AS ISO 18308—2005

Australian Standard™

Health Informatics—Requirements for an electronic health record architecture (ISO/TS 18308:2004, MOD)

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PREFACE

This Standard was prepared by the Joint Standards Australia/Standards New Zealand Committee IT-014, Health Informatics.

After consultation with stakeholders in both countries, Standards Australia and Standards New Zealand decided to develop this Standard as an Australian Standard rather than an Australian/New Zealand Standard.

The objective of this Standard is to technically specify how to assemble and collate a set of clinical and technical requirements for an electronic health record architecture (EHRA) that supports using, sharing, and exchanging electronic health records across different health sectors, different countries, and different models of healthcare delivery. Requirements for the architecture are given but not the specifications of the architecture itself.

This Standard is an adoption with national modifications and has been reproduced from ISO/TS 18308:2004, *Health informatics — Requirements for an electronic health record architecture*, and has been varied as indicated to take account of Australian conditions.

Variations to ISO/TS 18308:2004 are indicated at the appropriate places throughout this standard. Strikethrough (~~example~~) identifies ISO text, tables and figures which, for the purposes of this Australian Standard, are deleted. Where text, tables or figures are added, each is set in its proper place and identified by shading (example). Added figures are not themselves shaded, but are identified by a shaded border.

As this Standard is reproduced from an International Standard, the following applies:

(a) Its number does not appear on each page of text and its identity is shown only on the cover and title page.

(b) In the source text ‘this international standard’ should read ‘this Australian Standard’.

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The terms ‘normative’ and ‘informative’ are used to define the application of the annex to which they apply. A normative annex is an integral part of a standard, whereas an informative annex is only for information and guidance.

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INTRODUCTION

0.1 Overview

Before building a computer program for an electronic health record (EHR) system (or for any other application) it is imperative to have a clear and detailed set of user and technical requirements. Equally, it is imperative to develop a clear and detailed set of requirements for an EHR architecture for using, sharing, and exchanging electronic health records, independent of the technology used to implement the EHR system. It should also be independent of current organization structures. Many health informatics experts and healthcare professionals believe it should be possible to develop an international standard for a comprehensive and widely applicable architecture for the EHR globally. However, this cannot be achieved until the requirements for such a standard have first been specified and agreed. That is the principal purpose of this Technical Specification.

There has already been a large volume of work done internationally over the past decade on public domain EHR architecture requirements. In very broad terms the requirements for a truly global EHR should ensure that it can be used, shared, and exchanged between clinicians of all disciplines, across all sectors of health, different countries, and different models of healthcare and healthcare delivery. It should also support secondary uses such as research, epidemiology, population health, health administration, financing, and health service policy and planning. Finally, it should facilitate the evolution of existing systems as well as the construction of new systems.

0.2 What is an EHR?

Before defining the EHR architecture, it is first necessary to agree on the meaning and scope of the EHR itself. There is as yet no single ISO definition of the EHR. A number of common definitions for the EHR from a variety of different organizations are listed in Clause 3. These definitions range from very succinct to quite lengthy and encompass a range of somewhat different scopes. This is not surprising since several of these definitions originally referred to the more or less variant names for the EHR including the EHCR (Electronic Health Care Record), EPR (Electronic Patient Record), CPR (Computerized Patient Record), and EMR (Electronic Medical Record). Whilst it is recognised that these terms are sometimes given different shades of meaning in different countries and different health sectors (e.g. the English NHS makes a distinction between the EHR and the EPR), it is intended that the requirements in this Technical Specification will generally apply to all of these variants.

0.3 What is an EHR architecture?

The principal definition of an electronic health record architecture (EHRA) used in this Technical Specification is:

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

A more descriptive definition 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)

Note that the exclusions specified in this definition highlight the ability of an EHR architecture to encompass a variety of different EHR implementations to suit different purposes. For example, the definitions of EHR architecture above make no assumptions about the healthcare system of any country or region. They also make no assumptions about the granularity of information in the record or the temporal nature of the record. A hospital ICU record is an episodic record and is likely to be more granular than a longitudinal primary care record but both should be able to conform to a well constructed EHR architecture, which meets the requirements in this Technical Specification.

The EHR architecture should be broadly applicable to all healthcare sectors, professional healthcare disciplines, and methods of healthcare delivery. A “consumer” or “personal” EHR should be able to conform to the same EHR architecture as a more traditional EHR used by providers such as medical specialists, nurses, general practitioners and providers of allied health services. The same EHR architecture should be applicable to all variants of the EHR, regardless of whether these are called an EMR, EHCR, EPR, CPR, PHR or whatever.

An open standardised EHR architecture is the key to interoperability at the information level. A standardised EHR architecture enables the whole or parts of the EHR to be shared and exchanged between authorized members of a multi-disciplinary care team, including the patient/consumer, independently of any particular EHR system. EHR information conforming to a standardised EHR architecture should be capable of being accepted, processed and presented by an EHR system that uses the EHR architecture irrespective of the source application or the operating system, database, and hardware on which the EHR system depends.

