ISO/TC 215 Technical Report

Electronic Health Record Definition, Scope, and Context

Second Draft, August 2003

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1 Background

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 "Requirements for an Electronic Health Record Architecture" [ISO 18308, 2003] 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" [EHR AHG, 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. This definition was developed by a process of deconstruction and analysis of the seven EHR definitions contained in ISO/TS 18308 [EHR DSC DP, 2002]. This 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 [ISO/TR EHR DSCv0.1, 2003] was produced following the Oslo meeting using the material from that meeting and a number of candidate definitions and supporting 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 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 top-level definition and the notion of supplementary definitions based on some sort of EHR taxonomy was accepted at this meeting. However, it was agreed that the details of the draft taxonomy needed substantial revision to ensure that the types of EHRs

defined should have clear utility in both the standards and EHR-user domains and should be clearly distinguished from each other. This second draft Technical Report attempts to satisfy these requirements and also includes a new EHR positioning framework.

2 Purposes and scope of this Technical Report

The purpose of this Technical Report is 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 TS18308 – Requirements for an Electronic Health Record Reference Architecture, irrespective of whether their primary purpose or application is as a shareable EHR.

Accordingly, this Technical Report:

- Describes a pragmatic classification of electronic health records;
- Provides simple definitions for each EHR category; and
- Provides supporting descriptions of the characteristics of electronic health records and record systems.

3 Terms and definitions

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

3.1
archetype
1. Descriptive definition
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.

2. Technical definition
a computable expression of a domain-level concept in the form of structured constraint statements, based on some reference information model. Archetypes are one-to-one with domain concepts, which may themselves have interior complexity.

(Beale:2003)

NOTE 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).

3.2
attestation
the process of certifying and recording legal responsibility for a particular unit of information.

(ISO/TS 18308:2003)

3.3
clinician
a healthcare professional who delivers healthcare services directly to a patient/consumer.

(ISO/TS 18308:2003)

3.4
computer processable information
information which can be programmatically created, stored, manipulated, and retrieved in an electronic computer.

3.5
consumer (in relation to healthcare services)
a person requiring, scheduled to receive, receiving or having received a healthcare service.

(ISO/TS 18308:2003)

3.6
Electronic Health Record
EHR
A repository of information regarding the health of a subject of care, in computer processable form.

3.7
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.

(ISO/TS 18308:2003, modified)

3.8
EHR node
a physical location where EHRs are stored and maintained.

3.9
EHR system
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)

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

(ENV 13606-1:2000, modified)

3.10
episode (of care)
identifiable grouping of healthcare related activities characterized by the entity relationship between the subject of care and a healthcare provider, such grouping determined by the healthcare provider.

(ISO/TS 18308:2003)

3.11
functional interoperability
the ability of two or more systems to exchange information.

3.12
healthcare professional
a person who is authorised by a recognised body to be qualified to perform certain health duties.

(ISO/TS 17090:2001, modified)

3.13
health record
a repository of information regarding the health of a subject of care.

(ENV 13606-1:2000, modified)

3.14
Integrated Care EHR
ICEHR
1. Short form definition
a Shareable EHR whose primary purpose is the support of continuing, efficient and quality integrated healthcare. The ICEHR contains information which is retrospective, concurrent and prospective.

NOTE Since this definition is a specialisation of two higher level definitions, it can be re-phrased as an expanded concatenated definition to explicitly include the content of the EHR and SEHR definitions.

2. Long form definition
a repository of information regarding the health of a subject of care in computer processable form, stored and transmitted securely, and accessible by multiple authorised users. The ICEHR has a standardised information model which is independent of EHR systems. Its primary purpose is the support of continuing, efficient and quality integrated healthcare and it contains information which is retrospective, concurrent and prospective.

3.15
patient
an individual person that is a subject of care.

(ISO/TS 18308:2003)

3.16
semantic interoperability
the ability for information shared by systems to be understood at the level of formally defined domain concepts.

(ISO/TS 18308:2003, modified)

3.17
Shareable EHR
SEHR
an EHR with a standardised information model which is independent of EHR systems and accessible by multiple authorised users.

3.18
subject of care
one or more persons scheduled to receive, receiving, or having received a healthcare service.

(ISO/TS 18308:2003)

3.19
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. Templates in general have a one-to-many relationship with underlying concepts, each of which is described by an archetype.

