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Entwurf

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DIN EN ISO 13606-1:2012-12

**Medizinische Informatik –
Kommunikation von Patientendaten in elektronischer Form –
Teil 1: Referenzmodell (ISO/DIS 13606-1:2017);
Englische Fassung prEN ISO 13606-1:2017**

Health informatics –
Electronic health record communication –
Part 1: Reference model (ISO/DIS 13606-1:2017);
English version prEN ISO 13606-1:2017

Informatique de santé –
Communication du dossier de santé informatisé –
Partie 1: Modèle de référence (ISO/DIS 13606-1:2017);
Version anglaise prEN ISO 13606-1:2017

Anwendungswarnvermerk

Dieser Norm-Entwurf mit Erscheinungsdatum 2017-05-05 wird der Öffentlichkeit zur Prüfung und Stellungnahme vorgelegt.

Weil die beabsichtigte Norm von der vorliegenden Fassung abweichen kann, ist die Anwendung dieses Entwurfs besonders zu vereinbaren.

Stellungnahmen werden erbeten

- vorzugsweise online im Norm-Entwurfs-Portal von DIN unter www.din.de/go/entwuerfe bzw. für Norm-Entwürfe der DKE auch im Norm-Entwurfs-Portal der DKE unter www.entwuerfe.normenbibliothek.de, sofern dort wiedergegeben;
- oder als Datei per E-Mail an named@din.de möglichst in Form einer Tabelle. Die Vorlage dieser Tabelle kann im Internet unter www.din.de/go/stellungnahmen-norm-entwuerfe oder für Stellungnahmen zu Norm-Entwürfen der DKE unter www.dke.de/stellungnahme abgerufen werden;
- oder in Papierform an den DIN-Normenausschuss Medizin (NAMED), 10772 Berlin, Burggrafenstr. 6, 10787 Berlin.

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Gesamtumfang 107 Seiten

DIN-Normenausschuss Medizin (NAMED)

Nationales Vorwort

Dieses Dokument (prEN ISO 13606-1:2017) wurde in der WG 1 „Architecture, Frameworks and Models“ des Technischen Komitees ISO/TC 215 „Health Informatics“ und mit dem Technischen Komitee CEN/TC 251 „Medizinische Informatik“, dessen Sekretariat von NEN (Niederlande) gehalten wird, erarbeitet. Der Arbeitsausschuss NA 063-07-02 AA „Interoperabilität“ des Fachbereichs 7 „Medizinische Informatik“ des DIN-Normenausschusses Medizin (NAMed) hat an der Erarbeitung ebenfalls mitgewirkt.

Dieses Dokument enthält unter Berücksichtigung des Präsidialbeschlusses 1/2004 nur die englische Originalfassung von prEN ISO 13606-1:2017.

Für die in den Normativen Verweisungen zitierten Internationalen Normen wird im Folgenden auf die entsprechenden Deutschen Normen hingewiesen:

ISO 21090	siehe DIN EN ISO 21090
ISO 27789	siehe DIN EN ISO 27789

Änderungen

Gegenüber DIN EN ISO 13606-1:2012-12 wurden folgende Änderungen vorgenommen:

- a) Übernahme der Internationalen Norm;
- b) der Norminhalte wurde mit ISO 13940 *Medizinische Informatik — Begriffssystem zur Unterstützung der Kontinuität der Versorgung* und der Normenreihe ISO 12967 *Medizinische Informatik — Servicearchitektur* und harmonisierte;
- c) die Teile dieser Normenreihe wurden untereinander harmonisiert.

Zusammenfassung

Diese Norm legt fest, wie die elektronische Gesundheitsakte (eGA) von einem identifizierten Behandelten oder mehreren identifizierten Behandelten zwischen eGA-Systemen oder zwischen eGA-Systemen und einem zentralen eGA-Repository vollständig oder teilweise übermittelt werden kann.

Sie kann auch verwendet werden für die eGA-Übermittlung zwischen einem eGA-System oder -Repository und klinischen Anwendungen bzw. Middleware-Komponenten (wie z. B. Entscheidungsunterstützungskomponenten), wenn diese Zugriff auf eGA-Daten benötigen oder diese bereitstellen, oder als Darstellung von eGA-Daten innerhalb eines verteilten (föderierten) Datensatzsystems.

Diese Internationale Norm wird überwiegend zur Unterstützung der direkten Behandlung von identifizierbaren Personen oder zur Unterstützung von Bevölkerungsüberwachungssystemen wie Krankheitsregistern und der öffentlichen Gesundheitsüberwachung verwendet. Die Verwendung von Gesundheitsakten für andere Zwecke wie Lehre, klinisches Audit, Verwaltung und Berichterstattung, Service-Management, Forschung und Epidemiologie, die oft eine Anonymisierung oder Aggregation einzelner Datensätze erfordern, stehen nicht im Mittelpunkt dieser Internationalen Norm, allerdings könnte die Norm bei solchen sekundären Verwendungen ebenfalls nützlich sein.

Dieser Teil 1 der mehrteiligen Serie ist eine Datensicht-Spezifikation, wie sie von der Norm *Informationstechnik — Verteilte Verarbeitung in Offenen Systeme — Referenzmodell: Übersicht* (ISO/IEC 10746-1) festgelegt ist. Diese Internationale Norm hat nicht zum Ziel, die interne Architektur oder das Datenbankdesign von eGA-Systemen zu spezifizieren.

Nationaler Anhang NA (informativ)

Begriffe

Für die Anwendung dieses Dokuments gelten die folgenden Begriffe.

ISO und IEC stellen terminologische Datenbanken für die Verwendung in der Normung unter den folgenden Adressen bereit:

- IEC Electropedia: unter <http://www.electropedia.org/>
- ISO Online browsing platform: unter <http://www.iso.org/obp>

Aktivitäten

3.1

automatisches Medizinprodukt

(en: automatic medical device)

Medizinprodukt, das automatisierte Gesundheitsdienstleistungen durchführen kann

Anmerkung 1 zum Begriff: In EN 13940-1:2007 war das Konzept *Gerät im Gesundheitswesen* eine Spezialisierung des *Handlungsträgers im Gesundheitswesen* und definiert als „Gerät oder Einrichtung, womöglich einschließlich einer Software, das oder die an der Erbringung von *Gesundheitsdienstleistungen* beteiligt ist“.

BEISPIELE Ein spezifisches, identifizierbares Elektrokardiographiegerät, ein elektronisches Blutzuckermessgerät.

3.2

Gesundheitsdienstleistung

(en: healthcare activity)

Dienstleistung, die mit dem Ziel erbracht wird, die *Gesundheit* der betreffenden Person oder Personengruppe direkt oder indirekt zu verbessern

Anmerkung 1 zum Begriff: Jede Spezifizierung dieses Konzepts stellt *Gesundheitsdienstleistungen* dar, die durch eine Spezifizierung des *Handlungsträgers im Gesundheitswesen durchgeführt werden*.

Anmerkung 2 zum Begriff: Verschiedene Arten von *Gesundheitsdienstleistungselementen* (z. B. *Gesundheitsuntersuchung* oder *Gesundheitspflegebehandlung*) können während einer *Gesundheitsdienstleistung* durchgeführt werden.

