

DIN EN ISO 13940

ICS 35.240.80

Ersatz für
DIN EN 13940-1:2007-09

**Medizinische Informatik –
Begriffssystem zur Unterstützung der Kontinuität der Versorgung
(ISO 13940:2015);
Englische Fassung EN ISO 13940:2016**

Health informatics –
System of concepts to support continuity of care (ISO 13940:2015);
English version EN ISO 13940:2016

Informatique de santé –
Système de concepts en appui de la continuité des soins (ISO 13940:2015);
Version anglaise EN ISO 13940:2016

Gesamtumfang 169 Seiten

DIN-Normenausschuss Medizin (NAMed)

Nationales Vorwort

Dieses Dokument (EN ISO 13940:2016) wurde vom Technischen Komitee ISO/TC 215 „Health informatics“ (Sekretariat: ANSI, USA) unter Beteiligung deutscher Experten erarbeitet und vom Technischen Komitee CEN/TC 251 „Medizinische Informatik“ (Sekretariat: NEN, Niederlande) übernommen.

Das zuständige deutsche Normungsgremium ist der Arbeitsausschuss NA 063-07-03 AA „Terminologie“ im DIN-Normenausschuss Medizin (NAMed).

Dieses Dokument enthält unter Berücksichtigung des DIN-Präsidialbeschlusses 1/2004 nur die englische Originalfassung von EN ISO 13940:2016 bzw. ISO 13940:2015.

Für die in Abschnitt 2 zitierte Internationale Norm wird im Folgenden auf die entsprechende Deutsche Norm hingewiesen:

ISO 9000 siehe DIN EN ISO 9000

Zusammenfassung

Diese Internationale Norm legt ein Begriffssystem für unterschiedliche Aspekte der Pflege im Gesundheitswesen fest.

Im Gesundheitswesen geht es im Kern um die Interaktion zwischen der (den) zu pflegenden Person(en) und den Gesundheitsexperten. Zu solchen Interaktionen kommt es im Gesundheitswesen/in klinischen Prozessen, und sie sind der Grund für den Prozessansatz dieser Norm. Um die Darstellung von sowohl klinischen Inhalten als auch klinischem Kontext zu ermöglichen, basiert diese Internationale Norm auf einem generischen Modell klinischer Prozesse und auf umfassenden Konzeptdefinitionen und Konzeptmodellen für die klinischen, verwaltungstechnischen und ressourcenbezogenen Aspekte von Gesundheitsdienstleistungen.

In der Praxis behandelt die vorliegende Internationale Norm Begriffsdefinitionen, die benötigt werden, wenn strukturierte Informationen im Gesundheitswesen als Anforderungen festgelegt sind. Diese Internationale Norm gilt für alle Ebenen von Spezifikationen bei der Entwicklung von

- logischen Referenzmodellen unter dem Informationsaspekt als einer gemeinsamen Basis für semantische Interoperabilität auf internationaler, nationaler und lokaler Ebene,
- Informationssystemen und
- Informationen für festgelegte Arten von klinischen Prozessen.

Die Ausführung von speziellen gesundheitspflegerischen/klinischen/Informatik-Prozessen ist nicht Gegenstand der vorliegenden Internationalen Norm.

Forschungs- und Bildungsprozesse im Gesundheitswesen sind nicht Gegenstand der vorliegenden Internationalen Norm.

Änderungen

Gegenüber DIN EN 13940-1:2007-09 wurden folgende Änderungen vorgenommen:

- a) Integration der ursprünglich als Teil 2 „Kernprozess und Ablaufplan im Gesundheitswesen“ vorgesehenen Erweiterung als Normenreihe;
- b) komplette redaktionelle Überarbeitung.

Frühere Ausgaben

DIN V ENV 13940: 2002-10
DIN EN 13940-1: 2007-09

Nationaler Anhang NA (informativ)

Begriffe

Die Benummerung der folgenden Begriffe ist identisch mit der Benummerung in der englischen Fassung.

Für die Anwendung dieses Dokuments gelten die Begriffe nach ISO 9000 und die folgenden Begriffe.

3.1 Gesundheitswesen

3.1.1

Gesundheitswesen

(en: healthcare)

Pflegemaßnahmen, Dienstleistungen, Verwaltung oder Hilfs- und Betriebsstoffe, die der Gesundheit einer Person dienen

Anmerkung 1 zum Begriff: Dies umfasst mehr als die Durchführung von Verfahren an Behandelten bzw. zu Behandelnden. Es umfasst z. B. auch die Verwaltung von Informationen zu den Patienten, zu ihrem Gesundheitszustand sowie zum Status ihrer Einbindung in das Gesundheitswesen und kann auch die Verwaltung von klinischem Wissen umfassen.

[QUELLE: ISO/TR 18307:2001, 3.70, modifiziert]

3.1.2

Kontinuität der Pflege

(en: continuity of care)

effiziente, wirksame, ethische Pflege, die durch Interaktion, Integration, Koordination und gemeinsame Nutzung von *Informationen* (3.9.5) zwischen verschiedenen Akteuren des Gesundheitswesens über einen bestimmten Zeitraum erbracht wird

Anmerkung 1 zum Begriff: Der Begriff „Akteure im Gesundheitswesen“ wird in 5.2.1 definiert.

3.2 Begriffe und Benennungen

3.2.1

Begriff

(en: concept)

Wissenseinheit, die durch eine eindeutige Kombination von Merkmalen erzeugt wird

[QUELLE: ISO 1087-1:2000, 3.2.1]

3.2.2

Begriffssystem

ABGELEHNT: Konzeptsystem

(en: system of concepts

DEPRECATED: concept system)

Menge von *Begriffen* (3.2.1), die entsprechend den zwischen ihnen bestehenden Beziehungen strukturiert ist

[QUELLE: ISO 1087-1:2000, 3.2.11]

3.2.3**abgelehnte Benennung**

(en: deprecated term)

Benennung, die von einer zuständigen Stelle zurückgewiesen wird/wurde

[QUELLE: ISO 1087-1:2000, 3.4.17]

3.3 Akteure**3.3.1****Organisation**

(en: organization)

eindeutiger Autoritätsrahmen, innerhalb dessen eine oder mehrere *Person(en)* (3.3.4) für bestimmte Zwecke handelt (handeln) oder zu handeln benannt wurde(n)

[QUELLE: ISO/IEC 6523-1:1998, 3.1]

Anmerkung 1 zum Begriff: Gruppen oder Teile von Organisationen können ebenfalls als Organisationen angesehen werden, falls für die Zwecke des Informationsaustauschs die Notwendigkeit besteht, sie in dieser Weise zu identifizieren.

Anmerkung 2 zum Begriff: In der vorliegenden Internationalen Norm gilt diese Definition für alle Arten von Organisationen unabhängig von ihrer Rechtsform.

3.3.2**Organisationsstruktur**

(en: organizational pattern)

Beziehungen zwischen den verschiedenen Teilen einer *Organisation* (3.3.1)**3.3.3****Beteiligte(r)**

(en: party)

Person oder Gruppe, die eine *Funktion* (3.3.5) in Bezug auf die geschäftlichen Aktivitäten einer bestimmten Gemeinschaft oder Domäne ausübt

[QUELLE: ISO 8459:2009, 2.33]

3.3.4**Person**

(en: person)

ein als Individuum angesehener Mensch

3.3.5**Funktion**

(en: role)

Funktion (en: function) oder Position

[QUELLE: ISO/HL7 21731:2006]

3.3.6**persönliche Funktion**

(en: person role)

von einer *Person* (3.3.4) übernommene *Funktion* (3.3.5)

3.3.7

Organisationsfunktion

(en: organization role)

von einer *Organisation* (3.3.1) übernommene *Funktion* (3.3.5)

3.4 Ressourcen

3.4.1

Ressource

(en: resource)

Vermögenswert, der während der Ausführung eines *Prozesses* (3.6.1) zum Einsatz kommt oder verbraucht wird

Anmerkung 1 zum Begriff: Dazu gehören unterschiedliche Einheiten, wie z. B. die Finanzierung, Personal, Anlagen und Einrichtungen, finanzielle Ausstattung, Werkzeuge und Betriebsmittel wie Netzstrom, Wasser, Treibstoff und Kommunikationsinfrastruktur.

Anmerkung 2 zum Begriff: Zu den Ressourcen gehören auch solche, die wiederverwendbar, erneuerbar oder verbrauchbar sind.

BEISPIELE Zeit, Personal, soziale Kompetenzen und Wissen, technische Ausrüstung, Dienstleistungen, Hilfs- und Betriebsstoffe, Anlagen und Einrichtungen, Technologie, Daten, Geld

[QUELLE: ISO/IEC/IEEE 15288:2015, 4.1.38, modifiziert]

3.4.2

Medizinprodukt

(en: medical device)

alle Instrumente, Apparate, Geräte, Maschinen, Vorrichtungen, Implantate, In-vitro-Reagenzien, Kalibriermittel, Software, Stoffe oder anderen ähnlichen oder zugehörigen Gegenstände, die vom Hersteller zur Anwendung für Menschen einzeln oder in Kombination für einen oder mehrere der folgenden spezifischen Zwecke bestimmt sind:

- Erkennung, Verhütung, Überwachung, Behandlung oder Linderung von Krankheiten;
- Erkennung, Überwachung, Behandlung, Linderung oder Kompensierung von Verletzungen oder Behinderungen;
- Untersuchung, Ersatz, Veränderung oder Unterstützung des anatomischen Aufbaus oder eines physiologischen Vorgangs;
- Unterstützung oder Erhaltung des Lebens;
- Empfängnisregelung;
- Desinfektion von Medizinprodukten;
- Lieferung von *Informationen* (3.9.5) für medizinische Zwecke durch In-vitro-Untersuchung von vom Menschen stammenden Proben;

und deren bestimmungsgemäße Hauptwirkung im oder am menschlichen Körper weder durch pharmakologische oder immunologische Mittel noch metabolisch erreicht wird, deren Wirkungsweise aber durch solche Mittel unterstützt werden kann

Anmerkung 1 zum Begriff: Diese Definition wurde durch die Arbeitsgruppe für Globale Harmonisierung (GHTF) entwickelt.

Anmerkung 2 zum Begriff: Produkte, die unter einigen Gesetzgebungen als Medizinprodukt angesehen werden können, für die jedoch noch keine harmonisierten Herangehensweisen vorliegen, sind:

- Hilfen für Behinderte;
- Produkte für die Behandlung bzw. Diagnostik von Krankheiten und Verletzungen bei Tieren;
- Zubehör für Medizinprodukte (siehe Anmerkung 3);
- Desinfektionsmittel;
- tierisches und menschliches Gewebe enthaltende Produkte, die den Anforderungen der obigen Definition entsprechen können, jedoch unterschiedlichen Kontrollmaßnahmen unterliegen.

Anmerkung 3 zum Begriff: Zubehör, das von Herstellern spezifisch zur Verwendung zusammen mit einem „verwandten“ Medizinprodukt vorgesehen ist, damit dieses Medizinprodukt seine Zweckbestimmung erfüllen kann, sollte dieser Internationalen Norm unterliegen.

[QUELLE: ISO 14971:2007, 2.9]

3.4.3

Arzneimittel

(en: medicinal product)

Stoff oder Kombination von Stoffen, die dem Menschen oder Tieren verabreicht werden kann, um Krankheiten zu behandeln oder zu vermeiden, um eine medizinische Diagnose zu erstellen oder um physiologische Funktionen wiederherzustellen, zu berichtigen oder zu modifizieren

Anmerkung 1 zum Begriff: Ein Arzneimittel kann ein oder mehrere Erzeugnisse und ein oder mehrere pharmazeutische Produkte enthalten.

Anmerkung 2 zum Begriff: In bestimmten Zuständigkeitsbereichen kann ein Arzneimittel auch als ein Stoff oder eine Kombination von Stoffen definiert sein, der/die zur Erstellung einer medizinischen Diagnose verwendet werden kann.

Anmerkung 3 zum Begriff: Die Angaben in dieser Internationalen Norm betreffen sowohl markenrechtlich geschützte Arzneimittel für den menschlichen Gebrauch, die auf den Markt gebracht werden, als auch industriell hergestellte Arzneimittel, deren Vermarktung durch eine entsprechende Regulierungsbehörde genehmigt wurde. Allerdings betreffen die Angaben nicht Arzneimittel, die entsprechend der Verschreibung vorbereitet werden, z. B. in einer Apotheke nach einem Rezept für einen bestimmten Patienten vorbereitet werden; auch nicht betroffen sind Arzneimittel, die nach einer offiziellen Formel vorbereitet werden, z. B. in einer Apotheke nach Anweisung eines Arzneibuchs für die direkte Abgabe an den Patienten vorbereitet werden; Arzneimittel für Forschung und Entwicklung und Zwischenprodukte für die Weiterverarbeitung durch einen autorisierten Hersteller sind von den hier getroffenen Angaben ebenfalls nicht betroffen.

