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DIN EN 13940-1:2007-09

Entwurf

**Medizinische Informatik –
Begriffssystem zur Unterstützung der Kontinuität der Versorgung
(ISO/DIS 13940:2012);
Englische Fassung prEN ISO 13940:2012**

Health informatics –

System of concepts to support continuity of care (ISO/DIS 13940:2012);

English version prEN ISO 13940:2012

Informatique de la santé –

Système de concepts en appui de la continuité des soins (ISO/DIS 13940:2012);

Version anglaise prEN ISO 13940:2012

Anwendungswarnvermerk

Dieser Norm-Entwurf mit Erscheinungsdatum 2013-02-11 wird der Öffentlichkeit zur Prüfung und Stellungnahme vorgelegt.

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

Stellungnahmen werden erbeten

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

Die Empfänger dieses Norm-Entwurfs werden gebeten, mit ihren Kommentaren jegliche relevanten Patentrechte, die sie kennen, mitzuteilen und unterstützende Dokumentationen zur Verfügung zu stellen.

Gesamtumfang 186 Seiten

Normenausschuss Medizin (NAMed) im DIN

Nationales Vorwort

Dieses Dokument (prEN ISO 13940:2012) wurde vom Technischen Komitee CEN/TC 251 „Medizinische Informatik“ (Sekretariat: NEN, Niederlande) in Zusammenarbeit mit dem Technischen Komitee ISO/TC 215 „Health Informatics“ erarbeitet. Der Fachbereich 7 „Medizinische Informatik“ und insbesondere die Mitarbeiter des Arbeitsausschusses NA 063-07-03 AA „Terminologie“ des Normenausschusses Medizin (NAMed) im DIN haben an der Erarbeitung mitgewirkt. Dieser Norm-Entwurf enthält unter Berücksichtigung der Präsidialbeschlüsse 13/1983 und 1/2004 den englischen Originaltext des Internationalen Norm-Entwurfs ISO/DIS 13940:2012.

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

ISO 9000 siehe DIN EN ISO 9000
ISO 9001 siehe DIN EN ISO 9001

1 Anwendungsbereich

Diese Internationale Norm legt ein System von Konzepten für unterschiedliche Aspekte der Pflege im Gesundheitswesen fest. Das Ziel dieser Konzepte ist, die ununterbrochene Pflege im Gesundheitswesen und in klinischen Prozessen zu unterstützen. Ein weiteres Ziel ist, die Wiederverwendung von klinischen Informationen für andere Zwecke, wie z. B. die Zweitnutzung für Folgemaßnahmen und zur Wissensverwaltung, zu ermöglichen.

Das allgemeine Ziel dieser Norm ist, eine umfassende konzeptionelle Basis für den Inhalt und Kontext von Gesundheitsdienstleistungen zur Verfügung zu stellen. Sie sollte die Grundlage für eine alle Ebenen übergreifende Interoperabilität der im Gesundheitswesen tätigen Organisationen und für die Entwicklung von Informationssystemen im Gesundheitswesen bilden. Im Gesundheitswesen geht es im Kern um die Interaktion zwischen der (den) zu pflegenden Person(en) und den Medizinern. Zu solchen Interaktionen kommt es im Gesundheitswesen und 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 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 sollte diese Norm immer dann angewendet werden, wenn Informationen im Gesundheitswesen als Anforderung festgelegt sind. Dies gilt für alle Ebenen von Spezifikationen in der Entwicklung von:

- geschäftlichen oder klinischen Referenzmodellen als einer gemeinsamen Basis für die Interoperabilität auf internationaler, nationaler oder lokaler Ebene;
- Informationssystemen und
- Informationen für festgelegte Arten von klinischen Prozessen.

Die Ausführung von speziellen gesundheitspflegerischen und klinischen Prozessen sowie von Forschungs- und Bildungsprozessen im Gesundheitswesen sind nicht Gegenstand der vorliegenden Norm.

Änderungen

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

- a) Aufnahme des Teil 2 „Kernprozess und Ablaufplan im Gesundheitswesen“ der ursprünglich vorgesehenen Normenreihe und damit wesentliche Erweiterung;
- b) komplette redaktionelle Überarbeitung.

Nationaler Anhang NA (informativ)

Begriffe

Die Benennungen der folgenden Begriffe sind identisch mit den Benennungen in der Englischen Fassung.

3.1

klinische Daten

(en: clinical data)

Daten zur Gesundheitspflege oder zum klinischen Prozess

3.2

klinische Informationen

(en: clinical information)

Satz von *klinischen Daten*, die zur Nutzung in einem klinischen Kontext verarbeitet werden

Anmerkung 1 zum Begriff: Diese Definition weicht bewusst von der in EN 14822-3 enthaltenen ab, in der klinische Informationen als „Informationen über einen Patienten und Informationen, die für die Gesundheit oder Behandlung dieses Patienten maßgeblich sind und von einem *Mediziner* oder in dessen Namen aufgezeichnet werden“ definiert sind, ergänzt durch die Anmerkung, dass: „Klinische Informationen über einen Patienten Informationen über dessen Umfeld oder, sofern maßgeblich, über Verwandte des Patienten enthalten können“.

3.3

Verpflichtung

(en: commitment)

eine Zusage, Aktivitäten einer Anforderung oder einem Auftrag entsprechend zu leisten

3.4

Konzept

(en: concept)

Wissenseinheit, die durch eine einzigartige Kombination von Eigenschaften erzeugt wird

[ISO 1087-1:2000]

3.5

Zustimmung

(en: consent)

Vereinbarung, Bestätigung oder Genehmigung, die eine Aktion oder einen Zweck betrifft und aus freien Stücken von einer sachkundigen Person getroffen, ausgegeben oder erteilt wird

[ISO 18308:2011]

3.6

ununterbrochene Pflege

(en: continuity of care)

Qualitätsaspekt der Patientenpflege, der den Grad der aktivitätsbezogenen und zeitlichen Koordination sowohl zwischen den praktischen Ärzten als auch über Organisationen hinweg in Bezug auf die vom Patienten benötigte Pflege angibt

[ISO/TR 18307:2001]

3.7

Daten

(en: data)

reinterpretierbare Darstellung von Informationen in einer formalisierten Art und Weise, die sich zur Kommunikation, Auswertung und Interpretation oder zur Verarbeitung eignet

[ISO/IEC 2382-1:1993]

3.8

abgelehnter Begriff

(en: deprecated term)

Begriff, der von einer zuständigen Stelle als veraltet zurückgewiesen wird/wurde

[ISO 1087-1:2000]

3.9

Dateneinheit

(en: entity)

konkreter oder abstrahierter Gegenstand der Betrachtung, einschließlich der Zusammenhänge zwischen den Gegenständen

[ISO 18308:2011]

ISO 18308:2011, *Medizinische Informatik — Anforderungen an die Architektur einer elektronischen Gesundheitsakte*

3.10

Gesundheitswesen

(en: healthcare)

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

Anmerkung 1 zum Begriff: Hierzu gehört mehr als nur die Ausführung von bestimmten Vorgängen am Patienten oder Pflegebedürftigen. Eingeschlossen ist z. B. auch die Verwaltung von Informationen über Patienten, Gesundheitszustand und Beziehungen innerhalb des Gesundheitswesens.

Anmerkung 2 zum Begriff: In der vorliegenden Internationalen Norm ist die Benennung „Pflege“ (en: care) als Synonym für „Gesundheitswesen“ (en: healthcare) zu verstehen.

[In Anlehnung an ISO/TR 18307:2001]

3.11

Information

(en: information)

Wissen zu Betrachtungsgegenständen wie z. B. Fakten, Konzepten, Objekten, Ereignissen, Ideen

[ISO 1087-2:2000]

3.12

Informationsmodell

(en: information model)

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

[ISO 10303-1:1994]

ISO 10303-1:1994, *Industrielle Automatisierungssysteme und Integration — Produktdatendarstellung und -austausch — Teil 1: Überblick und grundlegende Prinzipien*

3.13**Wissen**

(en: knowledge)

Fakten, Informationen und Fähigkeiten, die durch Erfahrung, Überlegung oder Bildung gewonnen bzw. erworben wurden

[Oxford Dictionary of English]

3.14**Medizinprodukt**

(en: medical device)

Instrumente, Apparate, Geräte, Maschinen, Vorrichtungen, Implantate, In-vitro-Reagenzien, Kalibriermittel, Software, Stoffe oder andere ähnliche oder zugehörige 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;
- Bereitstellung von Informationen 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.

[EN ISO 14971:2009]

Anmerkung 4 zum Begriff: Diese Definition ist rekursiv, weil der Begriff im sechsten Aufzählungspunkt aufgeführt ist, was bedeutet, dass er nicht den in ISO 703 festgelegten terminologischen Regeln entspricht. Sie bedeutet einfach, dass Produkte, die zur Wartung eines Medizinproduktes verwendet werden, in dieser Definition enthalten sind.

3.15

Organisation

(en: organization)

eindeutiger Autoritätsrahmen, innerhalb dessen eine oder mehrere Personen für bestimmte Zwecke handeln oder benannt worden sind zu handeln

[ISO/IEC 6523-1:1998]

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.

3.16

Organisationsstruktur

(en: organizational pattern)

Beziehungen zwischen den verschiedenen Teilen einer *Organisation*

3.17

Organisationsfunktion

(en: organization role)

von einer *Organisation* übernommene Funktion

3.18

Beteiligte(r)

(en: party)

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

[ISO 8459:2009]

3.19

Person

(en: person)

ein als Individuum angesehener Mensch

[Oxford Dictionary of English]

3.20

persönliche Funktion

(en: person role)

von einer Person übernommene Funktion

3.21

Prozess

(en: process)

Satz von in Wechselbeziehung oder Wechselwirkung stehenden Tätigkeiten, der Eingaben in Ergebnisse umwandelt

Anmerkung 1 zum Begriff: Eingaben für einen Prozess sind üblicherweise Ergebnisse anderer Prozesse. In diesem Sinne können Aktivitäten als Ressourcen eines Prozesses angesehen werden, weil ihr Ergebnis als Eingabe für einen anderen Prozess verwendet werden kann.

