

ISO TC 215

Date: 2005-01-22

ISO/TR 20514

ISO TC 215/WG 1

Secretariat: CIHI

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

Informatique de santé — Dossier de santé informatisé — Définition, domaine et contexte

Copyright notice

This ISO document is a Draft International Standard and is copyright-protected by ISO. Except as permitted under the applicable laws of the user's country, neither this ISO draft nor any extract from it may be reproduced, stored in a retrieval system or transmitted in any form or by any means, electronic, photocopying, recording or otherwise, without prior written permission being secured.

Requests for permission to reproduce should be addressed to either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Reproduction may be subject to royalty payments or a licensing agreement.

Violators may be prosecuted.

Contents

Page

Foreword.....	v
Introduction	vi
1 Scope	1
1.1 General.....	1
2 Normative references	1
3 Terms and definitions	1
4 Definition of Electronic Health Record.....	6
4.1 Definitional approach	6
4.2 The key role of interoperability	7
4.3 The basic–generic EHR.....	8
4.3.1 Definition	8
4.3.2 The basic-generic EHR in context	8
4.4 The non-shareable EHR	9
4.5 The shareable EHR	9
4.6 The Integrated Care EHR (ICEHR).....	10
4.6.1 General.....	10
4.6.2 Definition	10
4.6.3 ICEHR in context.....	10
4.7 Other common types of health records	12
4.7.1 General.....	12
4.7.2 Common types of health records.....	12
4.8 The personal health record (PHR)	14
5 Scope of the EHR.....	14
5.1 Purpose of the EHR	15
5.2 The Core EHR.....	16
5.3 The Extended EHR.....	16
5.4 Comparative features of the Extended EHR and Core EHR.....	17
5.4.1 EHR systems functions.....	17
5.4.2 Information, knowledge, and inference.....	17
6 Context of the EHR	18
6.1 The EHR for different health paradigms.....	18
6.2 The EHR for different health systems	19
6.3 The EHR for different health sectors, disciplines, and settings	19
6.4 The temporal context of the EHR	19
6.5 The functional context of the EHR	20
6.6 Context of the EHR in the health information environment	20
7 EHR systems.....	21
7.1 Introduction.....	21
7.2 Survey of EHR system definitions	22
7.2.1 IOM definition	22
7.2.2 CEN definition	22
7.3 Categorisations of EHR systems	22
7.3.1 Local-EHR system	22
7.3.2 Shared-EHR system	23
7.4 EHR directory service system.....	23
7.5 EHR system summary characteristics	24
Annex A (informative) Background to Technical Report	25

Bibliography26

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

In exceptional circumstances, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example), it may decide by a simple majority vote of its participating members to publish a Technical Report. A Technical Report is entirely informative in nature and does not have to be reviewed until the data it provides are considered to be no longer valid or useful.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO/TR 20514 was prepared by Technical Committee ISO/TC 215, *Health informatics*, Working Group 1, *Health records and modelling coordination*.

Introduction

Health informatics – Electronic health record - Definition, scope, and context was prepared 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 maximise interoperability between electronic records and systems that are specifically intended to be shareable, irrespective of the technologies they employ and the platforms they reside on.

However, a variety of health information systems may include features and functionality that could be characterised 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, *Health informatics - Requirements for an electronic health record reference architecture*, irrespective of whether their primary purpose or application is as a shareable EHR.

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

1 Scope

1.1 General

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 Normative references

There are no normative references for this Technical Report. A bibliography is provided at the end of the report.

3 Terms and definitions

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

3.1

archetype, descriptive

a 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]

3.2

archetype, technical

a 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 may themselves have interior complexity.

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

[Beale:2003]

3.3

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]

3.4

client

an 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".

3.5

clinical data repository

CDR

a 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.

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.

[Infoway:2003]

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

3.6

clinician

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

NOTE Adapted from ISO/TS 18308:2004.

3.7

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

[prEN 13606-1:2004]

3.8

computer processable information

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

3.9

consumer

an individual who may become a subject of care

3.10

electronic health record (EHR) - for integrated care (ICEHR)

a repository of information regarding the health status of a subject of care in computer processable form, stored and transmitted securely, and accessible by multiple authorised users. It has a standardised or commonly agreed logical information model which is independent of EHR systems. Its primary purpose is the support of continuing, efficient and quality integrated health care and it contains information which is retrospective, concurrent, and prospective

3.11

electronic health record (EHR) – basic generic form

a 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 3.10 should be considered 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).

