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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex **(e.g. 3.1)**	Paragraph/ Figure/Table/Note	**Type of comment**	**Commend (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations on each comment submitted**
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

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DRAFT International Standard

ISO/DIS 13940

Health informatics — System of concepts to support continuity of care

Informatique de santé — Système de concepts en appui de la continuité des soins

ICS: 35.240.80

ISO/TC **215**

Secretariat: **ANSI**

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Foreword

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This document was prepared by Technical Committee ISO/TC 215, *Health informatics*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 251, *Health informatics*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 13940:2015), which has been technically revised.

The main changes are as follows:

— all concepts have been moved into Clause 3;

— content has been added to make it more explicit that continuity of care includes social care and related concepts. Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

— concepts have been aligned to 21838-3:2021

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Introduction

0.1 General

Continuity of care is an important prerequisite for ensuring that a subject of care receives effective and efficient care and the best possible outcomes over the course of any health condition, be it an injury, illness or social issue. Within any context, achieving continuity of care requires an ability to understand and define care processes, their interactions and sequencing within and across organizational boundaries and to communicate information about them unambiguously using an agreed system of concepts within a shared semantic framework. The purpose of this standard is to define the system of concepts and semantics needed to support the definition of care processes and the continuity of care.

This document does not seek to define or standardise specific processes used in the delivery of care. Instances of such standardisation can be found in some other standards documents, for instance ISO 12967-1.

In addition to supporting the continuity of care, the system of concepts in this document provides a rigorous semantic foundation for other purposes including the use of care data for secondary use and knowledge management in the health sector., and standardized definitions for use in health informatics standards, enterprise modelling and the formulation of health policies.

Figure 1 illustrates the way in which care processes must be supported by and interact with a hierarchy of other processes within and across organizations (including business, policy and technical processes) order to operate. The system of concepts specified in this document therefore includes concepts related the physical and financial resources needed to support care processes.

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Figure 1 — Architecture of the concept areas

0.2 Aims for this document

The primary aim for this document is to provide a comprehensive, conceptual basis for content and context in care services, be they social services, clinical services or integrated services that seamlessly engage across both these contexts. This document provides a foundation for interoperability for interoperability at all levels in care organizations, between care organizations, and for development of information systems in care.

0.3 'Health' as a concept

In this document, health is defined with reference to 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".[31] 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". The second amendment emphasizes the importance of social aspects in the context of health.

0.4 Care, clinical care and social care

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Both clinical care and social care have the objective of influencing, restoring and maintaining health as defined by WHO. In this document the term "care" is used to stress the common characteristics and objectives of both clinical care and social care. It is a common misunderstanding that healthcare is restricted to clinical action against physical and mental health problems. That does not align with the WHO description of health, which includes social aspects of care.

A key objective of this document is to support smooth transition between social care and clinical care including referral between any or all primary care, home care, community-based care, secondary and tertiary hospital care, specialist care services, and long-term institutional care.

In 2016-2017, two scientific papers[38,39] on the integration of social and clinical care were published. Based on these papers, a working group was launched at the UNINFO, the branch of the Italian National Unification (UNI) Standardization body that tackles Information and Communications Technology (ICT) activities. The task of the working group was to use *ISO 13940:2015* to establish a concept system not only for continuity of care in social care but also to ensure collaboration and continuity of care within, between and across the provision of both social care and clinical care. This resulted in technical report *UNI/TR 11802:2020Health Informatics - Extension of EN ISO 13940 standard to social concepts*.[30] This second edition of *ISO 13940* extends the system of concepts for the continuity of care to more explicitly support the continuity of care across social care and clinical care building on the contributions made in *UNI/TR 11802:2020*.

A generic model of the continuity of care process indicating the cyclic nature of care activities typically involved in delivering care to a subject of care is provided in Annex A.

0.5 Intended users for this document

All parties interested in the interoperability issues in clinical care and social care are intended users of this document. This includes, but is not limited to, care professionals and teams, social care personnel, subjects of care, care managers, care funding organizations and all types of care providers and local care teams.