(Beale:2003)

4 Definition of the Electronic Health Record

4.1 Definitional approach

Previous attempts to develop a definition for the Electronic Health Record 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 top-level definition is intentionally concise and generic to ensure the broadest applicability to the widest range of existing and future users of EHRs and EHR systems.

The top-level EHR definition is supplemented by additional definitions to cover two of the most essential characteristics of the EHR not covered by the top-level definition. 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 just two supplementary definitions. 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.

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 section 7.

The first specialisation of the top-level EHR definition is the Shareable EHR (SEHR). The SEHR in turn can be specialised to address the characteristics which are necessary for its use in a longitudinal integrated care setting. This is called the Integrated Care EHR (ICEHR).

The relationship between these types of EHR is shown diagrammatically below.

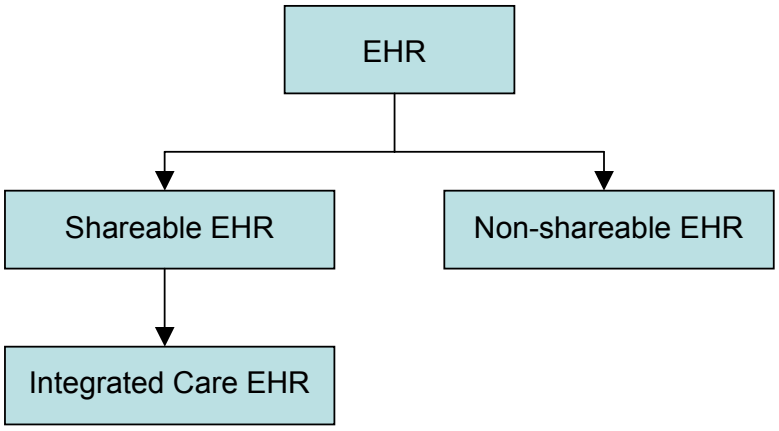

Figure 1 The Shareable and Integrated Care EHRs

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.

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 healthcare 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 tightly bound to the "EHR application").

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 information model EHR should be independent of any particular implementation technology. 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 pre-requisites, with the first two of these also being required for functional interoperability:

1. a standardised EHR Reference Model (i.e. the EHR information architecture) between the sender (or sharer) and receiver of the information;

2. standardised service interface models to provide interoperability between the EHR service and other components such as demographics, terminology, access control and security services in a comprehensive clinical information system;

3. a standardised set of domain-specific concept models - i.e. archetypes and templates for clinical, demographic, and other domain-specific concepts; and

4. standardised terminologies (which underpin the archetypes).

4.3 Top-level EHR definition

The generic top-level definition for the EHR is:

Definition: Electronic Health Record

EHR

A repository of information regarding the health of a subject of care, in computer processable form.

Note:

1. This definition makes no assumptions about the healthcare 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 healthcare sectors, professional healthcare disciplines, and methods of healthcare delivery.

2. 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") [ENV13606-1:2000], 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.

3. The term "subject of care" is used synonymously with "patient" and "consumer" (or "patient/consumer") throughout this Technical Report, depending on the context in which these terms are used. The term "subject" may also be used as an abbreviation for "subject of care".

4. "Subject of care" usually refers to a single individual. However, the definition in section 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 healthcare decisions at the family or other group level).

5. 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.

4.4 The Shareable EHR (SEHR)

The ability to share EHR information is arguably one of the greatest potential benefits of the EHR. The sharing of EHR information can take place at three different levels:

1. Sharing of EHR information between different applications at a single EHR node – i.e. at a particular location where the EHR is stored and maintained.
2. Sharing of EHR information between different clinicians or other users within a single location;
3. Sharing of EHR information across different EHR nodes – i.e. across different EHR locations and/or different EHR systems;

The SEHR 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 §7.2. 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. The SEHR used for level 3 will tend to contain mainly summary information which resides in a Shared-EHR system (§7.4) and is derived from the EHR nodes of two or more Local-EHR systems.

The type and granularity of the SEHR content may be defined by its individual contributors, based on what they think will be useful for shared-care purposes. Alternatively, it may be pre-determined at a community level by some organisation such as a local or regional health authority. This is the model proposed by the Australian Health*Connect* project where the type and granularity of SEHR content will be broadly defined in standardised "Event Summaries" [1] [Health*Connect*:2003]. These will be derived from a variety of source systems including both Local-EHR systems (e.g. in hospitals, GP clinics etc) and non-EHR systems such as results directly from a lab system or direct contributions from the patient/consumer.