3.12

electronic health record architecture

EHRA

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

[ISO/TS 18308:2004]

NOTE A more descriptive informal definition of an EHRA is... 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 which 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]

3.13

EHR extract

the 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 18308:2004.

3.14

EHR node

a physical location where EHRs are stored and maintained

3.15

EHR system

<components> the set of components that form the mechanism by which electronic health records are created, used, stored, and retrieved. It includes people, data, rules and procedures, processing and storage devices, and communication and support facilities

NOTE Adapted from IOM:1991. 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".

3.16

EHR system

<system> a system for recording, retrieving, and manipulating information in electronic health records

NOTE Adapted from ENV 13606-1:2000. 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 document.

3.17

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 Adapted from prEN 13940-1. 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 document.

3.18

functional interoperability

the ability of two or more systems to exchange information

**3.19
health**

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

[WHO:1948]

**3.20
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]

**3.21
health organization**

organisation involved in the direct provision of health activities

NOTE Adapted from prEN 13940-1. 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 document.

**3.22
health problem**

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

**3.23
health professional**

a person who is authorised by a recognised body to be qualified to perform certain health duties

NOTE 1 Adapted from ISO/TS 17090:2001.

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).

**3.24
health provider**

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

NOTE Adapted from prEN 13940-1. 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 document.

**3.25
health record**

a repository of information regarding the health of a subject of care

NOTE Adapted from ENV 13940:2000.

**3.26
health status**

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

**3.27
information service**

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

[prEN 12967:2004]

3.28**integrated care EHR****ICEHR**

See 3.10, electronic health record (EHR) - for integrated care (ICEHR)

3.29**logical information model**

an 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 17119:2004) defines three levels of specificity for information models and other artefacts – 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).

3.30**patient****client**

an individual who is a subject of care

NOTE 1 Adapted from ISO/TS 18308:2004.

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”.

3.31**semantic interoperability**

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

NOTE Adapted from ISO/TS 18308:2004.

3.32**service**

A number of processes, involving an organisation in the provision of specific objectives

[prEN 12967:2004]

NOTE See also the definition an information service at 3.21.

3.33**shareable EHR**

an 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 specialisation of the shareable EHR. The shareable EHR is probably of little use without the additional clinical characteristics which 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 should be noted that the large majority of EHRs in use at present are not even shareable let alone having 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.

**3.34
standard**

a document, established by consensus and approved by a recognised body, that 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 2:1996]

**3.35
subject of care**

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

[ISO/TS 18308:2004]

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 should be noted 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.

**3.36
template**

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

[Beale:2003]

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

4 Definition of Electronic Health Record

4.1 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 (to be 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 must 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 specialised 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 authorised 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 specialisation 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 3 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 which 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 specialisation of the shareable EHR.

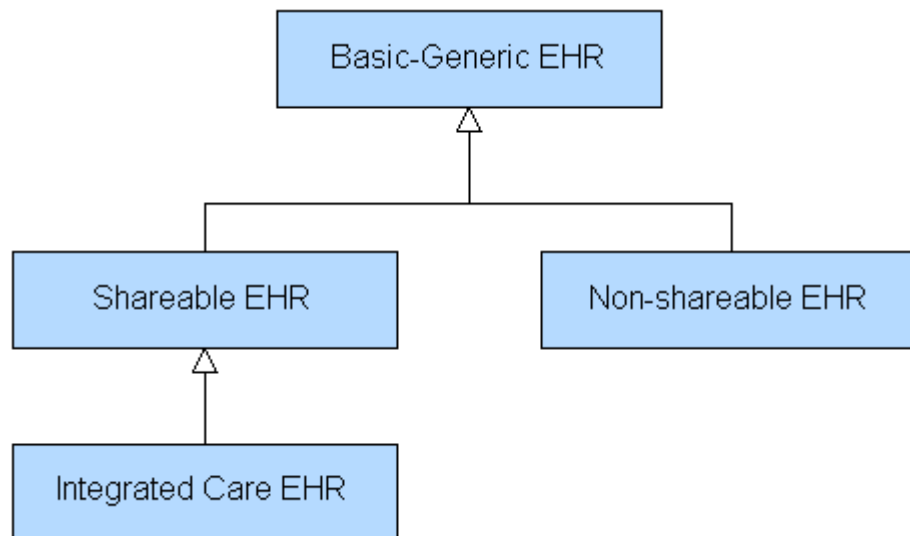


Figure 1 — Specialisation of the Basic-Generic EHR

Note that Figure 1 uses the conventions of object-oriented UML (Unified Modelling Language) diagrams. The unfilled arrows represent a generalisation/specialisation relationship which can be thought of as an “is a kind of” relationship. Thus a Shareable EHR is a specialisation 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 specialisation of (is a kind of) Shareable EHR.