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

0.6 Alignment with ontological principles

In this Second Edition all upper-level concepts and their definitions have been aligned with the DOLCE high level descriptive ontology for linguistic and cognitive engineering as defined in ISO/IEC 21838-3:2023 which has been built on ISO/IEC 21838-1:2021.

0.7 Description and display of concepts

In this document the concepts are listed in Clause 3. They are listed in logical order and grouped in subclauses according to the kinds of concepts.

Clauses 5 to 12 provide additional description of the concepts and extensive UML diagrams showing relations between the concepts listed in Clause 3. The large models include associations that are illustrated as undirected, describing conceptual relationships rather than data access paths.

Examples are provided wherever they are considered relevant and necessary.

The purpose of using a concept model in this document is to highlight the relationships between concepts. In conformance with ISO 24156:2014 no attributes are shown in the concept classes. Characteristics are shown as related concepts. Attributes of classes in an information model represent related concepts. They can be added during implementation and still be conformant to this document.

The relation of this system of concepts to an upper ontology is described in Annex B. Some ontological elements are needed for understanding of the conceptual structure of this document but are not part of the concept system supporting continuity of care.

0.8 Relationship of this standard to other relevant standards

— Appropriate terminology has been aligned with ISO 13606-1:2019 and HL7/FHIR.

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— ISO/IEC 21838-3:2024 [85] has been a guidance in the modelling work.

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Health informatics — System of concepts to support continuity of care

1 Scope

This document defines a system of concepts for different aspects of the provision of care encompassing social care as well as clinical care. The subject of the document is continuity of care.

This document covers the concept definitions needed whenever structured information in care is specified as a requirement. The definitions are intended to refer to the conceptual level only and not to details of implementation. This document covers 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;

— information for specified types of care processes.

This document does not specify how to perform specific care processes. This document does not cover research processes in the context of social and clinical care, welfare and educational processes.

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 1087:2019, *Terminology work and terminology science — Vocabulary [52]*

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary [4]*

3 Terms and definitions

3.1 General terms

3.1.1
knowledge
maintained, processed, and interpreted information

[SOURCE: ISO 5127:2017, 3.1.1.17]

3.1.2
health
state of complete physical, mental and social well-being

Note 1 to entry: The definition is drawn from the WHO description of health a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity

3.1.3
information
meaningful data

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

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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]

3.1.4
party
person or group performing a role in relation to the business of a specific community or domain

[SOURCE: ISO 8459:2009, 2.33]

3.1.5
process model
representation of a process

3.1.6
continuity of care
coherent and interconnected series of care events over time

Note 1 to entry: Care actor is defined in 5.2.1

3.1.7
event
situation considered to occur at a time point

[SOURCE: ISO 12381:2019, 3.6]

3.1.8
appointment
arrangement to meet someone at a particular time and place

3.1.9
mandate
commission to act

EXAMPLE A request for care means that an individual asks for help by care provider. But it is combined with the authorisation for the care provider to access the necessary care resources including documentation and deliver those services requested by the individual. Such a request contains a mandate given to care.

Note 1 to entry: A mandate is assigned by someone or as the consequence of legislation. It is always an obligation to do something together with the associated authority to do that. If a mission is given to somebody, this actor needs authority to perform what is necessary to fulfil the mission.

3.1.10
person
individual human being

[SOURCE: ISO/TS 23164:2025, 3.10.2, modified, the word “individual” added]

3.1.11
commitment
obligation by one or more of the participants in an 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 1:2020, 3.7.2]

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3.1.12
organization
person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives

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 document, this definition applies to any kind of organizations, whatever their legal status.

[SOURCE: ISO 9000:2015, 3.2.1, modified — Notes 1 and 2 to entry were removed and new notes to entry have been added.]