The shareable EHR is defined as:

Definition: Shareable EHR (SEHR)
an EHR with a standardised information model which is independent of EHR systems, stored and transmitted securely, and accessible by multiple authorised users using different applications.

The three additional attributes included in this specialisation of the top-level EHR definition are:

[1] An Event Summary in Health*Connect* is defined as "consumer/patient health information derived from a healthcare event that is relevant to the ongoing care of that individual". "Note: The collection of event summaries relating to an individual will constitute their (Health*Connect*) shared electronic health record."

1. a standardised EHR information model – this enables independence from the EHR system;
2. security of the information both when stored and transmitted; and
3. an EHR accessible 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 (eg the subject's agent such as a parent of a child subject) as well as treating clinicians.

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

The main use of the Shareable EHR is likely to be to facilitate the delivery of integrated shared care. A specialisation of the SEHR for this purpose, the Integrated Care EHR (ICEHR) is described below.

4.5 The Integrated Care EHR (ICEHR)

Over the past decade there has been a marked trend towards integrated healthcare 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. Based on these characteristics, the Integrated Care EHR is defined as:

Definition: Integrated Care EHR (ICEHR)
a Shareable EHR whose primary purpose is the support of continuing, efficient and quality integrated healthcare. The ICEHR contains information which is retrospective, concurrent and prospective.

Since this definition is a specialisation of two higher level definitions, it could be re-phrased as an expanded concatenated definition to explicitly include the content of the EHR and SEHR definitions.

Definition (long form): Integrated Care EHR (ICEHR)
a repository of information regarding the health of a subject of care in computer processable form, stored and transmitted securely, and accessible by multiple authorised users. The ICEHR has a standardised information model which is independent of EHR systems. Its primary purpose is the support of continuing, efficient and quality integrated healthcare and it contains information which is retrospective, concurrent and prospective.

Note:

1. 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 healthcare, 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.

2. The word 'longitudinal' has deliberately not been included in this definition due to differing views on what it really means. This is discussed in §6.2. 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. There is no mention in this definition 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, which is discussed in §6.

4.6 Other common types of health records

There are a number of other terms commonly used to describe different type of healthcare 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.

1. Electronic Medical Record (EMR)
   The EMR could be considered as a special case of the EHR or EPR but 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 [JAHIS:1996]:
   1) Departmental EMR – contains a patient's medical information entered by a single hospital department (e.g. Pathology, Radiology, Pharmacy);
   2) Inter-departmental EMR – contains a patient's medical information from two or more hospital departments;
   3) Hospital EMR – contains all or most of a patient's clinical information from a particular hospital;
   4) Inter-hospital EMR – contains a patient's medical information from two or more hospitals;

5) Electronic Healthcare Record – longitudinal collection of personal health information from all sources.

2. Electronic Patient Record (EPR)
   The English 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 healthcare 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. Computerised Patient Record (CPR)
   This term is mainly used in the USA and seems to have a wide range of meanings which may encompass the EMR or EPR.

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" [ENV 13606-1:2000]. It may be regarded as synonymous with the EHR and 'EHR' is now rapidly replacing the term 'EHCR' in Europe.

5. 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 §7.3.

6. Personal Health Record (PHR)
   This is an important entity and is discussed in the next section.

7. 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" [Waegemann:2002].

8. 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 [Waegemann:2002].

9. 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.

The first seven of these variants comply with the top-level EHR definition but the last two do not. The CMR does not comply since whilst it is computer readable, it is not computer processable in the sense defined in §3.4 – i.e. it does not support automatic processing to underpin decision support and other clinical applications.

The Population Health Record does not comply with the ISO EHR definition since it is not a health record, as defined in §3.13 "a repository of information regarding the health of a subject of care". It is true that the definition of "subject of care" (§3.18) 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.

4.7 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 healthcare 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 healthcare 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 SEHR and 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 three different forms:
1. A self-contained EHR, maintained and controlled by the patient/consumer;
2. The same as 1 but maintained by a third party such as a web service provider;
3. A component of a SEHR/ICEHR maintained by a healthcare provider (e.g. a GP) and controlled at least partially (i.e. the PHR component as a minimum) by the patient/consumer;
4. The same as 3 but maintained and controlled completely by the patient/consumer.

5 Scope of the EHR

There are currently two broadly different views of the scope of the EHR[2]. The first of these views has been called the "smallEHR" or "Core EHR" whilst the second has been called the "allEHR" or the "Extended EHR"[3].

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 top-level ISO 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 the ISO/TS 18308 EHR Requirements Technical Specification [ISO/TS 18308:2003].