It must be emphasised 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 7.

4.2 The key role of interoperability

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

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

- **functional interoperability** – the ability of two or more systems to exchange information (so that it is human readable by the receiver), and
- **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 will depend 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 standardised EHR reference model**, i.e. the EHR information architecture, between the sender (or sharer) and receiver of the information,
- b) **standardised 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 standardised set of domain-specific concept models**, i.e. archetypes and templates for clinical, demographic, and other domain-specific concepts, and
- d) **standardised terminologies** which underpin the archetypes. Note that this does not mean that there needs to be a single standardised 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 organisations will almost certainly take place in a distributed processing environment. ISO 10746:1998, *Reference model for open distributed processing (RM/ODP)* 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 Clause 6.6, 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 10746:1998, prEN 12967:2004, and openEHR:2003.

4.3 The basic–generic EHR

4.3.1 Definition

The basic–generic definition for the EHR is *a repository of information regarding the health status of a subject of care, in computer processable form.*

4.3.2 The basic-generic EHR in context

4.3.2.1 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.

4.3.2.2 Name of the EHR

It has been noted that in regard to the term "Electronic Health Record", the word "Computerised" 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 are 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.

4.3.2.3 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 13606-1:2000), 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.

4.3.2.4 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 3, 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.

4.4 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 Clause 4.2, 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 organisation. In fact, it is often impossible to share EHR information between different disciplines within a single organisation (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.

4.5 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), and
- 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 Clause 7.3. However, it will also usually contain at least some health summary information such as a problem list, allergies, past medical history, family history, current medications, 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).

4.6 The Integrated Care EHR (ICEHR)

4.6.1 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.

4.6.2 Definition

The Integrated Care EHR (ICEHR) is defined as *a repository of information regarding the health status of a subject of care in computer processable form, stored and transmitted securely, and accessible by multiple authorised users. It has a standardised or commonly agreed logical information model which is independent of EHR systems. Its primary purpose is the support of continuing, efficient and quality integrated health care and it contains information which is retrospective, concurrent, and prospective.*

4.6.3 ICEHR in context

4.6.3.1 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 standardisation 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 standardisation 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 standardised terminologies and the rapid development and standardisation of archetypes and templates.

4.6.3.2 Longitudinal

The term ‘longitudinal’ has deliberately not been included in the definition of ICEHR due to differing views on what it really means (see Clause 6.4). 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.”

4.6.3.3 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 6).

4.6.3.4 Standardised (or commonly agreed) logical information model

The ICEHR definition refers to “a standardised or commonly agreed logical information model.” This is the fundamental characteristic of a shareable EHR. A “standardised” logical information model, produced through the consensus standards development process of national and international standards development organisations 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.

4.6.3.5 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.

4.6.3.6 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 organisations. 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.

4.6.3.7 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, and
- b) accessibility by multiple authorised users (and only by authorised 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 authorised 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 that formal requirements or a specification of a) are not in the scope of this report. Such requirements or specifications are established locally or nationally.

4.7 Other common types of health records

4.7.1 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 organisations, their usage has generally been inconsistent and variable across different countries and health sectors. **They are discussed here for completeness but will not be formally defined in this Technical Report.**

4.7.2 Common types of health records

4.7.2.1 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):

- 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, and
- e) **Electronic healthcare record** – longitudinal collection of personal health information from all sources.

4.7.2.2 Electronic patient record (EPR)

England'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). 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.

4.7.2.3 Computerised patient record (CPR)

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

4.7.2.4 Electronic health care record (EHCR)

The EHCR is a term which was commonly used in Europe, including the CEN 13606 standard, *Health informatics – Electronic healthcare record communication* (see ENV 13606-1:2000). It may be regarded as synonymous with the EHR and EHR is now rapidly replacing the term EHCR in Europe.

4.7.2.5 Electronic client record (ECR)

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

4.7.2.6 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 Clause 7.3.

4.7.2.7 Personal health record (PHR)

This is an important entity and is discussed in the next section.

4.7.2.8 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:2002).

4.7.2.9 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). A CDR is usually organised 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.

4.7.2.10 Computerised medical record (CMR)

A CMR is defined by Waegemann as "a computerised record created by image scanning or optical character recognition (OCR) of a paper-based healthcare record" (see Waegemann:2002).