3.1.13
resource
asset that is utilized or consumed during the execution of activities

EXAMPLE 1 Time, personnel, human skills and knowledge, equipment, services, supplies, facilities, technology, data, money

EXAMPLE 2 Capital equipment, tools

EXAMPLE 3 Utilities such as power, water, fuel and communication infrastructures

Note 1 to entry: Resources may be reusable, renewable or consumable

Note 2 to entry: Resources are used, consumed or renewed during activities as part of a process

[SOURCE: ISO/IEC 15288:2015 (modified)]

3.1.14
social determinant of health
condition in which a subject of care is born, grows, lives, works and ages including their access to power, money and resources

[SOURCE: World Health Organization. Division of Health Promotion, Education, and Communication. (1998). Health promotion glossary. Modified.][33]

3.1.15
risk
combination of the probability of occurrence of harm and the severity of that harm

Note 1 to entry: The probability of occurrence includes the exposure to a hazardous situation and the possibility to avoid or limit the harm.

[SOURCE: ISO/IEC Guide 63:2019 3.10]

3.1.16
data
set of values of qualitative or quantitative variables

Note 1 to entry: Data are defined without any context in such a way that by itself one cannot tell its correct meaning, where it has meant those data are information

Note 2 to entry: Note to entry Data are defined without any context in such a way that by itself one cannot tell its correct meaning, where it has meaning this is information (3.9.5).

[SOURCE: ISO/IEC 2382:2015, 2121272, modified, notes removed, note 1 added]

3.1.17
data repository
identifiable data storage facility

[SOURCE: ISO 10303-22:1998, modified — the preferred term "repository" was changed to "data repository]

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3.1.18
information model
formal model of a bounded set of facts, concepts or instructions to meet a specified requirement

[SOURCE: ISO 13584-102:2006, 3.16]

3.1.19
care
provision of accommodations, comfort and treatment to an individual subject of care

3.1.20
role
set of competencies and/or performances that are associated with a task

[SOURCE: ISO 22600-2:2014, 3.33]

3.2 Health matters

3.2.1
health state
overall level of health of a subject of care

Note 1 to entry: Health is aspirational.

Note 2 to entry: The underlying health state is present, even if not observed. For example, the subject of care having a cancer before it gives symptoms.