[QUELLE: ISO 11615:2012, 3.1.49]

3.5 Management

3.5.1

Qualität im Gesundheitswesen

(en: quality in healthcare)

Grad, in dem das *Gesundheitswesen* (3.1.1) Anforderungen an festgelegte Qualitätsmerkmale erfüllt

Anmerkung 1 zum Begriff: Qualität ist in ISO 9000:2015, 3.6.2 als der „Grad, in dem ein Satz inhärenter Merkmale eines Objekts Anforderungen erfüllt“, definiert.

3.5.2

Qualitätsmanagement

(en: quality management)

Management bezüglich Qualität

Anmerkung 1 zum Begriff: Qualitätsmanagement kann das Festlegen der Qualitätspolitik und der Qualitätsziele, sowie Prozesse für das Erreichen der Qualitätsziele durch Qualitätsplanung, Qualitätssicherung, Qualitätssteuerung und Qualitätsverbesserung umfassen.

[QUELLE: ISO 9000:2015, 3.3.4]

3.5.3

Qualitätssicherung

(en: quality assurance)

Teil des *Qualitätsmanagements* (3.5.2), der auf das Erzeugen von Vertrauen darauf gerichtet ist, dass Qualitätsanforderungen erfüllt werden

[QUELLE: ISO 9000:2015, 3.3.6]

3.5.4

Qualitätslenkung

(en: quality control)

Teil des *Qualitätsmanagements* (3.5.2), der auf die Erfüllung von Qualitätsanforderungen gerichtet ist

[QUELLE: ISO 9000:2015, 3.3.7]

3.5.5

Risiko

(en: risk)

Kombination aus der Wahrscheinlichkeit eines Ereignisses und dessen Folgen

[QUELLE: ISO Guide 73:2009, 1.1]

3.5.6

unbeabsichtigtes Ereignis

(en: unintended event)

Phänomen, das nicht Teil des normalen Verlaufs eines *Prozesses* (3.6.1) ist, diesen aber beeinflussen kann

Anmerkung 1 zum Begriff: Ein unbeabsichtigtes Ereignis kann entweder erwartet oder unerwartet sein.

Anmerkung 2 zum Begriff: Aktivitäten in einem Prozess erfolgen bewusst und dienen einem Zweck. Im Idealfall werden Zwecke immer erfüllt. Wenn eine Aktivität in irgendeinem anderen Prozess Einfluss auf den gegenwärtig betrachteten Prozess hat, werden die Auswirkungen dieser Aktivität vom betrachteten Prozess als unbeabsichtigtes Ereignis wahrgenommen. In diesem Fall kann der Verlauf des Prozesses vom erwarteten Verlauf abweichen. Eine solche Abweichung vom gewünschten Verlauf kann sich im Vergleich mit dem gewünschten Prozessergebnis als negativ oder positiv erweisen.

BEISPIELE Chirurgische Komplikationen (Anatomie und Gewebe reagieren in unerwarteter Weise), elektrischer Ausfall, Verunreinigung in einem Medizinprodukt, Hardwarefehler, spontane Genesung, während der Patient auf therapeutische Maßnahmen wartet.

3.6 Prozessmanagement

3.6.1

Prozess

(en: process)

Satz zusammenhängender oder sich gegenseitig beeinflussender Tätigkeiten, der Eingaben zum Erzielen eines vorgesehenen Ergebnisses verwendet

Anmerkung 1 zum Begriff: Ob das "vorgesehene Ergebnis" eines Prozesses Ergebnis, Produkt oder Dienstleistung genannt wird, ist abhängig vom Bezugskontext.

Anmerkung 2 zum Begriff: Eingaben für einen Prozess sind üblicherweise Ergebnisse anderer Prozesse und Ergebnisse aus einem Prozess sind üblicherweise Eingaben für andere Prozesse.

Anmerkung 3 zum Begriff: Zwei oder mehr zusammenhängende und sich gegenseitig beeinflussende, aufeinanderfolgende Prozesse können auch als ein Prozess bezeichnet werden.

Anmerkung 4 zum Begriff: Prozesse in einer Organisation werden üblicherweise geplant und unter beherrschten Bedingungen durchgeführt, um Mehrwert zu schaffen.

Anmerkung 5 zum Begriff: Ein Prozess, bei dem die Konformität des dabei erzeugten Ergebnisses nicht ohne weiteres oder in wirtschaftlicher Weise validiert werden kann, wird häufig als "spezieller Prozess" bezeichnet.

Anmerkung 6 zum Begriff: Dieser Begriff stellt eine der gemeinsamen Benennungen und der Basisdefinitionen für ISO-Managementsystemnormen dar, die in ISO/IEC Directives, Part 1, Consolidated ISO Supplement, Anhang SL enthalten sind. Die ursprüngliche Definition wurde geändert, um einen Zirkelbezug zwischen "Prozess" und "Ergebnis" zu verhindern, und die Anmerkungen 1 bis 5 zum Begriff wurden hinzugefügt.

[QUELLE: ISO 9000:2015, 3.4.1]

3.6.2

Prozessmodell

(en: process modell)

Darstellung eines *Prozesses* (3.6.1)

3.6.3

Produkt

(en: product)

Ergebnis einer Organisation, das ohne jegliche Transaktion zwischen Organisation und Kunden erzeugt werden kann

Anmerkung 1 zum Begriff: Die Erzeugung eines Produkts wird erreicht, ohne dass notwendigerweise zwischen Anbieter und Kunden eine Transaktion stattfindet, sie kann jedoch dieses Dienstleistungselement bei der Lieferung an den Kunden einschließen.

Anmerkung 2 zum Begriff: Das vorherrschende Element eines Produkts ist, dass es üblicherweise materiell ist.

Anmerkung 3 zum Begriff: Hardware ist materiell, wobei ihre Menge ein zählbares Merkmal darstellt (z. B. Reifen). Verfahrenstechnische Produkte sind materiell, wobei ihre Menge ein kontinuierliches Merkmal (z. B. Treibstoff und Erfrischungsgetränke) darstellt. Hardware und verfahrenstechnische Produkte werden häufig als Waren bezeichnet. Software besteht aus Informationen, ungeachtet des Liefermediums (z. B. Computerprogramm, Anwendungen für Mobiltelefone, Bedienungsanleitung, Wörterbuchinhalte, Urheberrecht musikalischer Kompositionen, Fahrerlaubnis).

[QUELLE: ISO 9000:2015, 3.7.6]

3.6.4

Dienstleistung

(en: service)

Ergebnis einer *Organisation* (3.3.1) mit mindestens einer Tätigkeit, die notwendigerweise zwischen der Organisation und dem Kunden ausgeführt wird

Anmerkung 1 zum Begriff: Die vorherrschenden Elemente einer Dienstleistung sind üblicherweise immateriell.

Anmerkung 2 zum Begriff: Dienstleistung umfasst häufig Tätigkeiten an der Schnittstelle zum Kunden, um Kundenanforderungen festzulegen, sowie bei der Erbringung der Dienstleistung und kann eine kontinuierliche Beziehung einschließen, wie z.B. Banken, Buchführungen oder öffentliche Einrichtungen, z.B. Schulen und Krankenhäuser.

Anmerkung 3 zum Begriff: Zur Erbringung einer Dienstleistung kann z. B. folgendes gehören:

- eine Tätigkeit, die an einem vom Kunden gelieferten materiellen *Produkt* (3.6.3) ausgeführt wird (z. B. an einem zu reparierenden Auto);
- eine Tätigkeit, die an einem vom Kunden gelieferten immateriellen Produkt ausgeführt wird (z. B. am für die Erstellung einer Steuerrückerstattung erforderlichen Einkommensnachweis);
- die Lieferung eines immateriellen Produkts (z. B. die Lieferung von *Informationen* (3.9.5) im Zusammenhang mit der Vermittlung von Wissen);
- die Schaffung eines Ambientes für den Kunden (z. B. in Hotels und Restaurants).

Anmerkung 4 zum Begriff: Eine Dienstleistung wird üblicherweise durch den Kunden wahrgenommen.

[QUELLE: ISO 9000:2015, 3.7.7]

3.6.5

Ergebnis

(en: output)

Ergebnis eines Prozesses ^{N1)}

Anmerkung 1 zum Begriff: Ob ein Ergebnis der *Organisation* (3.3.1) ein *Produkt* (3.6.3) oder eine *Dienstleistung* (3.6.4) ist, ist abhängig davon, welche der betroffenen Merkmale überwiegen; z. B. ist ein in einer Galerie zum Verkauf stehendes Gemälde ein Produkt, die Lieferung eines in Auftrag gegebenen Gemäldes ist hingegen eine Dienstleistung, ein im Einzelhandel gekaufter Hamburger ist ein Produkt, während ein im Restaurant bestellter und servierter Hamburger hingegen Teil einer Dienstleistung ist.

[QUELLE: ISO 9000:2015, 3.7.5]

3.7 Zeit

3.7.1

Termin

(en: appointment)

Verabredung, jemanden zu einem bestimmten Zeitpunkt an einem bestimmten Ort zu treffen

^{N1)} Nationale Fußnote: Im Englischen werden die Begriffe "result" und "output" nahezu synonym verwendet. Im Deutschen werden sie einheitlich mit "Ergebnis" übersetzt. (Diese führt zu der Aussage, dass ein Ergebnis das Ergebnis eines Prozesses ist.)

3.8 Verantwortlichkeit

3.8.1

Selbstverpflichtung

(en: commitment)

Aktion, die zu einer Verpflichtung durch einen oder mehrere Teilnehmer am Prozess dahingehend führt, eine Regel oder einen Vertrag einzuhalten

Anmerkung 1 zum Begriff: Bei dem/den Unternehmensobjekt(en), das/die an einer Aktion teilnimmt/teilnehmen, die zu einer Selbstverpflichtung führt, kann es sich um Parteien handeln oder um Agenten, die im Namen einer Partei oder mehrerer Parteien agieren. Führt ein Agent eine derartige Aktion aus, ergibt sich daraus eine Verpflichtung für den Vertretenen.

[QUELLE: ISO 12967-1:2009, 3.6.2]

3.9 Informationsmanagement

3.9.1

Daten

(en: data)

Rückübertragbare, formalisierte Darstellung von Informationen, die für deren Kommunikation, Auswertung oder Weiterverarbeitung geeignet ist

Anmerkung 1 zum Begriff: Daten können durch Menschen oder durch automatische Mittel verarbeitet werden.

[QUELLE: ISO/IEC 2382:2015, 2121272, modifiziert]

3.9.2

Datenbehälter

(en: data repository)

identifizierbare Einrichtung zur Speicherung von *Daten* (3.9.1)

Anmerkung 1 zum Begriff: In ISO 10303-22:1998 ist dies die Definition zur englischen Benennung "repository".

3.9.3

Gesundheitsdaten

(en: healthcare data)

im Rahmen von Gesundheitspflegemaßnahmen erhobene *Daten* (3.9.1)

Anmerkung 1 zum Begriff: Gesundheitspflegemaßnahmen sind in 7.2 definiert.

3.9.4

Gesundheitsinformationen

(en: healthcare information)

Informationen (3.9.5) über eine *Person* (3.3.4), die für deren *Gesundheitswesen* (3.1.1) von Bedeutung sind

3.9.5

Information

(en: information)

Wissen in Bezug auf Objekte, das innerhalb eines bestimmten Kontexts eine spezielle Bedeutung hat

Anmerkung 1 zum Begriff: Beispiel von Objekten sind Fakten, Ereignisse, Dinge, Prozesse und Ideen, einschließlich Begriffen.

Anmerkung 2 zum Begriff: Informationen haben eine Bedeutung. Daten können als Informationen angesehen werden, sobald deren Bedeutung offengelegt wurde.

[QUELLE: ISO/IEC 2382:2015, 2123204, modifiziert]

3.9.6

Informationsmodell

(en: information model)

formales Modell einer begrenzten Menge von Fakten, Begriffen oder Anweisungen für die Erfüllung einer spezifizierten Anforderung

[QUELLE: ISO 10303-1:1994, 3.2.21]

3.9.7

elektronische Gesundheitsakte

(en: electronic health record)

Behälter bzw. Speicher für *Informationen* (3.9.5) zur Gesundheit einer zu pflegenden Person in einem mittels Computern zu verarbeitenden Format

Anmerkung 1 zum Begriff: Die zu pflegende Person ist in 5.2.1 definiert.

[QUELLE: ISO 13606-2:2008, 4.7, modifiziert]

3.9.8

Datenträger

(en: medium)

Material, auf dem Daten gespeichert werden (z. B. Magnetplatte)

[QUELLE: ISO/IEC 14776-151:2010, 3.1.117, modifiziert]

Nationaler Anhang NB
(informativ)

Literaturhinweise

DIN EN ISO 9000, *Qualitätsmanagementsysteme — Grundlagen und Begriffe*

— Leerseite —

English Version

Health informatics —
System of concepts to support continuity of care
(ISO 13940:2015)

Informatique de santé —
Système de concepts en appui
de la continuité des soins
(ISO 13940:2015)

Medizinische Informatik —
Begriffssystem zur Unterstützung
der Kontinuität der Versorgung
(ISO 13940:2015)

This European Standard was approved by CEN on 19 September 2015.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.



EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

European foreword

This document (EN ISO 13940:2016) has been prepared by Technical Committee ISO/TC 215 "Health informatics" in collaboration with 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 July 2016, and conflicting national standards shall be withdrawn at the latest by July 2016.

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.

This document supersedes EN 13940-1:2007.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Endorsement notice

The text of ISO 13940:2015 has been approved by CEN as EN ISO 13940:2016 without any modification.

Contents

Page

Foreword	vi
0 Introduction	vii
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
3.1 Healthcare	1
3.2 Concepts and terms	2
3.3 Actors	2
3.4 Resources	3
3.5 Management	4
3.6 Process management	5
3.7 Time	6
3.8 Responsibility	7
3.9 Information management	7
4 Symbols and abbreviations	8
5 Concepts related to healthcare actors	9
5.1 General	9
5.2 Healthcare actor	10
5.2.1 Subject of care	12
5.2.2 Next of kin	14
5.2.3 Healthcare provider	15
5.2.4 Healthcare third party	21
6 Concepts related to healthcare matters	24
6.1 General	24
6.2 Healthcare matter	25
6.3 Health issue	27
6.4 Health condition	28
6.4.1 Observed condition	29
6.4.2 Potential health condition	31
6.5 Health state	37
6.5.1 Input health state	38
6.5.2 Output health state	39
6.5.3 Health need	39
6.6 Health thread	40
6.6.1 Clinical process interest	41
6.6.2 Health problem list	42
6.6.3 Health condition evolution	42
7 Concepts related to activities	44
7.1 General	44
7.2 Healthcare activity	45
7.2.1 Healthcare provider activity	47
7.2.2 Healthcare activity directory	48
7.2.3 Self-care activity	48
7.2.4 Prescribed self-care	49
7.2.5 Healthcare third party activity	50
7.2.6 Prescribed third party activity	51
7.2.7 Healthcare activity element	51
7.2.8 Automated healthcare	60
7.2.9 Healthcare resource	61
7.2.10 Healthcare funds	63
8 Concepts related to process	65

8.1	General.....	65
8.2	Healthcare process.....	65
8.2.1	Clinical process.....	66
8.2.2	Healthcare quality management.....	68
8.2.3	Healthcare administration.....	68
8.2.4	Adverse event.....	69
8.2.5	Adverse event management.....	69
8.2.6	Healthcare service.....	70
8.2.7	Healthcare service directory.....	70
9	Concepts related to healthcare planning.....	72
9.1	General.....	72
9.2	Care plan.....	73
9.2.1	Uniprofessional care plan.....	74
9.2.2	Multi-professional care plan.....	75
9.2.3	Core care plan.....	75
9.2.4	Clinical guideline.....	76
9.2.5	Health objective.....	78
9.2.6	Healthcare goal.....	79
9.2.7	Healthcare activities bundle.....	79
9.2.8	Needed healthcare activity.....	80
10	Concepts related to time.....	82
10.1	General.....	82
10.2	Health related period.....	82
10.2.1	Mandated period of care.....	83
10.2.2	Healthcare activity period.....	84
10.2.3	Healthcare activity delay.....	90
10.2.4	Clinical process episode.....	93
10.2.5	Health condition period.....	93
10.2.6	Episode of care.....	94
11	Concepts related to responsibilities.....	97
11.1	General.....	97
11.2	Healthcare mandate.....	97
11.2.1	Demand mandate.....	99
11.2.2	Care period mandate.....	100
11.2.3	Healthcare activity mandate.....	101
11.2.4	Continuity facilitator mandate.....	102
11.2.5	Mandate to export personal information.....	102
11.2.6	Informed consent.....	103
11.2.7	Dissent.....	104
11.2.8	Consent competence.....	104
11.2.9	Authorization by law.....	105
11.2.10	Healthcare commitment.....	105
11.2.11	Subject of care desire.....	106
11.3	Demand for care.....	106
11.3.1	Demand for initial contact.....	108
11.3.2	Referral.....	108
11.3.3	Request.....	109
11.3.4	Reason for demand for care.....	110
12	Concepts related to information management.....	111
12.1	General.....	111
12.2	Health record.....	111
12.2.1	Professional health record.....	113
12.2.2	Personal health record.....	114
12.2.3	Health record component.....	114
12.2.4	Electronic health record component.....	115
12.3	Sharable data repository.....	116

12.4	Summarized healthcare information repository	117
12.5	Health record extract	117
12.5.1	Electronic health record extract	118
12.5.2	Electronic patient summary	119
12.5.3	Clinical Report	120
12.5.4	Health concern	123
12.5.5	Healthcare information request	124
12.6	Certificate related to a healthcare matter	125
13	Conformance	126
Annex A (informative) Framework for the normative concepts in this International Standard		127
Bibliography		142

Foreword

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

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

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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

The committee responsible for this document is ISO/TC 215, *Health informatics*.

0 Introduction

0.1 General

The purpose of this International Standard is to define the generic concepts needed to achieve continuity of care. Continuity of care is an important aspect of quality and safety in healthcare and semantic interoperability is a basic requirement for continuity of care. The concepts that are needed for these should represent both the content and context of the healthcare services.

Healthcare is provided through activities in healthcare and clinical processes. These types of processes reflect the interaction between a subject of care and healthcare professionals. A clinical process provides continuity from the subject of care's perspective. To complete the concepts representing continuity of care, a number of basic premises for management, resource handling and administration are also needed.

The system of concepts for continuity of care defined in this International Standard is based upon the clinical perspective with the clinical process as focus, it defines its component concepts and their descriptive terms regarding all types of healthcare and especially considering patient-centred continuity of care. This International Standard will establish a common conceptual framework across national, cultural and professional barriers.

0.2 Aims for this International Standard

The general aim for this International Standard is to provide a comprehensive, conceptual basis for content and context in healthcare services. It should be the foundation for interoperability at all levels in healthcare organizations and for development of information systems in healthcare.

The concepts aim to support the continuity of care in healthcare with clinical processes as the focus, enabling the use of healthcare information for other purposes such as secondary use for follow-up and knowledge management. The core business in healthcare is the interaction between subjects of care and healthcare professionals, such interactions occur in healthcare and clinical processes and are the justification for the process approach of this International Standard. To be able to represent both clinical content and clinical context, this International Standard is based upon the clinical perspective and has focus upon the clinical process as a main concept for achieving continuity of care.

To be able to support continuity of care, the standard also aims to include comprehensive concept definitions and concept relations for the clinical, management and resource aspects of healthcare.

In practice this International Standard aims to be used whenever requirements for information in healthcare are specified. This will cover all levels of specifications in the development of,

- enterprise models as a common basis for interoperability on international, national or local levels,
- information systems, and
- structured information for specified types of clinical processes.

0.3 About the concept of health

This International Standard is based on the World Health Organization's (WHO) declaration of health from 1948: "... a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". In 1986 WHO made two amendments to the above definition: "resource for everyday life, not the objective of living" and "health is a positive concept emphasizing social and personal resources, as well as physical capacities".

In the International Classification of Functioning, Disability and Health (ICF) of WHO, the concept of health is categorized in a more specified way. The theoretical model in ICF identifies health components; body function, body structure, activity and participation, personal and environmental factors respectively. This International Standard applies the ICF model of health based on the health declaration.

In this International Standard, the word “health” is not used as an isolated term designating any concept within the scope of the standard. The word “health” is merely used as prefix in several terms. The meaning of this prefix is that the concept represented by the term has to do with the subject of care’s health state or health condition, often in relation to a healthcare/clinical process.

0.4 Healthcare versus social care

Healthcare as well as social care has the objective to influence, restore and maintain health in the WHO sense. All kinds of activities that have the potential to influence any one of the five components of health mentioned in the ICF model can be a part of such care. There is an evident overlap between healthcare activities and social care activities. This International Standard is focused upon the part of healthcare that (in most cultures) does not include social care. The role of the subject of care is defined with respect to healthcare and the terms chosen are from this sector. However, many of the concepts are relevant for the social care sector and through the cooperation of the different domains of healthcare this International Standard should also be applicable for social care.

0.5 Intended users for this International Standard

All parties interested in the interoperability issues in health care are intended users of this health informatics standard. This includes, but is not limited to, healthcare professionals and teams, subjects of care, healthcare managers, healthcare funding organizations and all types of healthcare providers and community care teams.

This system of concepts is relevant across all healthcare information and the development and use of healthcare information systems. It can also be used for business analysis as a basis for organizational decisions and more widely in developments that are not inherently tied to the use of information systems.

0.6 Architecture of this system of concepts

To cover continuity of care, concepts are needed from all of these basic process aspects:

- Healthcare/clinical processes
- Management
- Support

This system of concepts is based upon the clinical perspective of healthcare, this being the healthcare/clinical processes. All other areas of work in healthcare both relate to and interact with the healthcare/clinical processes. As such, the management aspects of healthcare are identified in the process management areas and similarly the resource support areas are correspondingly identified as outcomes of the support processes. This architecture with the areas around the healthcare/clinical process is described in Figure 1.

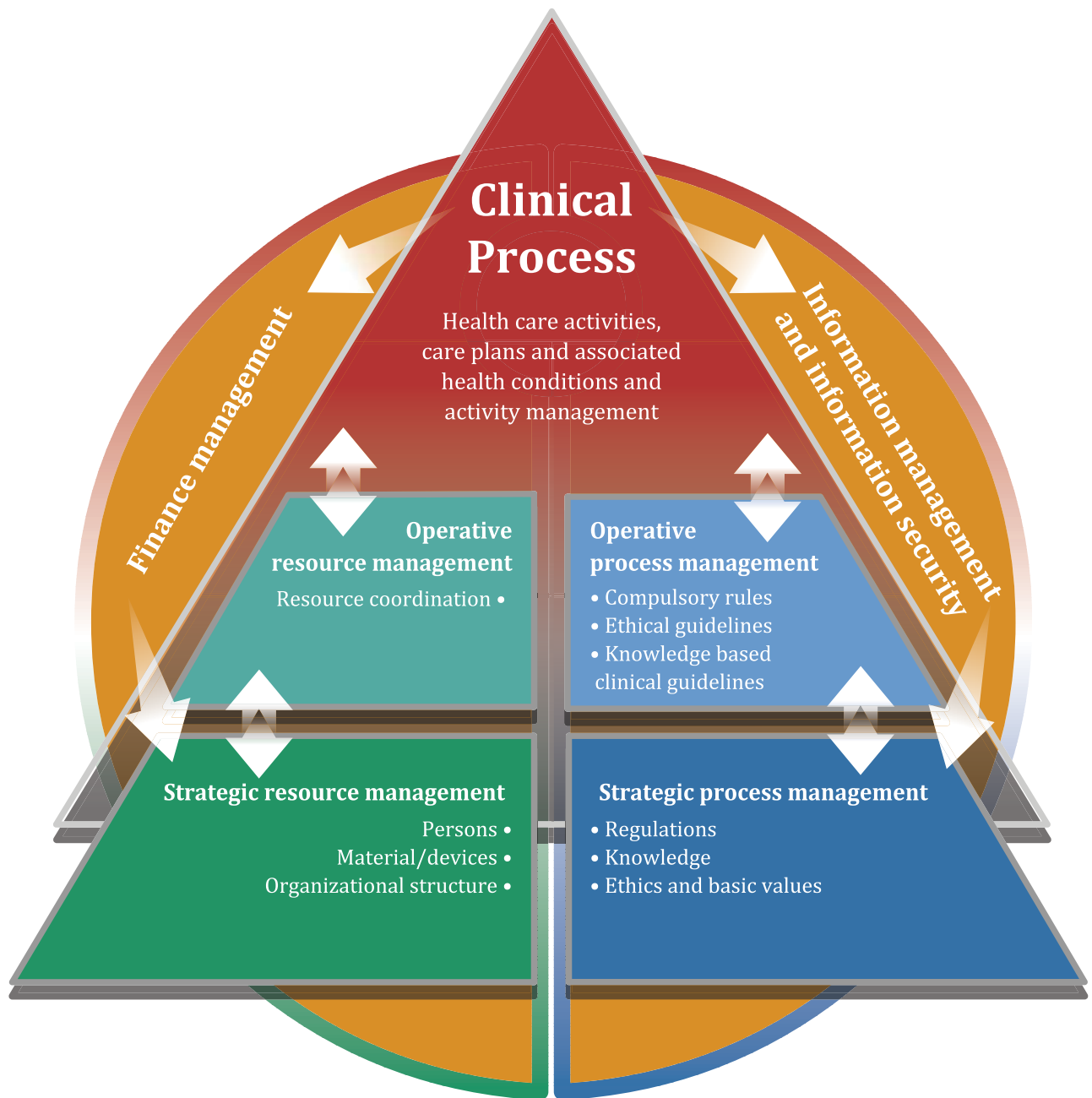


Figure 1 — Architecture of the concept areas

0.7 Description and display of concepts

In this International Standard the concepts are grouped into separate clauses. The relationships between the enterprise/information areas that need to be covered are used to structure this International Standard. Each of the concepts are defined and described systematically and their relations are shown in UML models.