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 uses 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;
- Research – development and evaluation of new diagnostic modalities, disease prevention measures and treatments, epidemiological studies, population health analysis;

[2] These different views first emerged during review of the draft ISO 18308 EHR Requirements Technical Specification in early 2002 and later in the development of the ISO/TC 215 EHR ad hoc Group report [EHR AHG: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.

[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.

- 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.

5.2 The "Core EHR"[4]

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 healthcare 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 [ISO/TS 18308:2003].

The Core EHR fits much more closely than the Extended EHR with the distributed systems or "systems-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] This section draws heavily from the ideas and writings of Thomas Beale, including the Health Information Standards Manifesto [Beale:2001].

5.3 The "Extended EHR"[5]

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" [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
- Health professional service recording, querying, and analysis
- Business operations recording, querying, and analysis
- Resource allocation

Most if not all of these functions are relevant to the Core EHR and each could form part of a comprehensive health information system.

5.4 Comparative features of the Extended EHR and Core EHR

Active Facilitator EHR vs Passive Repository EHR

The notion of an "Active Facilitator" EHR vs a "Passive Repository" EHR has been proposed in relation to EHR scope [Dickinson:2002a]. The Active Facilitator EHR actively manages the healthcare delivery process and incorporates real-time decision support and other functions such as workflow management, resource management, scheduling, costing etc. The Passive Repository EHR acts as the central data store and accepts multiple information feeds from front-end application systems, each with an EHR fragment [Dickenson:2002a].

The Extended EHR clearly includes the Active Facilitator component. The Core EHR on the other hand, would generally be regarded as a Passive Repository by this definition. However, it should be noted that most of the Active Facilitator functions are related to

[5] The "All EHR" term was coined by Gary Dickenson and much of the information in this and the following section is drawn from his submission on 30 Aug 2002 to the HL7 EHR SIG regarding EHR Definition and Scope [Dickenson:2002a]. Material is also taken from subsequent email commentaries on this document via the HL7 EHR SIG List Serv, from a range of experts including Thomas Beale, David Markwell, Gerard Freriks, and Alan Rector. A further document from Gary addressing these comments was submitted on 20 Sep 2002 [Dickinson:2002b].

applications in an operational clinical information system and are beyond the scope of the record *per se* (*cf*. the definition and characteristics of the EHR vs an EHR system).

It should also be noted that in terms of the Passive Repository status of the EHR, the proposed ISO EHR definition may include almost all[6] of the Extended EHR types of information – provided they can be considered as "personal health information concerning a single individual. Thus, although the scope of the Core EHR has been defined as being predominantly limited to clinical information, the proposed ISO EHR definition does not prevent the inclusion of information related to patient administration, scheduling, billing, decision support etc.

EHR systems functions

The distinction should also 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.

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 which apply to all entities of a class[7]. 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 [Rector:2001].

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.

[6] The exception to this would be population health information since this clearly does not constitute "personal health information concerning a single individual".

[7] The definitions of knowledge and information used here are by Thomas Beale from a paper on knowledge and information which is yet to be published.

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	concerned with both primary and secondary purposes
Relationship to ISO 18308 EHR requirements	defines the scope	many of the Extended EHR requirements beyond the scope of the 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
Active Facilitator EHR vs Passive Repository EHR	Passive Repository	Active Facilitator
Relationship to information and knowledge	contains only information	may contain information and knowledge

Table 2. Differences between the Core EHR and Extended EHR

6 Context of the EHR

6.1 EHR positioning framework

[Insert text from Ken Toyoda]

6.2 The EHR for different healthcare paradigms

Differences in healthcare paradigms or models will likely lead to major differences in EHR content. In "Western" countries, the allopathic or "orthodox" medical model is the dominant healthcare paradigm. However, there are also two other models of Western healthcare, 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 healthcare concept (e.g. "problems" in the medical model and "issues" in the social model). However, differences between Western and non-Western healthcare models are generally greater than those between the three Western models.

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 healthcare from practitioners of more than one healthcare model, sometimes for the same illness. The practitioners of these different healthcare models not only use different terms for the same entity but sometimes also use the same term to mean two quite different things. For example, the concepts of inflammation and elevated calcium have quite different meanings for Western and some alternative/complementary practitioners.

A single EHR, across different healthcare paradigms, could be very beneficial for the holistic care of patients seeking care from practitioners of different healthcare 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 concepts and terms are recognised and dealt with in the EHR.