Anmerkung 3 zum Begriff: Siehe die *Konzepte Gesundheitsdienstleistungen durch Anbieter, gesundheitliche Selbstversorgung, Gesundheitsdienstleistungen durch Dritte* und *automatisierte Gesundheitsdienstleistungen*, wenn es um die Aufzeichnung von *Informationen* geht, die das Ergebnis von *Gesundheitsdienstleistungen* (z. B. ratifizierte Beobachtungen) sind.

BEISPIEL Eine Blutdruckmessung, die von einer qualifizierten Krankenschwester abgeschlossen wurde, einschließlich der *Gesundheitsdienstleistungselemente* der Aufnahme, Dokumentation und Evaluation.

[QUELLE: ISO 13940:2015]

Handlungsträger

3.3

Attestierer

(en: attester)

Handlungsträger (Person), der die rechtliche Verantwortung für eine bestimmte Informationseinheit zertifiziert und aufzeichnet

3.4

Ersteller

(en: committer)

Agent (Partei, Gerät oder Software), dessen direkte Aktivitäten dazu geführt haben, dass Daten in eine elektronische Gesundheitsakte eingestellt wurden

3.5

Verfasser

(en: composer)

Handlungsträger, der für die Erstellung, Synthese oder Organisation von Informationen verantwortlich ist, die in eine elektronische Gesundheitsakte eingestellt wurden.

Anmerkung 1 zum Begriff: Dieser Handlungsträger trägt die Verantwortung für die Aufnahme der Informationen in diese elektronische Gesundheitsakte, auch dann, wenn er nicht deren Urheber ist und sogar dann, wenn er nicht der Ersteller dieser Information(en) ist

3.6

Anbieter von Auszügen einer elektronischen Gesundheitsakte

(en: electronic health record provider)

Handlungsträger im Gesundheitswesen, der rechtmäßig im Besitz von elektronischen Gesundheitsaktendaten und in der Lage ist, diese an eine andere geeignete Funktionseinheit zu übermitteln

3.7

Empfänger von Auszügen einer elektronischen Gesundheitsakte

(en: electronic health record recipient)

Funktionseinheit, an die elektronische Gesundheitsaktendaten von einem Anbieter von Auszügen einer elektronischen Gesundheitsakte übermittelt werden

3.8

Anbieter medizinischer Versorgungsleistungen

(en: healthcare provider)

Zulässige Begriffe: Pflegedienstleister, Gesundheitsversorger, Gesundheitsdienstleister, Dienstleister im Gesundheitswesen

Handlungsträger im Gesundheitswesen, dem ein oder mehrere Pflegezeitmandate zugewiesen werden können

Anmerkung 1 zum Begriff: Das Personal einer *Organisation des Gesundheitswesens*, die *Anbieter medizinischer Versorgungsleistungen* ist, kann sowohl *im Gesundheitswesen tätige, qualifizierte Personen* als auch Andere, die an der Bereitstellung von *medizinischen Versorgungsleistungen* teilnehmen, umfassen.

Anmerkung 2 zum Begriff: Diese Internationale Norm umfasst nur zwei Spezifizierungen von *Anbietern medizinischer Versorgungsleistungen*. Dies soll nicht die Möglichkeit anderer Spezialisierungen ausschließen. In Zuständigkeitsbereichen, in denen andere Arten von *Handlungsträgern im Gesundheitswesen* in das Konzept des *Anbieters medizinischer Versorgungsleistungen* einbezogen sind, können die notwendigen Spezialisierungen hinzugefügt werden.

Anmerkung 3 zum Begriff: Nach dieser Definition sind *Organisationen*, die ausschließlich für die Finanzierung, Bezahlung oder Erstattung von *Gesundheitsleistungen* zuständig sind, keine *Anbieter medizinischer Versorgungsleistungen*; Für die Zwecke dieser Internationalen Norm gelten sie als *Dritte im Bereich Gesundheitswesen*.

[QUELLE: ISO 13940:2015]

3.9

Funktion

(en: role)

Funktion oder Position

[QUELLE: ISO/HL7 21731:2006]

3.10

Behandelter

(en: subject of care)

Zulässige Begriffe: zu Behandelnder, Patient, Klient, Dienstbenutzer

Handlungsträger im Gesundheitswesen mit der persönlichen Funktion, für den Empfang von Gesundheitsdienstleistungen vorgesehen zu sein, diese zu erhalten oder diese bereits erhalten zu haben

Anmerkung 1 zum Begriff: Ein Fötus kann als *Behandelter* angesehen werden, wenn er *Gesundheitsdienstleistungen* erhält.

BEISPIELE Ein behandelter Patient, ein Klient eines Physiotherapeuten, jedes einzelne Mitglied einer Zielgruppe einer Vorsorgeuntersuchung, jedes einzelne Mitglied einer Gruppe von Diabetikern, die an einer Sitzung zur medizinischen Aufklärung teilnehmen, eine *Person*, die eine Gesundheitsberatung wünscht.

[QUELLE: ISO 13940:2015]

Konzepte und Begriffe

3.11

Generisch

(en: generic)

anwendbar auf Anforderungen oder Informationsmodelle in allen Gesundheitsberufen, Domänen und Ländern

Informationsmanagement

3.12

abstrakte Klasse

(en: abstract class)

eine Klasse, die nicht selbst instanziiert werden kann

[QUELLE: ISO/IEC/IEEE 24765:2010]

3.13

Archetyp

(en: archetype)

Instanz eines *Archetypenmodells*, die das klinische Konzept und die wertebezogenen Einschränkungen spezifiziert, die für eine Klasse von Instanzen von Aufzeichnungskomponenten in einem Auszug aus der elektronischen Gesundheitsakte gilt

3.14

Archetypenmodell

(en: archetype model)

Informationsmodell der Metadaten zur Darstellung der wertebereichsspezifischen Merkmale von Einträgen in der elektronischen Gesundheitsakte durch Festlegung von Werten oder wertebezogenen Einschränkungen für Klassen und Attribute im Referenzmodell der elektronischen Gesundheitsakte

3.15

Daten verwendende Anwendung

(en: client application)

Gesundheitsversorgungsanwendung, die sich im gegebenen Moment wie ein Anforderer von Gesundheitsaktendaten aus einer gemeinsamen *elektronischen Gesundheitsakte* verhält

3.16

übermittelte Information

(en: committed information)

Informationen, die in einem elektronischen Gesundheitsaktensystem persistent sind und die einen Teil der elektronischen Gesundheitsakte eines Behandelten darstellen

3.17

Daten

(en: data)

rückübertragbare, formalisierte Darstellung von Informationen, die für deren Übermittlung, Auswertung oder Weiterverarbeitung geeignet ist

Anmerkung 1 zum Begriff: Daten werden ohne jeglichen Kontext so definiert, dass man von selbst ihre korrekte Bedeutung nicht erschließen kann, und da wo dies möglich ist, handelt es sich um eine Information.

[QUELLE ISO/IEC 2382 1:1993, 01-01.02]

3.18

Datenbehälter

(en: data repository)

identifizierbare Einrichtung zur Speicherung von Daten (3.9.1)

Anmerkung 1 zum Begriff: In ISO 10303 22:1998 ist dies die Definition zur englischen Benennung „repository“

[QUELLE: ISO 13940:2015]

3.20

Gesundheitsdaten

(en: healthcare data)

im Rahmen von Gesundheitsdienstleistungen erhobene Daten

[QUELLE: ISO 13940:2015]

3.21

Gesundheitsinformationen

(en: healthcare information)

Informationen über eine Person, die für deren Gesundheitsversorgung von Bedeutung sind

[QUELLE: ISO 13940:2015]

3.22

Information

(en: information)

Kenntnisse über Objekte, die in einem gegebenen Zusammenhang eine bestimmte Bedeutung haben

Anmerkung 1 zum Begriff: Sachverhalte, Ereignisse, Gegenstände, Prozesse oder Ideen, einschließlich Konzepten, stellen Beispiele für Objekte dar.