Descriptions are framed within tables, following the same pattern, and information is systematically provided for all the concepts presented in Clauses 5 to 12. Some categories will intentionally be left blank as these are not relevant to a given concept.

Examples are provided wherever they are considered relevant and necessary. However and in general, examples for superordinate concepts are to be sought at the level of the corresponding subordinate concepts.

In order to help the reader understand the relationships between these concepts more easily, diagrams have been included based on UML conventions. For each one of the concepts described in Clauses 5 to 12, a partial view of the general subclause and comprehensive diagram is provided, showing only its direct relationships with other concepts belonging to the relevant aspect of the system of concepts.

At the beginning of Clauses 5 to 12 there are diagrams that provide partial views of the concepts that are to follow and focus upon the topic addressed in the corresponding clause. For clarity of reading,

- concepts shown in white with a solid border are defined in the same clause or subclause,
- concepts defined in other clauses or subclauses are shown in grey with a solid border,
- concepts not defined in this International Standard are shown in grey with a dashed border,
- for the concepts shown in white, all relationships are included,
- relationships between concepts shown in grey are not included,
- italic characters are used in the headings for concepts that are purely abstract and therefore supported only through their specializations.

The purpose of using concept models in this International Standard is to highlight the relationships between concepts. Attributes do not belong to the field of concept modelling. Attributes can be added in the course of implementation and still be conformant to this International Standard.

Health informatics — System of concepts to support continuity of care

1 Scope

This International standard defines a system of concepts for different aspects of the provision of healthcare.

The core business in healthcare is the interaction between subjects of care and healthcare professionals. Such interactions occur in healthcare/clinical processes and are the justification for the process approach of this International Standard. To be able to represent both clinical content and clinical context, this International Standard is related to a generic healthcare/clinical process model as well as comprehensive concept definitions and concept models for the clinical, management and resource aspects of healthcare services.

In practice this International Standard covers the concept definitions needed whenever structured information in healthcare is specified as a requirement. The definitions are intended to refer to the conceptual level only and not to details of implementation. This International Standard will cover all levels of specifications in the development of

- logical reference models within the information viewpoint as a common basis for semantic interoperability on international, national or local levels,
- information systems, and
- information for specified types of clinical processes.

How to perform specific healthcare/clinical/informatics processes is not covered by this International Standard.

Healthcare research processes and healthcare educational processes are not covered in this International Standard.

2 Normative references

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

ISO 9000, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000 and the following apply.

3.1 Healthcare

3.1.1

healthcare

care activities, services, management or supplies related to the health of an individual

Note 1 to entry: This includes more than performing procedures for subjects of care. It includes, for example, the management of information about patients, health status and relations within the healthcare delivery framework and may also include the management of clinical knowledge.

[SOURCE: ISO/TR 18307:2001, 3.70, modified]

3.1.2

continuity of care

efficient, effective, ethical care delivered through interaction, integration, co-ordination and sharing of *information* (3.9.5) between different healthcare actors over time

Note 1 to entry: "Healthcare actors" is defined in 5.2.1.

3.2 Concepts and terms

3.2.1

concept

unit of knowledge created by a unique combination of characteristics

[SOURCE: ISO 1087-1:2000, 3.2.1]

3.2.2

system of concepts

DEPRECATED: concept system

set of *concepts* (3.2.1) structured according to the relations among them

[SOURCE: ISO 1087-1:2000, 3.2.11]

3.2.3

deprecated term

term rejected by an authoritative body

[SOURCE: ISO 1087-1:2000, 3.4.17]

3.3 Actors

3.3.1

organization

unique framework of authority within which a *person* (3.3.4) or persons act, or are designated to act towards some purpose

[SOURCE: ISO/IEC 6523-1:1998, 3.1]

Note 1 to entry: Groupings or subdivisions of organizations may also be considered as organizations where there is need to identify them in this way for purposes of information interchange.

Note 2 to entry: In this International Standard, this definition applies to any kind of organizations, whatever their legal status.

3.3.2

organizational pattern

relationships between the various parts of an *organization* (3.3.1)

3.3.3

party

person or group performing a *role* (3.3.5) in relation to the business of a specific community or domain

[SOURCE: ISO 8459:2009, 2.33]

3.3.4

person

human being regarded as an individual

3.3.5

role

function or position

[SOURCE: ISO/HL7 21731:2006]

3.3.6

person role

role (3.3.5) of a *person* (3.3.4)

3.3.7

organization role

role (3.3.5) of an *organization* (3.3.1)

3.4 Resources

3.4.1

resource

asset that is utilized or consumed during the execution of a *process* (3.6.1)

Note 1 to entry: Includes diverse entities such as funding, personnel, facilities, capital equipment, tools, and utilities such as power, water, fuel and communication infrastructures.

Note 2 to entry: Resources include those that are reusable, renewable or consumable.

EXAMPLE Time, personnel, human skills and knowledge, equipment, services, supplies, facilities, technology, data, money

[SOURCE: ISO/IEC/IEEE 15288:2015, 4.1.38, modified]

3.4.2

medical device

any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
- investigation, replacement, modification, or support of the anatomy or of a physiological process,
- supporting or sustaining life,
- control of conception,
- disinfection of medical devices,
- providing *information* (3.9.5) for medical purposes by means of *in vitro* examination of specimens derived from the human body,

and which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means

Note 1 to entry: This definition has been developed by the Global Harmonization Task Force (GHTF)

Note 2 to entry: Products, which could be considered to be medical devices in some jurisdictions but for which there is not yet a harmonized approach, are:

- aids for disabled/handicapped people,
- devices for the treatment/diagnosis of diseases and injuries in animals,
- accessories for medical devices (see Note 3),

- disinfection substances,
- devices incorporating animal and human tissues which can meet the requirements of the above definition but are subject to different controls.

Note 3 to entry: Accessories intended specifically by manufacturers to be used together with a “parent” medical device to enable that medical device to achieve its intended purpose, should be subject to this International Standard.

[SOURCE: ISO 14971:2007, 2.9]

3.4.3 **medicinal product**

any substance or combination of substances that can be administered to human beings for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct, or modify physiological functions

Note 1 to entry: A medicinal product may contain one or more manufactured items and one or more pharmaceutical products.

Note 2 to entry: In certain jurisdictions a Medicinal Product may also be defined as any substance or combination of substances which may be used to make a medical diagnosis.

Note 3 to entry: The provisions in this International Standard apply to proprietary medicinal products for human use intended to be placed on the market and to industrially manufactured medicinal products, the marketing of which has been authorized by a Medicines Regulatory Agency. However, the provisions do not apply to medicinal products prepared according to prescription, for instance, prepared in a pharmacy from a prescription intended for a specific patient; medicinal products prepared in accordance with an official formula, for instance, prepared in a pharmacy in accordance with the instructions in a pharmacopoeia and intended to be given direct to the patient by the pharmacy; medicinal products intended for research and development trials; intermediate products intended for subsequent processing by an authorized manufacturer.

[SOURCE: ISO 11615:2012, 3.1.49]

3.5 Management

3.5.1 **quality in healthcare**

degree to which *healthcare* (3.1.1) fulfils requirements related to defined quality characteristics

Note 1 to entry: Quality is defined in ISO 9000:2015, 3.6.2, as the ‘degree to which a set of inherent characteristics of an object fulfils requirements’.

3.5.2 **quality management** management with regard to quality

Note 1 to entry: Quality management can include establishing quality policies and quality objectives, and processes to achieve these quality objectives through quality planning, quality assurance, quality control, and quality improvement.

[SOURCE: ISO 9000:2015, 3.3.4]

3.5.3 **quality assurance**

part of *quality management* (3.5.2) focused on providing confidence that quality requirements will be fulfilled

[SOURCE: ISO 9000:2015, 3.3.6]

3.5.4

quality control

part of *quality management* (3.5.2) focused on fulfilling quality requirements

[SOURCE: ISO 9000:2015, 3.3.7]

3.5.5

risk

combination of the probability of an event and its consequences

[SOURCE: ISO Guide 73:2009, 1.1]

3.5.6

unintended event

phenomenon that is not part of the normal course of a *process* (3.6.1) but might influence it

Note 1 to entry: An unintended event can be either expected or unexpected.

Note 2 to entry: Activities in a process are deliberate and have a purpose. In an ideal situation purposes are always fulfilled. If an activity in whatever other process has an impact on the process currently analysed, the effect of this activity is perceived by the current process as an unintended event. Then the course of the process may deviate from the expected one. Such an exception from the desired course might prove negative or positive in comparison to the desired process outcome.

EXAMPLE Surgical complication (anatomy and tissue reacts in an unexpected manner), electrical failure, contamination in a medicinal product, hardware failure, spontaneous recovery when the patient is awaiting therapy.

3.6 Process management

3.6.1

process

set of interrelated or interacting activities that use inputs to deliver an intended result

Note 1 to entry: Whether the “intended result” of a process is called output, product or service depends on the context of the reference.

Note 2 to entry: Inputs to a process are generally the outputs of other processes and outputs of a process are generally the inputs to other processes.

Note 3 to entry: Two or more interrelated and interacting processes in series can also be referred to as a process.

Note 4 to entry: Processes in an organization are generally planned and carried out under controlled conditions to add value.

Note 5 to entry: A process where the conformity of the resulting output cannot be readily or economically validated is frequently referred to as a “special process”.

Note 6 to entry: This constitutes one of the common terms and core definitions for ISO management system standards given in Annex SL of the Consolidated ISO Supplement to the ISO/IEC Directives, Part 1. The original definition has been modified to prevent circularity between process and output, and Notes 1 to 5 to entry have been added.

[SOURCE: ISO 9000:2015, 3.4.1]

3.6.2

process model

representation of a *process* (3.6.1)

3.6.3

product

output of an organization that can be produced without any transaction taking place between the organization and the customer

Note 1 to entry: Production of a product is achieved without any transaction necessarily taking place between provider and customer, but can often involve this service element upon its delivery to the customer.

Note 2 to entry: The dominant element of a product is that it is generally tangible.

Note 3 to entry: Hardware is tangible and its amount is a countable characteristic (e.g. tyres). Processed materials are tangible and their amount is a continuous characteristic (e.g. fuel and soft drinks). Hardware and processed materials are often referred to as goods. Software consists of information regardless of delivery medium (e.g. computer programme, mobile phone app, instruction manual, dictionary content, musical composition copyright, driver's license).

[SOURCE: ISO 9000:2015, 3.7.6]

3.6.4

service

output of an *organization* (3.3.1) with at least one activity necessarily performed between the organization and the customer

Note 1 to entry: The dominant elements of a service are generally intangible.

Note 2 to entry: Service often involves activities at the interface with the customer to establish customer requirements as well as upon delivery of the service and can involve a continuing relationship such as banks, accountancies or public organizations, e.g. schools or hospitals.

Note 3 to entry: Provision of a service can involve, for example, the following:

- an activity performed on a customer-supplied tangible *product* (3.6.3) (e.g. a car to be repaired);
- an activity performed on a customer-supplied intangible product (e.g. the income statement needed to prepare a tax return);
- the delivery of an intangible product (e.g. the delivery of *information* (3.9.5) in the context of knowledge transmission);
- the creation of ambience for the customer (e.g. in hotels and restaurants);

Note 4 to entry: A service is generally experienced by the customer.

[SOURCE: ISO 9000:2015, 3.7.7]

3.6.5

output

result of a process

Note 1 to entry: Whether an output of the *organization* (3.3.1) is a *product* (3.6.3) or a *service* (3.6.4) depends on the preponderance of the characteristics involved, e.g. a painting for sale in a gallery is a product whereas supply of a commissioned painting is a service, a hamburger bought in a retail store is a product whereas receiving an order and serving a hamburger ordered in a restaurant is part of a service.

[SOURCE: ISO 9000:2015, 3.7.5]

3.7 Time

3.7.1

appointment

arrangement to meet someone at a particular time and place

3.8 Responsibility

3.8.1

commitment

action resulting in an obligation by one or more of the participants in the act to comply with a rule or perform a contract

Note 1 to entry: The enterprise object(s) participating in an action of commitment may be parties or agents acting on behalf of a party or parties. In the case of an action of commitment by an agent, the principal becomes obligated.

[SOURCE: ISO 12967-1:2009, 3.6.2]

3.9 Information management

3.9.1

data

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

Note 1 to entry: Data can be processed by humans or by automatic means.

[SOURCE: ISO/IEC 2382:2015, 2121272, modified]

3.9.2

data repository

an identifiable *data* (3.9.1) storage facility

Note 1 to entry: In ISO 10303-22:1998 this is the definition of repository.

3.9.3

healthcare data

data (3.9.1) produced during healthcare activities

Note 1 to entry: Healthcare activity is defined in 7.2.