4.7.2.11 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.

4.7.2.12 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 Clause 3.20 “*a repository of information regarding the health of a subject of care*”. It is true that the definition of subject of care (see Clause 3.29) 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.

4.8 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 standardised 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, or
- d) the same as c) but maintained and controlled completely by the patient/consumer.

5 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 allowable 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 characterise 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.

5.1 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, utilisation 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, and
- **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.

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.

5.2 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 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 the next section.

The proponents of the Core EHR have adopted this view to facilitate standardisation 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 standardised 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 (see ISO/TS 18308:2004).

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.

5.3 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). 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,
- billing,
- decision support,
- access control and policy management,
- demographics,
- order management,
- guidelines,
- terminology,
- population health recording, querying, and analysis,

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

- health professional service recording, querying, and analysis,
- business operations recording, querying, and analysis, and
- 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 all⁶ 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, billing, decision support, etc.

5.4 Comparative features of the Extended EHR and Core EHR

5.4.1 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 standardisation 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 recognise that these types of functions may be just as relevant to Core EHR systems as to Extended EHR systems.

5.4.2 Information, knowledge, and inference

Another perspective on the Core EHR / Extended EHR scope is their relationship to information and knowledge. Rector (see Rector:2001) has described three classes of entities in the EHR environment:

- **knowledge** – statements which 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, billing, 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.

The table below provides a summary of the 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

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 (Beale:2002)

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 standardisation	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

Table 1 — Differences between the Core EHR and Extended EHR

6 Context of the EHR

6.1 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 wellness 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. For example, 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 recognised 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 13606-1:2000). For example 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

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.

6.2 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 services 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.

6.3 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. For example:

- **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, for example, 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 standardised EHR architecture. This will include at a minimum, a standardised logical information model to provide functional interoperability. Varying levels of semantic interoperability can then be added by the use of standardised terminologies, archetypes, and templates.

6.4 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 (*cf* Clause 3.10) by the statement that it contains information which is:

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

term sets to underpin the archetypes will also assist in avoiding problems due to different healthcare paradigms within a single EHR (see Beale:2002).

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 hour 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 specialisation together with a standardised EHR architecture will cover both extremes of “longitudinal” (a single encounter to a lifetime) and any period of time in-between.

6.5 The functional context of the EHR

The phrase “EHR functional requirements” or “EHR functional specification” in fact should relate to EHR systems (see Clause 7) and not to the Electronic Health Record *per se*. The EHR has a variety of purposes, which are discussed in Clause 5.1, but this is different from functions, which are properties of EHR systems which act upon the EHR.

6.6 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.