Anmerkung 2 zum Begriff: Information ist etwas, das aussagekräftig ist. Daten können als Information betrachtet werden, sobald ihre Bedeutung zum Vorschein kommt.

[QUELLE ISO/IEC 2382-1:1993, 01.01.01 – modifiziert]

3.23

verteilte Datenverarbeitung

(en: distributed processing)

Informationsverarbeitung, bei der sich diskrete Komponenten an verschiedenen Orten befinden können oder bei der die Kommunikation zwischen Komponenten verzögert oder unterbrochen sein kann

[QUELLE: ISO/IEC 10746-2:2009]

3.24

Gesundheitsakt

(en: health record)

Datenbehälter in Bezug auf die Gesundheit und die Gesundheitsversorgung eines Behandelten

Anmerkung 1 zum Begriff: Der Begriff *elektronische Gesundheitsakte* kann verwendet werden, wenn alle *Informationen* der *Gesundheitsakte* in elektronischen Medien gespeichert sind. Allerdings ist dieses Konzept in dieser Internationalen Norm nicht formal definiert.

Anmerkung 2 zum Begriff: Eine *Gesundheitsakte* kann zum Beispiel medizinische Aufzeichnungen, zahnärztliche Aufzeichnungen und Sozialpflegeaufzeichnungen enthalten.

[QUELLE: ISO 13940:2015]

3.25

Gesundheitsaktenbestandteil

(en: health record component)

Teil einer *Gesundheitsakte*, der für Referenz- und Revisionszwecke identifiziert werden kann

Anmerkung 1 zum Begriff: Diese Internationale Norm definiert eine Spezialisierung von *Gesundheitsaktenbestandteilen*, der *elektronische Aktenbestandteil*. Da jedoch der Inhalt einer *Gesundheitsakte* nicht auf *Informationen* in elektronischer Form beschränkt ist, kann der Inhalt von *Gesundheitsaktenbestandteilen* auch in anderen als in elektronischen Formaten vorliegen.

Anmerkung 2 zum Begriff: Ein *Gesundheitsaktenbestandteil* kann selbst aus einer Aggregation mehrerer *Gesundheitsaktenbestandteile* resultieren.

[QUELLE: ISO 13940:2015]

3.26

elektronische Gesundheitsakte

(en: electronic health record)

Gesundheitsakte, bei der alle *Informationen* in elektronischen Medien gespeichert sind

3.27

elektronisches Gesundheitsaktensystem

(en: electronic health record system)

System zum Aufzeichnen, Abrufen und Handhaben von Informationen in elektronischen Gesundheitsakten

[ISO 18308:2011]

3.28

Auszug aus der Gesundheitsakte

(en: health record extract)

Teil- oder Vollauszug aus einer *Gesundheitsakte* für den Zweck der Übermittlung

[QUELLE: ISO 13940:2015]

Gesundheitsversorgungsanwendung

(en: healthcare application)

System zum Sammeln, Speichern, Aufbereiten und Präsentieren von Gesundheitsinformationen mithilfe eines Computers.

ANMERKUNG 1 zum Begriff: Diese Definition basiert auf der Definition von „Anwendung“ in ISO/IEC 19770-5:2015

3.29

Informationsarchitektur

(en: information architecture)

Strukturelles Design eines Informationsraums zur Erleichterung der Aufgabenvervollständigung und zum intuitiven Zugriff auf Inhalte

3.30

Metadaten

(en: metadata)

Daten, die die Objektklasse und die Eigenschaften der erfassten Informationen definieren

[QUELLE: ISO/IEC 11179-3:2003]

3.31

semantische Interoperabilität

(en: semantic interoperability)

Fähigkeit der von mehreren Systemen gemeinsam genutzten Daten, auf der Ebene vollständig definierter Domain-Begriffe verstanden zu werden

[QUELLE: ISO 18308:2011]

3.32

Ansicht

(en: view)

ersatzweise Darstellung von Daten für einen anderen Benutzer oder Zweck

Privatsphäre und Sicherheit

3.33

Zugriffskontrolle

(en: access control)

Mittel zur Sicherstellung, dass nur autorisierte Entitäten in entsprechend autorisierter Weise Zugriff auf die Ressourcen eines Datenverarbeitungssystems nehmen können

[QUELLE: ISO 17090-1:2013]

3.34

Audit-Trail

(en: audit trail)

Sammlung von Auditeinträgen aus einem oder mehreren Auditprotokollen, die sich auf eine bestimmte behandelte Person oder eine bestimmte elektronische Gesundheitsakte beziehen

[QUELLE: ISO 27789:2013]

3.35

Authentifizierung

(en: authentication)

Beibringung eines Belegs für die von einer Entität behauptete Identität durch die sichere Verbindung eines Identifikators und seines Authentifikators

[QUELLE: ISO 22600-3:2014]

3.36

Autorisierung

(en: authorisation)

Gewährung von Privilegien

[ISO 22600-1:2014]

3.37

Vertraulichkeit

(en: confidentiality)

Eigenschaft, dass Informationen für nicht autorisierte Einheiten nicht zugänglich gemacht werden

[QUELLE: ISO 7498-2:1989]

3.38

Digitale Signatur

(en: digital signature)

an eine Dateneinheit angefügte Daten oder eine kryptografische Transformation einer Dateneinheit, mit der ein Empfänger der Dateneinheit die Möglichkeit der Überprüfung der Quelle und Integrität der Dateneinheit erhält und die einen Schutz gegen Fälschung z. B durch den Empfänger bietet

[QUELLE: ISO 7498-2:1989]

3.39

Privatsphäre

(en: privacy)

Verhinderung des Eindringens in das Privatleben oder die Angelegenheiten einer Person, sofern dieses Eindringen aus der unzulässigen oder illegalen Erfassung und Nutzung von Daten über diese Person resultiert

[QUELLE: ISO/IEC 2382-8:1998]

Prozessmanagement

3.40

Attestierung

(en: attestation)

Prozess der Zertifizierung und Aufzeichnung der rechtlichen Verantwortung für eine bestimmte Informationseinheit

3.41

Gesundheitsversorgungsprozess

Versorgungsprozess

(en: healthcare process)

Satz zusammenhängender und sich gegenseitig beeinflussender Gesundheitsdienstleistungen, die Eingaben in Ergebnisse umwandeln

Anmerkung 1 zum Begriff: Der wichtigste Typ eines Gesundheitsprozesses ist der klinische Prozess, der einen Gesundheitszustand als Eingabe und Ergebnis hat und alle Aktivitäten in Bezug auf ein oder mehrere spezifizierte Gesundheitsprobleme umfasst.

Anmerkung 2 zum Begriff: Ein Gesundheitsprozess ist nicht per Definition auf einen Anbieter medizinischer Versorgungsleistungen oder jegliche andere Organisationsgrenzen beschränkt.