3.9.4

healthcare information

information (3.9.5) about a *person* (3.3.4), relevant to his or her *healthcare* (3.1.1)

3.9.5

information

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

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

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

[SOURCE: ISO/IEC 2382:2015, 2123204, modified]

3.9.6

information model

formal model of a bounded set of facts, concepts or instructions to meet a specified requirement

[SOURCE: ISO 10303-1:1994, 3.2.21]

3.9.7

electronic health record

repository of *information* (3.9.5) regarding the health of a subject of care in computer processable format

Note 1 to entry: Subject of care is defined in 5.2.1.

[SOURCE: ISO 13606-2:2008, 4.7, modified]

3.9.8

medium

material on which data is stored (e.g. a magnetic disk)

[SOURCE: ISO/IEC 14776-151:2010, 3.1.117, modified]

4 Symbols and abbreviations

The following abbreviations are used for the terms defined in this International Standard.

DRG	Diagnosis-Related Group
EHR	Electronic Health Record
ICF	The International Classification of Functioning, Disability and Health
GP	General Medical Practitioner
WHO	World Health Organization
UML	Unified Modelling Language

5 Concepts related to healthcare actors

5.1 General

A model showing the associations between concepts related to actors in continuity of care is shown in Figures 2 and 3. For further detail about the diagram notation, please refer to 0.7 in the Introduction.

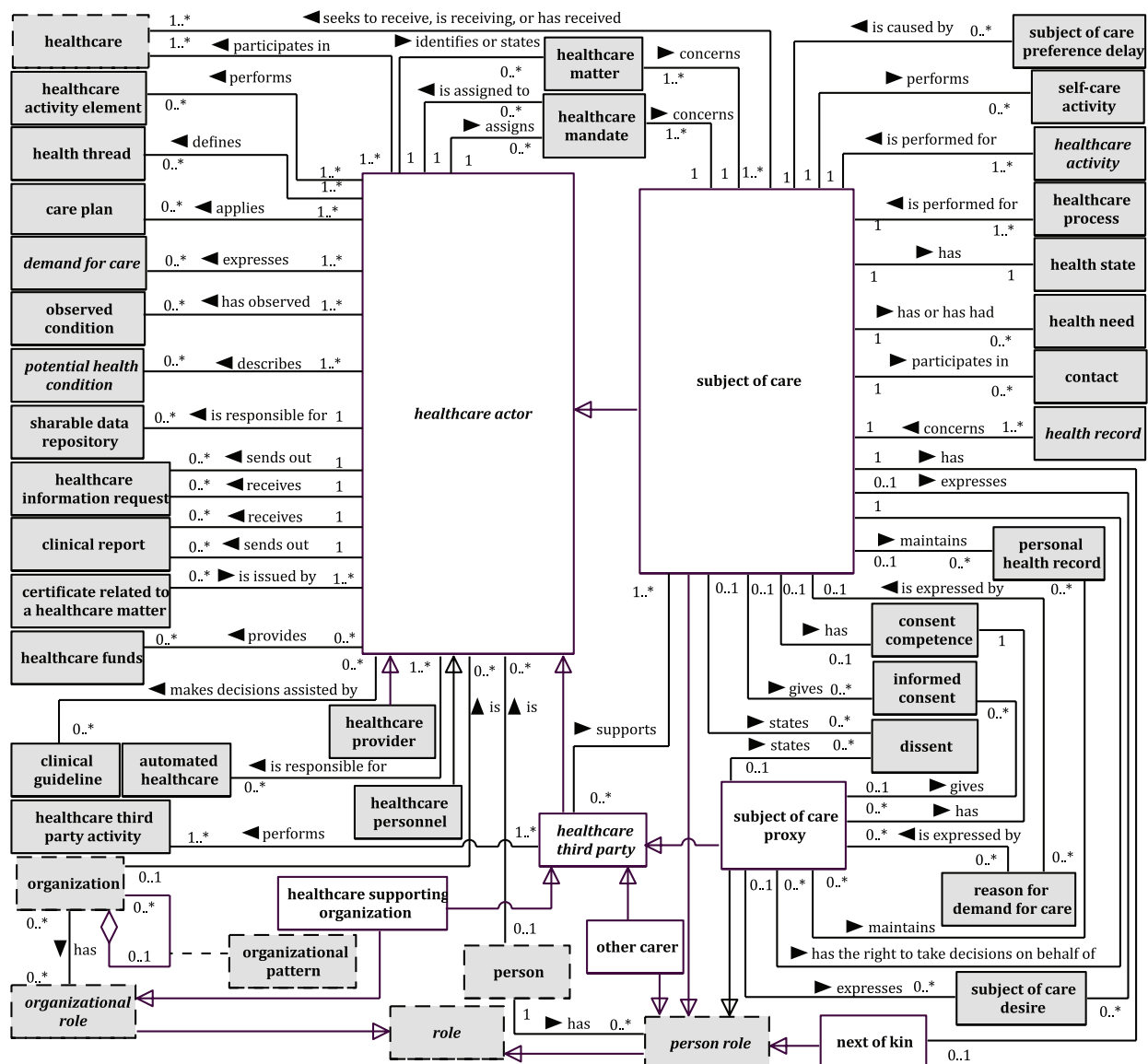


Figure 2 — Comprehensive UML diagram of concepts related to healthcare actors (i)

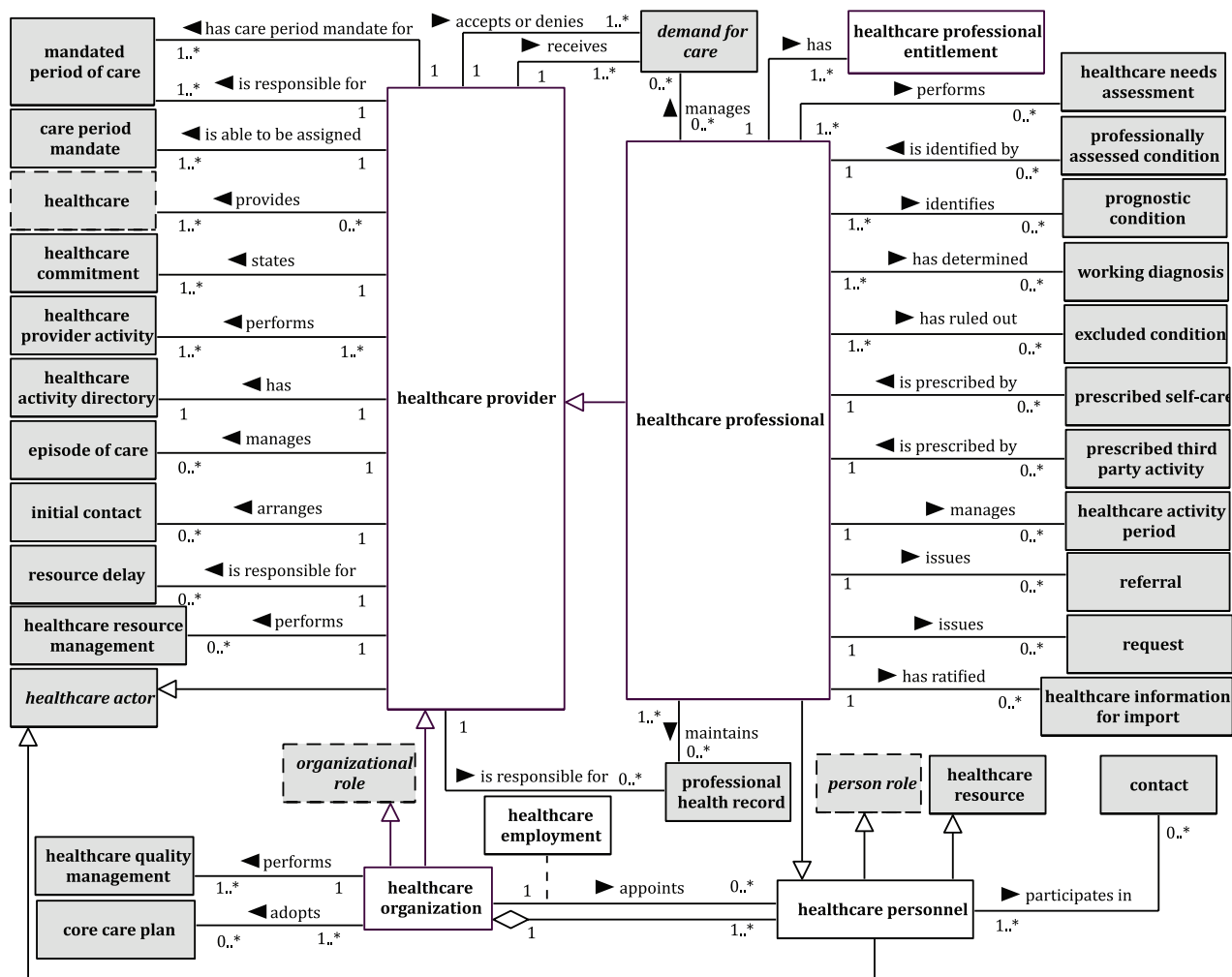


Figure 3 — Comprehensive UML diagram of concepts related to healthcare actors (ii)

5.2 Healthcare actor

Term: *healthcare actor*

Deprecated term: healthcare party

Definition: *organization or person participating in healthcare*

NOTE 1 The involvement of the *healthcare actor* will be either direct (for example, the actual provision of care), or indirect (for example, at organizational level).

NOTE2 According to this definition, people or organizations responsible for the funding, payment, or reimbursement of healthcare provision are *healthcare actors*, as well as organizations responsible for healthcare delivery.

NOTE 3 In EN 13940-1:2007 healthcare party was the preferred term for this concept.

Table 1 lists the associations of this concept; a UML representation of the concept is shown in Figure 4.

Table 1 — Associations of *healthcare actor*

Specialization of		Generalization of	
		healthcare provider	
		subject of care	
		healthcare personnel	
		healthcare third party	
Association from		Association name	Association to
1..*	healthcare actor	participates in	1..* healthcare
1	healthcare actor	identifies or states	0..* healthcare matter
1..*	healthcare actor	defines	0..* health thread
0..*	healthcare actor	makes decisions assisted by	0..* clinical guideline
1..*	healthcare actor	applies	0..* care plan
1	healthcare actor	is responsible for	0..* sharable data repository
1..*	healthcare actor	expresses	0..* demand for care
1	healthcare actor	sends out	0..* healthcare information request
1	healthcare actor	receives	0..* healthcare information request
1	healthcare actor	sends out	0..* clinical report
1	healthcare actor	receives	0..* clinical report
1..*	healthcare actor	performs	0..* healthcare activity element
1..*	healthcare actor	is responsible for	0..* automated healthcare
0..*	healthcare actor	provides	0..* healthcare funds
1..*	healthcare actor	has observed	0..* observed condition
1..*	healthcare actor	describes	0..* potential health condition
1	healthcare actor	assigns	0..* healthcare mandate
0..*	healthcare mandate	is assigned to	1 healthcare actor
0..1	person	is	0..* healthcare actor
0..1	organization	is	0..* healthcare actor
0..*	certificate related to a healthcare matter	is issued by	1..* healthcare actor

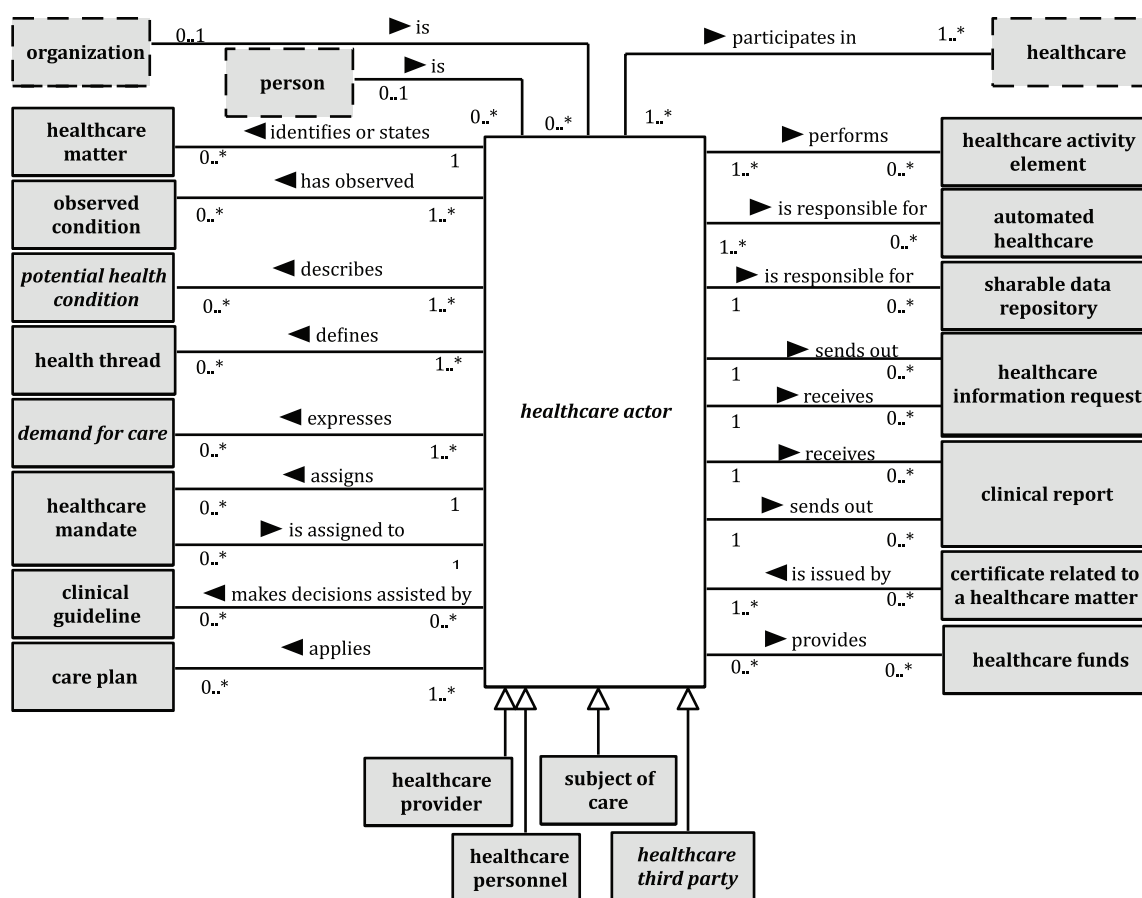


Figure 4 — Healthcare actor (UML representation)

5.2.1 Subject of care

Term: *subject of care*

Synonyms: subject of healthcare, patient, client, service user

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

NOTE A foetus may be considered as a subject of care when receiving or when having received healthcare.

