DEUTSCHE NORM

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Ersatz für
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Medizinische Informatik – Kommunikation von Patientendaten in elektronischer Form – Teil 1: Referenzmodell (ISO 13606-1:2008); Englische Fassung EN ISO 13606-1:2012

Health informatics –
Electronic health record communication –
Part 1: Reference model (ISO 13606-1:2008);
English version EN ISO 13606-1:2012

Informatique de santé –
Communication du dossier de santé informatisé –
Partie 1: Modèle de référence (ISO 13606-1:2008);
Version anglaise EN ISO 13606-1:2012

Gesamtumfang 114 Seiten

Normenausschuss Medizin (NAMed) im DIN

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Nationales Vorwort

Dieses Dokument enthält unter Berücksichtigung des Präsidialbeschlusses 13/1983 den englischen Originaltext der europäischen Norm EN ISO 13606-1:2012.

Dieses Dokument wurde vom Technischen Komitee ISO/TC 215 „Health informatics“ erarbeitet und als EN ISO 13606-1:2012 von der WG 1 „Modellierung von Systemen und Nachrichten“ des Technischen Komitees CEN/TC 251 „Medizinische Informatik“ (Sekretariat: NEN, Niederlande) übernommen.

Das zuständige deutsche Gremium ist der Arbeitsausschuss NA 063-07-02 AA „Interoperabilität“ des Fachbereichs 7 „Medizinische Informatik“ des Normenausschusses Medizin (NAMed) im DIN.

Für die im Abschnitt 2 zitierten Normen wird im Folgenden auf die entsprechenden Deutschen Normen hingewiesen:

CEN/TS 14796:2004 siehe DIN EN ISO 21090

Die DIN CEN/TS 14796 wurde im Februar 2012 zu Gunsten der DIN EN ISO 21090 zurückgezogen.

Änderungen

Gegenüber DIN EN 13606-1:2007-05 wurden folgende Änderungen vorgenommen:

a) Übernahme der Internationalen Norm;

b) der Text wurde inhaltlich leicht aktualisiert, aber grundsätzlich nicht geändert.

Frühere Ausgaben

DIN V ENV 13606-1: 2000-09

DIN EN 13606-1: 2007-05

Zusammenfassung und historische Entwicklung der Norm

Weltweit sind Bestrebungen im Gange, durch Schaffung so genannter *eHealth Infrastructures* die moderne Gesundheitsversorgung informationstechnologisch zu unterstützen. Auch in Deutschland sind entsprechende Entwicklungen zum Aufbau einer nationalen *Gesundheitstelematikplattform* (GTP) angestoßen. Aufgabe einer derartigen GTP ist, geeignete Verfahren und Werkzeuge für die Beteiligten der Gesundheitsversorgung bereitzustellen. Zentrales Element derartiger Plattformen ist die *Elektronische Gesundheitsakte* (EGA bzw. EHR für Electronic Health Record) — Sammelpunkt aller Informationen zu einem Patienten und die ihn betreffenden Behandlungsprozesse. Ihre Gestaltung ist ein komplexes Problem und hat Aspekte des Datenschutzes und der Datensicherheit ebenso einzubeziehen, wie ihre Integration in bestehende und zukünftige medizinische Informations- und Anwendungssysteme. Internationale Normen sind notwendig, diese Aufgaben zu lösen.

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Die Bemühungen der Arbeitsgruppe 1 „Modellierung von Systemen und Nachrichten“ des Technischen Komitees 251 „Medizinische Informatik“ des Europäischen Komitees für Normung (CEN) führten nun zur Überarbeitung der 1999/2000 nach mehrjähriger Vorarbeit verabschiedeten Vornormen-Reihe ENV 13606 zur *Electronic Healthcare Record (EHCR) Communication.* Diese hatte zum Ziel, die Interoperabilität zwischen Informationssystemen des Gesundheitswesens zu erhöhen. Künftige Systeme sollten anhand der vorgegebenen Strukturen entwickelt werden, d. h. Adressaten der Norm sind Entwickler für Informationssysteme und Standards aus Industrie und Forschung. Im Zentrum steht der Austausch von EHCR oder Teilen davon. Hierzu legt die alte Vornorm ENV 13606 Grundstrukturen eines EHCR und seiner Übermittlung fest. Diese Vornorm bestand aus vier Teilen:

Part 1: *Extended Architecture* – Dieser Teil gibt das Strukturmodell eines zu übermittelnden EHCR vor. Es handelt sich um eine *Communication View* auf einen beliebig gespeicherten EHCR bestehend aus hierarchisch angeordneten Komponenten wie *Ordnern* (*Folder*), *Zusammenstellungen* (*Compositions*), *Bezeichneten Bereichen* (*Headed Section*) und *Datenelementen* (*Data Items*).

Part 2: *Domain Termlist* – Während die *Extended Architecture* unabhängig von klinischen Inhalten ein Strukturmodell vorgibt, ermöglicht die Domain-Termlist eine inhaltliche Bezeichnung der Elemente des Strukturmodells innerhalb eines konkreten EHCR.

Part 3: *Distribution Rules* – Dieser Teil gibt ein konzeptuelles Sicherheitsmodell für Zugriffsregelungen und Auditing vor. Es stellt das „Subject of Care“ ins Zentrum der Kontrolle darüber, *wer wann was* zu *welchem Zweck auf welche Art und Weise* mit *welcher EHCR-Komponente* unternehmen darf.

Part 4: *Messages for the exchange of information* – Dieser Teil befasst sich mit der eigentlichen Kommunikation zwischen EHCR-Systemen, d. h. dem Austausch von Teilen eines EHCR oder des gesamten EHCR als Kopie, von Zusammenfassungen des EHCR oder von Nachrichten zur Konsistenzerhaltung verteilter Datenbestände. Er legt Kommunikationsszenarien, das Nachrichtenkonzept und ein aus den Teilen 1 bis 3 abgeleitetes *Domain Information Model* als Grundlage der Nachrichtenspezifikation fest.

Die überarbeitete 5-teilige Norm versucht nicht, die bisherigen Vornormen zu negieren, verfolgt aber teilweise andere Ansätze. Das Grundprinzip der EN 13606 ist nach wie vor die Festlegung einer Übertragungsnorm für Teile verteilt gespeicherter elektronischer Patientenakten. Nicht beabsichtigt ist, die interne Realisierung von EHR-Systemen zu standardisieren. Vielmehr soll ein *EHR-System 1* in die Lage versetzt werden, die Anfrage eines *EHR-Systems 2* nach Teilen oder der Gesamtheit einer lokal gespeicherten EHR zu einem Patienten entweder abschlägig oder durch Übersenden der angefragten Informationen (einem so genannten EHR-Extrakt) zu beantworten. Dabei wird dem Datenschutz dadurch Rechnung getragen, dass System 2 entsprechend hinterlegter Datenschutz-Policies entscheidet, ob und in welchem Umfang ein Zugriff durch die anfragende Partei erlaubt ist. Patientenindividuelle Policies sind dabei Teil jedes EHR. Werden EHR-Daten übertragen, können die Policies zur Zugriffsregelung für die übertragenen Daten mit übertragen werden.

Auch inhaltliche Vorgaben zu den auszutauschenden Informationen werden (zunächst) durch die EN 13606 nicht gemacht. Vielmehr werden Strukturen festgelegt, die Anwendern ermöglichen, inhaltliche Vorgaben für z. B. klinische Befunde oder Dokumente festzulegen. Auf dem Weg zur semantischen Interoperabilität spielt die Austauschbarkeit derartiger, möglichst standardisierter Festlegungen eine große Rolle. So genannte Archetypen können z. B. von Organisationen mit entsprechenden Beschreibungssprachen definiert und veröffentlicht werden, wobei diese Archetypen quasi als Bauplan für Informationseinheiten wie z. B. einen Blutdruckwert oder eine Erstdokumentation aus dem Disease-Management-Programm für Diabetes dienen. Die Beschreibung erfolgt dabei unabhängig von einer bestimmten (natürlichen) Sprache und kann so leicht an beliebige Sprachen angepasst werden.

Bei Anfrage und Übertragung von EHR-Extrakten kann dann auf Archetypen Bezug genommen werden, wobei nicht verlangt ist, dass die beteiligten EHR-Systeme intern die Daten nach den betreffenden Archetypen strukturieren und speichern. Vielmehr sollten sie in der Lage sein, die Daten konform zu den betreffenden Archetypen zusammenzusetzen und zu übertragen.

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Die fünf Teile EN 13606 sind gedacht, diese Konzepte umzusetzen. Dabei ähneln sie den ursprünglichen 4 Teilen, allerdings sind die ursprünglichen ersten zwei Teile nun – grob gesprochen – auf drei Teile aufgeteilt worden, wobei deutliche inhaltliche Änderungen vorgenommen worden sind. Die 5 neuen Teile beschreiben:

Part 1: *Reference model*: Das objektorientiert modellierte *Reference model* ist im Sinne eines generischen Informationsmodells die Grundlage für die Kommunikation eines EHR-Extrakts. Dabei wird ein *2-Modell-Ansatz* (dual model approach) verfolgt. Das *Reference Model* (Modell 1 und Gegenstand dieses Teils) legen als objektorientiertes Informationsmodell die Grundstrukturen eines EHR fest, die Gegenstand einer Übertragung sind und dies im Wesentlichen unabhängig von inhaltlichen Festlegungen. Dagegen erlauben die *Archetypen* (Modell 2 und Gegenstand von Teil 2) die formale Beschreibung von Schemata zur Kombination der so festgelegten Grundelemente im Zusammenhang mit einer inhaltlichen Festlegung bzw. einem klinischen Konzept.

Part 2: *Archetypes*: Dieser Teil gibt ein generisches Informationsmodell und eine formale Sprache zur Repräsentation und Kommunikation der Definitionen von Archetypen und ihrer Instanzen vor.