[QUELLE: ISO 13940:2015]

Nationaler Anhang NB (informativ)

Literaturhinweise

DIN EN ISO 12090, *Medizinische Informatik — Harmonisierte Datentypen für den Datenaustausch im Gesundheitswesen (ISO 21090:2011)*; Englische Fassung EN ISO 21090:2011, nur auf CD-ROM

DIN EN ISO 27789, *Medizinische Informatik — Audit-Trails für elektronische Gesundheitsakten (ISO 27789:2013)*; Deutsche Fassung EN ISO 27789:2013

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C.0 Cross-Domain Interoperability94

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2. www.iso.org/directives

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For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/TC 215.

0 Introduction (Informative)

0.1 Preface

The overall goal of this Standard is to define a rigorous and stable information architecture for communicating part or all of the Electronic Health Record (EHR) of a single subject of care (patient), or for a group of patients whose information might need to be communicated together (for example, a family). This is to support the interoperability of systems and components that need to communicate (access, transfer, add or modify) EHR data:

- preserving the original clinical meaning intended by the author;
- incorporating the necessary provenance metadata to inform the recipient or receiving system about the context in which the EHR data were obtained and composed;
- observing and communicating the confidentiality of that data as intended by the author and subject of care.

This Standard considers the EHR to be the persistent longitudinal and potentially multi-organisation or multi-national record of health and care provision, most often relating to a single subject of care (the patient), created and stored in one or more physical systems in order to inform each subject's future healthcare and to provide a medico-legal record of care that has been provided. This corresponds to the definition provided in ISO 18308:2011 (Requirements for an Electronic Health Record Architecture).

This Standard is not intended to specify the internal architecture or database design of EHR systems or components, nor is it intended to prescribe the kinds of clinical applications that might request or contribute EHR data in particular settings, domains or specialities. For this reason, the information model proposed here is called the EHR Extract, and might be used to define a message, an XML document or schema, or an object interface. These might be used to communicate EHR data between two repositories, to update a centralised regional or national EHR repository, or within a distributed network of EHR components, systems and services. Whilst an EHR service or system will need to interact with many other services or systems providing terminology, medical knowledge, guidelines, workflow, security, persons registries, billing etc. this Standard has only touched on those areas if some persistent trace of such interactions is required in the EHR itself, and requires specific features in the reference model to allow their communication.

This Standard may offer a practical and useful contribution to the design of EHR systems but will primarily be realised as a common set of external interfaces or messages built on otherwise heterogeneous clinical systems. The components that might support an interface conforming to this Standard will be not only electronic health record systems but also other middleware services such as security components, guideline and workflow systems, alerting and decision support services, personal health systems and applications, sensors and wearable devices, and medical knowledge management services. This standard might also prove useful for communicating data about individuals between electronic health record systems and population registries, and also for conducting (approved) research using electronic health records.

This Standard, EN ISO 13606 Part 1, is part of a five-part standard series, published jointly by CEN and ISO through the Vienna Agreement. These five parts are as follows.

Part 1: Reference Model. An information model, represented in UML, that may be used to communicate the content and context of any possible electronic health record information, for part or all of a person's electronic health record, or potentially for a set of persons such as a family. This model supports

communication between distinct electronic health record repositories or may act as the information model underpinning a federation, such as a regional, national or multi-national network of interconnected repositories of EHR data.

Part 2: Archetype Interchange Specification. An information model represented in UML, accompanied by requirements, for the representation of clinical models which specify how individual areas of healthcare information should be represented using the reference model of part 1.

Part 3: Reference Archetypes and Term Lists. A set of high-level archetype patterns that may be used (specialised) to develop specific archetypes covering commonly needed areas of healthcare and demographic information. This part standard also includes a set of vocabularies (term lists) to populate properties of the information models included in other parts of this overall standard.

Part 4: Security. A vocabulary framework, and a more detailed generic representation for policy information, to communicate the access permissions covering the EHR content that is being communicated according to this standard. This part standard additionally contains an interoperable specification for audit log information that could inform a subject of care about who has accessed their health record.

Part 5: Interchange Specification. The information properties that should be included within interfaces that implement communication according to the other parts of this standard.

In this part standard dependency upon any of the other parts of this series is explicitly stated where it applies.

0.2 Technical approach

This Standard is the second version of an original standard which was published in 2007 by CEN, and in 2008 by ISO. This revision has taken into account the experiences gained by EHR system developers and by large scale eHealth programmes from using the original standard. These were ascertained through an international survey, a wide range of 1:1 interviews, a review of the academic literature, and interactions with many experts active in R&D relating to the EHR. It also meets the relevant requirements in ISO 18308:2011 (Requirements for an Electronic Health Record Architecture). The revision has taken into account, and aligns as far as possible, with other CEN and ISO Standards and Technical Specifications with which this standard might also be used, with international terminology standards and with emerging standards from HL7: Fast Healthcare Interoperability Resources (FHIR). The specifications in this International Standard have drawn from, and align as far as possible with, the reference model specifications published by the openEHR Foundation, and with the archetype models published by the openEHR Foundation and by the Clinical Information Modeling Initiative (CIMI).

The information model in this Standard is an Information Viewpoint of the ISO Reference Model for Open Distributed Processing (ISO/IEC 10746-1:1998).

Given the diversity of deployed EHR systems, this Standard has made most features of EHR communication optional rather than mandatory. However, some degree of prescription is required to make EHR Extracts safely processable by an EHR recipient system, which is reflected through mandatory properties within the models in Parts 1, 2, and 4 of this series, and through normative term lists (defined in Part 3 of this series).

0.3 The Dual Model approach

The challenge for EHR interoperability is to devise a generalised approach to representing every conceivable kind of health record data structure in a consistent way. This needs to cater for records arising from any profession, speciality or service, whilst recognising that the healthcare data sets, value sets, templates etc. required by different healthcare domains will be diverse, complex and will change frequently as clinical practice and medical knowledge advance. This requirement is part of the widely acknowledged health informatics challenge of semantic interoperability.

The approach adopted by this Standard distinguishes a Reference Model, defined in Part 1 of this International Standard and used to represent the generic properties of health record information, and Archetypes (conforming to an Archetype Model, defined in Part 2 of this series), which are meta-data used to define patterns for the specific characteristics of the healthcare data that represents the requirements of each particular profession, speciality or service.

The Reference Model represents the global characteristics of health record components, how they are aggregated, and the context information required to meet ethical, legal and provenance requirements. This model defines the set of classes that form the generic building blocks of the EHR. It reflects the stable characteristics of an electronic health record, and would be embedded in a distributed (federated) EHR environment as specific messages or interfaces (as specified in Part 5 of this series).

This generic information model needs to be complemented by a formal method of communicating and sharing the organisational structure of predefined classes of EHR fragment corresponding to sets of record components made in particular clinical situations. These are effectively pre-coordinated combinations of named RECORD_COMPONENT hierarchies that are agreed within a community in order to ensure interoperability, data consistency and data quality.

An Archetype is the formal definition of prescribed combinations of the building-block classes defined in the Reference Model for particular clinical domains or organisations. An archetype is a formal expression of a distinct, domain-level concept, expressed in the form of constraints on data whose instances conform to the reference model. For an EHR_EXTRACT, as defined in this Standard, an archetype instance specifies (and effectively constrains) a particular hierarchy of RECORD_COMPONENT sub-classes, defining or constraining their names and other relevant attribute values, optionality and multiplicity at any point in the hierarchy, the data types and value ranges that ELEMENT data values may take, and other constraints.