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

Table 2 lists the associations of this concept; a UML representation of the concept is shown in Figure 5.

Table 2 — Associations of *subject of care*

Specialization of		Generalization of	
healthcare actor			
person role			
Association from		Association name	Association to
1	subject of care	seeks to receive, is receiving, or has received	1..* healthcare
1	subject of care	has	1 health state
1	subject of care	has or has had	0..* health need
0..1	subject of care	maintains	0..* personal health record
1	subject of care	performs	0..* self-care activity
1	subject of care	has	0..* next of kin
0..1	subject of care	has	0..1 consent competence
0..1	subject of care	expresses	0..* subject of care desire
0..1	subject of care	gives	0..* informed consent
0..1	subject of care	states	0..* dissent
1	subject of care	participates in	0..* contact
0..*	subject of care proxy	has the right to take decisions on behalf of	1 subject of care
0..*	subject of care preference delay	is caused by	1 subject of care
1..*	healthcare process	is performed for	1 subject of care
1..*	healthcare activity	is performed for	1 subject of care
1..*	healthcare matter	concerns	1 subject of care
1..*	healthcare mandate	concerns	1 subject of care
1..*	health record	concerns	1 subject of care
0..*	healthcare third party	supports	1..* subject of care
0..*	reason for demand for care	is expressed by	0..1 subject of care

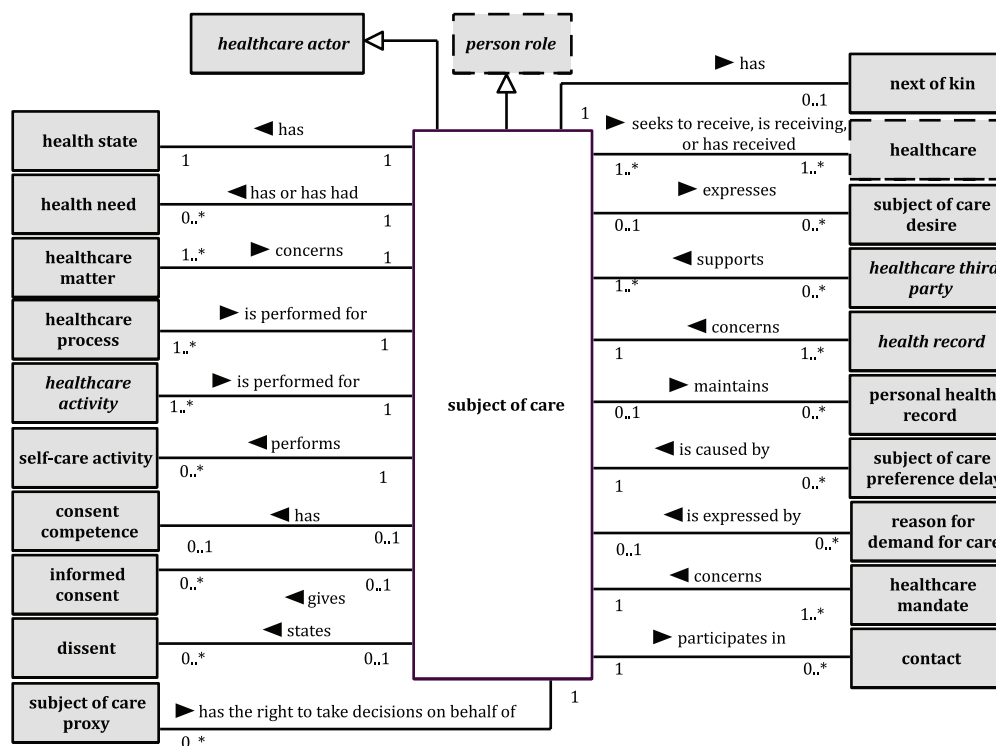


Figure 5 — Subject of care (UML representation)

5.2.2 Next of kin

Term: *next of kin*

Definition: *person role* being either the closest living relative of *the subject of care* or identified as the one he has a close relationship with

NOTE 1 The person that is the next of kin may participate implicitly or explicitly in healthcare by sometimes being a *subject of care proxy* when the *subject of care* has impaired consent competence. Thereby in these circumstances a person that is *next of kin* can perform the role of a *healthcare third party*.

NOTE 2 A person may play the role of *next of kin* to more than one *subject of care*

Table 3 lists the associations of this concept; a UML representation of the concept is shown in Figure 6.

Table 3 — Associations of *next of kin*

Specialization of		Generalization of	
person role			
Association from	Association name	Association to	
1 subject of care	has	0..1	next of kin

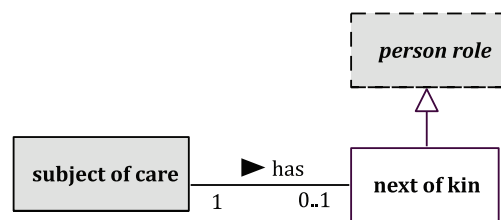


Figure 6 — Next of kin (UML representation)

5.2.3 Healthcare provider

Term: *healthcare provider*

Synonyms: care provider; health provider; health service provider; healthcare service provider

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

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

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

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

Table 4 lists the associations of this concept; a UML representation of the concept is shown in Figure 7.

Table 4 — Associations of *healthcare provider*

Specialization of		Generalization of	
healthcare actor		healthcare organization	
		healthcare professional	
Association from		Association name	Association to
0..*	healthcare provider	provides	1..* healthcare
1	healthcare provider	has care period mandate for	1..* mandated period of care
1	healthcare provider	is responsible for	1..* mandated period of care
1..*	healthcare provider	performs	1..* healthcare provider activity
1	healthcare provider	receives	1..* demand for care
1	healthcare provider	accepts or denies	1..* demand for care
1	healthcare provider	is responsible for	0..* professional health record
1	healthcare provider	manages	0..* episode of care
1	healthcare provider	is able to be assigned	1..* care period mandate
1	healthcare provider	arranges	0..* initial contact
1	healthcare provider	states	1..* healthcare commitment
1	healthcare provider	has	1 healthcare activity directory
1	healthcare provider	is responsible for	0..* resource delay
1	healthcare provider	performs	0..* healthcare resource management

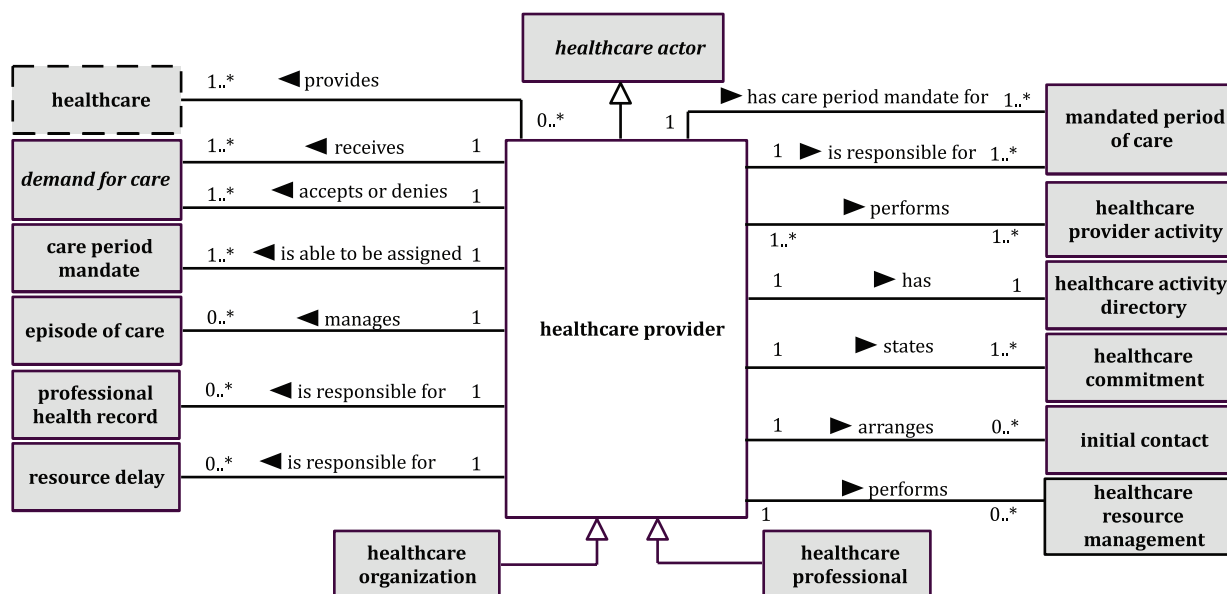


Figure 7 — Healthcare provider (UML representation)

5.2.3.1 Healthcare organization

Term: *healthcare organization*

Synonyms: care organization, healthcare delivery organization

Definition: *healthcare provider* having an *organization* role

NOTE 1 Groupings or subdivisions of an organization, such as departments or sub-departments, may also be considered as organizations where there is need to identify them. The internal structure of an organization is described by its organizational pattern. Therefore, an organization may be considered in itself as a standalone organization or as a superstructure containing departments and sub-departments, for instance, other lower level organizations. A *healthcare organization* represents the role any such organization plays when it is involved in the direct provision of *healthcare activities*.

NOTE 2 Effectively, a *healthcare organization* relies on the activity performed by healthcare personnel, whether employed, contracting, or with temporary informal though functional relationships between them. A healthcare team working together, for example, a specific type of *clinical process* with participants from different departments is also a kind of *healthcare organization*.

NOTE 3 A free-standing self-employed solo practising *healthcare professional* shall be considered as the only member of his/her own *healthcare organization*.

NOTE 4 Organizations may have a number of different roles. When an organization acts in a role where its *healthcare personnel* participate in the direct provision of healthcare, it is called a *healthcare organization*.

EXAMPLES A care team, a group practice, a hospital, a hospital department, a hospital care unit, self-employed GP

Table 5 lists the associations of this concept; a UML representation of the concept is shown in Figure 8.

Table 5 — Associations of *healthcare organization*

Specialization of	Generalization of
healthcare provider	

Table 5 (continued)

organizational role			
Component of		Aggregation of	
		1..*	healthcare personnel
Association from	Association name	Association to	
1..*	healthcare organization	appoints	0..* healthcare personnel
1..*	healthcare organization	adopts	0..* core care plan
1	healthcare organization	performs	1..* healthcare quality management

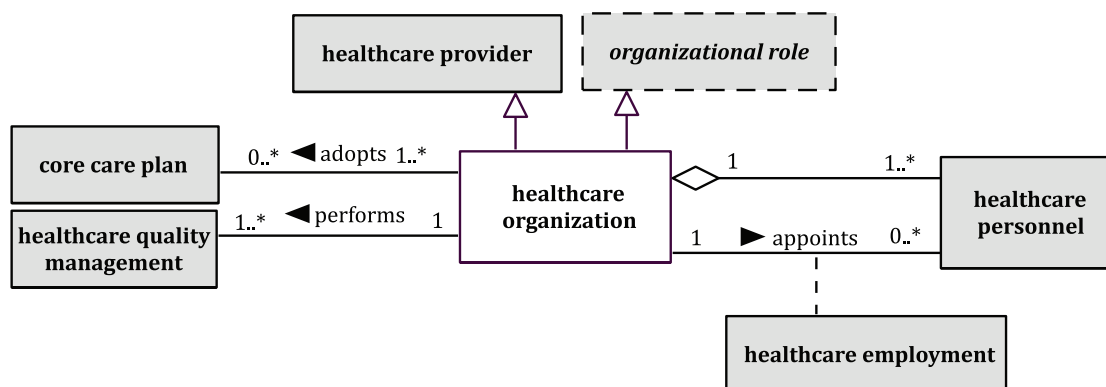


Figure 8 — Healthcare organization (UML representation)

5.2.3.2 Healthcare employment

Term: *healthcare employment*

Synonym: care employment

Definition: contractual framework between a *healthcare personnel* and a *healthcare organization* describing the roles and responsibilities assigned to that *healthcare personnel*

Table 6 lists the associations of this concept; a UML representation of the concept is shown in Figure 9.