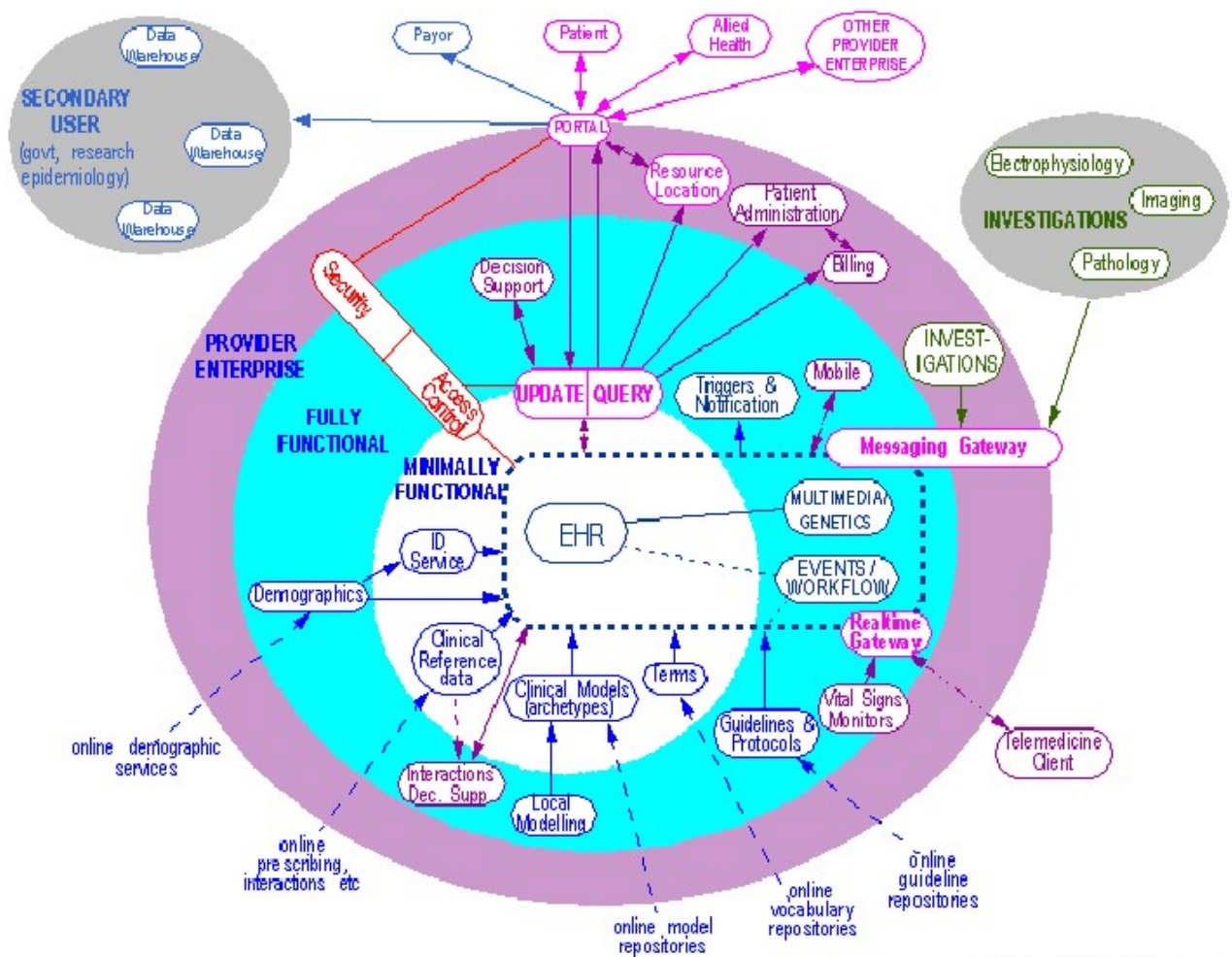
The “provider enterprise” level includes further services typical within provider organisations seen as economic entities, and also as cooperative institutions in a larger network of public or private health information facilities.

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 the diagram.

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

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



copyright © 2002-2004 Thomas Beale

NOTE 1 For details of each of the services in Figure 2, see the HIS Manifesto, pp. 5-8 (see Beale:2001).

NOTE 2 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. This is the typical characterisation 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.

Figure 2 — A health information environment

7 EHR systems

7.1 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 standardisation 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 standardisation of requirements for the EHR (record) architecture (e.g. ISO/TS 18308:2004) and ultimately the standardisation of the EHR

architecture itself (e.g. ENV 13606-1:2000). As discussed in Clause 4.2, the EHR must be independent of the EHR application software and database technology if widespread interoperability (i.e. vendor independent interoperability) and a “future-proof” EHR is to be achieved. This is not to diminish the importance of architectural and functional requirements standards for EHR systems, which will promote the development and implementation of better quality and more usable EHR systems.

7.2 Survey of EHR system definitions

As with the EHR, there have been many different definitions of an EHR system by a variety of different organisations and countries. Two which are very similar and frequently quoted are those of the US Institute of Medicine and the CEN/TC 251 definition from ENV 13606-1. The CEN definition is more concise and includes just the IT components of an EHR system. The IOM definition extends this to include people, procedures, and rules as well as the IT components.

The first definition below is a slight modification of the IOM definition to change the words “patient record” to “electronic health record” to maintain consistency with the terminology used in this Technical Report. The original IOM definition also referred to a CPR (Computer-based Patient Record) system rather than an EHR system. The CEN definition is also modified to change the words “health care” to “health”.

7.2.1 IOM definition

the set of components that form the mechanism by which electronic health records are created, used, stored, and retrieved. It includes people, data, rules and procedures, processing and storage devices, and communication and support facilities. (IOM:1991, modified)

7.2.2 CEN definition

a system for recording, retrieving, and manipulating information in electronic health records. (ENV 13606-1:2000, modified)

7.3 Categorisations of EHR systems

The following sections discuss several different categorisations of EHR systems which may be useful in further contextualising the EHR in terms of the settings in which it is created, stored and used. These systems are given names such as “Local-EHR system” and “Shared-EHR system” but they will not be formally defined in this Technical Report and there may be overlap between these different types. Moreover, the different types of EHR systems do not necessarily imply similarly different types of EHRs used in these systems. For example, an Integrated Care EHR will have its natural ‘home’ in a Shared-EHR system but it may also reside in a Local-EHR system. This could occur where the GP is the custodian of the EHR (e.g. the English NHS) which is maintained on the GP’s Local-EHR system but is nevertheless an ICEHR.