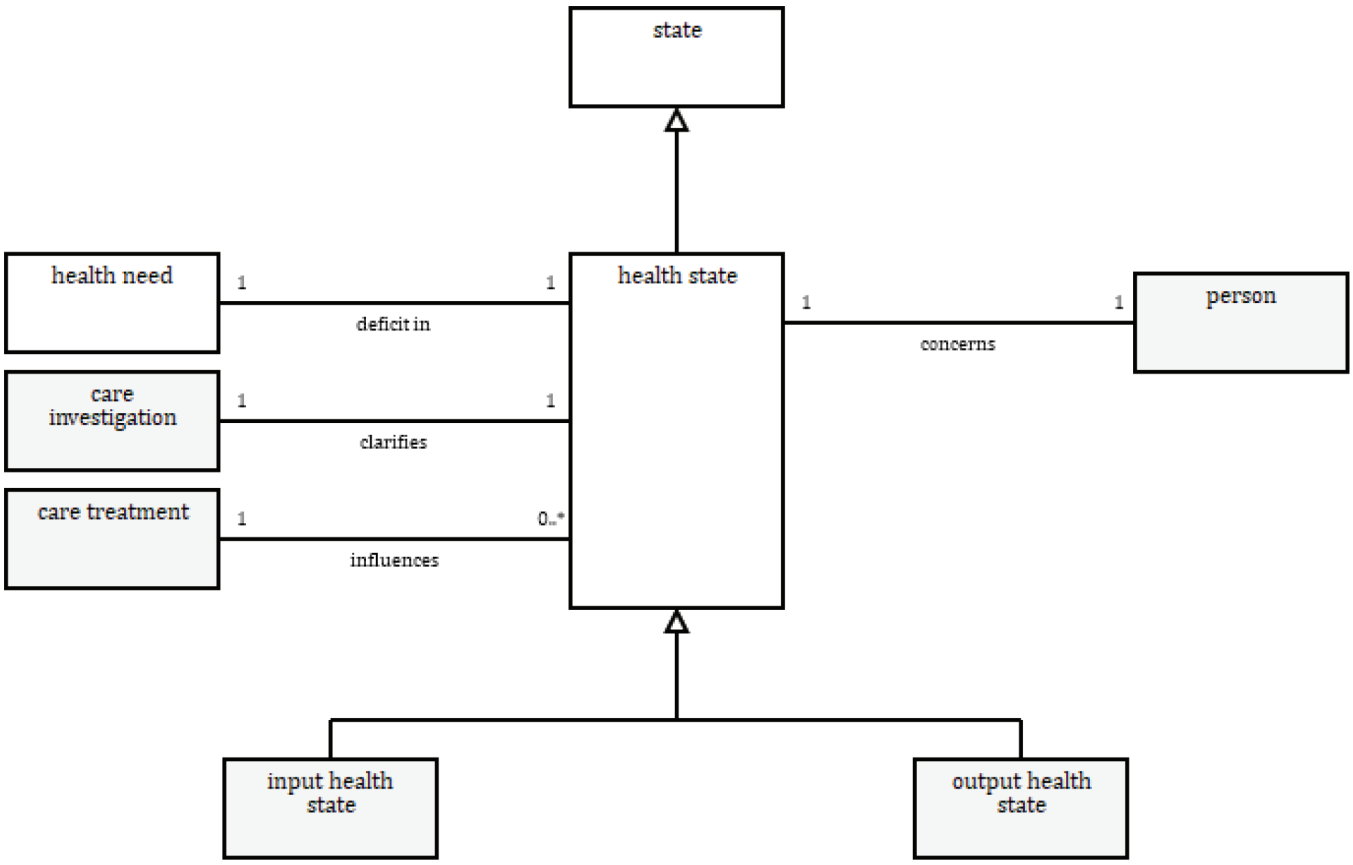


Figure 2 — health state (UML Representation)

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3.2.2
health matter
circumstance contributing to the health state of a person

Note 1 to entry: This is a matter which may call for care intervention, e.g. a medical statement, and immunisation, a treatment but it may also be a matter which the person can manage alone e.g. by means of self-care activities or needs no management