Table 6 — Associations of *healthcare employment*

Association concept		Links			
1	healthcare employment	1	healthcare personnel	1	healthcare organization

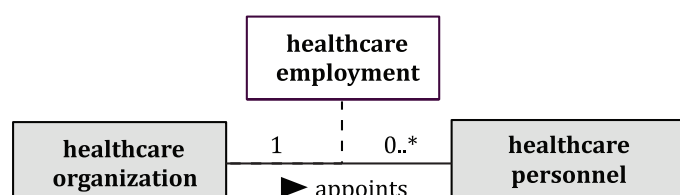


Figure 9 — Healthcare employment (UML representation)

5.2.3.3 Healthcare personnel

Term: *healthcare personnel*

Synonyms: care personnel, individual provider

Definition: individual *healthcare actor* having a *person role* in a *healthcare organization*

EXAMPLES GP, medical consultant, therapist, dentist, nurse, social worker, radiographer, nurse's assistant, children's nurse, nursing officer, head of department, social worker, medical consultant, etc.

Table 7 lists the associations of this concept; a UML representation of the concept is shown in Figure 10.

Table 7 — Associations of *healthcare personnel*

Specialization of		Generalization of	
healthcare actor		healthcare professional	
person role			
healthcare resource			
Component of		Aggregation of	
1	healthcare organization		
Association from	Association name	Association to	
1	healthcare organization	appoints	0..* healthcare personnel
1..*	healthcare personnel	participates in	0..* contact

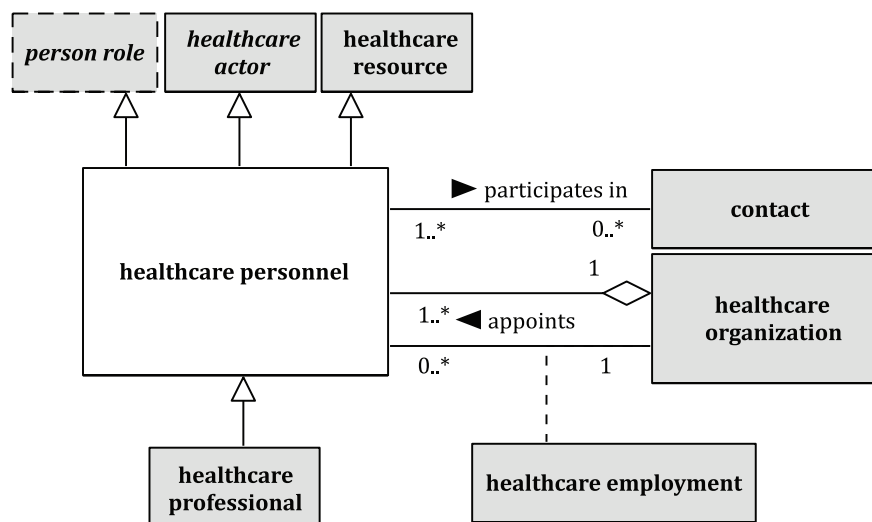


Figure 10 — Healthcare personnel (UML representation)

5.2.3.3.1 Healthcare professional

Term: *healthcare professional*

Synonym: care professional

Definition: *healthcare personnel* having a *healthcare professional entitlement* recognized in a given jurisdiction

NOTE The *healthcare professional entitlement* entitles a *healthcare professional* to provide healthcare independent of a role in a *healthcare organization*.

EXAMPLES GP, medical consultant, therapist, dentist, nurse, radiographer, etc.

Table 8 lists the associations of this concept; a UML representation of the concept is shown in Figure 11.

Table 8 — Associations of *healthcare professional*

Specialization of		Generalization of	
healthcare provider			
healthcare personnel			
Association from		Association name	Association to
1	healthcare professional	has	1..* healthcare professional entitlement
1	healthcare professional	issues	0..* referral
1	healthcare professional	issues	0..* request
1	healthcare professional	manages	0..* healthcare activity period
1..*	healthcare professional	maintains	0..* professional health record
1	healthcare professional	has ratified	0..* healthcare information for import
0..*	healthcare professional	manages	0..* demand for care
1..*	healthcare professional	identifies	0..* prognostic condition
1	healthcare professional	has determined	0..* working diagnosis
1..*	healthcare professional	has ruled out	0..* excluded condition
0..*	professionally assessed condition	is identified by	1 healthcare professional
0..*	prescribed self-care	is prescribed by	1 healthcare professional
0..*	prescribed third party activity	is prescribed by	1 healthcare professional
1..*	healthcare professional	performs	0..* healthcare needs assessment

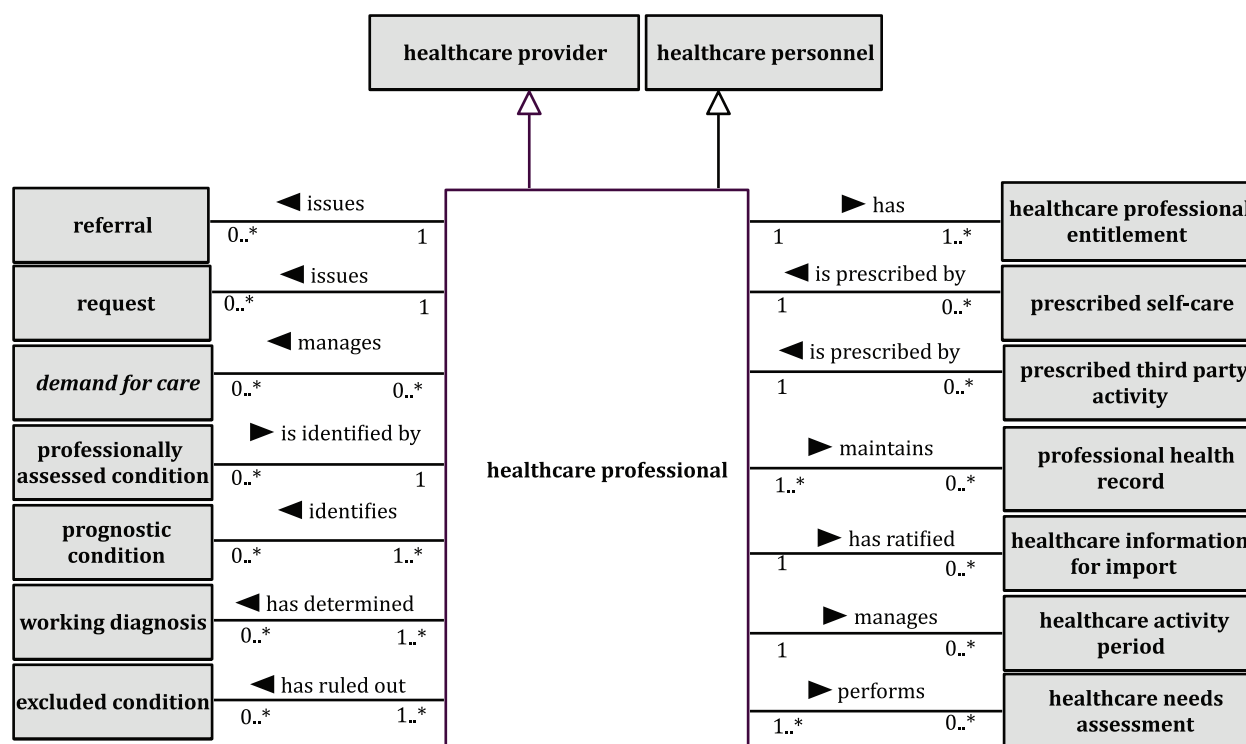


Figure 11 — Healthcare professional (UML representation)

5.2.3.3.2 Healthcare professional entitlement

Term: *healthcare professional entitlement*

Synonym: care professional entitlement

Definition: registered authorization given to a *person* in order to allow the *person* to have or perform specific roles in healthcare

NOTE 1 Entitlement is usually backed by evidence of having received, or continuously receiving, the necessary qualification, the relevant education and training.

NOTE 2 The official entitlement of a *healthcare professional* forms the foundation for his/her official duties and rights.

EXAMPLES Diploma, professional registration (e.g. registered nurse).

Table 9 lists the associations of this concept; a UML representation of the concept is shown in Figure 12.

Table 9 — Associations of *healthcare professional entitlement*

Association from		Association name	Association to	
1	healthcare professional	has	1..*	healthcare professional entitlement

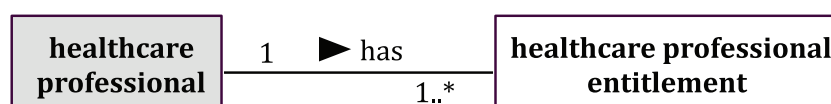


Figure 12 — Healthcare professional entitlement (UML representation)

5.2.4 Healthcare third party

Term: *healthcare third party*

Synonym: care third party

Definition: *healthcare actor other than a healthcare provider or the subject of care*

NOTE 1 According to this definition, a relative (family member) aiding the subject of care, any actor responsible for social support, or for the funding, payment, or reimbursement of healthcare provision are *healthcare third parties*.

NOTE 2 *Healthcare third party* is an abstract superordinate generic concept which is only fully supported through the use of one of its subordinate specific concepts.

Table 10 lists the associations of this concept; a UML representation of the concept is shown in Figure 13.

Table 10 — Associations of *healthcare third party*

Specialization of		Generalization of	
healthcare actor		other carer	
		subject of care proxy	
		healthcare supporting organization	
Association from	Association name	Association to	
0..*	healthcare third party	supports	1..* subject of care
1..*	healthcare third party	performs	1..* healthcare third party activity

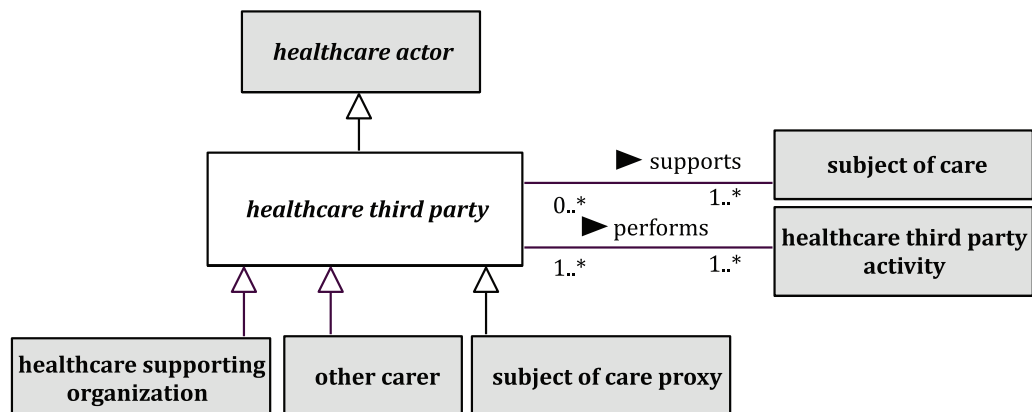


Figure 13 — Healthcare third party (UML representation)

5.2.4.1 Other carer

Term: *other carer*

Synonym: informal carer

Definition: *healthcare third party having person role*

EXAMPLES A relative (family member), a neighbour.

Table 11 lists the associations of this concept; a UML representation of the concept is shown in Figure 14.

Table 11 — Associations of *other carer*

Specialization of	Generalization of
healthcare third party	
person role	

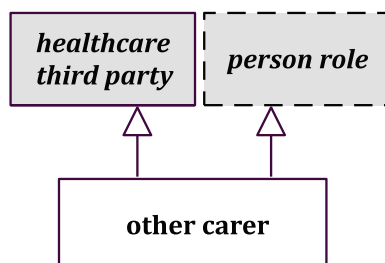


Figure 14 — Other carer (UML representation)

5.2.4.2 Healthcare supporting organization

Term: *healthcare supporting organization*

Synonym: care supporting organization

Definition: *healthcare third party* having *organizational role*

EXAMPLES Voluntary aid organization, a homecare service organization, a health insurance fund, the operator of a telemedicine system, family.

Table 12 lists the associations of this concept; a UML representation of the concept is shown in Figure 15.

Table 12 — Associations of *healthcare supporting organization*

Specialization of	Generalization of
healthcare third party	
organizational role	

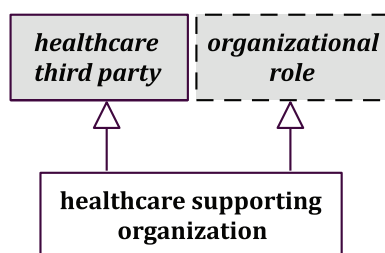


Figure 15 — Healthcare supporting organization (UML representation)

5.2.4.3 Subject of care proxy

Term: *subject of care proxy*

Synonym: subject of care agent

Definition: *healthcare third party* having *person role* with the right to take decisions on behalf of the *subject of care*

NOTE In ISO/TS 21298 subject of care agent is the preferred term for this concept.

