of “folders” within the EHR is one way to segregate different types of EHR content (see ENV 13606-1^[6]); e.g. different folders may be used for acute hospital care, GP care, mental health and “alternative” care practitioners such as herbalists and naturopaths. The use of archetypes for clinical content and distinct domain-specific term sets to underpin the archetypes will also assist in avoiding problems due to different healthcare paradigms within a single EHR (see Beale:2002^[10]).

Despite the challenges and current lack of experience in the use of an EHR across different health paradigms, it is hoped that the evolving EHR standards will be able to accommodate these differences.

5.2 The EHR for different health systems

Differences in national and regional health system models may also result in different types of content in the EHR, although the core clinical content will usually be similar regardless of the health system. Health systems are usually specific to a particular jurisdiction such as a country or region (e.g. state, province, territory). The major differences between health systems usually relate to their funding models, but they also differ in regard to access to the system, types of service available, methods of health delivery and credentialing of health providers. These differences may result in the mandatory collection and inclusion in the EHR of certain types of demographic, insurance, financial and clinical information.

5.3 The EHR for different health sectors, disciplines and settings

The content and granularity of an EHR may vary widely within a given health system between different health disciplines, different health sectors and different health settings, e.g.:

- **health sectors** (e.g. acute hospitals, community clinics, rehabilitation facilities): the information in a hospital record is likely to be of a finer granularity, but narrower in scope, than a primary care record;
- **health disciplines** (e.g. doctor, nurse, physiotherapist, dentist, social worker): the record of a GP or a dentist is generally likely to contain more structured information than the record of, e.g., a psychiatrist or social worker which may tend to contain more narrative free text;
- **health discipline within sector**: the entries in a hospital ICU record will differ in form and content from a general hospital record; individual health discipline records will differ from each other within the health sector;
- **health setting** (e.g. emergency department, office, operating room, battlefield, home); the detail of the patient history (presenting complaint, past medical history, allergies, medications, review of systems etc.) will vary markedly in its components and detail between a health encounter in a hospital outpatient department, on a battlefield and in a home-care setting.

Despite these substantial differences in the type, granularity and amount of structured information recorded, the needs of all health sectors and health disciplines, regardless of the setting, can be accommodated by a single standardized EHR architecture. This will include at a minimum, a standardized logical information model to provide functional interoperability. Varying levels of semantic interoperability can then be added by the use of standardized terminologies, archetypes and templates.

5.4 The temporal context of the EHR

Many definitions of the EHR stress the notion that the EHR is a longitudinal collection of (personal health) information. Unfortunately, the definition of longitudinal in the context of the EHR is not given. However, a further elaboration of the temporal nature of the EHR is given in the definition of the ICEHR (see 2.10) by the statement that it contains information which is:

- a) **retrospective**: a historical view of health status and interventions;
- b) **concurrent**: a “now” view of health status and active interventions;
- c) **prospective**: a future view of planned health activities and interventions.

The “Concise Oxford Dictionary” defines longitudinal as “*involving information about an individual or group over a prolonged period*”. The dictionary defines prolonged as “lengthy” which in turn is defined as “*of considerable or unusual duration*”. Whilst this would usually be interpreted to be a period of months or years in relation to clinical events and the EHR it could be much shorter in some health contexts.

Some definitions of the EHR specify the time period as “lifetime”, “birth to death” (“cradle to grave”) or even “before birth to after death” (“sperm to worm”). Whilst this clearly defines the limits of the EHR and may well be a desirable goal for some form of the EHR, it does not preclude lesser periods of time being regarded as longitudinal and still meeting the criteria of the ISO ICEHR definition. In fact, even a record consisting of a single health encounter could be considered to be longitudinal. An emergency department encounter with a patient may last for many hours and involve the recording of patient information (history, examinations, investigations, treatments, plans) by a number of different health specialities and disciplines. Similarly a 24 h stay in an intensive care unit will often, if not always, involve retrospective, concurrent and future information by the time of discharge from the unit.

The point is that again, the ISO basic-generic EHR definition and its ICEHR specialization, together with a standardized EHR architecture, will cover both extremes of “longitudinal” (a single encounter to a lifetime) and any period of time in between.

5.5 The functional context of the EHR

The phrase “EHR functional requirements” or “EHR functional specification” in fact should relate to EHR systems (see Clause 6) and not to the Electronic Health *Record per se*. The EHR has a variety of purposes, which are discussed in 4.1, but this is different from functions, which are properties of EHR systems that act upon the EHR.

5.6 Context of the EHR in the health information environment

Figure 2 is an attempt to illustrate a notional health information environment.⁹⁾ It can also be understood more broadly as a “landscape” of issue areas or focal points in the area of electronic health information. Most of these areas have one or more standards currently available. One of the big challenges in an integrated health information environment is to make these work together.¹⁰⁾

The diagram should be read from the inside out, starting at the level of a “minimally functional” EHR environment, in which some basic level of patient health information is available, along with terminology, reference data (e.g. generic drug data), patient identification and archetypes. This level corresponds to the scope of the Core EHR.

The next level out, “fully functional”, contains other services which would be expected in a fuller environment, such as at a hospital, including decision support, guidelines and protocols, and mobile computing. Note in particular, that at this level, the notion of the EHR has been extended to include events, workflow, multimedia, and genetic information.