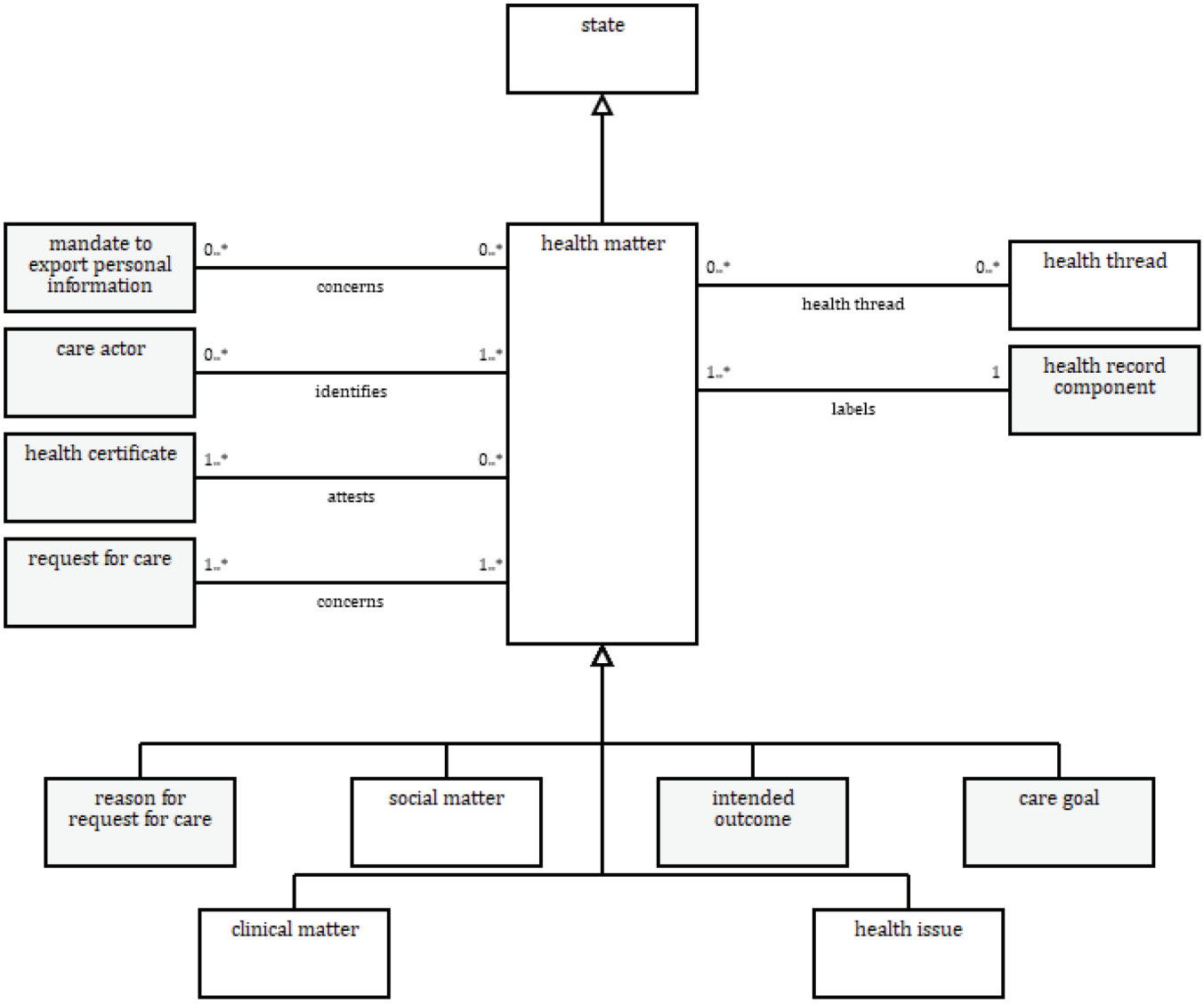


Figure 3 — health matter (UML Representation)

3.2.3
clinical care
care activity concerned with physical or mental care needs

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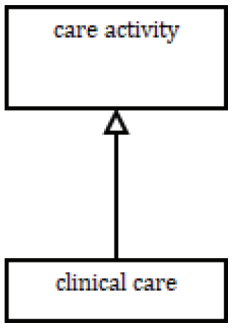


Figure 4 — clinical care (UML Representation)

3.2.4
clinical matter
health matter concerned with the body or mind

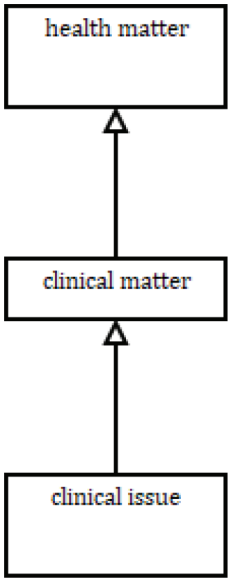


Figure 5 — clinical matter (UML Representation)

3.2.5
social matter
health matter concerning how a subject of care lives in their social environment

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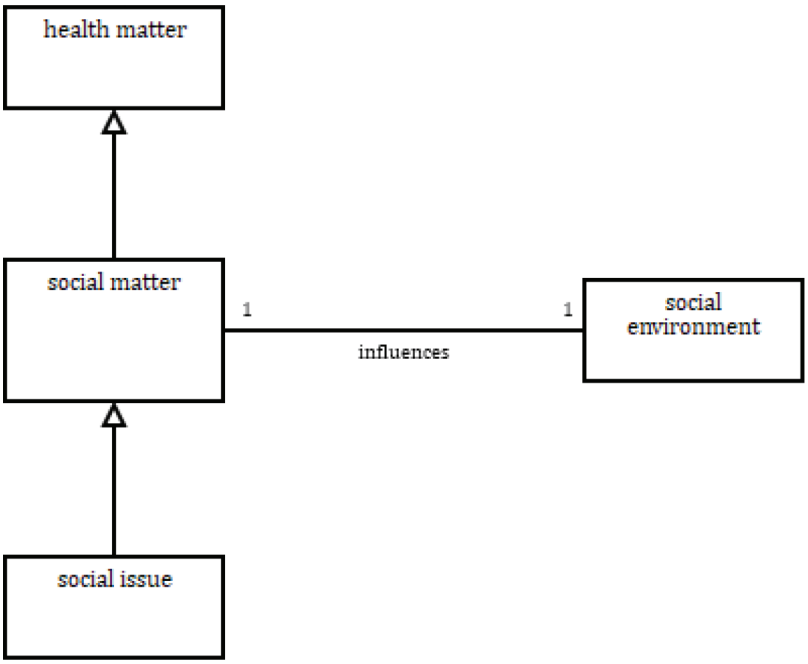