This Standard recognises that archetypes (or equivalent clinical models) are not always directly incorporated within the present day architectures of electronic health record systems. This standard therefore does not mandate that archetypes are used within such systems. It does, however, require that the clinical information models or equivalents (data items, data item aggregations, data value constraints, terminology bindings, units of measure etc.) that have been used to generate an EHR_EXTRACT are themselves created and communicated, or referenced, within each EHR_EXTRACT. These communicated or referenced archetypes must conform to Part 2 of this Standard, and maybe communicated through an interface conforming to part 5 of this Standard..

0.4 Overview of the EHR_EXTRACT record hierarchy

The information in a health record is inherently hierarchical. Clinical observations, reasoning and intentions can have a simple or a more complex structure. They are generally organised under headings, and contained in “documents” such as consultation notes, letters and reports. These

documents are usually filed in folders, and a subject of care may have more than one folder within a healthcare enterprise (e.g. medical, nursing, obstetric).

The EHR Communications Reference Model needs to reflect this hierarchical structure and organisation, meeting published requirements in order to be faithful to the original clinical context and to ensure meaning is preserved when records are communicated between heterogeneous clinical systems. To do this, the model formally sub-divides the EHR hierarchy into parts that have been found to provide a consistent mapping to the ways which individual EHRs are organised within heterogeneous EHR systems.

These parts are summarised in Table 1 below

Table 1 — Main hierarchy components of the EHR Extract Reference Model

EHR HIERARCHY COMPONENT	DESCRIPTION	EXAMPLES
EHR_EXTRACT	The top-level container of part or all of the EHR of a single subject of care or for a group of subjects of care (such as a family), for communication between an EHR Provider system and an EHR Recipient.	(Not applicable)
FOLDER	The high level organisation within an EHR, dividing it into compartments relating to care provided to a single subject of care, for a single condition, by a clinical team or institution, or over a fixed time period such as an episode of care.	Diabetes care, Schizophrenia, Cholecystectomy, Paediatrics, St Mungo's Hospital, GP Folder, Episodes 2000-2001.
COMPOSITION	The set of information committed to one EHR by one agent, as a result of a single clinical encounter or record documentation session.	Progress note, Laboratory test result form, Radiology report, Referral letter, Clinic visit, Clinic letter, Discharge summary, Functional health assessment, Diabetes review.
SECTION	EHR data within a COMPOSITION that belongs under one clinical heading, usually reflecting the flow of information gathering during a clinical encounter, or structured for the benefit of future human readership.	Reason for encounter, Past history, Family history, Allergy information, Subjective symptoms, Objective findings, Analysis, Plan, Treatment, Diet, Posture, Abdominal examination, Retinal examination.
ENTRY	The information recorded in an EHR as a result of one clinical action, one observation, one clinical interpretation, or an intention. This is also known as a clinical statement.	A symptom, an observation, one test result, a prescribed drug, an allergy reaction, a diagnosis, a differential diagnosis, a differential white cell count, blood pressure measurement.
CLUSTER	The means of organising nested multi-part data structures such as time series, and to represent the columns of a table.	Audiogram results, electro-encephalogram interpretation, weighted differential diagnoses.
ELEMENT	The leaf node of the EHR hierarchy, containing a single data value.	Systolic blood pressure, heart rate, drug name, symptom, body weight.

An EHR_EXTRACT contains EHR data as COMPOSITIONs, organised in a FOLDER hierarchy.

COMPOSITIONs contain ENTRYs, optionally contained within a SECTION hierarchy.

ENTRYs contain ELEMENTs, optionally contained within a CLUSTER hierarchy.

Representing participation: The Reference Model in the previous version of this standard provided explicit classes at certain parts of the Record Component hierarchy through which it was possible to represent the identity and roles played by actors contributing to healthcare and to its documentation. In this version of the Reference Model the LINK class is intended to be used to reference demographic entities. The roles played by these entities can be labelled using extended term lists defined in Part 3 of this standard. This updated mechanism offers greater flexibility than the previous version in where the references to such demographic entities may be represented within the Record Component hierarchy.

Representing context: Any EHR_EXTRACT references any other RECORD_COMPONENTS that are connected to the communicated content, for example via the RECORD_COMPONENT hierarchy and via LINK targets. If the EHR exchange service (e.g. as specified in Part 5) permits access to referenced components, any user would be able to access and review any additional areas of content that were not originally included. (Archetypes bring together the key elements of immediate documentation context.)

Representing authenticity: Every EHR_EXTRACT may contain attested views: these might be PDF or html or other renderings that are the authentic view of what was seen and persisted by the original author. The proof may also optionally be included, which is the evidence of a digital signature.

EHR_EXTRACTs are created for specific purposes, and will not automatically guarantee that these will be fit for other purposes.

Health informatics — Electronic health record communication — Part 1: Reference model

1 Scope

This Standard specifies a means for communicating part or all of the electronic health record (EHR) of one or more identified subjects of care between EHR systems, or between EHR systems and a centralised EHR data repository.

It may also be used for EHR communication between an EHR system or repository and clinical applications or middleware components (such as decision support components) that need to access or provide EHR data, or as the representation of EHR data within a distributed (federated) record system.

This International Standard will predominantly be used to support the direct care given to identifiable individuals, or to support population monitoring systems such as disease registries and public health surveillance. Uses of health records for other purposes such as teaching, clinical audit, administration and reporting, service management, research and epidemiology, which often require anonymisation or aggregation of individual records, are not the focus of this International Standard but such secondary uses might also find the standard useful.

This Part 1 of the multipart series is an Information Viewpoint specification as defined by the Open Distributed Processing – Reference model: Overview (ISO/IEC 10746-1). This International Standard is not intended to specify the internal architecture or database design of EHR systems.

2 Normative references

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

ISO 21090:2011; Health informatics - Harmonized data types for information interchange

ISO 27789:2013 Health informatics - Audit trails for electronic health records

ISO/IEC 10746-1:1998 Information technology - Open Distributed Processing - Reference model

Drafting note: References to the other Parts of EN ISO 13606 will be added before publication.

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <http://www.iso.org/obp>

Activities

3.1

automatic medical device

medical device capable of performing automated *healthcare activities*

NOTE In EN 13940-1:2007 the concept *healthcare device* was a specialization of *healthcare actor* and defined as 'device or equipment, possibly including a piece of software, involved in the provision of *healthcare activities*'.

EXAMPLES A specific identifiable Electrocardiography machine, electronic blood-sugar monitor.

3.2

healthcare activity

activity intended directly or indirectly to improve or maintain a *health state*

NOTE 1 to entry: Each specialization of this concept represents *healthcare activities* performed by a specialization of *healthcare actor*.

NOTE 2 to entry: Different types of *healthcare activity elements* (e.g. *healthcare investigation* or *healthcare treatment*) may be performed during a *healthcare activity*.

NOTE 3 to entry: See the concepts *healthcare provider activity*, *self-care activity*, *healthcare third party activity* and *automated healthcare* when it comes to the recording of *information* that are the result of *healthcare activities* (e.g. ratified observations).

EXAMPLE A blood pressure measurement completed by a qualified nurse including the *healthcare activity elements* of taking, documenting and evaluation.