Part 3: *Terminology*: *Term Lists*: Vorgabe definierter Terme für die Benennung von Objekten des Referenzmodells bzw. ihrer Attribute und Beziehungen.

Part 4: *Security*: In recht deutlicher Veränderung zur ENV 13606-3:2000 gibt dieser Teil Sicherheitskonzepte im Zusammenhang mit der Kommunikation von EHR-Extrakten vor.

Part 5: *Messages for Exchange*: Ähnlich ENV 13606-4:2000 legt dieser Teil die Grundlage für die nachrichtenbasierte Kommunikation von EHR-Systemen.

Das *Reference model* ist Gegenstand der vorliegenden EN 13606-1. Als erstes der beiden Modelle des 2-Modell-Ansatzes legt es die Grundstrukturen zu übermittelnder Komponenten eines EHR zu einem Patienten fest. Es ist beschrieben als Objektsystem in der Unified Modelling Language (UML). Das Modell ist nicht gedacht, die interne Datenstruktur von EHR-Systemen vorzugeben, vielmehr sollen diese Systeme in der Lage sein, die von ihnen gespeicherten EHRs entsprechend der Anfrage eines anderen EHR-Systems in eine Instanziierung des Referenz-Modells zu überführen. Diese Instanziierung kann dann in die Nachrichtenstruktur nach der in Bearbeitung befindlichen EN 13606-5 überführt und übertragen werden.

Grundidee des *Reference model* ist die Übertragung eines EGA-Auszugs (Klasse EHR-Extrat) in Gestalt einer entsprechenden Nachricht. Ein solcher Auszug verweist auf alle damit in Bezug stehenden Personen, Organisationen, Geräte oder Softwareprodukte in Form eines Verzeichnisses (Klasse Identified_Entity im Package Demographics), das neben den IDs der Entitäten identifizierende Informationen im Klartext enthält. Des Weiteren kann das EHR-Extrakt mit Informationen zum Zugriffsschutz verknüpft werden.

Basisklasse aller zu übertragenden Inhalte ist die abstrakte Klasse Record_Component. Neben Strukturobjekten wie Ordnern (Klasse Folder), Zusammenstellungen (Klasse Composition), Gruppierungen (Klasse Cluster) und Abschnitten (Klasse Section) sind die wesentlichen inhaltstragenden Objekte Einträge (Klasse Entry) und Einzelinformation (abstrakte Klasse Item bzw. Klasse Element) von Record_Component abgeleitet. Ordner erlauben die beliebig geartete, hierarchische Anordnung von Inhalten eines EHR z. B. in Bezug auf Behandlungsepisoden, klinische Abteilungen usw. Zusammenstellungen stellen eine Art Klammer um klinische Informationen dar, die während eines abgrenzbaren klinischen Abschnitts (Klasse Clinical_Session) entstanden, und von einer Person (Composer) dokumentiert worden sind. Der eigentliche Inhalt des Extrakts (abstakte Klasse Content) kann in Abschnitten gegliedert Einträge enthalten, die sich auf eine abgrenzbare klinische Aktivität beziehen. Die Einträge enthalten einzelne Informationseinheiten (wie z. B. einen Temperaturwert; Klasse Element) gegebenenfalls. strukturiert in Clustern (z. B. Blutdruckwert bestehend aus diastolischem und systolischem Blutdruck).

Für jede EHR-Komponente können beliebig viele Versionen erzeugt werden. Nicht aktuelle Versionen können bei Bedarf ebenfalls übertragen werden, i.d.R. werden aber nur aktuelle Versionen Gegenstand von Anfragen sein. Jede EHR-Komponente ist hierzu verknüpft mit einer Prüfinformation (Klasse Audit_Info), die Angaben zur Version der Komponente enthält und durch Bezugnahme auf den Einsteller der jeweiligen Daten (committer) den Verlauf von Datenänderungen nachzuvollziehen erlaubt. Jede Version kann zudem mit rechtswirksamen Beglaubigungen (Klasse Attestation_Info) versehen werden, die i.d.R. jeweils verknüpft sind mit der elektronischen Signatur des Attestierenden (attester).

Teil 1 der EN 13606 liefert so die zentrale Grundlage für eine auf zeitliche Stabilität ausgerichtete Standardisierung des Austauschs von patientenbezogenen Informationen zwischen den Beteiligten der Gesundheitsversorgung.

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Nationaler Anhang NA
(informativ)

Literaturhinweise

DIN EN ISO 21090, *Medizinische Informatik — Harmonisierte Datentypen für den Datenaustausch im Gesundheitswesen*

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Nationaler Anhang NB
(informativ)

Begriffe

Für die Anwendung dieses Dokuments gelten die folgenden Begriffe.

3.1
abstrakte Klasse
virtueller gemeinsamer Vorgänger von mindestens zwei Klassen, der nicht selbst instanziiert werden kann

3.2
Zugriffskontrolle
Hilfsmittel zur Sicherstellung, dass nur entsprechend autorisierte Funktionseinheiten auf die Ressourcen eines Datenverarbeitungssystems zugreifen können und dass dies nur auf autorisierte Art und Weise erfolgt

[ISO/IEC 2382-8:1998, Begriff 08.04.01]

3.3
Zurechenbarkeit
Eigenschaft, die sicherstellt, dass die Handlungen einer Funktionseinheit eindeutig auf diese Funktionseinheit zurückgeführt werden können

[ISO/IEC 2382-8:1998, Begriff 08.01.10]

3.4
Archetyp-Instanz
Instanz der Metadatenklasse eines Archetyp-Modells, die das klinische Konzept und die für eine Klasse von Aktenbestandteil-Instanzen in einem Auszug einer elektronischen Gesundheitsakte geltenden wertebezogenen Randbedingungen festlegt

3.5
Archetyp-Modell
Informationsmodell der Metadaten zur Darstellung von domain-spezifischen Eigenschaften der Einträge von elektronischen Gesundheitsakten durch Festlegung von Werten oder wertebezogenen Randbedingungen für Klassen und Attribute im Referenzmodell der elektronischen Gesundheitsakte

3.6
Archetyp-Repository
Archetyp-Magazin
persistenter Speicher von Archetyp-Definitionen, auf den von einem client-spezifischen Entwicklungswerkzeug oder von einer Laufzeitkomponente im Rahmen eines elektronischen Gesundheitsaktendienstes zugegriffen wird

3.7
Attestierende(r)
Partei (Person), die die rechtliche Verantwortung für eine bestimmte Informationseinheit beglaubigt und aufzeichnet

3.8
Attestierung
Prozess der Beglaubigung und Aufzeichnung der rechtlichen Verantwortung für eine bestimmte Informationseinheit

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3.9
Zugriffsprotokollierung
Audit-Trail
chronologische Aufzeichnung der Aktivitäten von Benutzern eines Informationssystems, die die getreue Wiederherstellung früherer Zustände der betreffenden Information(en) ermöglicht

3.10
Authentisierung
Prozess der zuverlässigen Identifikation von Sicherheitsobjekten durch die sichere Zuordnung eines Bezeichners bzw. Identifikators zu seinem authentifizierenden Merkmal

3.11
Autorisierung
Gewährung von Rechten

3.12
Daten verwendende Anwendung
Gesundheitsversorgungsanwendung, die sich im gegebenen Moment wie ein Anforderer von Gesundheitsaktendaten aus einer gemeinsamen elektronischen Gesundheitsakte verhält

3.13
klinische Information(en)
Information(en) über eine Person, die für deren Gesundheit oder Gesundheitsversorgung von Bedeutung ist

3.14
eingestellt
Informationen, die in einem EGA-System dauerhaft gespeichert wurden und Bestandteil der elektronischen Gesundheitsakte einer behandelten oder zu behandelnden Person sind

3.15
Ersteller
Handlungsträger (Partei, Gerät oder Software), dessen direkte Aktivitäten dazu geführt haben, dass Daten in eine elektronische Gesundheitsakte eingestellt wurden

3.16
Verfasser
Handlungsträger (Partei, Gerät oder Software), der für die Erstellung, Synthese oder Organisation von Informationen verantwortlich ist, die in eine elektronische Gesundheitsakte eingestellt wurden

ANMERKUNG 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.

3.17
Vertraulichkeit
Eigenschaft, die dazu führt, dass die betreffende(n) Information(en) keinen Personen, Funktionseinheiten oder Prozessen, die nicht über die entsprechende Berechtigung verfügen, verfügbar gemacht oder diesen gegenüber offengelegt wird (werden)

[ISO 7498-2:1989]

3.18
Beitrag für eine EGA
Satz von Aktenbestandteilen, der von einem Benutzer zu einem gegebenen Zeitpunkt in die elektronische Gesundheitsakte einer behandelten oder zu behandelnden Person eingestellt wird

3.19
digitale Signatur
an eine Dateneinheit angehängte Daten oder eine verschlüsselte Umsetzung einer Dateneinheit, die es einem Empfänger dieser Dateneinheit ermöglicht, deren Quelle und Integrität nachzuweisen und sie vor Fälschung z. B. durch den Empfänger zu schützen

[ISO 7498-2:1989, Begriff 3.3.16]

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3.20
verteilte Datenverarbeitung
Informationsverarbeitung, bei der sich diskrete Komponenten an verschiedenen Orten befinden können oder bei der die Kommunikation zwischen Komponenten verzögert oder unterbrochen sein kann

3.21
EGA-Auszug
ein Teil der Gesundheitsakte oder die gesamte Gesundheitsakte der behandelten oder zu behandelnden Person, der bzw. die in Übereinstimmung mit dem vorliegenden Teil von ISO 13606 übermittelt wird

3.22
Informationsarchitektur der elektronischen Gesundheitsakte
Festlegung des ODP-Informationsstandpunktes einer elektronischen Gesundheitsakte