7.3.1 Local-EHR system

The majority of health care for most people is delivered within their local community. This will usually include a preferred primary health provider (e.g. a General Practitioner or Family Physician) together with a range of other community-based health providers (e.g. medical specialists, allied health professionals, “alternative” health practitioners) and health services such as diagnostic services and acute hospital in-patient treatment.

In most health systems, individual health facilities and community-based health providers maintain their own local patient/consumer health records, whether manual or electronic or a combination of both. An important characteristic of these records is that they contain detailed health information on the subject, collected during encounters with that particular health provider. They usually also contain externally sourced material such as diagnostic results and referrals but access to the information in the Local-EHR system is usually restricted to authorised health professionals within the particular facility. It is increasingly common in many countries for the EHR subject of care to also have access to her/his own EHR but the nature and extent of such access (including direct contributions to the EHR by the subject of care) is still very much jurisdiction dependent.

The systems architecture for Local-EHR systems can be highly variable (but still consistent with EHR functional and architectural requirements standards) to meet the needs of different health sectors and health disciplines. The systems architecture of a Local-EHR system for a GP family practice will be quite different from that of a large hospital Local-EHR system or a community nursing Local-EHR system.

7.3.2 Shared-EHR system

A Local-EHR system can support an Integrated Care EHR but the primary purpose of such a system is the care of a patient within a single hospital, clinic, or other health organisation. A Shared-EHR system on the other hand is purpose built to facilitate integrated shared care within a “community of care” and supports sending and receiving of extracts and integrated workflow. The community of care will most often be within a restricted geographic region, typically 10-20 km from the patient/consumer’s home. It will consist of a range of health organisations and clinicians attended by the patient/consumer on a regular or episodic basis. This will typically include one or more primary care clinicians, specialist clinics (e.g. endocrinologist and ophthalmologist for periodic specialist diabetic review, family planning clinic, STD clinic), hospitals, allied health professionals and alternative/complementary practitioners.

Notwithstanding the fact that most people will obtain the majority of their health needs within a local community of care, Shared-EHR systems may have utility beyond local communities to a regional (e.g. state, province) or even national level. In fact state/province-level Shared-EHR systems are already being planned and built in a number of countries.

In some cases, a community of care may not be defined in geographic terms but rather in terms of an organisation. An example of this is the military services whose personnel may travel extensively in the course of their duty. Their community of care may be defined by their service organisation which provides a shared-care community that could extend from their home base to any country in the world during periods of active service.

For the Integrated Care EHR, there are two main Shared-EHR system models which have been proposed:

- **The Federated ICEHR model** in which the Integrated Care EHR is constructed in real time. This may be considered as a “virtual” EHR and may consist of a logical view or physical assembly of two or more EHR extracts “on the fly” from two or more distributed EHR sources. The federated approach is appealing in theory but has many implementation and performance difficulties in practice, particularly for large systems with many records and many different federated EHR sources (or EHR nodes). Successful federated systems rely on a number of factors such as efficient distributed queries, short latencies, and compatible security models and are only as good as the weakest link in the chain.
- **The Consolidated ICEHR model** in which the Integrated Care EHR is put together when it is created and updated, not when it is requested. Contributions to the ICEHR are entered from a Local-EHR source system or by direct entry into the ICEHR, near to the time of the original health event (i.e. usually within hours to a day or so after the event). The consolidated model is not without its own technical difficulties but some important advantages include much simpler access control and security compared to federated systems and the likelihood of a much better price/performance ratio.

Each model has its proponents and there is insufficient implementation experience as yet to know if one model will become a clear “winner” or whether both may co-exist in some form. The consolidated model is already being adopted by several countries with regional and national Shareable EHR projects such as Australia, Brazil, Canada, and the United Kingdom.

7.4 EHR directory service system

The EHR directory service system is really a meta-EHR system which contains no personal health information but rather, a set of links to distributed EHR nodes for particular subjects. This is essentially the same as for any distributed directory service system but there is little or no experience of this in EHR systems to date. The proposed OMG (Object Management Group) specification for a Health Information Locator Service (HILS) could be the basis for an EHR Directory Service and more generic existing directory systems could probably also be used for this purpose.