[SOURCE: ISO 13940:2015]

Actors

3.3

attester

actor (person) who certifies and records legal responsibility for a particular unit of information

3.4

committer

agent (party, device or software) whose direct actions have resulted in information being committed

3.5

composer

healthcare actor responsible for creating, synthesising or organising information that is committed to an electronic health record.

NOTE 1 to entry: This agent takes responsibility for its inclusion in that electronic health record, even if not the originator of it and even if not the committer of it

3.6

electronic health record provider

healthcare actor in legitimate possession of electronic health record data and in a position to communicate it to another appropriate entity

3.7

electronic health record recipient

entity to whom electronic health record data is communicated by an electronic health record provider

3.8

healthcare provider

Admitted terms: care provider, health provider, health service provider, healthcare service provider

healthcare actor that is able to be assigned one or more *care period mandates*

NOTE 1 to entry: The personnel of a *healthcare organization* that is a *healthcare provider* may include both *healthcare professionals* and others which participate in the provision of *healthcare*.

NOTE 2 to entry: This International Standard includes only two specializations of *healthcare provider*. This is not meant to exclude the possibility of other specializations. In jurisdictions where other kinds of *healthcare actors* are included in the concept of *healthcare provider*, the necessary specializations may be added.

NOTE 3 to entry: According to this definition, *organizations* solely responsible for the funding, payment, or reimbursement of *healthcare* provision are not *healthcare providers*; for the purpose of this International Standard they are considered as *healthcare third parties*.

[SOURCE: ISO 13940:2015]

3.9

role

function or position

[SOURCE: ISO/HL7 21731:2006]

3.10

subject of care

Admitted terms: subject of healthcare, patient, client, service user

healthcare actor with a *person role*; who seeks to receive, is receiving, or has received *healthcare*

NOTE to entry: A foetus may be considered as a *subject of care* when receiving *healthcare*.

EXAMPLES A treated patient, a client of a physiotherapist, each particular member of a target population for screening, each particular member of a group of diabetic people attending a session of medical education, a *person* seeking health advice.

[SOURCE: ISO 13940:2015]

Concepts and terms

3.11

generic

applicable to requirements or information models across healthcare professions, domains and countries

Information management

3.12

abstract class

a class that cannot be instantiated independently

[SOURCE: ISO/IEC/IEEE 24765:2010]

3.13

archetype

instance of an *archetype model*, specifying the clinical concept and the value constraints that apply to one class of Record Component instances in an electronic health record extract

3.14

archetype model

information model of the metadata to represent the domain-specific characteristics of electronic health record entries, by specifying values or value constraints for classes and attributes in the electronic health record reference model

3.15

client application

healthcare application which is behaving at that moment as a requester of health record data from a shareable *electronic health record*

3.16

committed information

information that has been persisted within an electronic health record system and which constitutes part of the electronic health record of a subject of care

3.17

data

reinterpretable representation of information in a formalized manner suitable for communication, interpretation or processing

NOTE 1 to entry: Data are defined without any context in such a way that by itself one cannot tell its correct meaning, where it has meaning this is information.

[SOURCE ISO/IEC 2382 1:1993, 01-01.02]

3.18

data repository

an identifiable data (3.9.1) storage facility

NOTE 1 to entry: In ISO 10303 22:1998 this is the definition of repository

[SOURCE: ISO 13940:2015]

3.20

healthcare data

data produced during healthcare activities

[SOURCE: ISO 13940:2015]

3.21

healthcare information

information about a person, relevant to his or her healthcare

[SOURCE: ISO 13940:2015]

3.22

information

knowledge concerning objects that within a certain context has a particular meaning

NOTE 1 to entry: Facts, events, things, processes, and ideas, including concepts, are examples of objects.

NOTE 2 to entry: Information is something that is meaningful. Data might be regarded as information once its meaning is revealed.

[SOURCE ISO/IEC 2382-1:1993, 01.01.01 — modified]

3.23

distributed processing

information processing in which discrete components may be located in different places, and where communication between components may suffer delay or may fail

[SOURCE: ISO/IEC 10746-2:2009]

3.24

health record

data repository regarding the health and healthcare of a subject of care

NOTE 1 to entry: The term *electronic health record* may be used for a *health record* where all *information* is stored on electronic media. However, this concept is not formally defined in this International Standard.

NOTE 2 to entry: A *health record* may include, for example, medical records, dental records, social care records.

[SOURCE: ISO 13940:2015]

3.25

health record component

part of a *health record* that is identifiable for the purposes of referencing and revision

NOTE 1 to entry: This International Standard defines one *health record component* specialization, the *electronic record component*. However, as the content of a *health record* is not limited to *information* in electronic format, the content of *health record components* may be in formats other than electronic.

NOTE 2 to entry: A *health record component* may itself result from an aggregation of multiple *health record components*.

[SOURCE: ISO 13940:2015]

3.26

electronic health record

health record where all *information* is stored on electronic media

3.27

electronic health record system

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

[ISO 18308:2011]

3.28

health record extract

part or all of a *health record* extracted for the purpose of communication

[Source: ISO 13940:2015]

healthcare application

system for collecting, saving, processing, and presenting healthcare information by means of a computer.

NOTE 1 to entry: This definition is based on the definition of application in ISO/IEC 19770-5:2015

3.29

information architecture

structural design of an information space to facilitate task completion and intuitive access to content

3.30

metadata

data that defines object class and property for the information collected

[SOURCE: ISO/IEC 11179-3:2003]

3.31

semantic interoperability

ability for data shared by systems to be understood at the level of fully defined domain concepts

[SOURCE: ISO 18308:2011]

3.32

view

alternate presentation of data for a different user or purpose

Privacy and security

3.33

access control

means of ensuring that the resources of a data processing system can be accessed only by authorised entities in authorised ways

[SOURCE: ISO 17090-1:2013]

3.34

audit trail

collection of audit records from one or more audit logs relating to a specific subject of care or a specific electronic health record

[SOURCE: ISO 27789:2013]

3.35

authentication

provision of assurance of the claimed identity of an entity by securely associating an identifier and its authenticator

[SOURCE: ISO 22600-3:2014]

3.36

authorisation

granting of privileges

[ISO 22600-1:2014]

3.37

confidentiality

property that information is not made available or disclosed to unauthorised individuals, entities, or processes

[SOURCE: ISO 7498-2:1989]

3.38

digital signature

data appended to, or a cryptographic transformation of, a data unit that allows a recipient of the data unit to prove the source and integrity of the unit and protect against forgery e.g. by the recipient

[SOURCE: ISO 7498-2:1989]

3.39

privacy

freedom from intrusion into the private life or affairs of an individual when that intrusion results from undue or illegal gathering and use of data about that individual

[SOURCE: ISO/IEC 2382-8:1998]

Process management

3.40

attestation

process of certifying and recording legal responsibility for a particular unit of information

3.41

healthcare process

Synonym: care process

set of interrelated or interacting healthcare activities which transforms inputs into outputs

NOTE 1 The main type of healthcare process is the clinical process that has a health state as input and output and includes all activities in relation to one or more specified health issues.

NOTE 2 A healthcare process is not by definition restricted to one healthcare provider or any other organizational unit borders.

[SOURCE: ISO 13940:2015]

4 Abbreviations

For the purposes of this document, the following abbreviations apply.