0.4 Methodology for the development of this Technical Specification

The EHR requirements in this Technical Specification are derived from over 30 primary sources which were found by extensive literature search and input from member countries. This initial set of over 700 source requirements was reduced to around 600 by the exclusion of duplicate requirements statements and requirements which clearly related to EHR systems rather than to the record. A hierarchical framework of headings for different types of requirements was developed and successively refined during the project. The final stage of the project was the development of a smaller consolidated set of 123 requirements which encapsulate the larger set of source requirements and which use a consistent format of presentation. Further background on the development methodology is contained in Annex A.

The following sub-sections “Purpose of the EHR” and “Principles underpinning the EHR” have been derived from the EHR requirements source material. The “Purpose of the EHR” is derived principally from GEHR-08, 1994, with some modification. The “Principles underpinning the EHR” is an amalgam of material from several sources of the original requirements. A short list of EHR characteristics from EHR Design Principles (*open*EHR, 2002) is also included. These three sub-sections are included here to provide further context for this Technical Specification in terms of the features and functions of EHR systems that must be supported in defining any EHRA from which such EHR systems will ultimately be developed.

0.5 Purpose of the EHR (GEHR-08, 1994, modified)

The primary purpose of the EHR is to provide a documented record of care which 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/consumer and the clinician(s).

Any other purpose for which the medical record is used is considered secondary, as is any other beneficiary. Much of the content of EHRs is now defined by the secondary purposes, as the information collected for primary purposes was insufficient for many secondary purposes such as billing, policy and planning, statistical analysis, accreditation etc.

The secondary uses of EHRs are:

— 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 — of students of the health professions, patients/consumers, and clinicians.

— Research — development and evaluation of new diagnostic modalities, disease prevention measures and treatments, epidemiological studies, population health analysis.

— Public and population health.

— Policy development — health statistics analysis, trends analysis, casemix analysis.

— Health service management — resource allocation and management, cost management, reports and publications, marketing strategies, enterprise risk management.

— Billing/finance/reimbursement — insurers, government agencies, funding bodies.

NOTE Many of the secondary uses of the EHR may require additional data which are not contained in the EHR.

0.6 Principles underpinning the EHR

The EHR should be timely, reliable, complete, accurate, secure and accessible and designed to support the delivery of healthcare services regardless of the model of healthcare being applied. It should interoperate in a way which is truly global yet respects local customs, language and culture.

The EHR should not be considered applicable only to patients, that is, individuals with the presence of some pathological condition. Rather, the focus should be on individual's health, encompassing both well-being and morbidity.

The EHR recognises that an individual's health data will be distributed over different systems, and in different locations around the world. To achieve the integration of data, the EHR will require the adoption of a common information model by compliant systems and the adoption of relevant international standards wherever possible.

To permit the development of meaningful EHR standards, boundaries must exist to define what is and is not regarded as part of the EHR at the time of standardization.

0.7 Characteristics of the EHR (*open*EHR, 2002)

— the EHR is patient/consumer-centred, and ideally includes information relevant to all kinds of carers, including allied health, and emergency services as well as patients themselves. This is in contrast to provider-centred or purely episodic records;

— the EHR contains observations (what has occurred), opinions (decisions about what should occur), and care plans (plans for what should occur);

— the level of abstraction of the EHR is generalist, that is to say, specialised information such as images, guidelines or decision support algorithms are not typically part of the EHR per se; rather interfaces exist to standards for other, specialised, systems;

— the EHR is a sink of diagnostic and other test data;

— the EHR is a source of clinical information for human carers, decision support, research purposes, governments, statistical bureaux, and other entities;

— the EHR is a long-term accumulator of information about what has happened to or for the patient.

NOTES

STANDARDS AUSTRALIA

Australian Standard

Health Informatics—Requirements for an electronic health record architecture (ISO/TS 18308:2004, MOD)

Any table, figure or text of the international standard that is struck through is not part of this standard. Any Australian table, figure or text that is added is part of this standard and is identified by shading.

1 Scope

The purpose of this Technical Specification is to assemble and collate a set of clinical and technical requirements for an electronic health record architecture (EHRA) that supports using, sharing, and exchanging electronic health records across different health sectors, different countries, and different models of healthcare delivery.

This Technical Specification gives requirements for the architecture but not the specifications of the architecture itself.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

References to international standards that are struck through in this clause are replaced by references to Australian or Australian/New Zealand Standards that are listed immediately thereafter and identified by shading. Any Australian or Australian/New Zealand Standard that is identical to the International Standard it replaces is identified as such.

NOTE In addition to these references cited as sources of the definitions in Clause 3, this Technical Specification contains in the Bibliography a list of references used as inspiration for the formulation of the EHR requirements.

ASTM E 1769-95, *Standard Guide for Properties of Electronic Health Records and Record Systems*

ISO/IEC 2382-8:1998, *Information technology — Vocabulary — Part 8: Security*

ENV 13606-1:2000, *Health informatics — Electronic healthcare record communication — Part 1: Extended architecture*

~~ISO/TS 17090-1:2002, Health informatics — Public key infrastructure — Part 1: Framework and overview~~

AS ISO 17090.1—2003 Health informatics — Public key infrastructure — Part 1: Framework and overview

CPRI:1995, Computer-based Patient Record Institute. Description of the Computer-based Patient Record (CPR) and Computer-based Patient Record System. May 1995

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