3.23
Anbieter von Auszügen einer elektronischen Gesundheitsakte
Funktionseinheit, die rechtmäßig im Besitz von elektronischen Gesundheitsaktendaten und in der Lage ist, diese an eine andere geeignete Funktionseinheit zu übermitteln

3.24
Empfänger von Auszügen einer elektronischen Gesundheitsakte
Funktionseinheit, an die elektronische Gesundheitsaktendaten von einem Anbieter von Auszügen einer elektronischen Gesundheitsakte übermittelt werden

3.25
Anforderer von Auszügen einer elektronischen Gesundheitsakte
Funktionseinheit, die die Übermittlung von elektronischen Gesundheitsakten zwischen einem Anbieter und einem Empfänger von Auszügen einer elektronischen Gesundheitsakte beantragt

3.26
elektronisches Gesundheitsaktensystem,
EGA-System
System für die Aufzeichnung, den Abruf und die Veränderung von in einer elektronischen Gesundheitsakte enthaltenen Informationen

3.27
Einträge
Gesundheitsaktendaten im Allgemeinen (klinische Beobachtungen, Befunde, Begründungen, geplante Vorhaben, Pläne oder Maßnahmen) ohne spezielle Festlegung ihrer formalen Darstellung, hierarchischen Struktur oder der jeweiligen Klasse(n) der Aktenbestandteile, die zu ihrer Darstellung verwendet werden könnte(n)

3.28
föderierte Gesundheitsakte
virtuelle Ansicht der Gesundheitsakte eines Patienten, die aus allen elektronischen Gesundheitsakteneinträgen über diesen Patienten bezogen werden kann, die in unterschiedlichen Systemen gespeichert sind, die mittels genormter Auszüge aus den elektronischen Gesundheitsakten miteinander kommunizieren

3.29
EGA-Quellsystem
Repository bzw. Speicher (für Gesundheitsaktendaten), das bzw. der innerhalb eines Verbunds von elektronischen Gesundheitsaktensystemen abgefragt werden kann, um Beiträge zu einer föderierten Gesundheitsakte zu erstellen

3.30
generisch
Adjektiv zu Anforderungen oder Informationsmodellen, die im Bereich von Heilberufen, Domains und Ländern zur Anwendung kommen

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3.31
Agent im Gesundheitswesen
Handlungsträger des Gesundheitswesens
Person, Gerät oder Software, die im Rahmen einer Gesundheitsversorgungsmaßnahme eine bestimmte Funktion erfüllt

[EN 13940-1:2005]

3.32
technische Einrichtung des Gesundheitswesens
Gerät oder Einrichtung, das oder die an der direkten oder indirekten Erbringung von Gesundheitsdienstleistungen für eine Person oder eine Gruppe von Personen beteiligt ist

3.33
Organisation des Gesundheitswesens
Organisation, die an der direkten oder indirekten Erbringung von Gesundheitsdienstleistungen für eine Person oder eine Gruppe von Personen beteiligt ist

3.34
Beteiligte(r) des Gesundheitswesens
Partei im Gesundheitswesen
Person, die an der direkten oder indirekten Erbringung von Gesundheitsdienstleistungen für eine Person oder eine Gruppe von Personen beteiligt ist

3.35
Dienstleistung des Gesundheitswesens
Gesundheitsdienstleistung
Dienstleistung, die mit dem Ziel erbracht wird, die Gesundheit der betreffenden Person oder Personengruppe direkt oder indirekt zu verbessern

3.36
Daten aus Altsystemen
Daten, die mit Hilfe eines „älteren“ Systems erfasst und verwaltet wurden, jetzt aber auf einem „aktuellen“ System gespeichert sind

3.37
Metadaten
Daten, die die Objektklasse und die Eigenschaften der erfassten Informationen definieren

3.38
Nichtabstreitbarkeit
Dienstleistung zur Erbringung des Nachweises von Integrität und Ursprung der Daten (jeweils in einer fälschungssicheren Beziehung), der von jeder Partei überprüft werden kann

[ISO/TS 17090-1:2002, Begriff 3.2.21]

3.39
Patient
Synonym für eine behandelte oder zu behandelnde Person

3.40
persistente Daten
Daten, die dauerhaft gespeichert werden

3.41
persönliche Gesundheitsakte
Gesundheitsakte, deren Daten von der behandelten oder zu behandelnden Person oder deren Bevollmächtigtem geprüft und gesteuert werden

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3.42
Privatsphäre
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

[ISO/IEC 2382-8:1998, Begriff 08.01.23]

3.43
Aktenbestandteil
Teil des Auszugs einer elektronischen Gesundheitsakte einer einzelnen behandelten oder zu behandelnden Person, der als Knoten innerhalb einer hierarchischen Datenstruktur dargestellt wird, die dem vorliegenden Teil von ISO 13606 entspricht

3.44
Rolle
Funktion
Reihe von Verhaltensweisen, die mit einer Aufgabe verbunden sind

[ISO/TS 17090-1:2002, Begriff 3.2.24]

3.45
semantische Interoperabilität
Fähigkeit der von mehreren Systemen gemeinsam genutzten Daten, auf der Ebene vollständig definierter Domain-Begriffe verstanden zu werden

[ISO/TS 18308:2004, Begriff 3.38]

3.46
gemeinsame elektronische Gesundheitsakte
elektronische Gesundheitsakte mit einem genormten Informationsmodell, die unabhängig von elektronischen Gesundheitsaktensystemen und mehreren autorisierten Benutzern zugänglich ist

[in angepasster Form übernommen aus ISO/TR 20514:2005, Begriff 2.33]

3.47
Norm
Dokument, das mit Konsens erstellt und von einer anerkannten Institution angenommen wurde und das für die allgemeine und wiederkehrende Anwendung Regeln, Leitlinien oder Merkmale für Tätigkeiten oder deren Ergebnisse festlegt, wobei ein optimaler Ordnungsgrad in einem gegebenen Zusammenhang angestrebt wird

[ISO/IEC Guide 2:2004, Begriff 3.2]

3.48
Status
⟨eines Prozesses⟩ Zustand oder Situation im Verlauf des Lebenszyklus eines Objekts, in dem oder der dieses eine bestimmte Bedingung erfüllt, eine Aktivität ausführt oder auf ein bestimmtes Ereignis wartet

[ISO/TS 18308:2004, Begriff 3.39]

3.49
behandelte Person
zu behandelnde Person
Person, die Gesundheitsdienstleistungen erhalten soll, erhält oder erhalten hat

3.50
Ansicht
ersatzweise Darstellung von Daten für einen anderen Benutzer oder Zweck

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

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Communication du dossier de santé informatisé —
Partie 1: Modèle de référence (ISO 13606-1:2008)

Medizinische Informatik —
Kommunikation von Patientendaten in elektronischer Form —
Teil 1: Referenzmodell (ISO 13606-1:2008)

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Foreword

The text of ISO 13606-1:2008 has been prepared by Technical Committee ISO/TC 215 “Health informatics” of the International Organization for Standardization (ISO) and has been taken over as EN ISO 13606-1:2012 by Technical Committee CEN/TC 251 “Health informatics” the secretariat of which is held by NEN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by April 2013, and conflicting national standards shall be withdrawn at the latest by April 2013.

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

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The text of ISO 13606-1:2008 has been approved by CEN as a EN ISO 13606-1:2012 without any modification.

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0 Introduction

0.1 Preface

The overall goal of ISO 13606 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). This is to support the interoperability of systems and components that need to communicate (access, transfer, add or modify) EHR data via electronic messages or as distributed objects:

— preserving the original clinical meaning intended by the author;

— reflecting the confidentiality of that data as intended by the author and patient.

ISO 13606 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 application that might require 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. The information model in this part of ISO 13606 is an ISO Reference Model for Open Distributed Processing (RM-ODP) RM-ODP Information Viewpoint of the EHR Extract.

ISO 13606 considers the EHR to be the persistent longitudinal and potentially multi-enterprise or multi-national record of health and care provision relating to a single subject of care (the patient), created and stored in one or more physical systems in order to inform the subject's future healthcare and to provide a medico-legal record of care that has been provided. 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., ISO 13606 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.

ISO 13606 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.

This part of ISO 13606 is the first part to be published of a five-part series. In this part of ISO 13606 dependency upon one of the other parts of this series is explicitly stated where it applies.

0.2 Technical approach

ISO 13606 has drawn on the practical experience that has been gained in implementing a European precursor prestandard, ENV 13606, other EHR-related standards and specifications, commercial systems and demonstrator pilots in the communication of whole or part of patients' EHRs, and on fifteen years of research findings in the field. ISO 13606 builds on ENV 13606, in order to provide a more rigorous and complete specification, to accommodate new requirements identified, to incorporate a robust means of applying the generic models to individual clinical domains, and to enable communication using HL7 version 3 messages. A mapping from the European prestandard is also provided to support implementers of systems that conformed to it. The technical approach to producing ISO 13606 has taken into account several contemporary areas of requirement.

a) In addition to a traditional message-based communication between isolated clinical systems, the Electronic Health Record will in some cases be implemented as a middleware component (a record server) using distributed object technology and/or web services.

b) "Customers" of such record services will be not only other electronic health record systems but also other middleware services such as security components, workflow systems, alerting and decision support services and other medical knowledge agents.

c) There is wide international interest in this work, and this part of ISO 13606 has been drafted jointly through CEN and ISO with significant input from many member countries.

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d) Mapping to HL7 version 3 has been considered an important goal, to enable conformance to this part of ISO 13606 within an HL7 version 3 environment.

e) The research and development (R & D) inputs on which ENV 13606 was based have moved forward since 1999 and important new contributions to the field have been taken into account. The *open* EHR foundation, integrating threads of R & D in Europe and Australia, is one such example.

Given the diversity of deployed EHR systems, ISO 13606 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, and through normative term lists (defined in Part 3).