CEN	Comité Européen de Normalisation (European Committee for Standardization, a federation of 28 national standards bodies that are also ISO member bodies)
CEN/TC 251	CEN Technical Committee 251 (develops standards within health informatics)
EHR	Electronic Health Record
EU	European Union
GP	General Practitioner
HL7	Health Level Seven
IANA	Internet Assigned Numbers Authority
IETF	Internet Engineering Task Force
ISO	International Organization for Standardization
ODP	Open Distributed Processing (ISO/IEC 10746, used for describing distributed systems)
OID	Object Identifier
R&D	Research and Development
RFC	Request For Comments
UML	Unified Modelling Language
W3C	World Wide Web Consortium
XML	Extensible Mark-up Language

5 Overview

5.1 Overview of the reference model

Figure 1 shows a reference model that includes both the EHR extracts and the demographic extract.

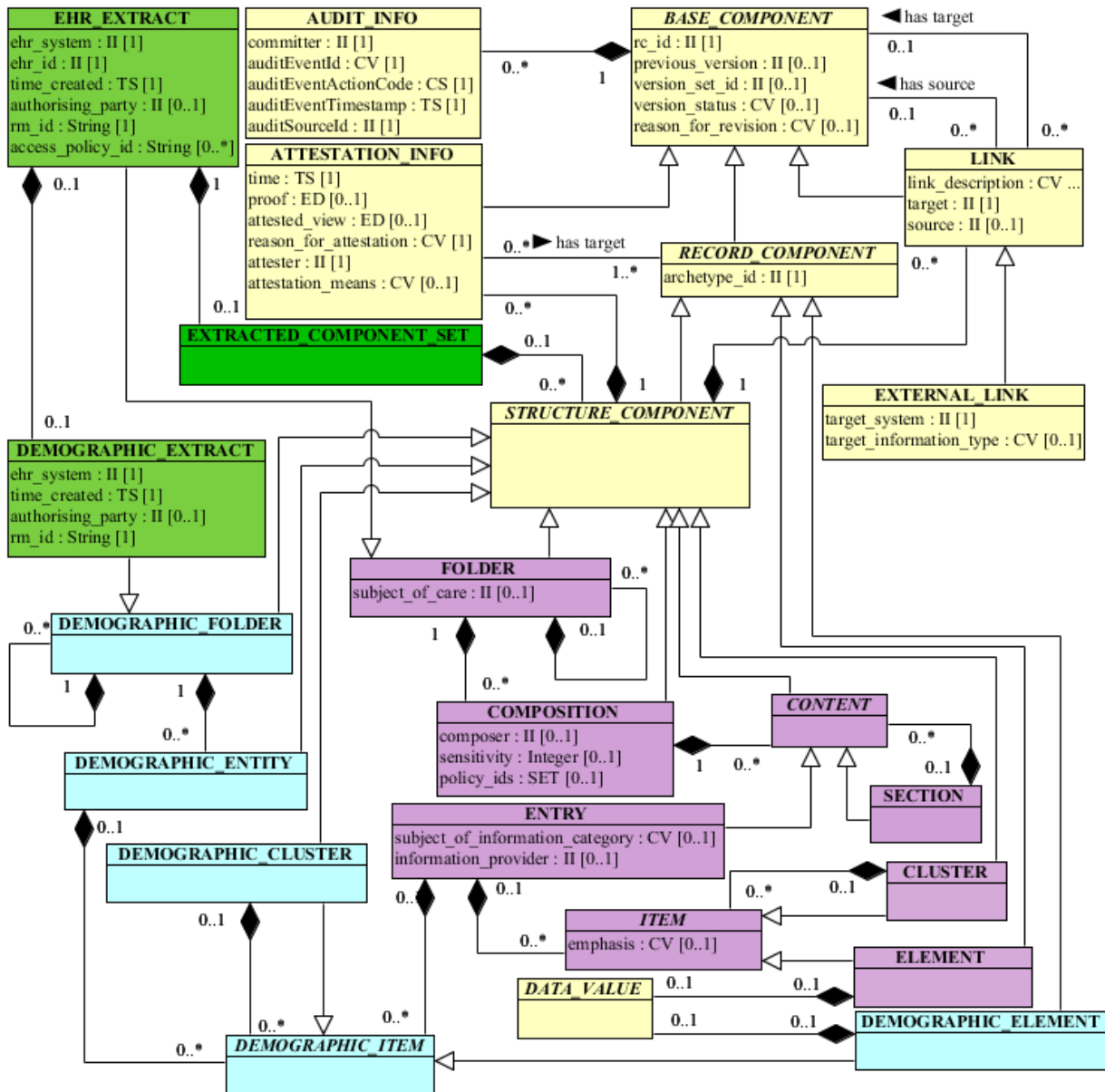


Figure 1 – Reference model for EHR extract and demographics

Note: the colours in Figure 1, and subsequent diagrams, are offered only as an aid to the reader and have no normative significance. The green coloured classes are the high level containers of the EHR content being communicated. The purple classes represent the main specialisations of RECORD_COMPONENT that provide the main hierarchical organisation of the healthcare information being communicated. The blue classes provide a similar hierarchical organisation to the demographic information being communicated. The cream coloured classes provide additional context to the other classes of the diagram.

5.2 Representing roles and responsibilities within the EHR_EXTRACT

5.2.1 General

One of the key areas of provenance that must be communicated as part of a shared electronic health record is information about the actors involved in care provision and its documentation. Performing a care act in a modern health service can involve a large number of actors, with different roles and responsibilities, each of whom might need to be represented in a subject of care's EHR. The approach taken in most generic EHR architectures, including this Standard, is to differentiate these into three broad categories.

5.2.2 Actors playing a role in the actual healthcare process

This set will usually include a core actor who is the key person relating to the subject of care during that care activity (e.g. general practitioner, midwife), and a series of collaborating actors who may be providing or supporting parts of the care (e.g. physiotherapist), are involved in making decisions (e.g. anaesthetist), are observers (e.g. medical students), or are present to support or co-represent the subject of care (e.g. the subject of care's husband). These actors might not all be present: for example, the policies of a consultant in charge of care may be followed because the subject of care is under his team, even if he is himself not with the subject of care on that occasion. Sometimes actors might be documenting a case review or a care planning negotiation involving one or more professionals but where the subject of care is not present. On the other hand, the subject of care might be the only actor involved in the care process, for illness self-management or prevention activities.

5.2.3 Actors contributing to the process of documenting care within the EHR

This will usually be a subset of those involved in care (and most commonly, the key actor), but might include people who were not part of delivering the care (e.g. a secretary or a transcriptionist) and may (more so in the future) include the person who is the subject of their care. It is important to recognise that the different actors will sometimes need to complete separate records of the same activity and may also attest them independently.

5.2.4 Actors confirming the validity of the EHR documentation

The paper analogy of this is the signing of a letter or report. Most commonly the act of signing a document combines two intentions: to confirm that the document is correct (e.g. is a complete record, is free of errors and omissions) and for the signer to confirm that he or she agrees to the content (e.g. to validate a prescription). In most of these situations the status or seniority of the signer is important. Some of the actors described in a care act will not themselves sign the entries describing their contribution to care: much of healthcare works through delegation. For example, the medical record documentation made by a junior doctor on a ward round is rarely reviewed by the consultant and almost never countersigned. Most observations on a paper monitoring chart are not individually signed. With electronic systems this practice might change, but some level of delegation and trust will probably always exist within care teams.