[ISO 9000:2005]

3.22

Prozessmodell

(en: process model)

Darstellung eines Prozesses

3.23**Qualität im Gesundheitswesen**

(en: quality in healthcare)

Grad, in dem das Gesundheitswesen Anforderungen an festgelegte Qualitätsmerkmale erfüllt

Anmerkung 1 zum Begriff: Qualität ist in ISO 9000:2005, 3.1.1 als der „Grad, in dem ein Satz inhärenter Merkmale Anforderungen erfüllt“, definiert

3.24**Qualitätsmanagement**

(en: quality management)

aufeinander abgestimmte Tätigkeiten zum Leiten und Lenken einer *Organisation* bezüglich Qualität

Anmerkung 1 zum Begriff: Leiten und Lenken bezüglich Qualität umfassen üblicherweise das Festlegen der Qualitätspolitik und der Qualitätsziele, die Qualitätsplanung, die Qualitätslenkung, die Qualitätssicherung und die Qualitätsverbesserung.

[ISO 9000:2005, 3.2.8]

3.25**Qualitätssicherung**

(en: quality assurance)

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

[ISO 9000:2005, 3.2.11]

3.26**Qualitätslenkung**

(en: quality control)

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

[ISO 9000:2005, 3.2.10]

3.27**Qualitätsmanagementsystem**

(en: quality management system)

Managementsystem zum Leiten und Lenken einer *Organisation* bezüglich der Qualität

[ISO 9000:2005, 3.2.3]

3.28**Ressource**

(en: resource)

Vermögenswert, der während der Ausführung eines Prozesses zum Einsatz kommt oder verbraucht wird

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

Anmerkung 2 zum Begriff: Ressourcen können wiederverwendbar, erneuerbar oder verbrauchbar sein.

BEISPIEL Zeit, Personal, soziale Kompetenzen und Wissen, technische Ausrüstung, Dienstleistungen, versorgt Hilfs- und Betriebsstoffe, Anlagen und Einrichtungen, Technologie, Daten, Geld usw.

[ISO/IEC 15288:2008]

3.29

Risiko

(en: risk)

Kombination aus der Wahrscheinlichkeit eines Ereignisses und dessen Folgen

[ISO Guide 73]

3.30

Funktion

(en: role)

Reihe von Kompetenzen und/oder Leistungen, die mit einer Aufgabe verbunden sind

Anmerkung 1 zum Begriff: In EN 13606-1 ist „Funktion“ wie folgt definiert: „Name einer Reihe von Verhaltensweisen, die mit einer Aufgabe verbunden sind“.

[ISO/TS 22600-1:2006]

3.31

System von Konzepten

ABGELEHNT: Konzeptsystem

(en: system of concepts

DEPRECATED: concept system)

Menge von Konzepten, die entsprechend den zwischen diesen bestehenden Beziehungen strukturiert ist

[ISO 1087-1:2000]

3.32

unbeabsichtigtes Ereignis

(en: unintended event)

Phänomen, das nicht Teil des normalen Verlaufs eines *Prozesses* 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.

BEISPIEL 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.

3.33

Arbeitsablauf

(en: workflow)

Darstellung der tatsächlichen Abfolge der in einem *Prozess* stattfindenden Betriebsvorgänge oder Aktionen

Anmerkung 1 zum Begriff: Ein Arbeitsablauf spiegelt die in der Ausführung eines Prozesses aufeinander folgenden Entscheidungen und Aktivitäten wider.

[ISO 18308:2011]

Nationaler Anhang NB (informativ)

Literaturhinweise

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

DIN EN ISO 9001, *Qualitätsmanagementsysteme — Anforderungen*

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English Version

Health informatics —
System of concepts to support continuity of care
(ISO/DIS 13940:2012)

Informatique de santé —
Système de concepts en appui de la continuité des soins
(ISO/DIS 13940:2012)

Medizinische Informatik —
System von Konzepten zur Unterstützung der
ununterbrochenen Pflege
(ISO/DIS 13940:2012)

This draft European Standard is submitted to CEN members for parallel enquiry. It has been drawn up by the Technical Committee CEN/TC 251.

If this draft becomes a European Standard, 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.

This draft European Standard was established by CEN 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.

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Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

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COMITÉ EUROPÉEN DE NORMALISATION
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Foreword

This document (prEN ISO 13940:2012) 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 document is currently submitted to the parallel Enquiry.

This document will supersede EN 13940-1:2007.

Endorsement notice

The text of ISO/DIS 13940:2012 has been approved by CEN as a prEN ISO 13940:2012 without any modification.

0. Introduction

0.1 General

The purpose of this 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 with semantic interoperability 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; and to cover the concepts for this, 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 standard is based on a clinical process model and defines its component classes and their descriptive terms, regarding all types of healthcare and especially considering patient-centred continuity of care. This standard will establish a common conceptual framework across national, cultural and professional barriers.

0.2 Aims for this standard

The general aim for this 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 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 standard. To be able to represent both clinical content and clinical context, this standard is based upon a generic 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 standard should be used whenever information in healthcare is specified as a requirement. This will cover all levels of specifications in the development of:-

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

0.3 Target groups

Target groups for this standard are all interested parties in interoperability issues in health care. This includes e.g. healthcare professionals and teams, subjects of care, healthcare managers, healthcare funding organizations and all types of healthcare providers and community care teams.

In general, this system of concepts is also relevant for all use of healthcare information and for the development and use of Electronic Health Records. It may 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.

0.4 Business oriented architecture of the system of concepts

This system of concepts is based upon the clinical perspective of the core business of healthcare, this being the clinical processes. All other areas of work in the healthcare business should both relate to and interact with the clinical process. As such, the management aspect of the healthcare business is identified in the process management areas and similarly the resource support areas are correspondingly identified as outcomes of the support processes.

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

- Core healthcare and clinical processes
- Management
- Support

In this International Standard the concepts are grouped into separate clauses. The relationships between the business areas that need to be covered from continuity perspectives are used to structure this standard. Each of the concepts are described systematically and their relations are shown in UML models. Figure 1 illustrates the traceability between the concept groups in this standard and the business areas.

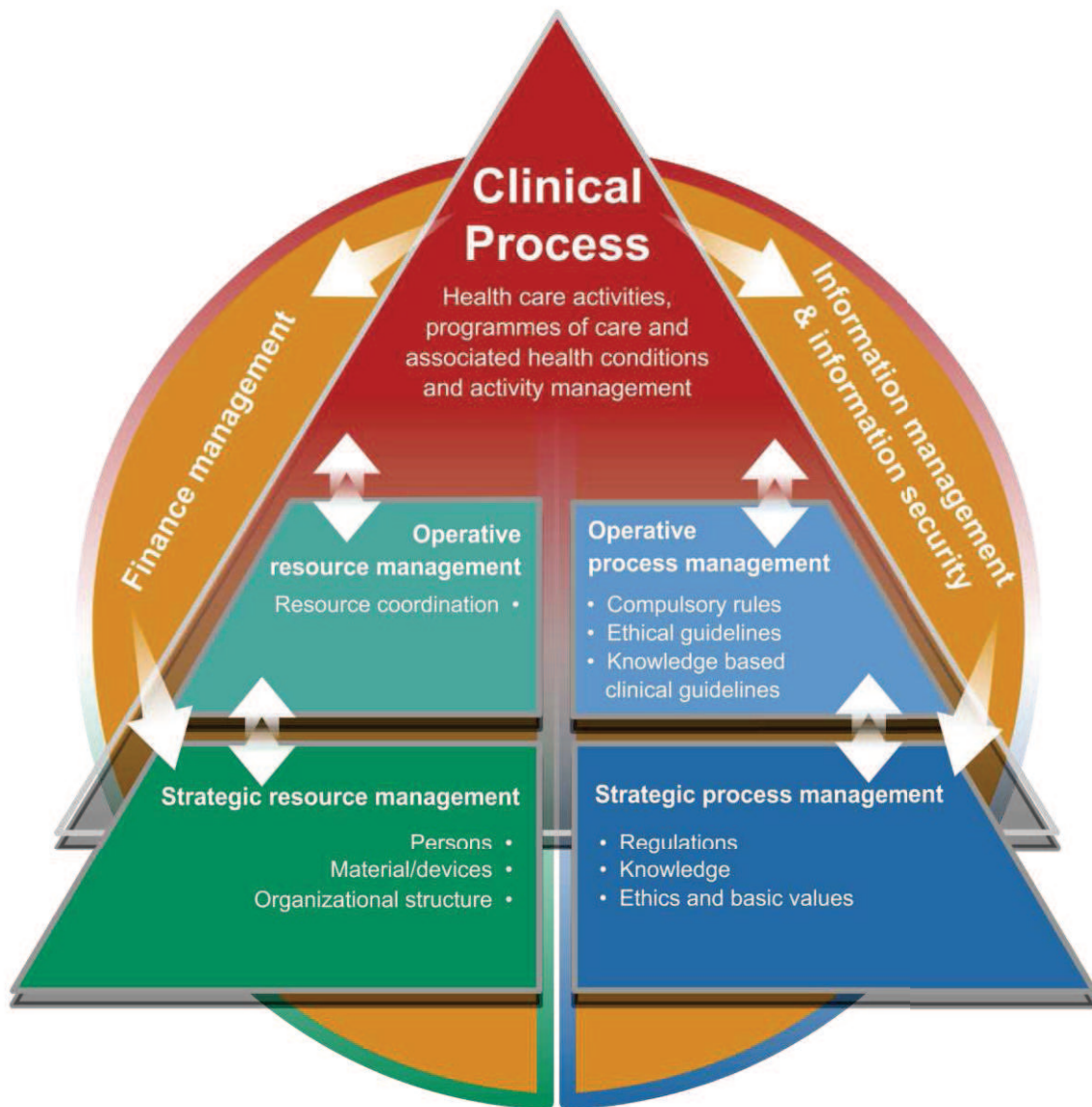


Figure 1 — Business areas and grouping of concepts

0.5 Description and display of concepts

Descriptions framed in tables and following the same procedural pattern are systematically provided for all the concepts presented in Clauses 7 to 12. Wherever these are not relevant to a given concept, some categories will intentionally be left blank. Italic characters are used in the headings of those concepts that are purely abstract constructs and therefore supported only through their specializations.