There is little if any experience as yet in using a single EHR across different healthcare 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. 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 term sets to underpin the archetypes will also assist in avoiding problems due to different healthcare paradigms within a single EHR.

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

6.3 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 healthcare delivery, and credentialing of healthcare service providers. These differences may result in the mandatory collection and inclusion in the EHR of certain types of demographic, insurance, financial, and clinical information.

6.4 The EHR for different healthcare sectors, disciplines, and settings

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

Healthcare 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.

Healthcare disciplines (e.g. doctor, nurse, physiotherapist, dentist, social worker)
The record of a GP or a dentist is likely to contain more structured information than the record of a psychiatrist, psychologist, or social worker which will tend to contain more narrative free text.

Healthcare discipline within sector
The nursing entries in a hospital ICU record will differ in form and content from those of the doctor and the physiotherapist's entries will be different again.

Healthcare 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 healthcare 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 healthcare sectors and healthcare disciplines, regardless of the setting, can be accommodated by a single standardised EHR architecture. This will include at a minimum, a standardised Reference Information Model to provide functional interoperability. Varying levels of semantic interoperability can then be added by the use of standardised terminologies, archetypes, and templates.

6.5 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* §4.5) by the statement that it contains information which is:

1. retrospective: an historical view of health status and interventions;
2. concurrent: a "now" view of health status and active interventions; and
3. 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 COD 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 healthcare 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 healthcare 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 healthcare 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 EHR definition and its SEHR and ICEHR specialisations and a standardised EHR architecture will cover both extremes of "longitudinal" (a single encounter to a lifetime) and any period of time in-between.

6.6 The functional context of the EHR

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

6.7 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

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

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. 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" 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 provider, 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.

For details of each of the services in Figure 2, see the HIS Manifesto, pp5-8 [Beale:2001]. 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 healthcare 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.

[10] A primary inspiration for the separation of interests shown in this document has been Corbamed [OMG HDTF:2003], now known as OMG HDTF - Health Domain Taskforce; the HDTF standards specify interfaces for many of areas on the diagram.