ISO 13606 will, in practice, usually be adopted alongside other health informatics standards that define particular aspects of health data representation. Annex B explains how ISO 13606 can be used alongside key complementary standards, including the HL7 Version 3 Reference Information Model (RIM), EN 14822-1, EN 14822-2, EN 14822-3, CEN/TS 14822-4 (GPIC), prEN 12967 (HISA) and prEN13940 (CONTSYS).

0.3 The Dual Model approach

The challenge for EHR interoperability is to devise a generalized 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 clinical 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 ISO 13606 distinguishes a reference model, defined in this part of ISO 13606 and used to represent the generic properties of health record information, and archetypes (conforming to an archetype model, defined in Part 2), which are meta-data used to define patterns for the specific characteristics of the clinical data that represent 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).

This generic information model needs to be complemented by a formal method of communicating and sharing the organizational structure of predefined classes of EHR fragment corresponding to sets of record components made in particular clinical situations. These are effectively precoordinated 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 organizations. 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 part of ISO 13606, 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 part of ISO 13606 recognises that archetypes might be used to support communication between some EHR systems in the future, or might be used as a knowledge specification by some EHR system external interfaces when mapping parts of an EHR to an EHR_EXTRACT, or might not be used at all between some EHR systems. The use of archetypes is therefore supported, but not made mandatory, by this part of ISO 13606. A specification for communicating archetypes is defined by Part 2.

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0.4 Requirements basis for this part of ISO 13606

From the early 1990s it was recognised that a generic representation is required for the communication of arbitrary health record information between systems, and in Europe this has resulted in a succession of EU sponsored R & D projects and two generations of CEN health informatics standards prior to this International Standard. These projects and standards have sought to define the generic characteristics of EHR information and to embody these in information models and message models that could provide a standard interface between clinical systems. The vision of such work has been to enable diverse and specialist clinical systems to exchange whole or parts of a person's EHR in a standardized way that can rigorously and generically represent the data values and contextual organization of the information in any originating system. A complementary goal has been to accommodate the evolving nature of medical knowledge and the inherent diversity of clinical practice.

Many investigations of user and enterprise requirements for the EHR have taken place over this period, which have sought to span the information needs of diverse specialties across primary, secondary and tertiary care, between professions and across countries. These requirements have been distilled and analysed by expert groups, mainly within Europe, in order to identify the basic information that needs to be accommodated within an EHR information architecture to:

— capture faithfully the original meaning intended by the author of a record entry or set of entries;

— provide a framework appropriate to the needs of professionals and enterprises to analyse and interpret EHRs on an individual or population basis;

— incorporate the necessary medico-legal constructs to support the safe and relevant communication of EHR entries between professionals working on the same or different sites.

This work includes the GEHR [41, 48, 57], EHCR-SupA [36-38], Synapses [42, 43], I4C and Nora projects and work by the Swedish Institute for Health Services Development (SPRI). These key requirement publications are listed in the Bibliography [51]. These requirements have recently been consolidated on the international stage within an ISO Technical Specification, ISO/TS 18308[9].

In this reference model the key EHR contextual requirements for such faithfulness are related to a set of logical building block classes, with suitable attributes proposed for each level in the EHR extract hierarchy. ISO/TS 18308 has been adopted as the reference set of requirements to underpin the features within this EHR communications reference model, and a mapping of these requirements statements to the constructs in the reference model is given in Annex D.

0.5 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 organized under headings, and contained in "documents" such as consultation notes, letters and reports. These documents are usually filed in folders, and a patient may have more than one folder within a healthcare enterprise (e.g. medical, nursing, obstetric).

The EHR extract reference model needs to reflect this hierarchical structure and organization, 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 organized within heterogeneous EHR systems.

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These parts are summarised in Table 1.

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, for communication between an EHR provider system and an EHR recipient.	Not applicable
FOLDER	The high level organization within an EHR, dividing it into compartments relating to care provided 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, Italy
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 organizing 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, optionally organized by a FOLDER hierarchy.

COMPOSITIONs contain ENTRYs, optionally contained within a SECTION hierarchy.

ENTRYs contain ELEMENTS, optionally contained within a CLUSTER hierarchy.

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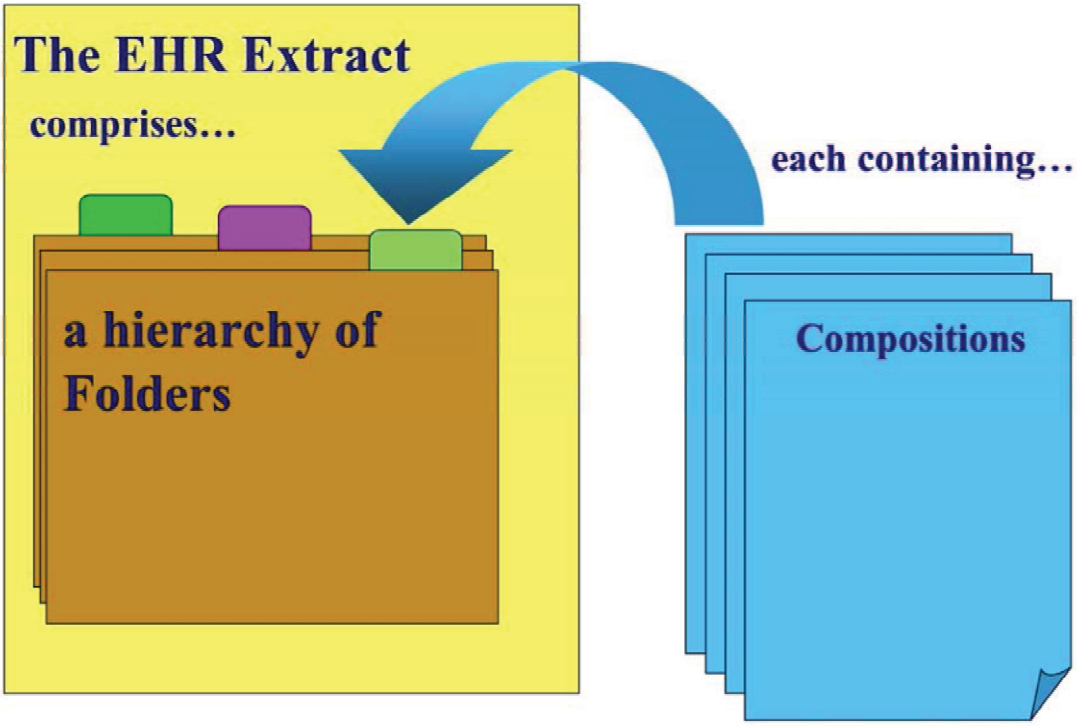

Figure 1 — Diagram of the EHR Extract hierarchy (Part 1)

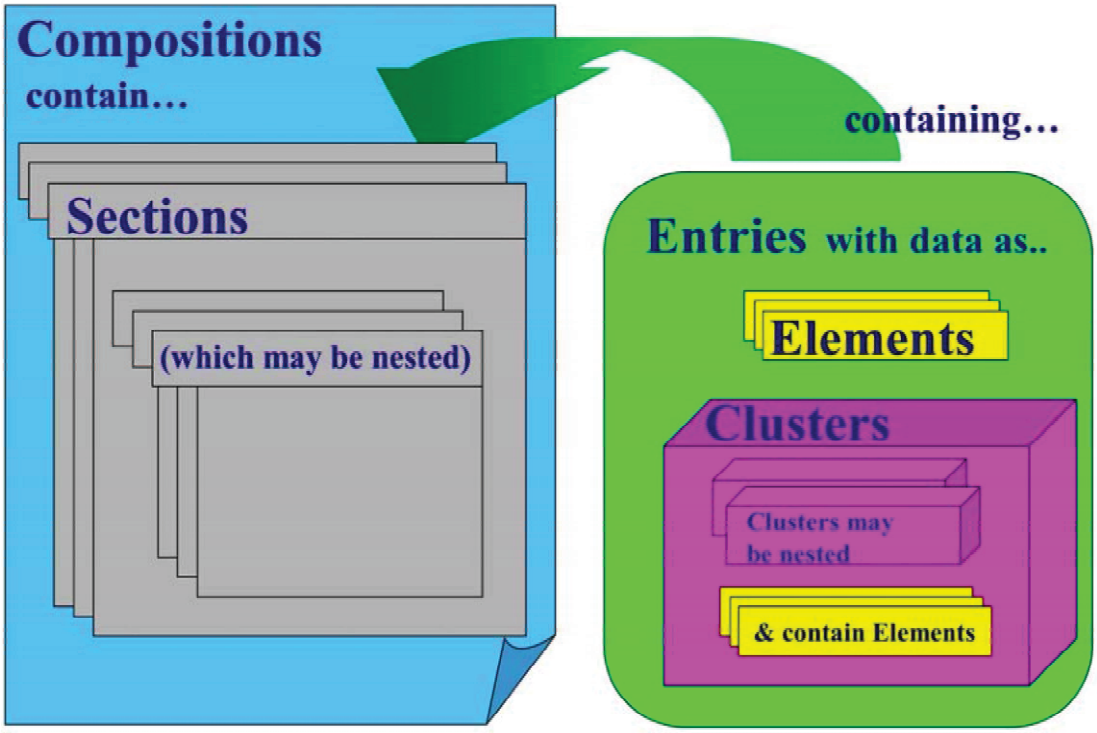

Figure 2 — Diagram of the EHR Extract hierarchy (Part 2)

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0.6 Description of the main Reference Model classes

EHR_EXTRACT

The EHR_EXTRACT is used to represent part or all of the health record information extracted from an EHR provider system for the purposes of communication to an EHR recipient (which might be another EHR system, a clinical data repository, a client application or a middleware service such as an electronic guideline component) and supporting the faithful inclusion of the communicated data in the receiving system.

The EHR_EXTRACT class contains attributes to identify the subject of care whose record this is, the EHR Provider system from which it has been derived and the identifier of that subject's EHR in that system, and optionally the agent responsible for creating it.