Table 13 lists the associations of this concept; a UML representation of the concept is shown in Figure 16.

Table 13 — Associations of *subject of care proxy*

Specialization of		Generalization of	
person role			
healthcare third party			
Association from	Association name	Association to	
0..1 subject of care proxy	gives	0..*	informed consent
0..* subject of care proxy	has the right to take decisions on behalf of	1	subject of care
0..1 subject of care proxy	states	0..*	dissent
0..* subject of care proxy	has	1	consent competence
0..* reason for demand for care	is expressed by	0..*	subject of care proxy
0..* subject of care proxy	maintains	0..*	personal health record
0..1 subject of care proxy	expresses	0..*	subject of care desire

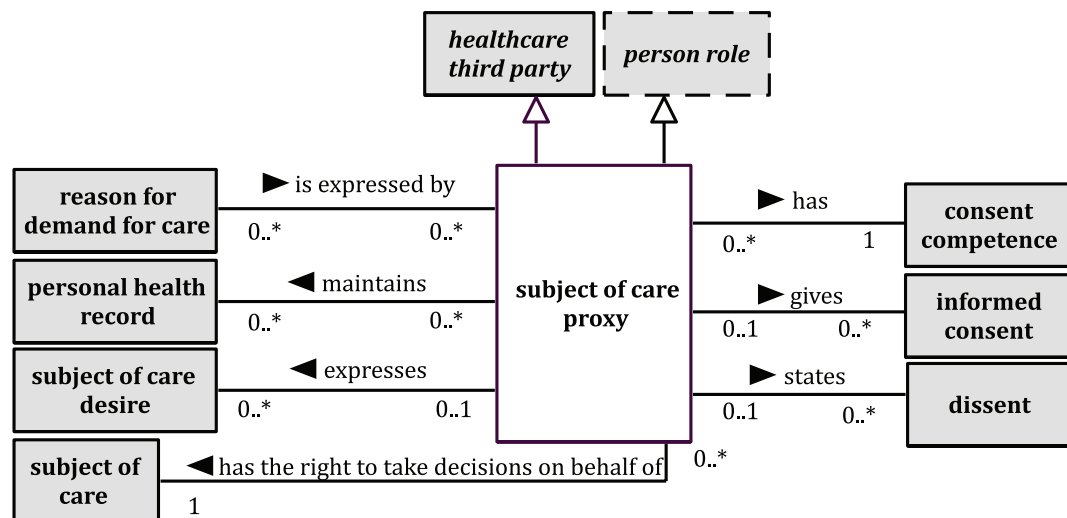


Figure 16 — Subject of care proxy (UML representation)

6 Concepts related to healthcare matters

6.1 General

A model showing the associations between concepts related to healthcare matters and the other concepts defined in this International Standard is shown in Figures 17 and 18. For further detail about the diagram notation, please refer to 0.7 in the Introduction.

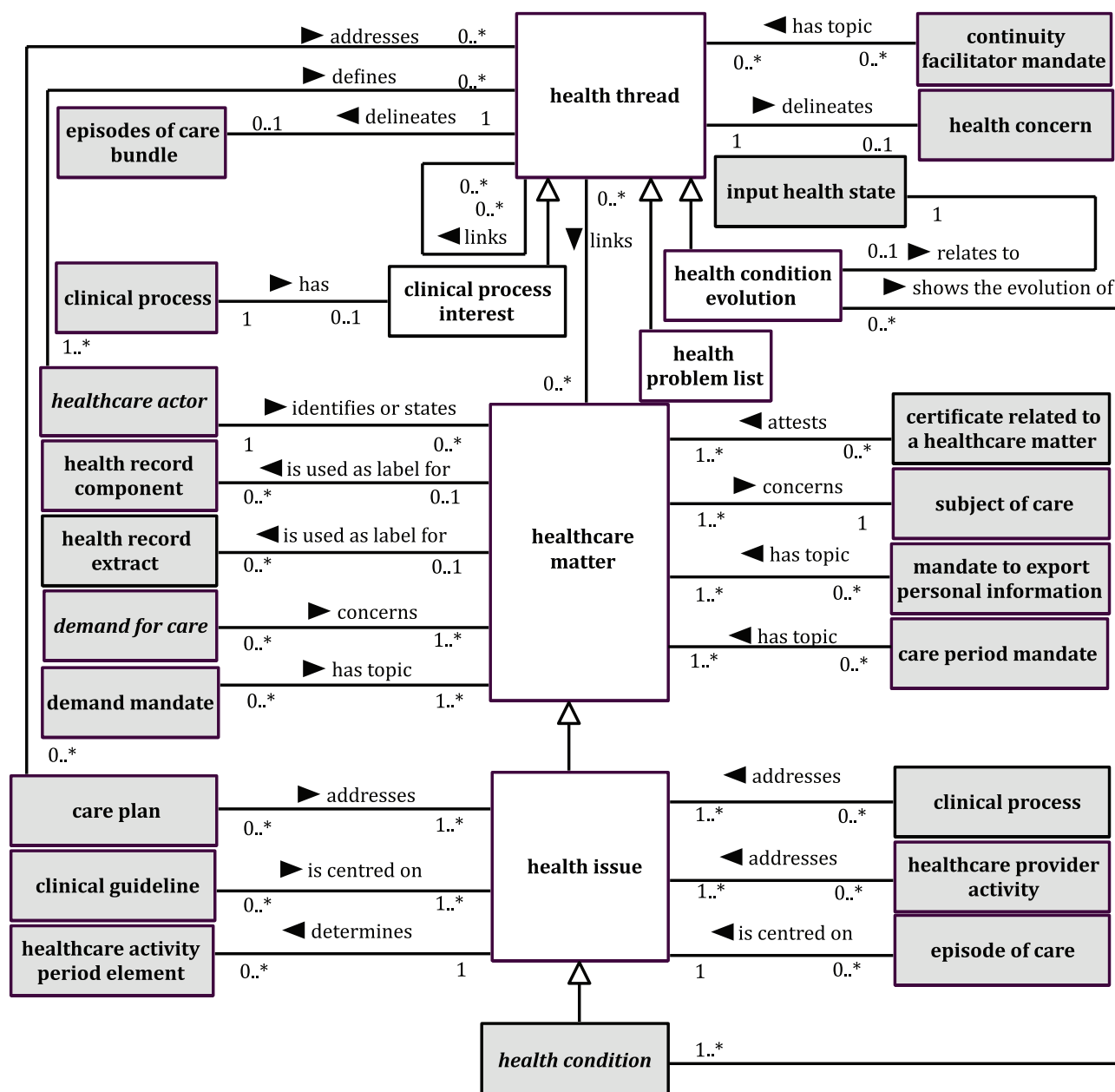


Figure 17 — Comprehensive UML diagram of concepts related to healthcare matters (i)

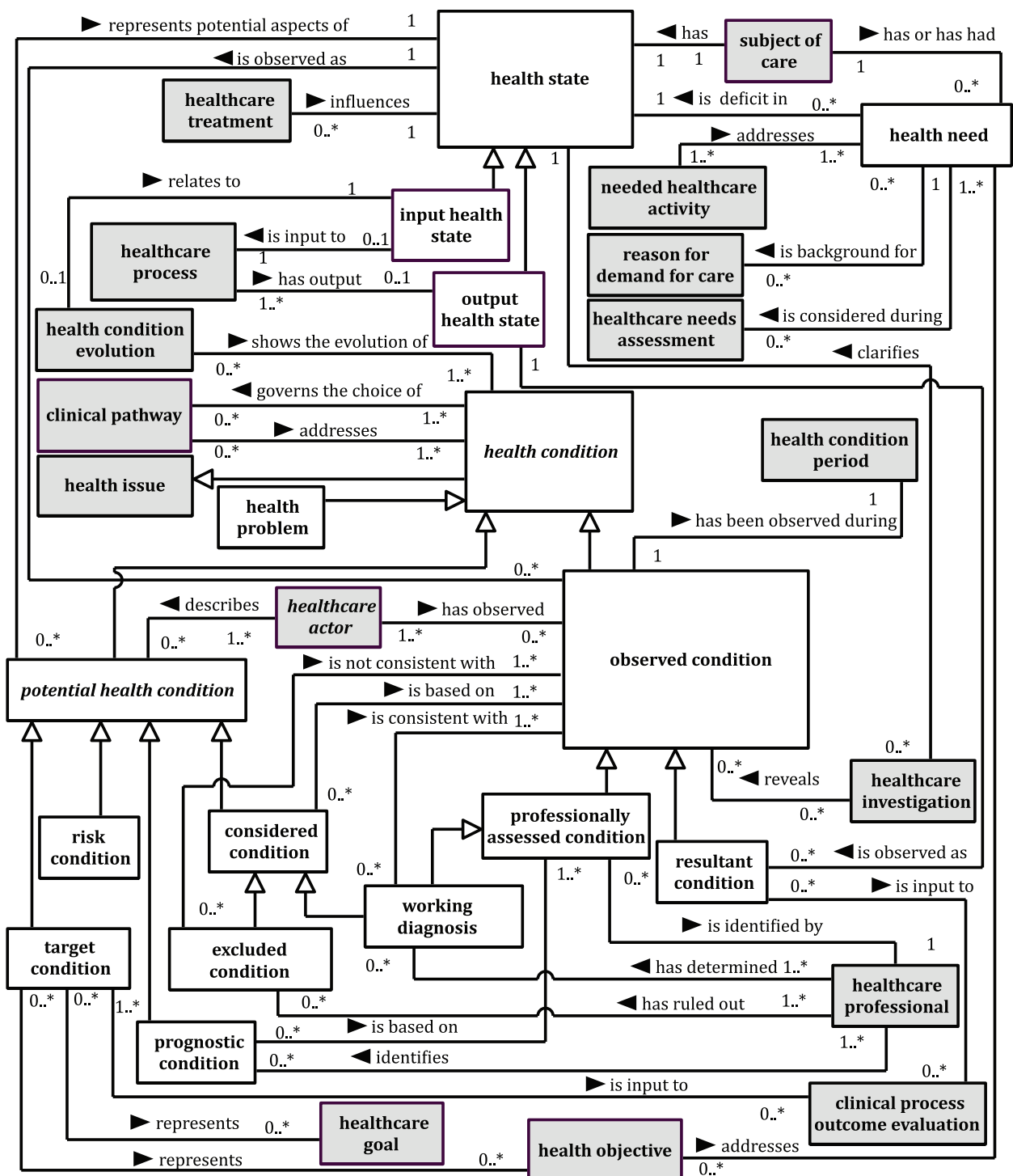


Figure 18 — Comprehensive UML diagram of concepts related to healthcare matters (ii)

6.2 Healthcare matter

Term: *healthcare matter*

Synonym: care matter

Definition: representation of a matter related to the health of a *subject of care* and/or the provision of healthcare to that *subject of care*, as identified by one or more *healthcare actors*

NOTE 1 *Healthcare matter* is a very broad and flexible concept that includes anything related to the health or the healthcare of a *subject of care*. This means that *health conditions*, *healthcare activities*, *health problems*, the result of *healthcare activities*, etc. all are possible to be identified as *healthcare matters*. Thereby *healthcare matter* might have several specializations and further associations.

NOTE 2 According to this definition, a *healthcare matter* can represent a disease, an illness or another kind of *health condition*. In addition a *healthcare matter* may represent, for example, a request for a procedure (therapeutic or preventive) by the subject of care or another *healthcare actor*.

NOTE 3 Concepts described and/or identified in a clinical terminology may represent types of *healthcare matter*.

NOTE 4 Other specializations of this concept than those included in this International Standard, may be created when needed.

EXAMPLES A loss of weight, an immunization, a heart attack, a drug addiction, a case of meningitis in the school, a water fluoridation, a health certificate, an injury, dermatitis, an X-ray investigation, an arthroscopy, an administration of an oral antibiotic, a post-operative infection.

Table 14 lists the associations of this concept; a UML representation of the concept is shown in Figure 19.

Table 14 — Associations of *healthcare matter*

Specialization of		Generalization of	
		health issue	
Association from		Association name	Association to
1..*	healthcare matter	concerns	1 subject of care
0..1	healthcare matter	is used as label for	0..* health record component
0..1	healthcare matter	is used as label for	0..* health record extract
1	healthcare actor	identifies or states	0..* healthcare matter
0..*	demand mandate	has topic	1..* healthcare matter
0..*	care period mandate	has topic	1..* healthcare matter
0..*	demand for care	concerns	1..* healthcare matter
0..*	mandate to export personal information	has topic	1..* healthcare matter
0..*	health thread	links	0..* healthcare matter
0..*	certificate related to a healthcare matter	attests	1..* healthcare matter