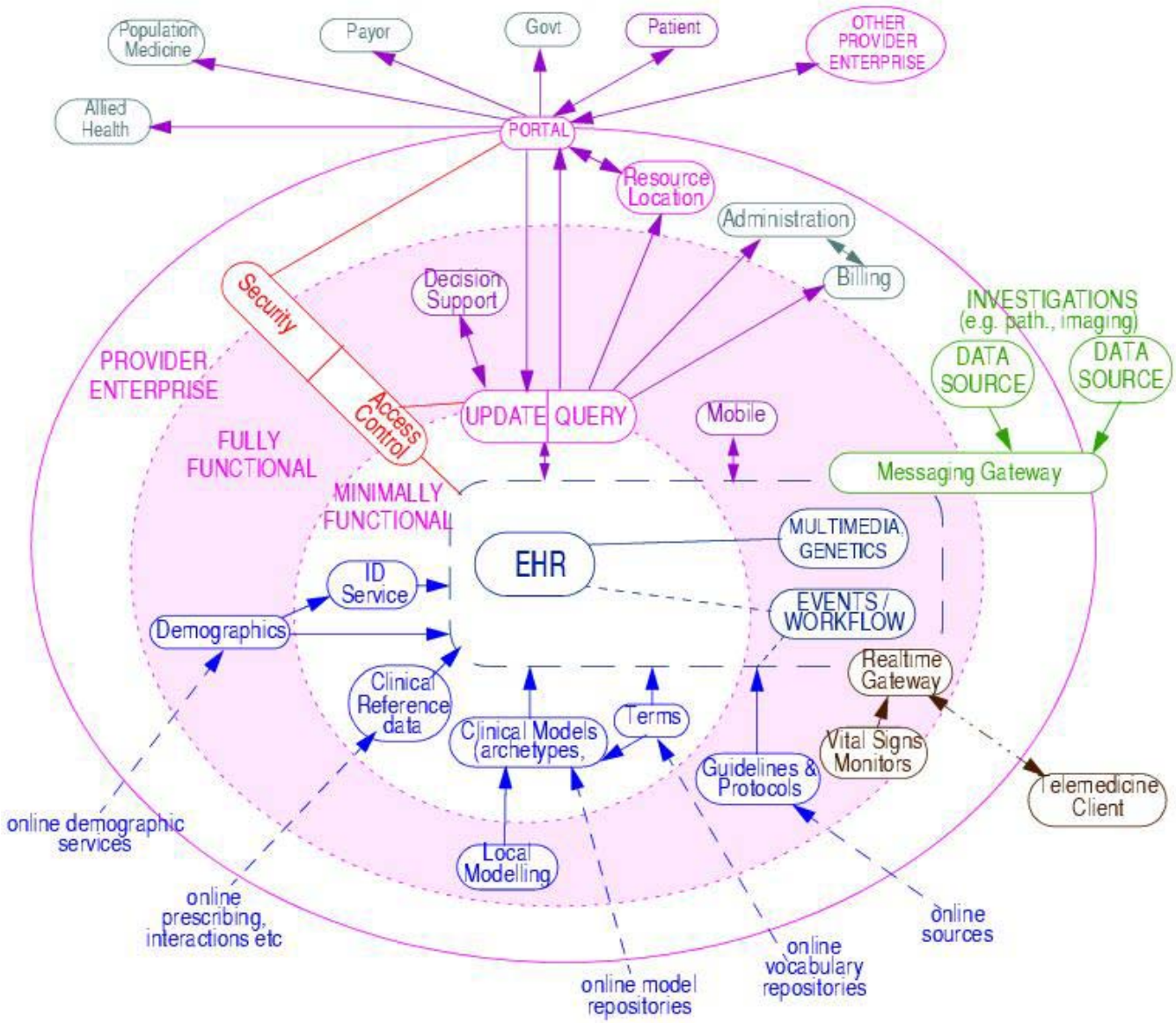

FIGURE 1 A Health Information Environment

7 EHR systems

7.1 EHR system definition

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.

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. The CEN definition is more concise and includes 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 CEN definition is similarly modified to change the word "healthcare" to "health"

Definition: EHR system

1. (IOM:1991, modified)
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.

2. (ENV13606-1, modified)
a system for recording, retrieving, and manipulating information in electronic health records.

The key to interoperability between diverse EHR systems is through standardisation of requirements for the EHR (record) architecture (e.g. ISO 18308 [ISO 18308:2003]) and ultimately the standardisation of the EHR architecture itself (e.g. CEN 13606 [ENV 13606-1:2000]). As discussed in §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.

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 these 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, a Shareable EHR (SEHR) 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 a Shareable EHR.

7.2 Local-EHR system

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

In most health systems, individual healthcare facilities and community-based healthcare providers maintain their own local patient/consumer healthcare records, whether manual or electronic or a combination of both. An important characteristic of these records is that they contain detailed healthcare information on the subject, collected during encounters with that particular healthcare 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 healthcare professionals within the particular facility. It is increasingly common in many countries for the EHR subject 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) is still very much jurisdiction dependent.

The systems architecture for Local-EHR systems can be highly variable (but consistent with EHR functional and architectural requirements standards) to meet the needs of different healthcare sectors and healthcare 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 Shared-EHR system

A Local-EHR system can support a Shareable EHR but the primary purpose of such a system is the care of a patient within a single hospital, clinic, or other healthcare 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 10-20km from the patient/consumer's home. It will consist of a range of healthcare 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, etc), hospitals, allied health professionals and alternative/complementary practitioners.

Notwithstanding the fact that most people will obtain the majority of their healthcare 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 countries such as Australia and Canada and national Shared-EHR systems in Australia, Brazil and several other 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 Shareable EHR, there are two main Shared-EHR system models which have been proposed:

1. The Federated SEHR model in which the Shareable 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.

2. The Consolidated SEHR model in which the Shareable EHR is put together when it is created and updated, not when it is requested. Contributions to the SEHR are entered from a Local-EHR source system or by direct entry into the SEHR, near to the time of the original healthcare 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, and Canada.

7.4 EHR Directory Service system

This 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 there usual community of care, particularly when 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 healthcare providers	Local care communities Regional or national	National Trans-national
Type of EHR	Non-shareable EHR SEHR/ICEHR	SEHR/ICEHR	Index to SEHR or ICEHR
Type of data	Detailed local data	Shared data	Meta-data index
Granularity of data	Fine	Course (summary)	N/A
Contributors and access to EHR*	Local healthcare providers	Local care community or extended community (regional/national)	N/A**
Custodian/maintainer	Health Care Facility (Hospital, GP clinic etc)	Local health authority, HMO, GP custodian etc	Public health departments or similar

Notes:

* Contributors and access control may in each case include the subject of care

** Records of healthcare 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 SEHR/ICEHR.

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