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 compliant with ISO/TR 24156:2008. For each one of the concepts

described in Clauses 7 to 12, a partial view of the general and comprehensive diagram is provided, showing only its direct relationships with other concepts belonging to the current system of concepts.

Diagrams providing partial views of the system of concepts are also shown at the beginning of Clauses 5 to 12. These diagrams are focused on the topic addressed in the corresponding clause. For clarity of reading, concepts shown in white with a solid border are defined in the clause to which the diagram belongs. Concepts defined in other clauses of the standard are shown in grey with a solid border while concepts not defined in this standard are shown in grey with a dashed border. While all relationships are included for the concepts shown in white, the relationships between concepts shown in grey are not included in the diagrams.

The purpose of using concept models in this standard is to highlight the relationships between concepts. Their attributes, which do not belong to the field of concept modeling, are not addressed in this standard. This means that additional attributes may be felt useful or necessary in the course of implementation, without conformance with the current standard being at stake.

0.6 About the concept of health

This 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 emphasising 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 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.

0.7 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 that healthcare. There is an evident overlap between healthcare activities and social care activities. This 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 standard should also be applicable.

0.8 Explanatory comments

0.8.1 Process and workflow

0.8.1.1. Process concepts in general

The generic definition of a process, outlined in ISO 9000:2005, is a "set of interrelated or interacting activities which transforms inputs into outputs".

Processes are built up by activities that influence process objects. Processes can be aggregated and/or subdivided into different parts that can be considered as processes by themselves. A process model does not explicitly describe the sequence of the activities: this is the topic of a workflow description; and so the flow described in a process model usually represents a value flow and not a time sequence.

The definition and scope of a process depends upon the defined inputs and targeted outputs. When a process is subdivided, the output of a given part of that process is often the input of another part of the process. Figure 2 shows the general schematic representation of a process, with inputs, nested

activities/processes, management, resource supply and outputs.

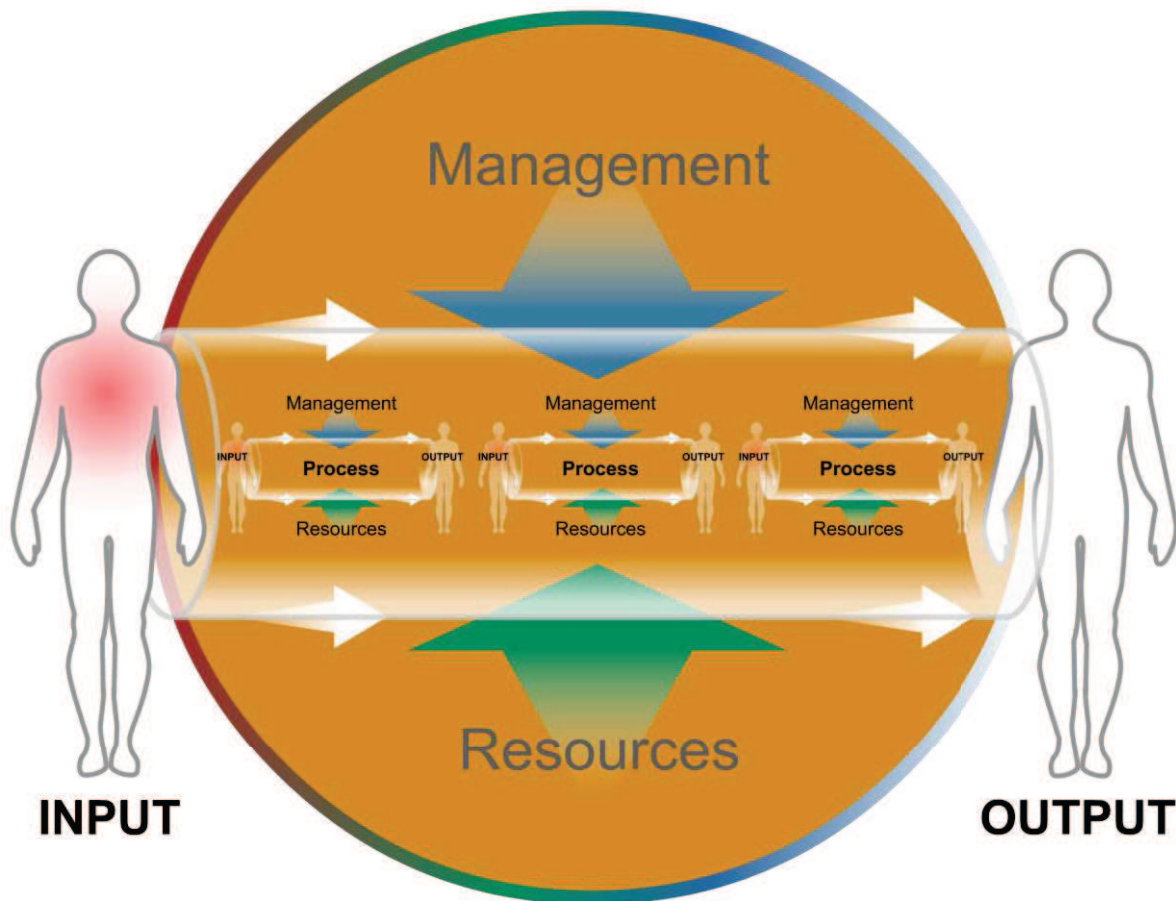


Figure 2 — Schematic general process

In any organization many kinds of processes can be identified and defined by their inputs and outputs, the activities included, and the value the activities add to the process objectives in the transformation of the inputs etc. In general there are certain kinds of processes that are more important when it comes to fulfilling the requirements of the main customers. These processes are sometimes called the core processes.

One method to describe processes is to use a modelling technique. In general, a process model describes the inputs (the primary objects processed), the activities that transform inputs, the life cycle of the activities during that transformation and the resulting outputs. A process model does not describe the sequence of the activities: this is the topic of a workflow description; and so the flow described in a process model is a value flow and not a time sequence.

0.8.1.2. Workflow in general

A workflow is the order in which the activities in a process are performed; and as such a workflow is a time-related application of the activities in a corresponding process. A workflow depicts the actual sequence of the activities in a process. It also identifies the participants (actors) and roles in the process.

0.8.2 Types of processes in healthcare

In this standard a *healthcare organization* is defined as an 'organization involved in the direct provision of healthcare'. In this standard, three main types of processes in healthcare organizations are identified:

- Healthcare and clinical processes
- Healthcare research processes
- Healthcare educational processes

0.8.2.1. Healthcare and clinical processes

The main operations in all healthcare organizations are related to the interaction between subjects of care and healthcare professionals. A healthcare process could include any set of activities related to the interaction between a subject of care and healthcare professionals. It can be subdivided into parts or aggregated to provide a comprehensive picture.

Continuity of care, process management and patient orientation are important quality aspects of healthcare. To achieve good quality care a specialized type of healthcare process with specific characteristics is defined as a clinical process.

The clinical processes are comprehensive and consider certain identified health issues. For example, the complete chain of care (including primary care, care at hospitals, rehabilitation and medication regardless of organizational units involved) for a patient with stroke should be regarded as a clinical process. The clinical processes are identified so as to give prerequisites for an organization to fulfil their requirements, including continuity of care, related to process management in their quality management system. The clinical processes represent the clinical context where activities can be coordinated from the subject of care's perspective. The information 'container' for a clinical process is called a 'clinical process interest' in this standard.

Like all kinds of processes the healthcare and clinical processes are dependent upon management and resource support; as shown in Figure 3.