The EHR_EXTRACT contains the EHR data, in three parts:

1) a set of COMPOSITIONs;

2) optionally, a directory of FOLDERs that provide a high-level grouping and organizing of the COMPOSITIONs;

3) optionally, a set of demographic descriptors for each of the persons, organizations, devices or software components that are identified within (1) and (2) above. This approach allows such entities to be referenced uniquely via an identifier within the body of the EHR, without repetition of the descriptive details each time, and also ensures that any EHR_EXTRACT can be interpreted in isolation if the recipient system does not have access to the services needed to decode the entity identifiers used by the EHR Provider.

A formal mechanism is defined in Part 4 of ISO 13606 for including access policy information within the EHR_EXTRACT. This is intended to inform the EHR recipient about the wishes of the subject of care and of healthcare providers for how future access requests for the data should be managed.

The EHR_EXTRACT also contains a summary of the filter or selection criteria by which this EHR_EXTRACT was created. This may or may not correspond directly to the criteria in the EHR request, and provides a record of the kind of subset this EHR_EXTRACT is of the overall EHR held by the EHR provider. This might be of importance if the EHR_EXTRACT is retained intact by the EHR provider or EHR recipient, and subsequently accessed by agents who do not have access to the original EHR request. For example, this class can specify if this EHR_EXTRACT is limited to the most recent version of each COMPOSITION (as required for most clinical care purposes) or if it includes all historic versions (which might be required for legal purposes). It might specify the maximum level of sensitivity of the data (implying that data that is more sensitive than this level may exist and have been filtered out), or that multi-media objects have been excluded to limit its total size. If the EHR_EXTRACT was created by selecting particular categories of clinical data (e.g., only laboratory data) then this may be indicated through a list of the archetypes that were included in the selection criteria. An option exists to include additional criteria (expressed as strings); this may be used to provide additional human readable information about this EHR_EXTRACT or may be used for locally-agreed computer-interpretable constraint information.

RECORD_COMPONENT

The main building block classes that are used to construct the EHR data hierarchy within an EHR_EXTRACT are kinds of RECORD_COMPONENT. This is an abstract class, the super-class of all of the concrete nodes in the EHR hierarchy: FOLDER, COMPOSITION, SECTION, ENTRY, CLUSTER, ELEMENT, and also the super-class for two other abstract class nodes: CONTENT and ITEM.

RECORD_COMPONENT defines the information properties that are common to all of these building blocks, including:

— the unique identifier that was issued to this EHR node by the EHR system in which it was first committed (its originating EHR system); other holders of this RECORD_COMPONENT need to retain this attribute value to ensure that any subsequent extracts are always consistently identified;

— the clinical name, used in its originating EHR system to label this part of the EHR data;

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— optionally, a standardized coded concept to which the name has been mapped to support the semantic interoperability of equivalent EHR instances even if these have been given different clinical names by different EHR systems;

— the identifier of the archetype node to which this RECORD_COMPONENT conforms, to be used by archetype enabled-EHR systems or if archetypes have been used when mapping the data into the EHR_EXTRACT format;

— a sensitivity code and references to access control policies that should be used by the EHR recipient to govern future access to the data;

— support for links between any record components.

When generating an EHR_EXTRACT conformant to this part of ISO 13606 the EHR provider system might, in some situations, need to introduce a RECORD_COMPONENT into the hierarchy that does not have a direct correspondence with any original data in the EHR system. The synthesised attribute of RECORD_COMPONENT permits the exporting EHR provider system to indicate that a RECORD_COMPONENT has been created within the EHR_EXTRACT for this purpose.

Health record entries often refer to other pre-existing entries, and include them as “copies”. A common example of this is a discharge summary, which might include copies of several parts of an inpatient stay record such as the admission circumstances, the main diagnoses, principal interventions and treatments. In most cases the EHR_EXTRACT needs to contain these referenced RECORD_COMPONENTS explicitly by value, so that each COMPOSITION can be interpreted by the EHR Recipient. However, it is also important, medico-legally, to communicate that these entries are copies, and that they originate from a different part of that subject’s EHR. The optional attribute original_parent_ref may be used to represent the rc_id of the original parent RECORD_COMPONENT if the data are a copy.

Any RECORD_COMPONENT may include audit data about when and by whom it was committed in its originating EHR system. Each revised version of a RECORD_COMPONENT may document the version status, the reason for the revision and the identifier of the preceding version. However, for data protection reasons it is usually advised that previous (erroneous) versions of an EHR are not communicated as part of normal clinical shared care, but only in circumstances where an EHR transfer is being made for legal reasons.

It is important that each RECORD_COMPONENT be uniquely and consistently identified across multiple EHR_EXTRACTS, so that references to or between them remain valid. Examples of such references are semantic links, revision and attestation. The rc_id attribute is of data type *Instance Identifier (II)*, which incorporates an ISO OID; II is currently considered internationally to be the most appropriate data type for persistent identifiers that are required to be globally unique. It is unlikely that contemporary EHR systems will have existing primary keys or internal identifiers that correspond directly to globally-unique II instances. However, an EHR provider system that has been issued with an organizational OID might use its internal references to construct unique *local extensions* to that OID and thereby construct globally-unique rc_id values. Alternatively, it might create completely new rc_ids and retain a record of the mapping of these to each internal identifier, so that any future EHR_EXTRACTS it generates will use consistent rc_id values. It is also unlikely that an EHR recipient system will be able to use received rc_id values as its internal primary keys for the data, since every database uses a slightly different approach to generating and using such keys. The EHR recipient might therefore also need to keep a record of the mapping of imported rc_id values to its primary keys, so that future references to those RECORD_COMPONENTS can be appropriately matched, and it can create EHR_EXTRACTs that reapply those rc_id values to the exported data. An alternative approach is for EHR systems to explicitly store the rc_id values along with the clinical data, and treat this as part of the “payload” data and not attempt to use these also as primary keys. It should also be noted that the rc_id does not function as a primary key equivalent within an EHR_EXTRACT i.e. duplicate values of rc_id are permitted if each instance does indeed refer to the same piece of clinical data within the EHR provider system.

FOLDER

This class is used to represent the highest-level organizations of EHR data within the EHR_EXTRACT, e.g., to group COMPOSITIONs by episode, care team, clinical speciality, clinical condition or time interval. Internationally, this kind of organizing structure is used variably: in some enterprises and systems the folder concept is treated as an informal compartmentalization of the overall health record; in others it might represent a significant legal portion of the EHR relating to the services provided by an enterprise or team.

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In the EHR_EXTRACT, FOLDERs are an optional hierarchy. FOLDERs may contain other FOLDERs to form a complete directory system, and may include any pertinent information about their committal or revision within the EHR Provider system. FOLDERs reference COMPOSITIONs via a list of unique identifiers, rather than by physically containing them. This permits any COMPOSITION to appear within more than one FOLDER, which is a requirement that some vendors and jurisdictions have indicated.

In some situations FOLDERs might be created specifically to organize the EHR_EXTRACT, or contain only a selected subset of the data in the corresponding folder in the EHR provider system. In such circumstances the FOLDERs within the EHR_EXTRACT will not have a direct correspondence with those in the contributing EHR provider system, i.e. they will have been synthesised.

A FOLDER may be used to group a set of COMPOSITIONS comprising the individual records made of members of a multi-professional team during a single clinical encounter. In situations like this where a FOLDER represents a finite interval of care, it may be attested. This approach should be used to communicate that the FOLDER's contents are a complete record of that interval of care. This also provides an indication to the EHR recipient that additional COMPOSITIONS ought not to be added to this FOLDER.

Since folder systems are used variably within EHR systems, this International Standard cannot prescribe how they should be handled within the EHR recipient's system: i.e. it does not require that the EHR recipient explicitly use these within its EHR system. However, if a FOLDER has been attested, an intact copy of this information shall be retained for future reference and possible onward communication.

COMPOSITION

The COMPOSITION represents the set of RECORD_COMPONENTS composed (authored) during one user's clinical session or record documentation session, for committal within one EHR. Common examples of this include a consultation note, a progress note, a report or a letter, an investigation report, a prescription form and a set of bedside nursing observations. The COMPOSITION documents the date and time or interval of the clinical encounter, and the legal jurisdiction in which the records were composed.

The composer is the agent (party, device or software) responsible for creating, synthesising or organizing information that is committed to an EHR. This agent takes responsibility for its inclusion in that EHR, even if not the originator of it and even if not the committer of it. The content of the COMPOSITION is primarily attributed to this person. Whether or not the composer is changed when a revision is made is optional. Applications will generally use the composer's name to label COMPOSITION data when used for clinical care. There may be occasions when there is no single main composer (e.g. a multi-professional tele-consultation, or a case conference); in such cases the composer role might not be formally specified even though each participant and clinical role is declared. The composer is therefore optional.

Provision is made for a COMPOSITION to include the details and locations of any other participants involved in the clinical encounter or record documentation session. Some of these might have participated from different locations (for example on the telephone, or via a video-consultation).

The COMPOSITION is the main container class for EHR data within the extract itself, to ensure that a consistent containment hierarchy is used within all Extracts: the EHR_EXTRACT contains a set of COMPOSITIONs together with audit data about the committal of each within the EHR Provider's system. A COMPOSITION is always used to communicate version updates between EHR systems, even if the actual updates refer to parts of that COMPOSITION. If multiple versions of EHR data are to be communicated within one EHR_EXTRACT, this will be as a set of distinct COMPOSITIONs, each referencing the preceding version and collectively referencing a version set identifier.

Each COMPOSITION also optionally documents any attestations (e.g. digital signatures) that pertain to it or to any of its contents.