The main use of such systems will probably be for people travelling beyond their usual community of care, particularly when travelling across state/provincial boundaries within their own country or travelling in other countries.

7.5 EHR system summary characteristics

Table 2 below lists the characteristics which apply to each of the three types of EHR systems described above. It is important to note that these characteristics are indicative only and not necessarily sharply demarcated between the different types of EHR systems. Nevertheless, it is hoped that the table will provide a useful summary of the broad differences between EHR system types.

EHR system type	Local-EHR system	Shared-EHR system	EHR Directory Service
Scope and purpose	Individual local health providers	Local care communities Regional or national	National Trans-national
Type of EHR	Non-shareable EHR ICEHR	ICEHR	Index to ICEHR
Type of data	Detailed local data	Shared data	Meta-data index
Granularity of data	Fine	Coarse (selected or summary data)	N/A
Contributors and access to EHR₁	Local health providers	Local care community or extended community (regional/national)	N/A ₂
Custodian/maintainer	Health Care Facility (Hospital, GP clinic etc)	Local health authority, HMO, GP custodian etc	Public health departments or similar
NOTE 1 Contributors and access control may in each case include the subject of care.			
NOTE 2 Records of health episodes provided beyond the boundary of local or extended care community (e.g. whilst travelling overseas) may be indexed in the home country Directory Service and therefore available for future access by home country users. Alternatively, a copy or summary of the overseas record may be sent to the subject's primary clinician for inclusion in his/her ICEHR.			

Table 2 — EHR system summary characteristics

Annex A (informative)

Background to Technical Report

There has to date been no agreed definition of the EHR at the international level and very few formal EHR definitions even at a national level. ISO/TS 18308, *Health informatics - Requirements for an electronic health record reference architecture* (ISO/TS 18308:2004) lists seven separate definitions for the Electronic Health Record from different countries and organisations around the world. Some of these and other similar definitions do not actually use the term “Electronic Health Record” or its abbreviation “EHR” but rather, a wide range of more or less variant terms such as EMR (Electronic Medical Record), EPR (Electronic Patient Record), CPR (Computerised Patient Record), and EHCR (Electronic Health Care Record).

In August 2001, ISO/TC 215 formed an EHR *ad hoc* Task Group as one of five such groups established to determine the requirements for international standards from specific functional and application viewpoints. The first recommendation in the final report of the EHR *ad hoc* Task Group in July 2002 was that “ISO/TC 215 should develop a comprehensive consensus definition of the EHR” (Schloeffel & Jeselon:2002).

The EHR Definition, Scope and Context work item was initiated in August 2002. There was widespread agreement on the need for this work item, particularly to develop an ISO definition for the EHR, but also to characterise the EHR scope and context. This is desirable in order to clarify and agree the boundaries of the EHR and to facilitate the development of international EHR standards in this area.

An initial draft ISO EHR definition was proposed in a discussion paper written in October 2002 (Schloeffel:2002). This definition was developed by a process of deconstruction and analysis of the seven EHR definitions contained in ISO/TS 18308. The definition was subsequently discussed and agreed in principal at a special project meeting in February 2003. However, at a cross-working group project meeting held in Oslo in May 2003, a diversity of opinion emerged on both the content and the form of definition which should be adopted by ISO. There were essentially two opinion groups. The first group broadly accepted the structure and content of the draft definition from the discussion paper but made many suggestions on further refinements to the wording. The second group questioned the fundamental nature of the draft definition and generally advocated a shorter and more generic definition. Some people in this group also made a strong case for a clear distinction to be made between the content of the EHR and its structure. Others made the point that there are many different purposes and users of EHRs and this needs to be recognised in the definition(s) and scope of the EHR.

A first draft of the Technical Report was produced following the Oslo meeting using the material from that meeting and a number of candidate definitions and supportive material subsequently provided by a selected group of experts. The draft report formed the basis for discussion at a special project meeting held in Sydney in July 2003. The draft contained a concise top-level (later called basic-generic) definition of the EHR and a series of supplementary definitions for a three-level taxonomy of EHRs based on the context of care and the main use of the subject's health information at each level. The basic-generic definition and the notion of supplementary definitions based on some sort of EHR taxonomy was accepted at this meeting.

Three further drafts were produced and discussed at TC 215 meetings in Aarhus (October 2003), Toronto (January 2004), and Washington (May 2004) respectively. The format of each of these meetings was a joint forum involving all TC 215 working groups. This was done because of the strong relevance and interest of this work item beyond its 'home' working group (WG1 Health Records and Modelling Coordination). This was a first for TC 215 and was very successful in achieving the broadest possible range of views and consensus on this important definitional project which affects all areas of health informatics.