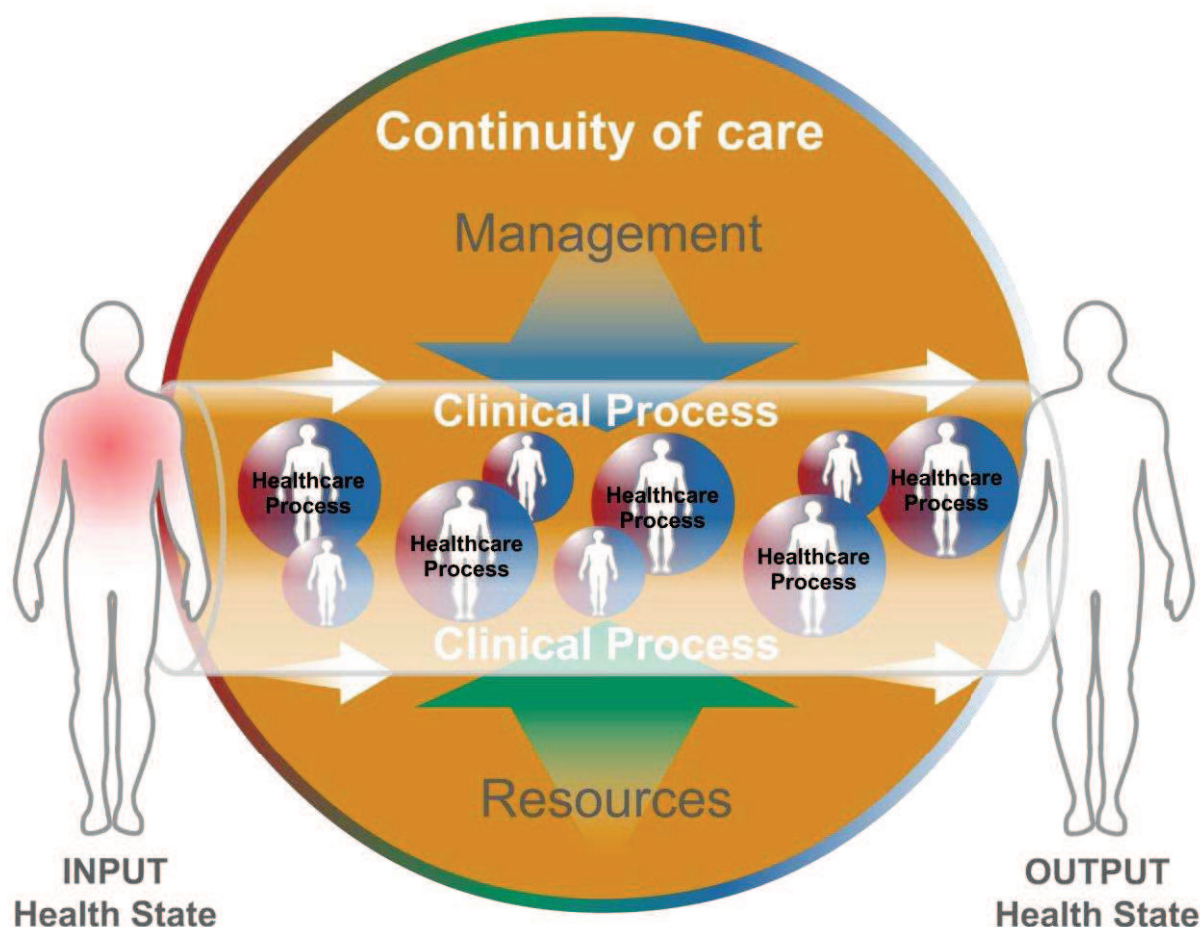


Figure 3 — The clinical process in continuity of care

0.8.2.2. Healthcare research process

The *healthcare research process* is a kind of process in some healthcare organizations such as university hospitals. Its objective is to contribute to medical knowledge in general. These types of processes are not in the scope of this standard.

0.8.2.3. Healthcare educational process

Another kind of process in some healthcare organizations is the *healthcare educational process*. These processes are meant to improve the skills of the *healthcare professionals*. The educational processes encompass the basic professional education. The continuous competence development is not regarded as an educational process but is integrated in the resource management of all healthcare organizations. The healthcare educational process is not in the scope of this standard.

0.8.3 Workflow in healthcare

In healthcare and from the perspective of continuity of care, the workflow related to a *healthcare* or *clinical process* describes how and in which order care providers (singularly or as an organization) are given, take responsibility for and perform activities according to the *health objective* or *healthcare goals* stated in a *care plan*. This is in addition to how the activities performed are managed, documented and reported.

0.8.4 The Clinical process model

A model of a generic clinical process is needed to give the context and traceability of the concepts for continuity of care.

A clinical and/or a healthcare process model describes the healthcare activities and the value added by describing the health conditions that represent the health state as the process object. The main concepts in a process model are the health conditions and the healthcare activities. The types of activities and the types of conditions motivating and/or resulting from these activities in any applied healthcare process can be derived and/or traced from the clinical process model. The process model used to give the context for the concepts in this standard is shown in Figure 4. A more elaborate description and analysis of this process model is given in Annex A.

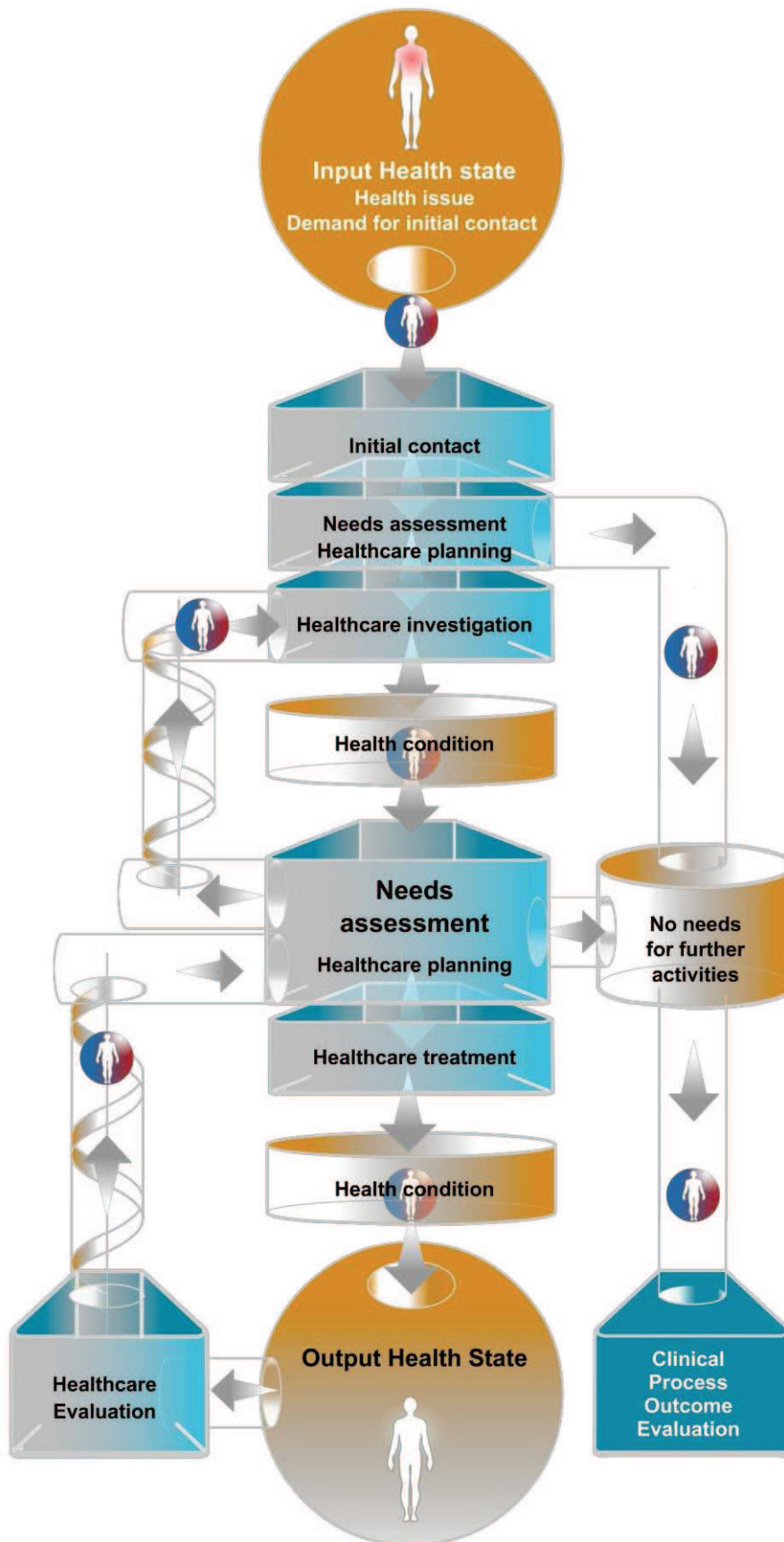


Figure 4 – Main concepts of the clinical process

1. Scope

This International standard defines a system of concepts for different aspects of the provision of healthcare. The concepts aim to support the continuity of care in healthcare and clinical processes. An additional aim is to enable the reuse of clinical information for other purposes such as secondary use for follow-up and knowledge management.

The general aim for this 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 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 standard. To be able to represent both clinical content and clinical context, this standard is based upon a generic 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 standard should be used whenever information in healthcare is specified as a requirement. This will cover all levels of specifications in the development of:-

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

The performance of any specific healthcare and clinical processes, healthcare research processes and healthcare educational processes are not covered in this standard.

2. Normative references

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

ISO 704:2000, Terminology work — Principles and methods

ISO 10241, International terminology standards – Preparation and layout

ISO/IEC 1087-1:2000, Terminology work — Vocabulary — Part 1: Theory and application

ISO/IEC 6523-1:1998, Information technology — Structure for the identification of organisations and organisation parts — Part 1: Identification of organisation identification schemes

EN-ISO 9000:2005, Quality management systems – Fundamentals and vocabulary

EN-ISO 9001:2008, Quality management systems – Requirements

ISO/IEC 15414:2002, Information technology — Open distributed processing — Reference model — Enterprise language

ISO TS 18308:2004, Health informatics — Requirements for an electronic health record architecture

ISO TR 20514:2005, Health informatics — Electronic health record — Definition, scope and context

EN 12264:2005, Health Informatics — Categorical structures for systems of concepts

EN 12381:2005, Health Informatics — Time standards for health care specific problems

EN 13606-1:2007, Health Informatics — Electronic health record communication — Part 1: Reference model

EN 13606-4:2007, Health Informatics — Electronic health record communication — Part 4: Security

EN 13940-1, Health informatics – System of concepts to support continuity of care — Part 1: Basic concepts

EN 14822-2:2005, Health Informatics — General purpose information components — Part 2: Non clinical

EN 14822-3:2005, Health Informatics — General purpose information components — Part 3: Clinical

CEN/TS 15524, Health services – Quality management systems – Guide for the use of ISO 9001:2000

3. Terms and definitions

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

3.1 clinical data

data regarding the health care or clinical process

3.2 clinical information

set of *clinical data* processed for use in a clinical context

NOTE 1 to entry: This definition deliberately departs from the one provided by EN 14822-3 where clinical information is defined as the "information about a patient, relevant to the health or treatment of this patient, that is recorded by or on behalf of a *healthcare professional*", with a note stating that "Clinical information about a patient may include information about the patient's environment, or, wherever relevant, about related people."