Contribution The Contribution is the set of COMPOSITIONs committed by one user at one point in time in the EHR of one subject of care. Some clinical applications include complex screens capable of presenting multiple parts of an EHR simultaneously (for example through tabbed panes). On saving the screen, a user might actually be committing data to more than one part of the patient's EHR (e.g. the addition of a new consultation note and the revision of a medication entry stored elsewhere in the EHR). The Contribution refers to all of the changes and updates committed to that EHR during that committer's session. All of the COMPOSITIONs comprising one Contribution can be collectively identified by providing a common value for the contribution_id attribute.

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SECTION

The record entries relating to a single clinical session are usually grouped under headings that represent phases or sub-topics within the clinical encounter, or assist with layout and navigation. Clinical headings usually reflect the clinical workflow during a care session, and might also reflect the main author's reasoning processes. Much research has demonstrated that headings are used differently by different professional groups and specialties, and that headings are not used consistently enough to support safe automatic processing of the EHR. They are therefore treated in this part of ISO 13606 as an optional (informal) containment for human navigation, filtering and readability.

SECTIONs may be used to represent the containment hierarchy of clinical headings used within the EHR provider system to group and organize entries within a COMPOSITION. Each SECTION may contain additional SECTIONs and/or ENTRYs.

ENTRY

The ENTRY is the container class for the ITEM data structure that represents the information acquired and recorded for a single observation or observation-set (battery or time series), a single clinical statement such as a portion of the patient's history or an inference or assertion, or a single action that might be intended or has actually been performed. The ENTRY class associates this ITEM structure with a set of context attributes to facilitate safe interpretation:

— information in an ENTRY may be about someone other than the patient (e.g. a relative): ENTRY defines the subject of the information;

— information in an ENTRY may have been provided by or is attributed to a particular individual: ENTRY defines the information provider;

— other participants might need to be associated with a particular ENTRY;

— the ENTRY may represent the evolving status of a clinical act (e.g. requested, performed, reported, cancelled) and may optionally carry an identifier that links it with a workflow system;

— the ENTRY may use a flag to advise the EHR recipient that the data structure includes some indication of uncertain findings or opinions, and that care needs to be taken when using the data for automated processing.

The ENTRY contains a data structure represented using CLUSTERS and ELEMENTS. It is important to note that ENTRY cannot contain further ENTRYs. The set of contexts defined at the ENTRY level (e.g. the subject of information) apply to the whole data structure and cannot be overridden.

ITEM, CLUSTER and ELEMENT

The ITEM may represent both the actual data describing the observation, inference, or action, and optionally the details describing the examination method, the patient’s physical state or details supporting the clinical reasoning process such as a reference to an electronic guideline, decision support system or other knowledge reference. The item_category attribute provides an optional means of distinguishing these different parts of a data structure, as an aid to the automated analysis or filtering of the ITEMS in an ENTRY. The codeset for this attribute is defined in ISO 13606-3.

Information in an ITEM (CLUSTER or ELEMENT) might have originated at a date/time different from the care activity or its recording. The obs_time attribute permits representation of a single date or time or an interval, to any level of granularity. This would permit, for example, an operation to be dated only by the year, the onset of a symptom to a month and year, a period of employment to be a precise date range or an interval in years, the precise time-stamping of an arrhythmia, or an angiogram to be organized as a time series of images.

Information in an ITEM might be emphasised by the author as being exceptional or noteworthy. This part of ISO 13606 does not define a code set for this attribute; any agreed terminology may be used to specify the degree of emphasis or to specify the kind of exception.

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The CLUSTER supports the representation of complex data structures needed to represent the actual data values within a multi-part (nested) observation, clinical statement or instruction. These may need to be represented as a table, a tree or a time series. Specific examples include an ECG tracing, a full blood count, ankle reflex examination, the prescription of an intravenous drug infusion.

The ELEMENT class represents the leaf node within the EHR hierarchy. Each instance of this class will have a single data value. (A ratio, an interval or a co-ordinated term are considered here to be examples of single data values). Examples of ELEMENT might include reason for encounter, body weight, pulse. An ELEMENT may have a null data value, for example if a value is not known.

Data values

Each ELEMENT contains one data value, to represent the actual instance values. This is one of the CEN Data Types (CEN/TS 14796) for:

— text and coded terms;

— quantities including ratios, intervals and durations;

— dates and time;

— graphical and other MIME type (e.g. image, signal).

It is recognised that, at the time of producing this part of ISO 13606, a new set of health informatic data types is being developed by ISO/TC 215. Once this is published, CEN is expected to deprecate CEN/TS 14796 in favour of this new standard. In doing so, it will need to provide a mapping correspondence to the new data type standard, and this mapping will also need to be used in order to adopt the new data types alongside this part of ISO 13606.

In order to support the adoption of this part of ISO 13606 more widely internationally than the jurisdiction of CEN/TS 14967, the set of attribute data types actually used within this reference model (other than the data value of ELEMENT) are explicitly included in this part of ISO 13606 in a support package. These should also be deprecated in favour of ISO data types once published.

NOTE Primitive data types such as Boolean, Integer are assumed to follow ISO/IEC 11404 and are not further defined here.

0.7 Description of the other principal classes of the reference model

AUDIT_INFO

It is a medico-legal requirement to document and to communicate when and by whom EHR data were entered into an EHR system. It is also important to track changes to EHR data if modifications are made, and to communicate this within an EHR_EXTRACT. The AUDIT_INFO class is used to represent these audit data:

a) for any RECORD_COMPONENT, as a permanent record of its commitment in its originating EHR system;

b) for any COMPOSITION, as a record of its commitment within the EHR provider system that has generated this EHR_EXTRACT.

A COMPOSITION might therefore have up to two audit data sets, one relating to its originating EHR system (called “feeder_audit”) and one to its subsequent commitment within the EHR provider’s system (called “committal”), if these are different. This part of ISO 13606 does not, however, require or support the communication of an indefinite accumulation of audit data sets for every system into which a COMPOSITION is committed. This is because a cumulative set of audit data sets without the actual clinical data to show the details of what was changed each time is not considered to be of clinical value. If a full change history is required to be communicated, each version of the COMPOSITION needs to be included in the EHR_EXTRACT.

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For committal, the AUDIT_INFO class represents the timestamp of committal, it identifies the committer, and the EHR system into which the data were committed. The timestamp reflects when this RECORD_COMPONENT was persisted with in an EHR system and therefore became part of the EHR of the subject of care. The committer is responsible for including this RECORD_COMPONENT within the EHR, but might not be responsible for deciding upon the clinical content being committed.

The committer and time committed attributes are optional, to allow for the possibility that some data will have been imported from simple legacy systems in which the clinical data originated but for which these values are not known. However, for the committal AUDIT_INFO association these attributes are required to have non-null values, since they represent the time and party responsible for authorizing the clinical data to be included within an EHR system conforming to this part of ISO 13606.

For revision, the AUDIT_INFO class represents the version status, an optional reason for revision, the identity of the immediately previous version that was the basis of this revision, and an identifier that is common to all versions so that non-sequential versions made on different EHR systems can still be related to each other. An optional version status attribute indicates if the present version was, at the time of its committal, a draft (i.e. intended to be replaced in the near future), an update to a previous draft version, a correction of an erroneous former version, or an empty COMPOSITION or ENTRY that is the logical deletion of its predecessor (e.g. if the predecessor was saved in the wrong EHR). If no status is given, it is assumed that this is the definitive (first) version.

EHR systems vary in the granularity of EHR data at which committal and revision are permitted, and it is quite likely that all of the RECORD_COMPONENTs within a part of an EHR hierarchy (e.g. within one COMPOSITION) will share the same audit data. The standard therefore only requires the representation of this information if it is different from that of the parent RECORD_COMPONENT.

FUNCTIONAL_ROLE

This class is used to represent the details of who and where an individual agent has contributed to the healthcare or health record of a subject of care. This class identifies:

— the function that was performed in the situation being documented;

— the identity of the agent performing the function;

— the mode in which participation was made (e.g. in person, by telephone);

— the healthcare facility at which the agent was present;

— the kind of service location, department or setting in which the agent performed that role.

Some of this information may be omitted if the performer was not acting within a healthcare facility, e.g. a subject of care entering data from home.

ATTESTATION_INFO

Attestation is the process of certifying and recording legal responsibility for a particular unit of information. The attestation of part of an EHR is a mechanism whereby the attester can provide his or her authority that those contents are, in his or her opinion, correct. This means that he or she is satisfied that the contents are a fair and faithful reflection of the processes they document, and do not deliberately misrepresent the truth. Attesting a part of an EHR will not have modified its content or interpretation, other than by adding weight to its authenticity. (Anything which added an opinion, a new viewpoint or perspective would have been either a revision or a new set of entries with a link to this one.)

Clearly any modification to a part of an EHR through revision cannot automatically carry forward any previous attestations; if necessary the original attester would have been invited to re-attest that he or she remains happy now it has been modified or the reviser attested the new version or both or neither.

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There has been much debate over many years about what information needs to be retained within electronic systems:

a) to verify the authorization of the attester (ranging from a simple flag to indicate that he had been authenticated in that system's normal way, to a complex hash of the user's digital key, date and time and part or all of the document being signed and optionally sent to a trusted third party notary service);

b) as a permanent legal record of what was attested (ranging from no specific addition to the raw database record that is being signed, to XML output files with a stylesheet as a proxy to show how it was presented, to bitmaps of each screen as it was actually presented for signature).

Attestation may be carried out by more than one person, at different times from the committal, and might not always be required in some healthcare services. The attester will sometimes also be the committer, but might not be, for example, if a medical secretary is typing in the data.

This part of ISO 13606 acknowledges that in some situations it will be appropriate to communicate the detailed evidence of an attestation, and in others to simply confirm that the data were attested in the EHR provider's system and to only communicate the name of the signatory and date of the attestation.