Figure 6 — social matter (UML Representation)

3.2.6
health condition
aspect of a health state

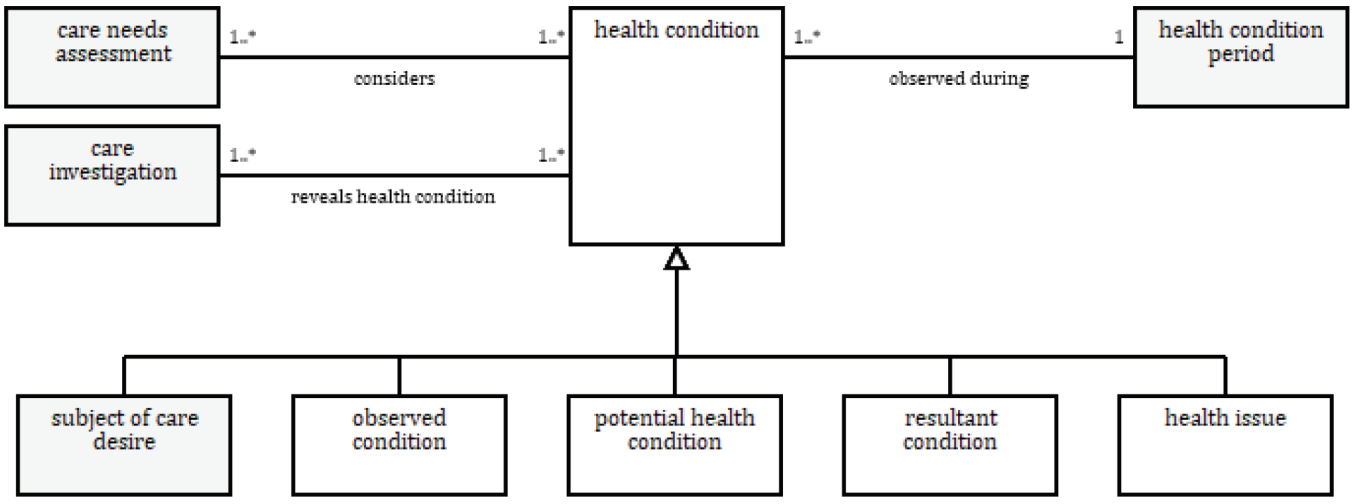


Figure 7 — health condition (UML Representation)

3.2.7
health issue
health condition motivating care

EXAMPLE Loss of weight, heart attack, drug addiction, injury, dermatitis, requirement for a health certificate, inability to prepare meals, suitability for immunisation

Note 1 to entry: A health issue may correspond to a health problem a disease, an illness or another kind of health condition