3.3 commitment

a promise to provide activities according to acceptance of a request or of an assignment

3.4 concept

unit of knowledge created by a unique combination of characteristics

[ISO 1087-1:2000]

3.5 consent

agreement, approval, or permission as to some act or purpose given voluntarily by a competent person

[ISO 18308:2011]

3.6 continuity of care

component of patient care quality consisting of the degree to which the care needed by a patient is coordinated among practitioners and across organizations and time

[ISO/TR 18307:2001]

3.7 data

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

[ISO/IEC 2382-1:1993]

3.8 deprecated term

term rejected by an authoritative body

[ISO 1087-1:2000]

3.9 entity

concrete or abstract thing of interest, including associations among things

[ISO 18308:2011]

| ISO 18308:2011 Health informatics -- Requirements for an electronic health record architecture

3.10 healthcare

activities, services, 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 healthcare framework.

NOTE 2 to entry: In this International Standard, the term 'care' is to be understood as a synonym for 'healthcare'.

[Adapted from ISO/TR 18307:2001]

3.11 information

knowledge concerning such things as facts, concepts, objects, events, ideas

[ISO 1087-2:2000]

3.12 information model

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

[ISO 10303-1:1994]

ISO 10303-1:1994 Industrial automation systems and integration -- Product data representation and exchange -- Part 1: Overview and fundamental principles

3.13 knowledge

facts, information and skills acquired through experience, reasoning or education

[Oxford dictionary of English]

3.14 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 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.

[EN ISO 14971:2009]

NOTE 4 to entry: The definition is recursive as the term appears in the sixth bullet point, which means that it does not comply with terminological rules according to ISO 703. The meaning is simply, that a device used for service of a medical device is included in the definition.

3.15 organization

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

[ISO/IEC 6523-1:1998]

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.

3.16 organizational pattern

relationships between the various parts of an *organization*

3.17 organization role

role undertaken by an *organization*

3.18 party

person or group performing a role in relation to the business of a specific community or domain

[ISO 8459:2009]

3.19 person

human being regarded as an individual

[Oxford English Dictionary]

3.20 person role

role undertaken by a person

3.21 process

set of interrelated or interacting activities which transforms inputs into outputs

NOTE 1 to entry: Inputs to a process are generally outputs of other processes. In that sense, because their output can be used as an input to another process, activities may be considered as resources in a process.

[ISO 9000:2005]

3.22 process model

a representation of a process

3.23 quality in healthcare

degree to which healthcare fulfils requirements related to defined quality characteristics

NOTE 1 to entry: Quality is defined in ISO 9000:2005, 3.11 as the 'degree to which a set of inherent characteristics fulfil requirements'

3.24 quality management

coordinated activities to direct and control an *organization* with regard to quality

NOTE 1 to entry: Direction and control with regard to quality generally includes establishment of the quality policy and quality objectives, quality planning, quality control, quality assurance and quality improvement.

[ISO 9000:2005, 3.2.8]

3.25 quality assurance

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

[ISO 9000:2005, 3.2.11]

3.26 quality control

part of *quality management* focused on fulfilling quality requirements

[ISO 9000:2005, 3.2.10]

3.27 quality management system

management system to direct and control an *organization* with regard to quality

[ISO 9000:2005, 3.2.3]

3.28 resource

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

NOTE 1 to entry: Resources may include 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 may be reusable, renewable or consumable.

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

[ISO/IEC 15288:2008]

3.29 risk

combination of the probability of an event and its consequences

[ISO Guide 73]

3.30 role

set of competences and/or performances that are associated with a task

NOTE 1 to entry: In EN 13606-1 'role' is defined as: "name of a set of behaviours that is associated with a task".

[ISO/TS 22600-1:2006]

3.31 system of concepts

DEPRECATED: concept system

set of concepts structured according to the relations among them

[ISO 1087-1:2000]

3.32 unintended event

phenomenon that is not part of the normal course of a *process* but may 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 may prove negative or positive in comparison to the desired process outcome.

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

3.33 workflow

depiction of the actual sequence of the operations or actions taken in a *process*

NOTE 1 to entry: A workflow reflects the successive decisions and activities in the performance of a process.

[ISO 18308:2011]

4. Symbols and abbreviations

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

ACG	Ambulatory Care Group
DRG	Diagnosis-Related Group
EHR	Electronic Health Record
ICF	The International Classification of Functioning, Disability and Health
ICT	Information and Communications Technology
GP	General Medical Practitioner
JCAHO	Joint Commission for Accreditation of Healthcare Organizations
UML	Unified Modelling Language

5. Actors in continuity of care

5.1 General

A model showing the associations between concepts related to actors in continuity of care is shown in Figures 5 and 6. For further detail please refer to clause 0.5 of this document.

NOTE For the guidelines for using UML diagrams please see PD ISO/TR 24156:2008 *Guidelines for using UML notation in terminology work*.