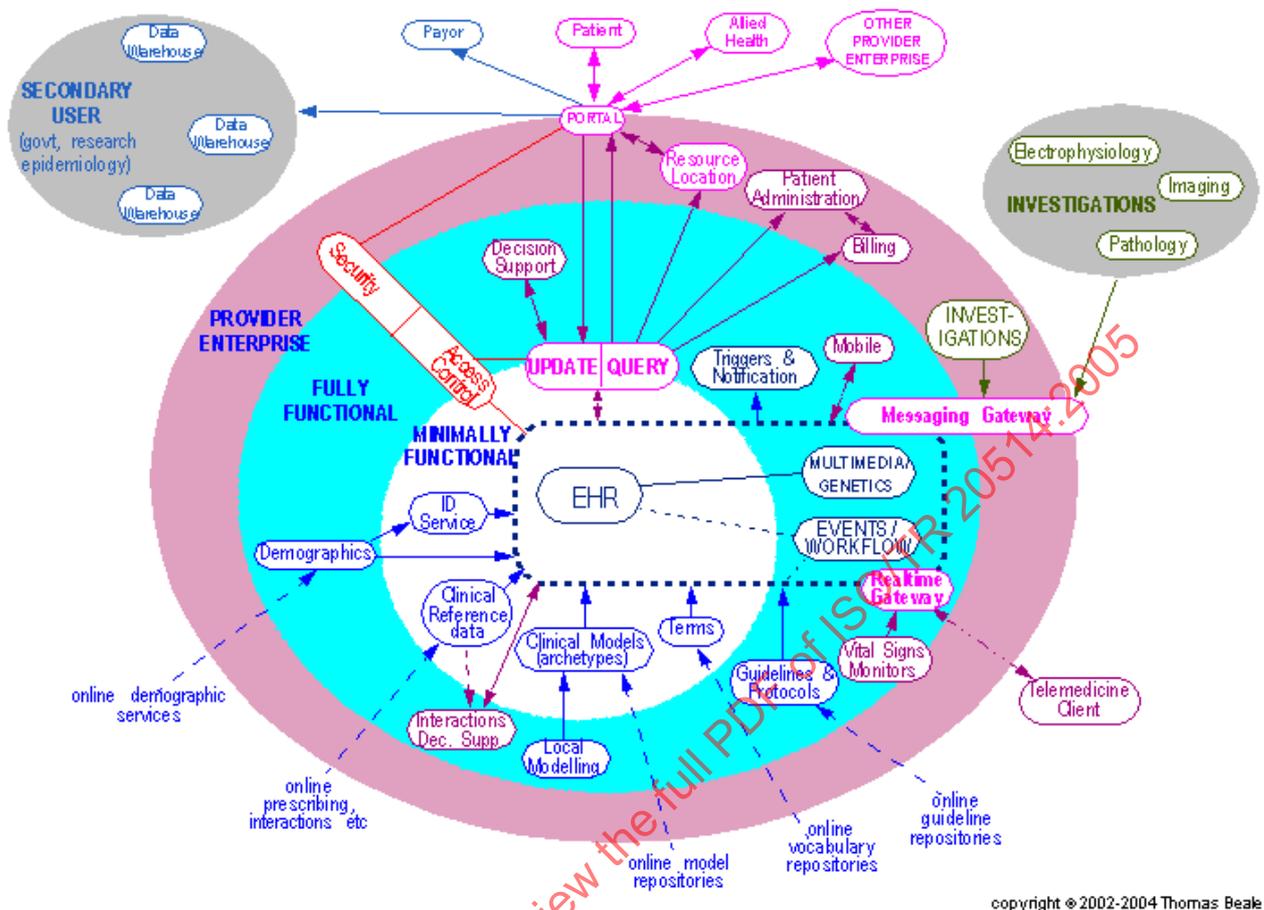
The “provider enterprise” level includes further services typical within provider organizations seen as economic entities, and also as cooperative institutions in a larger network of public or private health information facilities.

Security and access control services appear across all levels of the health information environment, indicating that they provide a level of support appropriate to the other services available at each level.

The scope of the Extended EHR corresponds to the sum of all levels shown in Figure 2.

9) This section is taken from the HIS Manifesto pp3-5 (see Beale:2001^[9]) with permission.

10) A primary inspiration for the separation of interests shown in this document has been Corbamed (see OMG:2004^[17]), now known as OMG HDTF – Health Domain Taskforce; the HDTF standards specify interfaces for many of the areas on the diagram.



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NOTE For details of each of the services in Figure 2, see the HIS Manifesto, pp. 5-8 (see Beale:2001^[9]).

Figure 2 — A health information environment

Figure 2 should not be treated as an accurate software engineering diagram, but as an illustration of the number and diversity of systems used to support the human activities which take place in a health institution. The computer infrastructure can be seen as a whole, or in terms of its parts, most of which can and do operate independently, but which also enable larger scale functions involving more than one system to function. This is the typical characterization of systems that are really a system-of-systems. Another characteristic of the system-of-systems is its ongoing evolution: functions and purposes are added, removed and modified with experience.

6 EHR systems

6.1 Introduction

A detailed discussion of EHR systems is beyond the scope of this Technical Report. However, a formal definition of an EHR system and brief discussion of the major issues of EHR systems directly relevant to the EHR will be given since it is crucial for the purpose of standardization to distinguish clearly between the EHR *per se* (i.e. the record as an entity) and an EHR system.

The key to interoperability between diverse EHR systems is through standardization of requirements for the EHR (record) architecture (e.g. ISO/TS 18308:2004) and ultimately the standardization of the EHR architecture itself (e.g. ENV 13606-1^[6]). As discussed in 3.2, the EHR must be independent of the EHR application software and database technology if widespread interoperability (i.e. vendor independent