There is therefore a wide range of potential roles and responsibilities that might need to be represented in an EHR, and as patterns of health service evolve these might change in the future. The goal of the EHR_EXTRACT architecture is to permit any number of actors and roles to be defined within a COMPOSITION: either for the whole COMPOSITION or more narrowly for individual ENTRIES.

The approach taken in this Standard is:

- to specify a small number of roles that need to be unambiguously communicated to ensure safe interpretation of EHR_EXTRACTs by a receiving system, and which are likely to arise frequently;
- to permit other ad hoc participations to be defined by health services, systems or in individual EHR instances at the COMPOSITION or ENTRY level;
- to permit any number of attestations to be added to the EHR, to sign FOLDERS or COMPOSITIONs or only parts of COMPOSITIONs.

The specific roles that have been defined in this Reference Model are discussed below.

5.2.5 Subject of care

In response to requirements received during the revision of this standard, the EHR_EXTRACT may contain part or all of the electronic health record of one or more subjects of care. If the EHR of more than one subject of care is included, these must be separated at the root FOLDER level within the EHR_EXTRACT. The standard does not specify the precise rules governing when it is appropriate to combine extracts of more than one subject of care within a single EHR_EXTRACT, but examples of when this might be meaningful will include communicating records of multiple members of a single family or who live at the same address, multiple persons who have shared a common risk or incident, or are being transferred collectively to receive care in another setting.

However, there will be occasions when the FOLDER for a single subject of care still contains information about more than one person. Some commonly occurring examples are listed here.

- Pregnancy: it is common practice for the mother's record to contain the full pregnancy care record including that of her baby or babies until after birth, when any relevant information is copied into the new records of those babies.
- In utero interventions: in some situations, a new record is created well before a baby is born, perhaps if significant healthcare is required. In such situations the new record is created for the foetus as a convenience to permit a separation of data from the mother's record, and in anticipation of a new legal record for the baby. Depending upon the age of the foetus, and the laws pertaining to each country, either the baby or the mother will be the legal data subject, but in any case there is still a single identifiable subject of care for each record.
- Multiple pregnancy with each fetus having its own record: this is often cited as a situation in which health actions might really "belong" to two, conjoint twins or more subjects of care. In these situations it would seem logical that each baby's EHR_EXTRACT contains a copy of the relevant COMPOSITIONs, rather than attempting a complex join between two or more records to reference a single COMPOSITION held in one of these records. (Of course, more complex cross-linkage arrangements might be made within local EHR systems, permitting users to enter the data once and have it logically added to both records).
- Donated organs: Some test results relating to the donor of an organ may be appropriate to store in the EHR of the person receiving the donated organ – such as the viral status or genetic record of the donor – as the person will from this time on be a genetic mosaic. For this reason, information in the EHR may be classified as pertaining to a "donor".

The subject of care identifier in the root FOLDER will reference a snapshot of demographic information as held by the EHR Provider, to enable the subject of care to be matched to the demographics repository of the EHR Recipient, and/or for the EHR_EXTRACT to be referenced to the individual subject of care even if external demographics services are not available.

5.2.6 Composer

This actor is the person who has actually composed the words, terms, figures and values etc. that are represented in the COMPOSITION. The composer will almost always have played a key role in the information gathering, thinking or enacting aspects of the healthcare being documented. Sometimes, though, he or she might be a junior team member creating a record on behalf of a team.

The Composer attribute therefore represents the party who composed the data in a COMPOSITION, irrespective of who committed it or who attested it. The COMPOSITION will be seen as being primarily attributed to this person. Whether or not the composer is changed when a revision is made is optional, as it will depend upon the extent of the change made and if the revising party is willing and in a position to assume primary responsibility for the revised COMPOSITION as its composer. Applications may use the composer's name to label COMPOSITION data for display purposes. (The role of team members other than the composer can be added for individual ENTRYs as additional demographic_items.)

5.2.7 Committer

In many situations the person who composes the words is not the one who types them in. A common example is dictated letters and reports, which may be typed up by a secretary or transcriptionist. A junior clinical team member might also describe himself as the committer if he is really only acting as the scribe for another (composing) senior team colleague. In some transcription scenarios the typed text is checked by the composer who then commits it to the subject of care's EHR himself. In some scenarios several clinical team members are working in collaboration to deliver a care service; each of these might be able to document (and attest) their own portions of this care in the subject of care's record.

Other situations might arise in which the committer is not responsible for data entry, for example when a measurement device is directly feeding a clinical application. In these situations the information_provider or demographic_items attributes of ENTRY can be used to supplement the set of defined actors.

5.2.8 Subject of information

This attribute is needed to identify the person about whom the information in an ENTRY relates if not the subject of care. The commonest example of this is family history, but information about the subject of care's friend, life partner, sexual partner, employer, child etc. might sometimes be recorded in an EHR. This needs to be unambiguously distinguished from the majority of the EHR information which is about the subject of care.

In some contexts, parties might only be specified precisely if they are registered within the local demographics service AND they have given their consent to be identified in this subject of care's EHR. This will increasingly arise in clinical fields like cancer genetics that manage subjects of care within their family context. The more common situation is where the subject of care is describing the health of others.

The subject_of_information category permits the relationship of that subject to the subject of care to be defined as a coded term, and optionally for more details of that subject to be provided through a LINK to DEMOGRAPHIC_ITEM. This approach will allow archetypes to be reused with different subjects of care, and the unambiguous processing of EHR ENTRYs to distinguish data about the subject of care from data about other parties. It is also possible to let an ENTRY contain a DEMOGRAPHIC_ITEM with information on the subject of information (but then the *subject of information DEMOGRAPHIC_ITEM* would have to be specified in the archetype, just as all other ITEMS).

5.2.9 Information provider

Most of the information documented in an EHR will originate from the subject of care or one of the other participants in the care act. However at times ENTRYs may be added whose data values have been provided by some other party, for example a relative or carer who might be with the subject of care or seeing the subject of care's doctor alone confidentially. Other clinical parties might provide information indirectly (e.g. by phone) to the composer. The information_provider property of ENTRY allows for the formal identification of such parties.

5.3 About the use of datatypes in this standard

A constrained subset of ISO 21090 Health informatics - Harmonized datatypes for information interchange is used both in the reference model and for defining the datatypes (DATA_VALUE specializations) to be used when creating archetypes.

Implementations that claims conformance to this standard shall not use any of the attributes from the ISO 21090 classes ANY and HXIT:

- validTimeLow
- validTimeHigh
- controlInformationRoot
- controlInformationExtension
- nullFlavor
- flavorId
- updateMode

The following datatypes and UML support types specified in ISO 21090, are used in this document

- II - Implementations that claims conformance to this standard shall not use the ISO 21090 II attributes displayable, scope and reliability.
- TS
- CD.CV (In the diagrams shown as CV)
- ED - Implementations that claims conformance to this standard shall not use any of the ISO 21090 ED attributes value, xml, compression, charset, language and translation.
- CS
- TEL.URL (In the diagrams shown as URL) - Implementations that claims conformance to this standard shall not use any of the ISO 21090 TEL.URL attributes use, capabilities and usablePeriod.
- Boolean
- Binary
- String
- Integer
- Float
- Uid

The DATA_VALUE specialisations are defined in Section 7.2 of this document. These are the datatypes to be used when creating archetypes.