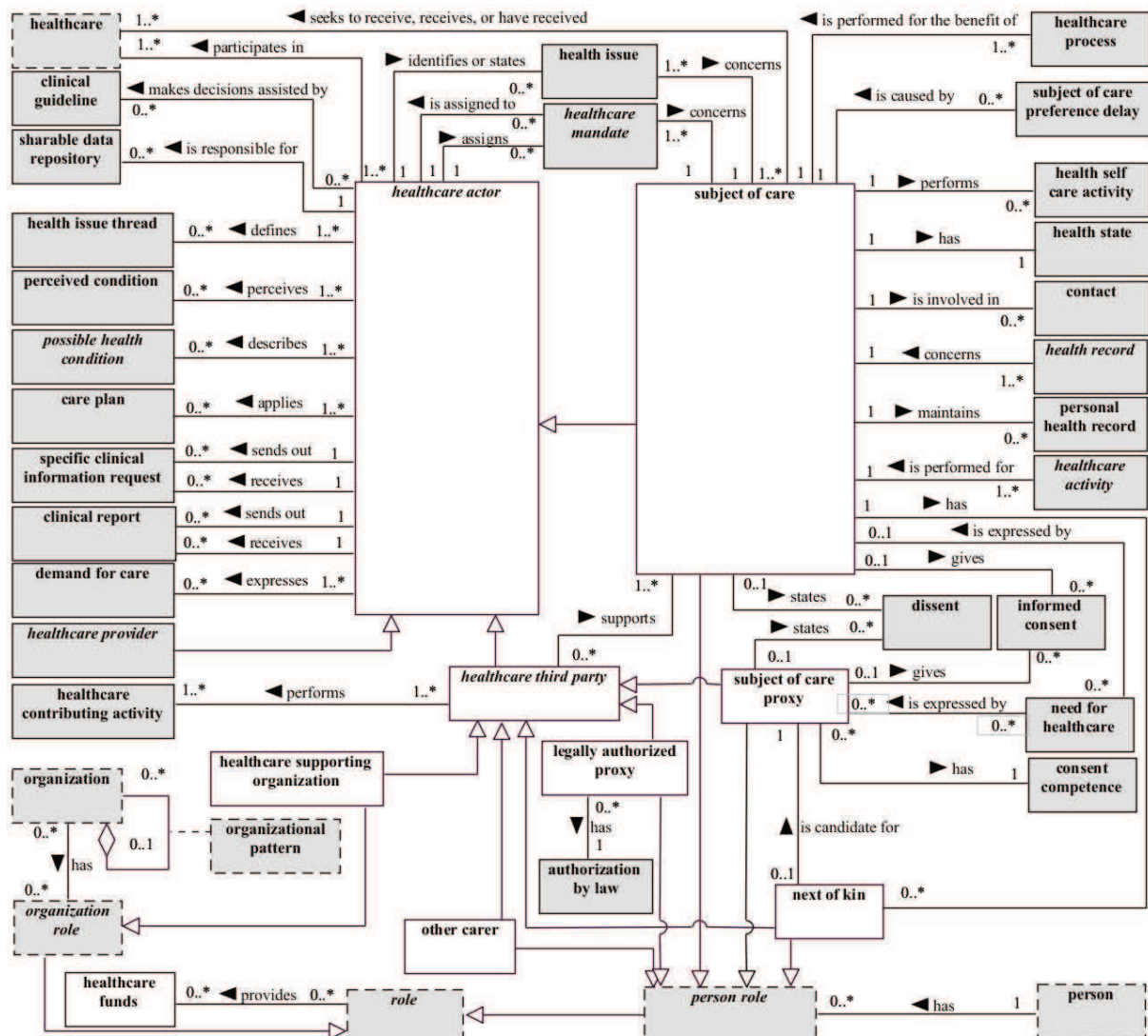


Figure 5 — Comprehensive UML diagram of actors in Continuity of Care, part 1

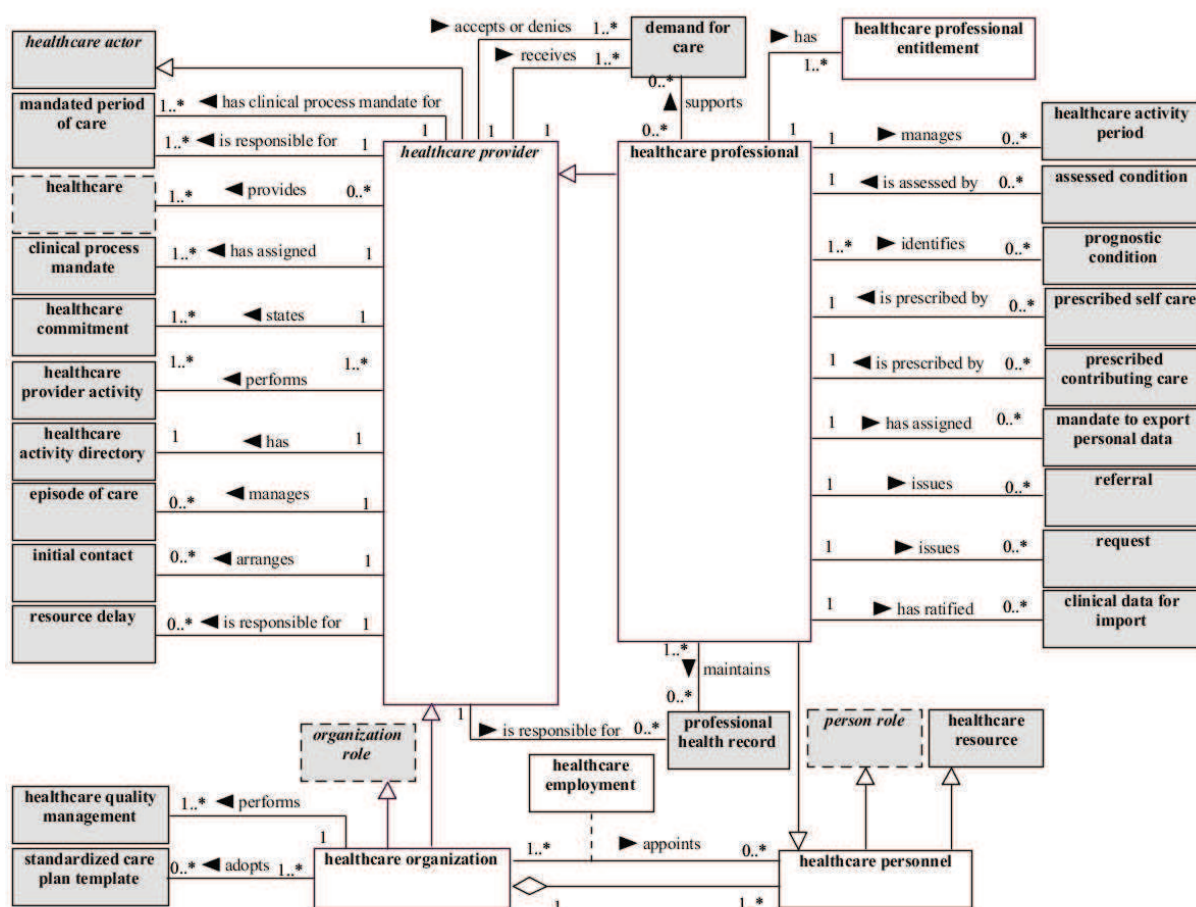


Figure 6 — Comprehensive UML diagram of actors in Continuity of Care, part 2

5.2 Healthcare actor

Term: <i>healthcare actor</i>			
Deprecated term: healthcare party			
Definition: <i>organization or person participating in healthcare</i> <p>NOTE 1 The involvement of the <i>healthcare actor</i> will be either direct (for example the actual provision of care), or indirect (for example at organizational level).</p> <p>NOTE 2 According to this definition, people or organizations responsible for the funding, payment, or reimbursement of healthcare provision are <i>healthcare actors</i>, as well as organizations responsible for healthcare delivery.</p> <p>According to this definition, <i>healthcare actor</i> is a superordinate concept to <i>healthcare provider</i>, (i.e. <i>healthcare organization</i> and <i>healthcare professional</i>), healthcare third party and also subject of care.</p> <p>NOTE 3 This superordinate concept can only be fully supported through the use of one of its subordinate concepts.</p> <p>NOTE 4 In EN 13940-1:2007 healthcare party was the preferred term for this concept.</p>			
Specialization of		Generalization of	
		healthcare provider	
		subject of care	
		healthcare third party	
Association from		Association name	Association to
1	healthcare actor	identifies or states	0..* health issue
1	healthcare actor	defines	0..* health issue thread
1	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..* specific clinical information request
1	healthcare actor	receives	0..* specific clinical information request
1	healthcare actor	sends out	0..* clinical report
1	healthcare actor	receives	0..* clinical report
1	healthcare actor	assigns	0..* healthcare mandate
1..*	healthcare actor	perceives	0..* perceived condition
1..*	healthcare actor	describes	0..* possible health condition
0..*	healthcare mandate	is assigned to	1 healthcare actor

A model showing the associations of this concept is shown in Figure 7.

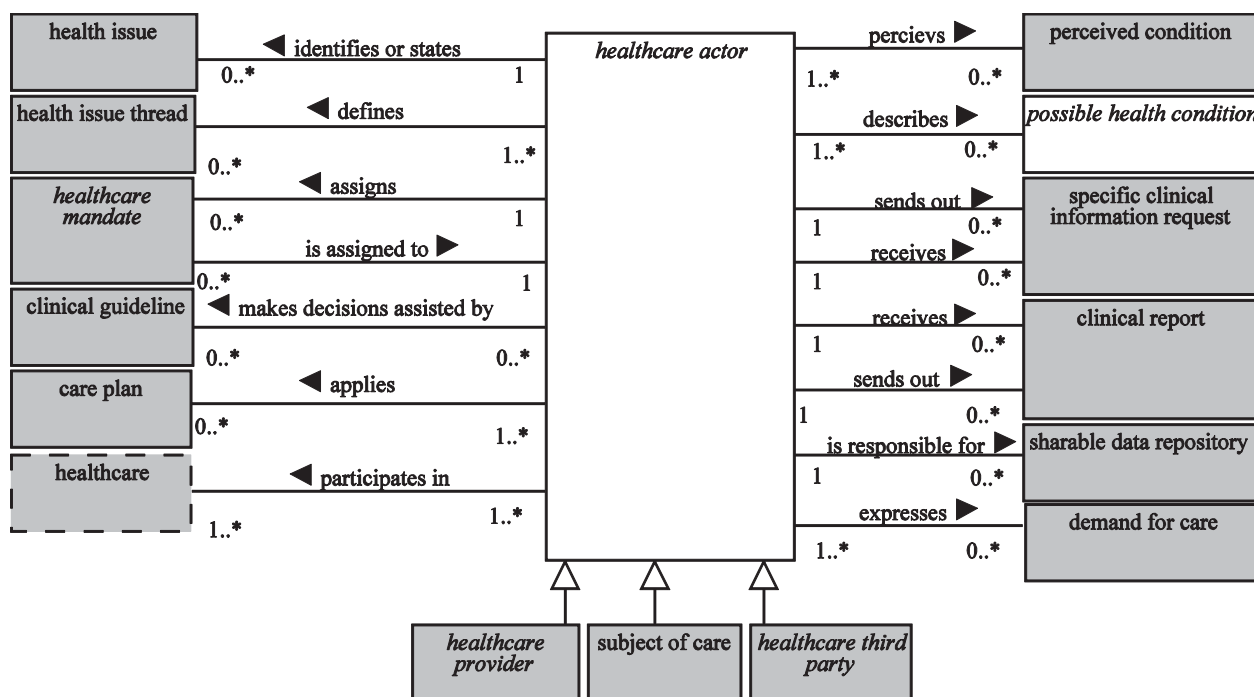


Figure 7 — Healthcare actor (UML representation)

5.2.1 Subject of care

Term: <i>subject of care</i>			
Synonyms: subject of healthcare, patient, client, service user, subject of care role			
Definition: <i>person seeking to receive, receiving, or having received healthcare</i> <p>NOTE 1 In some previous standards, a <i>subject of care</i> has sometimes been defined as a "<i>person or defined group of people having received, receiving, or to receive healthcare</i>". A <i>subject of care</i> may be a group of people, for example a family, a therapy group, a population based group etc. However, this International Standard restricts this concept to an individual <i>person</i>.</p> <p>In this International Standard, <i>subject of care</i> is definitely restricted to an individual. It is assumed that in those cases where a <i>healthcare activity</i> addresses a group of more than one individual (e.g. a family, a community) and where a single <i>health record</i> is used to capture the <i>healthcare activities</i> provided to the group, each individual within the group will be referenced explicitly within that <i>health record</i>.</p> <p>NOTE 2 In the real world, a <i>subject of care</i> may be designated by different professions using different names, for instance 'a patient', 'a client' etc.</p> <p>NOTE 3 A foetus, when receiving <i>healthcare</i>, is to be considered as a subject of care.</p> <p>NOTE 4 Seeking to receive, receiving, or having received <i>healthcare</i> are activities performed by a person acting in a <i>subject of care</i> role.</p> <p>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.</p>			
Specialization of		Generalization of	
healthcare actor			
person role			
Association from	Association name		Association to
1 subject of care	has		1 health state
1 subject of care	has		1..* need for healthcare
1 subject of care	maintains		0..* personal electronic health record
1 subject of care	is involved in		0..* contact
1 subject of care	performs		0..* health self care activity
1 subject of care	has		0..* next of kin
0..1 subject of care	gives		0..* informed consent
0..1 subject of care	states		0..* dissent
0..* subject of care preference delay	is caused by		1 subject of care
1..* healthcare process	is performed in benefit of		1 subject of care
1..* healthcare activity	is performed for		1 subject of care
1..* health issue	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..* need for healthcare	is expressed by		0..1 subject of care

A model showing the associations of this concept is shown in Figure 8.