The ATTESTATION_INFO class represents the following data about an attestation:

— the date and time at which it occurred;

— the person who made this attestation, as a reference to the FUNCTIONAL_ROLE class described above;

— the list of RECORD_COMPONENTS that were attested;

— optionally the reason for, or legal significance of, this attestation;

— optionally the electronic signature (as encapsulated data, or as reference to it) that verifies the attestation;

— optionally the encapsulated data, or a reference to it, that represents the visual image that was actually viewed by the attester; it is now required in some EU countries that this is retained within the EHR in addition to the data in its processable form.

Attestations relating to a FOLDER are contained by that FOLDER; it is anticipated that this will be rare. More commonly, whole COMPOSITIONS or individual ENTRYs within a COMPOSITION will be attested; all attestations pertaining to a COMPOSITION or any of its contents are contained by the COMPOSITION.

RELATED_PARTY

It is occasionally the case that EHR data describe the health or a healthcare event about someone other than 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 and this needs to be unambiguously distinguished from the majority of EHR information which is about the subject of care. The ENTRY includes an attribute "subject_of_information", which uses the RELATED_PARTY class to represent an information subject who is not the subject of care.

This class may be used:

a) to identify a person in terms of his or her relationship to the subject of care, as a coded term or textual description;

b) optionally to identify the person through an identifier, and to provide a demographic description set for that person within the demographics package of the EHR_EXTRACT.

It is recognised that, for data protection reasons, it is not common to actually link the EHR of one data subject to that of another (e.g. if a family member is also a patient at the same enterprise), but that this will occasionally occur within clinics providing genetic or family therapies, and sometimes in primary care. This part of ISO 13606 does not formally support a linkage between the EHRs of different subjects of care, although this class may be used to provide identifiers that are the actual identifiers by which another person is known within the EHR Provider's system, if such use is permitted.

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LINK

A user may wish to create *ad hoc* semantic links between any arbitrary points in an EHR, for example to indicate the evolution of a condition, the likely historic cause of a problem, or a response to a previous request, to indicate cause and effect, to track the evolution of orders from request to completion, or to form linkage networks for clinical problems or episodes. In these situations a mechanism is required for a composer to point from any node in their current screen form or electronic document to any previous component in the EHR, and to label the link with an appropriate clinical term. Sometimes one location in the EHR may act as a kind of linkage hub, for example the formal statement of a clinical condition might be used as an anchor point for all historic and subsequent entries relating to that condition (e.g. in a problem oriented record).

Such links might be created by the user as a pointer from a new record entry to a pre-existing one, or might be created as a new statement of a clinical relationship between two or more pre-existing entries (by pointing to each of them from a current entry justifying the relationship). A wide range of end user interfaces can be envisaged for such functionality, but the task of this International Standard is to provide a generic and safe means for communicating the existence of such links to diverse EHR systems. This might at times require the communication of the link target as well at the link source, because a composer felt that any future recipient needs to be aware of the content of both entries, for example if a procedure or a drug prescription had catastrophic complications.

The LINK class that is associated with RECORD_COMPONENT permits any number of labelled links to be represented from a source component to any number of targets (by referencing their unique identifiers).

Two attributes are available to label each LINK:

a) a coarse-grained link category, which needs to be one of several values defined in Part 3;

b) an optional fine-grained label; an informative list of terms for this is given in Part 3, but other terminologies may be used.

A further and important feature is the follow_link Boolean attribute which, if true, indicates that the composer intended that any EHR_EXTRACT that includes the COMPOSITION containing the source shall also include the COMPOSITION containing the target and vice versa. The receiving system will need to indicate the existence of this additional information to users accessing data that are at one end of such a LINK.

0.8 Discussion of particular representation topics

Representing roles and responsibilities within the EHR _EXTRACT

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 patient's EHR. The approach taken in most generic EHR architectures, including this part of ISO 13606, is to differentiate these into three broad categories.

Actors playing a role in the actual healthcare process

This set will usually include a core party who is the key person relating to the patient during that act (e.g. during a forceps delivery in an industrialized country it will normally be an obstetrician) and a series of related parties who may be providing or supporting parts of the care (e.g. midwives) are involved in making decisions (e.g. an anaesthetist) are observers (e.g. medical students) or are present to support or co-represent the patient (e.g. the patient'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 patient is under his team, even if he is himself not with the patient on that occasion. Sometimes actors might be documenting a case review or a care planning negotiation involving one or more professionals but where the patient is not present.

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 often complete different records of events and may also attest them independently.

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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. free of typos and omissions) and for the signator to confirm that he agrees to the content (e.g. to validate a prescription). In most of these situations the status or seniority of the signator 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 an observation 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.

Clearly there is 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 ENTRYs.

The approach taken in this part of ISO 13606 (as in other EHR architectures such as ENV 13606 and HL7 CDA), 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 to permit attestation only of parts of COMPOSITIONs.

Some specific roles that have been defined in this reference model are discussed below.

Subject of care

It is assumed that each EHR, and therefore any EHR_EXTRACT, will be about the health and healthcare of one person, who is also, in data protection terms, the data subject. This does have important implications for data contained in that EHR that might relate to a different data subject (as in the case of family history); this is discussed below under subject of information.

Several “special case” exceptions are often cited to the norm that each EHR is about one data subject.

Pregnancy: here it is usual 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 being 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 foetus having its own record: this is often cited as a situation in which health actions might really “belong” to two 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).

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“Siamese” twins: yes, there has been discussion on such rare cases! Again in this case it seems logical and safe for each twin to have a copy of the relevant COMPOSITIONs, whenever separate EHRs are created, rather than inter-linked record extracts that might not be safely managed by receiving systems.

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 of the donor and in future the genetic record of the donor – as the person will from this time on be a genetic mosaic. For this reason, the subject of the information or some information in the EHR may be “donor”.

The subject of care identifier in the EHR_EXTRACT will reference a snapshot of demographic information as held by the EHR Provider, to enable the patient 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. Subject of care is defined at the root of the model, in the EHR_EXTRACT class.

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 writing up the notes on behalf of a team. Even so, it will be the composer's words or phrases that shape the documentation.

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 as other participations, either for the whole COMPOSITION or for individual ENTRYs.)

Committer

In many situations the person who composes the words is not the one who keys 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 patient'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 patient’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 other_participations attributes of ENTRY can be used to supplement the set of defined actors.

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 e.g. if the information is about a family member, such as the patient's father or mother. This is regarded as an important “safety” attribute to supplement any meaning implied by a component name or archetype, particularly if records are communicated across countries and languages.

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 patient's EHR. This will increasingly arise in clinical fields like cancer genetics that manage patients within their family context. The more common situation is where the patient is describing the health of others.

The subject_of_information association from ENTRY refers to the class RELATED_PARTY, permitting the relationship of that subject to the patient to be defined as a coded term, and optionally also through a party identifier (probably linking to the demographics service within the EHR system).

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This approach will allow archetypes to be re-used with different subjects of care, and the unambiguous processing of EHR ENTRYs to distinguish data about the patient from data about other parties.

Information provider

Most of the information documented in an EHR will originate from the patient or one of the other participants in the care act. However at times ENTRYs may be added whose data values have originated from some other party, for example a relative or carer who might be with the patient or seeing the patient's doctor alone confidentially. Other clinical parties might provide information indirectly (e.g. by telephone) to the composer.

The info_provider association from ENTRY refers to the class FUNCTIONAL_ROLE, permitting their function and mode of contribution (by telephone, in person, etc.) to be represented. As with the subject of information, the party might or might not be formally identified, depending on consent and if they are registered in the local demographic service. The formal identification of information providers provides one way for a composer to attribute some ENTRYs in that COMPOSITION to other clinicians or to devices (the other_participations attribute in another way).

Demographics

An electronic health record may refer to a wide range of specific entity instances, such as the subject of care, the various healthcare and other agents who have played roles in the delivery of healthcare, devices that have measured body parameters or delivered treatments, and organizations that have assumed responsibilities for care. Many of these referenced entities multiply within any given EHR, and in any enterprise might be defined within a demographics server.

In this reference model an equivalent approach has been taken: specific entities are defined once within a demographic extract package, and referenced as necessary throughout the rest of the EHR_EXTRACT by a dedicated instance identifier. The instance identifier used within the EHR_EXTRACT might be, but need not be, one of the actual identifiers by which each entity is known in the EHR Provider system.

The goal of this part of the model is to provide a necessary and sufficient description of each entity to support human interpretation of the EHR, and demographic matching to enable the EHR recipient to identify the corresponding entities within its own demographic server. If a more detailed exchange of demographic information is required, it is recommended that an appropriate alternative standard be used, such as CEN/TS 14796.

The whole DEMOGRAPHIC_EXTRACT package is optional, and the demographic details of each entity need not be communicated if it is known that both EHR Provider and EHR Recipient share or can access a common demographic service – for example within one enterprise, region or health service.

Revision

Revision is an important and potentially complicated area. In addition to the well-known medico-legal requirements for tracking and attributing revisions, the following functional requirements have underpinned the approach taken:

1) the vast majority of requests for parts of or whole EHRs will warrant the generation of an EHR_EXTRACT that contains the most up-to-date versions of the contained RECORD_COMPONENTs;

2) even in such situations, it may be important to know that the communicated RECORD_COMPONENTs have been the subject of a correction;

3) there will be an infrequent need to transfer serial versions of RECORD_COMPONENTs for clinical care purposes, for example to explain an error;

4) there is a need to be able to transfer a whole EHR, including all versions of revised components, for example when care is legally being transferred between enterprises;

5) the COMPOSITION should anchor the communication of committal and revision within the EHR_EXTRACT, even though the changes made through a revision might only affect a few of its contained components;

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6) the evolution of FOLDERs over time may also need to be similarly revision-managed, although this will usually be within EHR systems and a FOLDER audit log will probably only occasionally be included within an EHR_EXTRACT;

7) in many cases it might not be legal to communicate errors that have been corrected; revised components should therefore not “contain” the original data that have been corrected, even if marked as logically deleted. For example, erroneous data corrected at the request of a patient need not be communicated according to EU Directives and most national data protection legislation;

8) in some cases, for example if determined by a court of law, data might be physically deleted from an EHR system; in such cases it might sometimes be appropriate to retain an empty place-holder RECORD-COMPONENT at the same point in the hierarchy, to indicate when and why the deletion took place.