Bibliography

- [1] Beale T. 2001. *Health Information Standards Manifesto*. V2.5, December 2001. Available at <http://www.deepthought.com.au/health/HIS_manifesto/his_manifesto.pdf>
- [2] Beale T. 2002. *Archetypes: Constraint-based Domain Models for Future-proof Information Systems*. OOPSLA 2002 Workshop on Behavioural Semantics. October 2002. Available at <www.oceaninformatics.biz/publications/archetypes_new.pdf>
- [3] Beale T. 2003. *A Shared Archetype and Template Language, Part I*. V0.3, May 2003. Available at <http://www.oceaninformatics.biz/publications/archetype_language.doc>
- [4] ENV 13606-1:2000, *Health informatics – Electronic healthcare record communication – Part 1: Extended architecture*. Committee European Normalisation, CEN/TC 251 Health Informatics Technical Committee, available at <<http://www.cen251.org/>>
- [5] ENV 13940:2000, *Health Informatics – System of concepts to support continuity of care*. Committee European Normalisation, CEN/TC 251 Health Informatics Technical Committee, available at <<http://www.cen251.org/>>
- [6] EU-CEN:1997. Comité Européen de Normalisation (CEN). *Proceedings of the second EU-CEN workshop on the electronic healthcare record*. CEN, 1997.
- [7] Infoway:2003. Canada Health Infoway. *EHRs Blueprint -> an interoperable EHR Framework*. V1.0 July 2003, available at <www.infoway-inforoute.ca>
- [8] IOM:1991, Dick R., Steen E. *The Computer-Based Patient Record: An Essential Technology for Health Care*. US National Academy of Sciences, Institute of Medicine, 1991.
- [9] ISO/IEC 10746,1-4:1998, *Information technology – Open distributed processing – Reference model*
- [10] ISO/IEC Guide 2:1996, *Standardisation and related activities – General vocabulary*
- [11] ISO/TR 17119:2004, *Health informatics – Health informatics profiling framework*
- [12] ISO/TS 17090-1:2001, *Health informatics – Public key infrastructure – Part 1: Framework and overview*
- [13] ISO/TS 18308:2004, *Health informatics – Requirements for an electronic health record architecture*
- [14] JAHIS:1996. Japanese Association of Healthcare Information Systems. *Classification of EMR systems*. V1.1, March 1996.
- [15] NHS:1998. NHS Executive. *Information for Health: An Information Strategy for the Modern NHS 1998-2005*. 1998, available at <<http://www.nhsia.nhs.uk/def/pages/info4health/contents.asp>>
- [16] OMG:2004. OMG Health Domain Taskforce (formerly CORBAmed). http://healthcare.omg.org/Healthcare_info.htm.
- [17] OpenEHR:2003. openEHR Foundation. *The openEHR Technical Roadmap*. 2003. <http://www.openehr.org/repositories/spec/latest/publishing/architecture/top.html>.
- [18] prEN 12967,1-3:2004, *Health informatics – Service architecture (HISA)*. Committee European Normalisation, CEN/TC 251 Health Informatics Technical Committee, available at <<http://www.cen251.org/>>

- [19] Rector A. 2001. *The interface between Information, Terminology, and Inference Models*. Proceedings of Medinfo 2001, V Patel et. al. (eds.), Amsterdam: IOS Press, 2001.
- [20] Schloeffel P. 2002. *Electronic Health Record Definition, Scope and Context: ISO/TC 215 Discussion Paper*, October 2002, available at <<https://committees.standards.com.au/COMMITTEES/IT-014-09-02/N0004/IT-014-09-02-N0004.DOC>>
- [21] Schloeffel P., Jeselon P. 2002. *Standards Requirements for the Electronic Health Record and Discharge/Referral Plans*. ISO/TC 215 EHR ad hoc Group, Final Report, July 26 2002, available at <http://secure.cihi.ca/cihiweb/en/downloads/infostand_ihisd_isowg1_finalreportJan03_e.pdf>
- [22] Waegemann P. 2002. *Status Report 2002: Electronic Health Records*. Medical Records Institute, 2002.
- [23] World Health Organisation, 1948. Preamble to the Constitution of the World Health Organization as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.
- [24] Zachman J. 1996. *Enterprise Architecture: The Issue of the Century*. Zachman International, 1996.