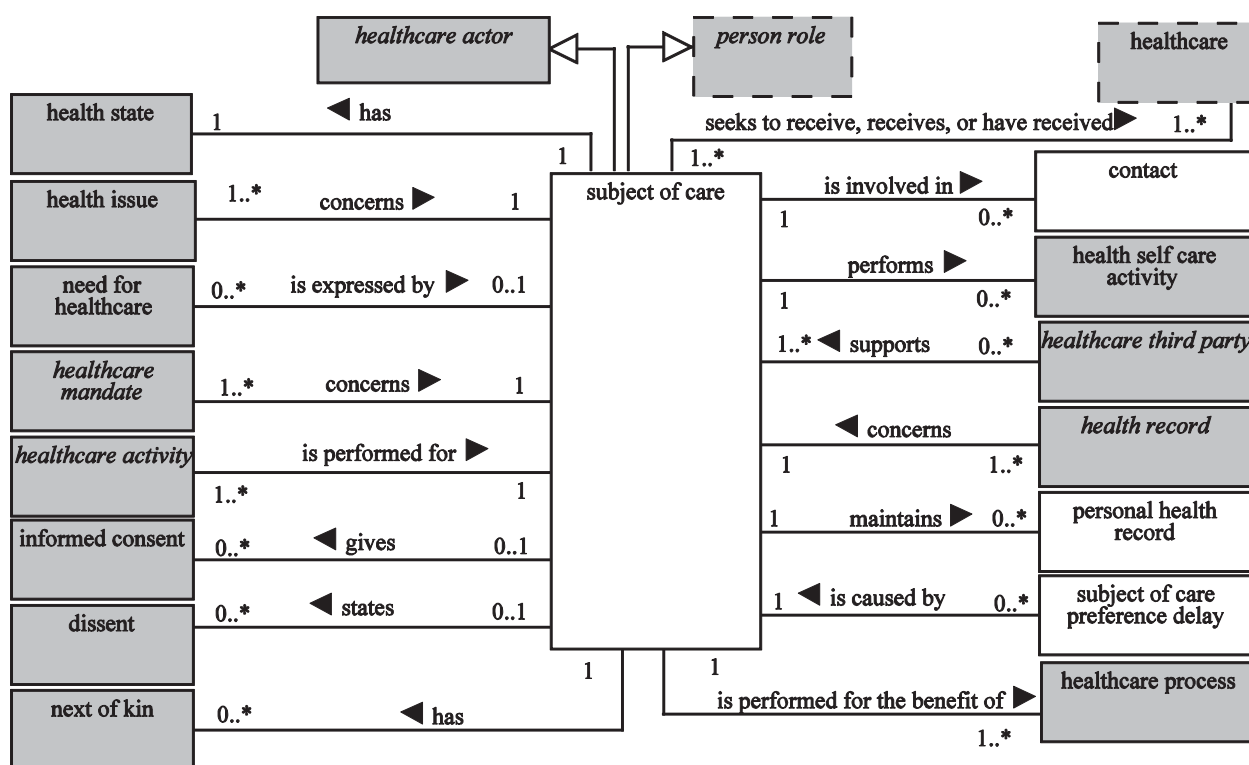


Figure 8 — Subject of care (UML representation)

5.2.2 Healthcare provider

Term: <i>healthcare provider</i>				
Synonym: care provider				
Definition: <i>healthcare actor</i> participating in the direct provision of <i>healthcare</i>				
NOTE 1 The personnel of <i>healthcare organizations</i> may include both <i>healthcare professionals</i> and others which participate in the provision of healthcare.				
NOTE 2 This International Standard includes only two specializations of <i>healthcare provider</i> . This is not meant to exclude the possibility of other specializations. In jurisdictions where other kinds of <i>healthcare actors</i> are included in the concept of <i>healthcare provider</i> , 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 <i>healthcare providers</i> ; for the purpose of this International Standard they are considered as <i>healthcare third parties</i> .				
Specialization of			Generalization of	
healthcare actor			healthcare organization	
			healthcare professional	
Association from		Association name	Association to	
1	healthcare provider	has clinical process 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	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	has assigned	0..*	clinical process mandate
1	healthcare provider	receives	1..*	demand for care
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

A model showing the associations of this concept is shown in Figure 9.

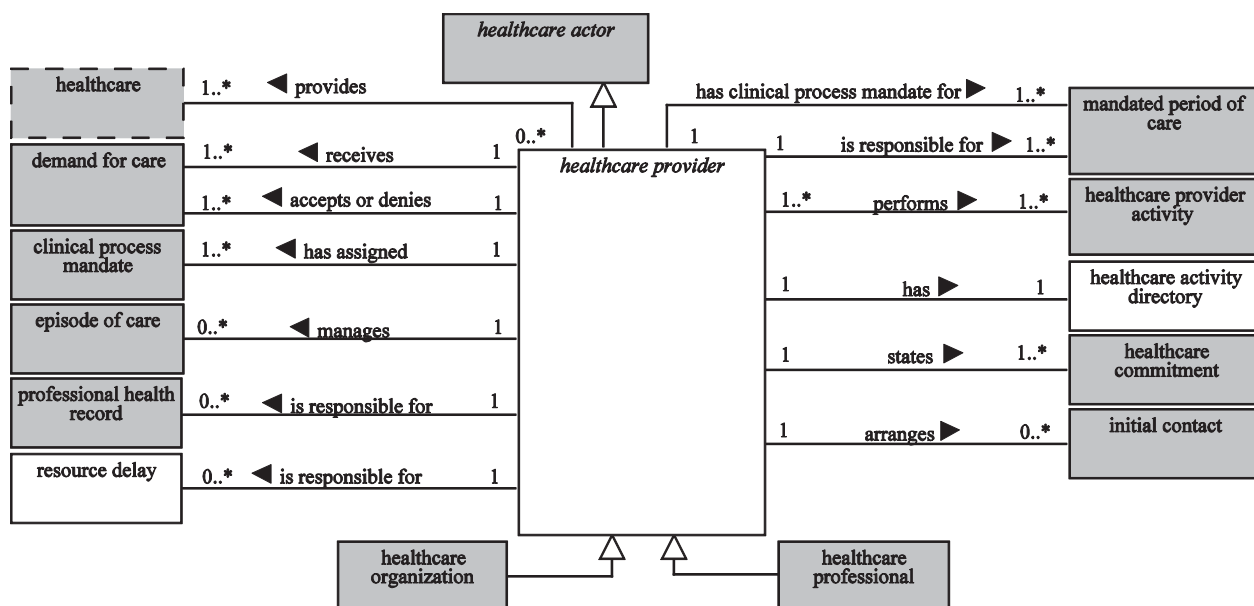


Figure 9 — Healthcare provider (UML representation)

5.2.2.1. Healthcare organization

Term: <i>healthcare organization</i>			
Synonym: care organization			
Definition: organization whose <i>healthcare personnel</i> participate in the direct provision of healthcare 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, i.e. other lower level organizations. A <i>healthcare organization</i> represents the role any such organization plays when it is involved in the direct provision of <i>healthcare activities</i> . NOTE 2 Effectively, a <i>healthcare organization</i> relies on the activity performed by healthcare personnel, whether employed, contracting, or with temporary informal though functional relationships between them: within <i>healthcare organizations</i> , the leads will be <i>healthcare professionals</i> . A healthcare team working together e.g. a specific type of <i>clinical process</i> with participants from different departments is also a kind of <i>healthcare organization</i> . NOTE 3 A free-standing self employed solo practising <i>healthcare professional</i> shall be considered as the only member of his/her own <i>healthcare organization</i> . NOTE 4 Organizations may have a number of different roles. When an organization acts in a role where its <i>healthcare personnel</i> participate in the direct provision of healthcare, it is called a <i>healthcare organization</i> . EXAMPLES A care team, a group practice, a hospital, a hospital department, a hospital care unit, self employed GP			
Specialization of		Generalization of	
healthcare provider			
health 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..*	standardized care plan template
1 healthcare organization	performs	1..*	healthcare quality management

A model showing the associations of this concept is shown in Figure 10.

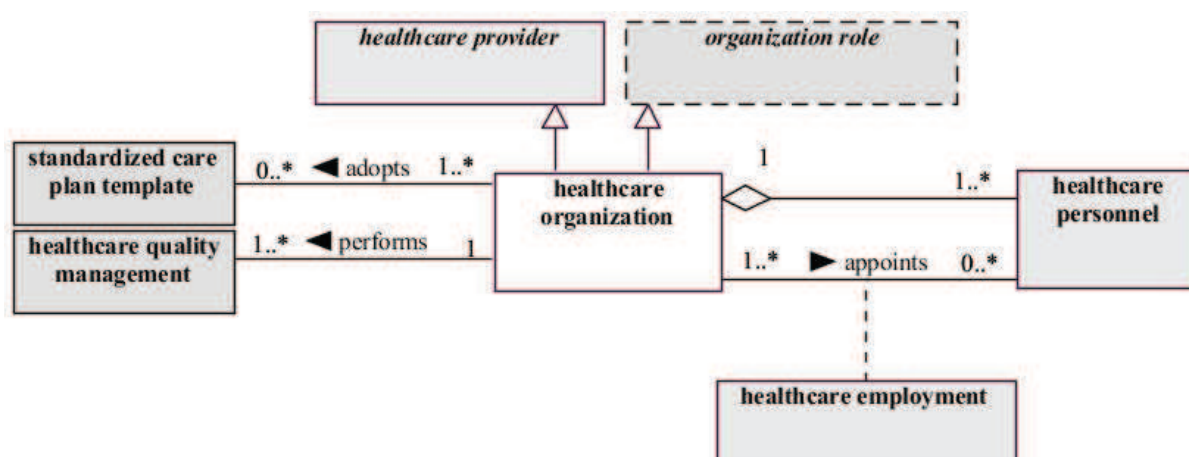


Figure 10 — Healthcare organization (UML representation)

5.2.3 Healthcare personnel

Term: <i>healthcare personnel</i>			
Synonyms: care personnel			
Definition: role of a <i>person</i> in a <i>healthcare organization</i>			
EXAMPLES GP, medical consultant, therapist, dentist, nurse, social worker, radiographer, nurse's assistant, children's nurse etc.			
Specialization of		Generalization of	
person role		healthcare professional	
healthcare resource			
Component of		Aggregation of	
0..* healthcare organization			
Association from		Association name	Association to
1..*	healthcare organization	appoints	0..* healthcare personnel

A model showing the associations of this concept is shown in Figure 11.