A variety of techniques exists for version-tracking of modifications within databases, any of which might be used within individual EHR systems. The approach taken for this part of ISO 13606 is to specify a structured way in which the necessary clinical and medico-legal requirements can be met within an EHR_EXTRACT, without prescribing any particular versioning methodology to be used inside these EHR systems.

The AUDIT_INFO class contains a set of attributes that define the EHR system, committer and time committed that define the origin of any RECORD_COMPONENT within the EHR system in which it was first created. This data set needs to be included within the EHR_EXTRACT whenever this RECORD_COMPONENT is communicated. If the RECORD_COMPONENT is a revision of a former version, an additional set of descriptions and references to previous versions needs also to be provided. It is therefore always possible to know if a RECORD_COMPONENT has been revised, when, why, by whom and in which EHR system. The identity of the previous version is known, but it is only possible to access this previous version if the EHR recipient has the necessary privileges and the EHR provider is prepared to release it.

Communicating EHR queries

Users frequently require views of certain types of entry or of higher level groupings, which can be derived computationally by filtering the longitudinal EHR for certain classes of information (in future this could be by archetype). Certain attribute or data values might be used to sort the resulting filtrate into a suitable user view, for example by date, alphabetically or by descending size of the value.

There are no specific features required of the underlying EHR entries to support this, and the logic for deriving each view will usually reside within a clinical application, not within each individual EHR. The result of performing the query is not normally itself stored in the EHR or communicated, so the EHR communications reference model does not need to represent it. Examples might be a graph of blood pressures over time or a list of medication prescribed within the past 30 d.

Some views or filtrations might be derived by a “custom” query that has been specifically composed for use within a particular subject of care’s EHR. In such cases it may be desirable to store the query parameters within the patient's EHR for the benefit of future clinicians. The extent to which this is useful to share between enterprises and systems depends on how interoperable that query specification is. Given that the language for specifying archetype definitions and constraints (Archetype Definition Language – ADL) has now been standardized (in Part 2), and the guidelines community is also progressing towards interoperable specifications, it seems likely that a generic EHR query specification will emerge.

There is, as yet, no standardized convention for specifying an EHR-related query, but it is likely that these specifications will be a data set of string values or name value pairs. Such a specification can be represented within the ITEM sub-classes CLUSTER and ELEMENT, with data values of type STRING. ENTRY archetypes can therefore be used to define the representation of any EHR queries that need to be communicated. This has the advantage that more than one such query specification can be defined for use within healthcare systems, and refined over time, without requiring any modification to this part of ISO 13606. An illustrative example is given below.

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ENTRY Blood Pressure Graph Query

CLUSTER: Query Specification

ELEMENT: Query Syntax: <EHR_OQLv1>

ELEMENT: Query String: "Select….

where Cluster.meaning = <Blood Pressure>

and containing.Entry.subject_of_information = <Patient>

and containing.Composition.Clinical_Session.session_time.start

> (now>-365days)"

ELEMENT: Datetime first authored: 20 February 2003

NOTE The actual syntax of the query string in the example above is for illustration only, and does not conform to any known syntax. In the case of such a real query stored in the record the syntax would have to follow whatever scheme is identified in the query syntax ELEMENT.

Communicating presentation information

It is not generally regarded as appropriate to include details within an EHR communication of how the clinical data were originally presented on screen at the time of data capture, for several reasons:

1) data capture screens do not often correspond directly to data presentation screens, even within one clinical application, so it is not of much clinical use for another healthcare professional to be informed about how the screen looked just before it was saved;

2) clinical data can often be displayed in more than one way (e.g. on summary screens, detail screens), and different users might find different presentations of more or less use to their situation;

3) the EHR recipient system might not be able to precisely display the screen layouts supported by the EHR provider's system;

4) the EHR recipient's healthcare professionals are likely to have their own applications through which they wish to view both imported and locally-created data consistently.

However, there are two scenarios in which precise presentation information might be important to communicate along with the EHR data:

a) if there is a need to capture the appearance of the screen and the way the data were organized for medico-legal purposes (e.g., to show what data a clinician actually saw when signing the data);

b) if a particular presentation of the data conveys unique insight into its interpretation, such as a diagram or chart.

In both cases, the attested_view attribute of ATTESTATION_INFO can be used to include an encapsulated data representation for any level of granularity of EHR data. This attribute may be used, for example, to include the rendered view of an HL7 version 3 CDA Release 1 or Release 2 document.

Rather than presentation, clinical requirements investigations have shown the more frequent need to highlight a particular part of the data as being noteworthy, abnormal or unexpected. In such situations the requirement is usually to indicate that the data should be emphasised appropriately to the end user rather than dictate if it needs to be shown in bold or in red font. The ITEM emphasis attribute permits this to be communicated as a coded value.

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Communicating multimedia data

The requirement to include and communicate multimedia data within EHRs, for example the results of diagnostic imaging studies, is without question. Health professionals from all disciplines and specialities wish to be fully informed when making care decisions, and patients themselves increasingly wish to be able to see and understand their own health problems, including visual formats such as images. Downstream users of multimedia reports might include those offering supplementary specialist opinions on a study and advising on subsequent care planning, or those needing to review former studies when interpreting a new one (potentially at another site or in another country).

Within an EHR, data of a wide range of media types may be included as the specific data value of an ELEMENT. More complex multimedia data structures can therefore be represented by combinations of ELEMENT classes optionally contained by CLUSTERs, as tables, lists or trees. Particular data structures or multimedia reports can be represented as specific ENTRYs or COMPOSITIONs, and can be archetyped.

The data type option for encapsulated data (short code ED), as defined by CEN/TS 14796, permits any MIME data type to be represented.

0.9 Comparison between ISO 13606-1 and EN 13606-1

In February 2007, CEN published EN 13606-1, which is the European version of this part of ISO 13606 and which applies jurisdictionally to European Member Bodies. This International Standard, ISO 13606-1, is materially identical to its European equivalent. There are several areas of minor difference between the two documents, which will not affect its adoption, implementation or conformance, but which are summarised here for the benefit of those readers in possession of both documents.

ISO 13606-1 differs from EN 13606-1 in the following normative provisions:

— the wording of Clause 1 **Scope** has been modified (extended) to include the following phrase at the end of the second paragraph: “or as the representation of EHR data within a distributed (federated) record system.”;

— Subclause 5.2 Member State Conformance has been reworded to be more appropriate to the ISO context, and been re-titled **Member Country Conformance**;

— the value of the attribute rm_id within the class EHR_EXTRACT has been changed from “EN 13606-1” to “ISO 13606-1”.

This Introduction has been edited to clarify (but not to alter) the receiver responsibilities in respect of FOLDERs and LINKs, and the circumstances in which the identity of the composer of a revised COMPOSITION might be changed if it is revised.

The following editorial changes have been made:

— references to a European Standard have been changed to International Standard throughout;

— references to EN 13606 have been changed to ISO 13606 throughout;

— general wording that refers to Europe or to European prestandards has been modified where appropriate for an International Standard readership;

— a few definitions for terms that did not confirm to ISO regulations have been editorially rephrased but not materially reworded – i.e. their technical interpretation is unchanged;

— a few outstanding minor typographical errors and inconsistencies of terms used within the document have been tidied.

This section of the Introduction does not have a corresponding counterpart in EN 13606-1, as the exact content of this ISO 13606-1 was not known when EN 13606-1 was published.

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1 Scope

This part of ISO 13606 specifies the communication of part or all of the electronic health record (EHR) of a single identified subject of care between EHR systems, or between EHR systems and a centralized 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 part of ISO 13606 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 anonymization or aggregation of individual records, are not the focus of this part of ISO 13606 but such secondary uses might also find this document useful.

This part of the multipart series, ISO 13606, is an information viewpoint specification as defined in ISO/IEC 10746-1[13]. This part of ISO 13606 is not intended to specify the internal architecture or database design of EHR systems.

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.

CEN/TS 14796:2004, *Health Informatics — Data Types*

3 Terms and definitions

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

3.1
abstract class
virtual common parent to two or more classes which cannot itself be instantiated

3.2
access control
means of ensuring that the resources of a data processing system can be accessed only by authorized entities in authorized ways

[ISO/IEC 2382-8:1998, definition 08.04.01]

3.3
accountability
property that ensures that the actions of an entity may be traced uniquely to that entity

[ISO/IEC 2382-8:1998, definition 08.01.10]

3.4
archetype instance
metadata class 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

3.5
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

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3.6
archetype repository
persistent repository of archetype definitions, accessed by a client authoring tool or by a run-time component within an electronic health record service

3.7
attester
party (person) who certifies and records legal responsibility for a particular unit of information

3.8
attestation
process of certifying and recording legal responsibility for a particular unit of information

3.9
audit trail
chronological record of activities of information system users which enables prior states of the information to be faithfully reconstructed

3.10
authentication
process of reliably identifying security subjects by securely associating an identifier and its authenticator

3.11
authorization
granting of rights

3.12
client application
healthcare application that is behaving at that moment as a requester of health record data from a shareable electronic health record

3.13
clinical information
information about a person, relevant to his or her health or healthcare

3.14
committed
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

3.15
committer
agent (party, device or software) whose direct actions have resulted in data being committed to an electronic health record

3.16
composer
agent (party, device or software) responsible for creating, synthesising or organizing information that is committed to an electronic health record

NOTE 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.

3.17
confidentiality
property that information is not made available or disclosed to unauthorized individuals, entities or processes

[ISO 7498-2:1989]

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