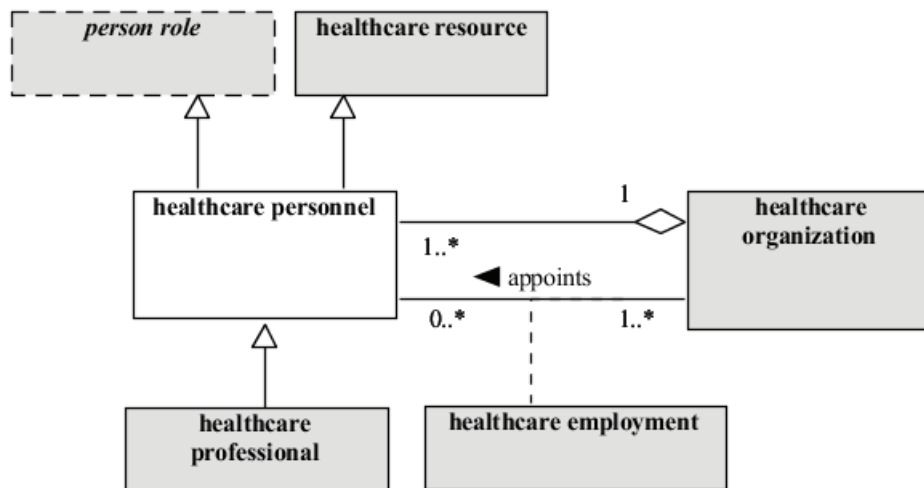


Figure 11 — Healthcare personnel (UML representation)

5.2.3.1. Healthcare employment

Term: <i>healthcare employment</i>	
Synonym: care employment	
Definition: contractual framework between a <i>healthcare personnel</i> and a <i>healthcare organization</i> describing the roles and responsibilities assigned to that <i>healthcare personnel</i>	
EXAMPLES Nursing officer, head of department, lead GP, social worker, medical consultant.	
Association concept	
Links	
1 healthcare employment	1 healthcare personnel 1 healthcare organization

A model showing the associations of this concept is shown in Figure 12.

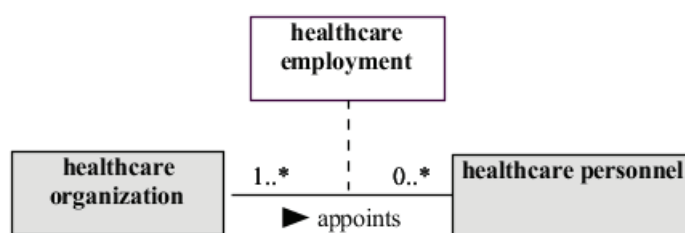


Figure 12 — Healthcare employment (UML representation)

5.2.3.2. Healthcare professional

Term: <i>healthcare professional</i>				
Synonym: care professional				
Definition: <i>healthcare personnel</i> having a <i>healthcare professional entitlement</i> recognized in a given jurisdiction				
EXAMPLES GP, medical consultant, therapist, dentist, nurse, radiographer etc.				
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..*	clinical data for import
1	healthcare professional	has assigned	0..*	mandate to export personal data
0..*	healthcare professional	supports	0..*	demand for care
1..*	healthcare professional	identifies	0..*	prognostic condition
0..*	assessed condition	is assessed by	1	healthcare professional
0..*	prescribed self care	is prescribed by	1	healthcare professional
0..*	prescribed contributing care	is prescribed by	1	healthcare professional

A model showing the associations of this concept is shown in Figure 13.

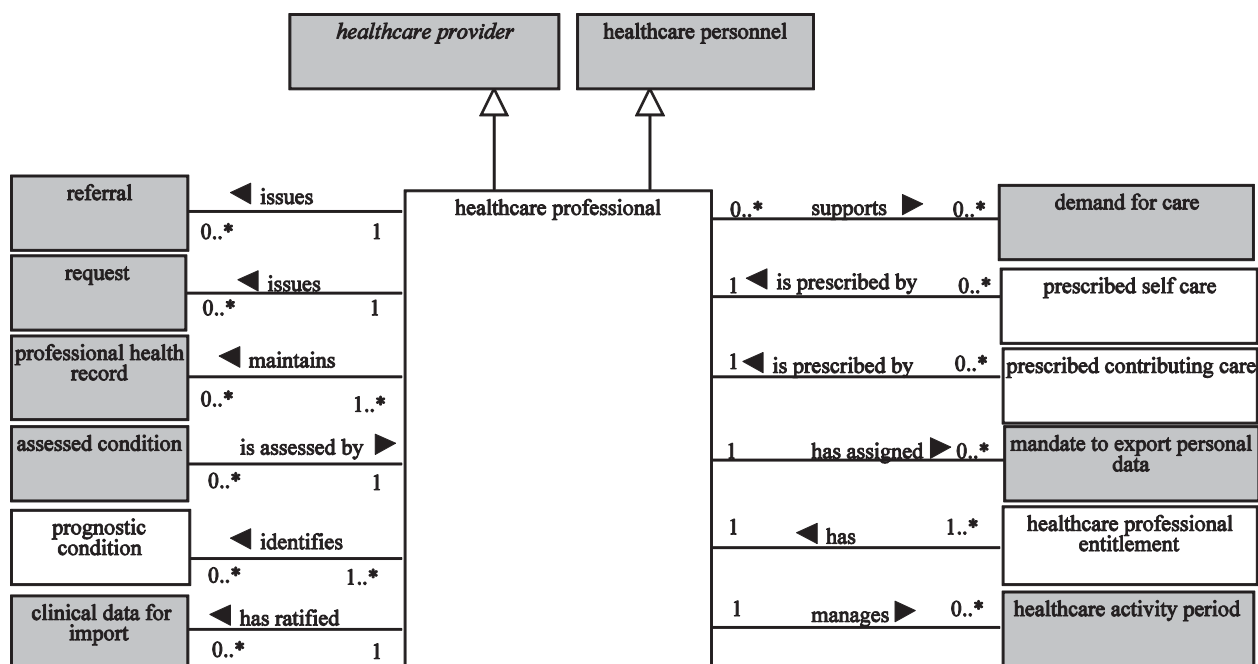


Figure 13 — Healthcare professional (UML representation)

5.2.3.3. Healthcare professional entitlement

Term: <i>healthcare professional entitlement</i> Synonym: care professional entitlement			
Definition: registered authorization given to a <i>person</i> in order to allow the <i>person</i> 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 <i>healthcare professional</i> forms the foundation for his/her official duties and rights. EXAMPLES Diploma, professional registration (e.g. registered nurse).			
Association from		Association name	Association to
1	healthcare professional	has	1..* healthcare professional entitlement

A model showing the associations of this concept is shown in Figure 14.

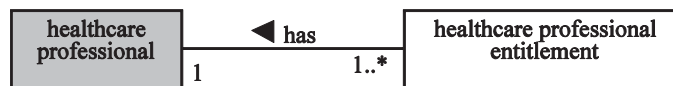


Figure 14 — Healthcare professional entitlement (UML representation)

5.2.4 Healthcare third party

Term:	<i>healthcare third party</i>			
Synonym:	care third party			
Definition:	<i>healthcare actor</i> other than a <i>healthcare provider</i> or the <i>subject of care</i> NOTE 1 According to this definition, a relative (family member), any actor responsible for social support, or for the funding, payment, or reimbursement of healthcare provision are <i>healthcare third parties</i> . NOTE 2 <i>Healthcare third party</i> is an abstract superordinate generic concept which is only fully supported through the use of one of its subordinate specific concepts.			
Specialization of	Generalization of			
healthcare actor	other carer			
	next of kin			
	subject of care proxy			
	legally authorized 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 contributing activity

A model showing the associations of this concept is shown in Figure 15.

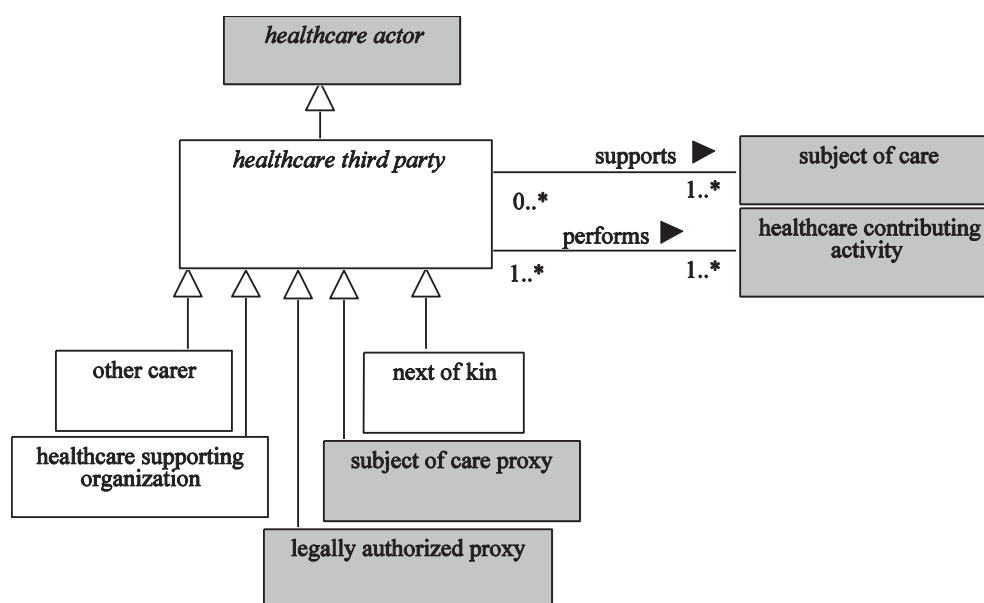


Figure 15 — Healthcare third party (UML representation)