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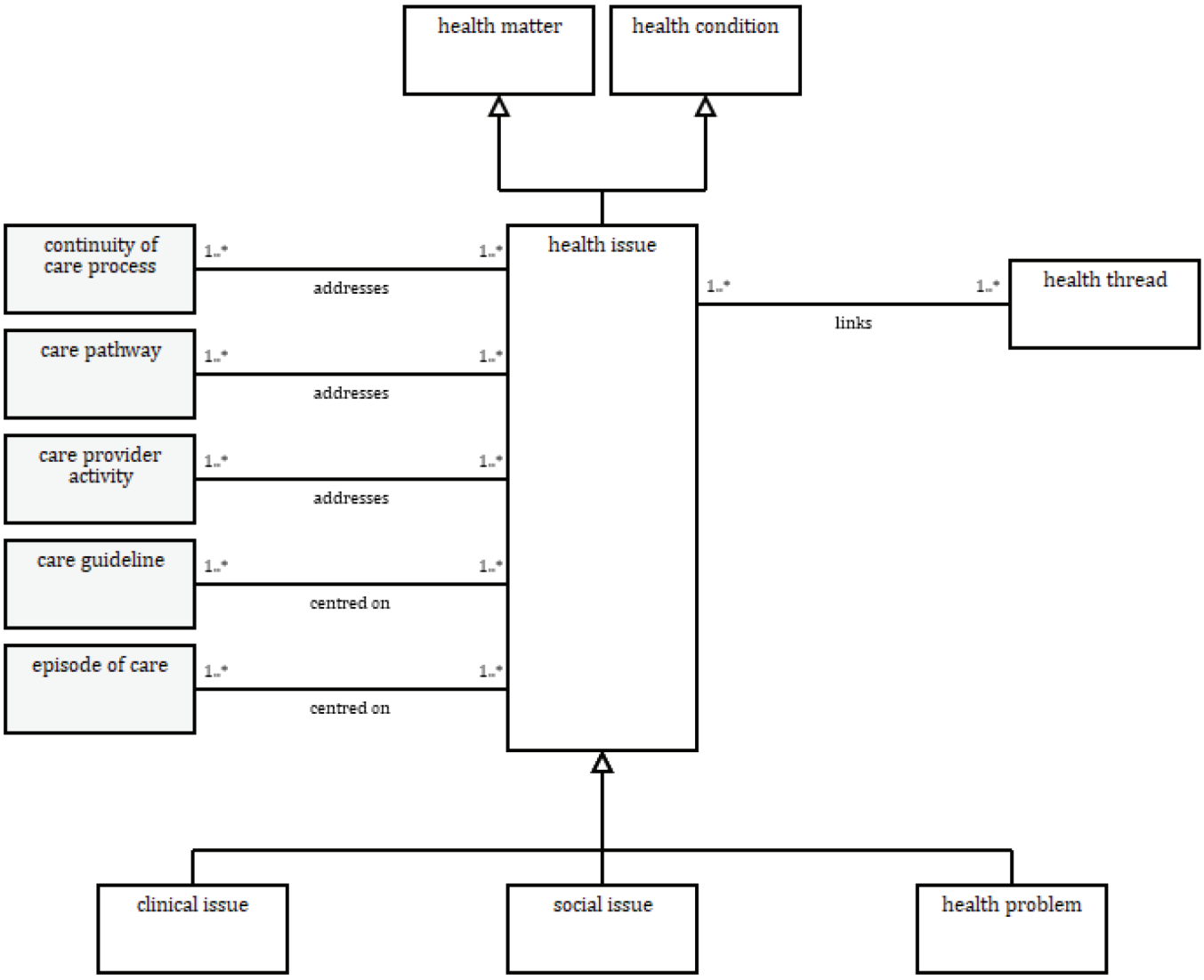


Figure 8 — health issue (UML Representation)

3.2.8
social issue
health issue that is a social matter

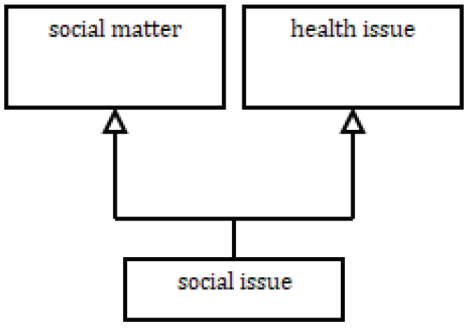


Figure 9 — social issue (UML Representation)

3.2.9
clinical issue
health issue that is a clinical matter

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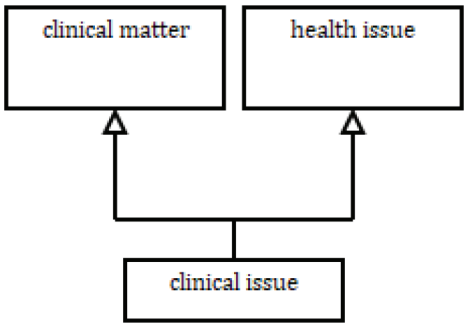


Figure 10 — clinical issue (UML Representation)

3.2.10
health problem
health condition considered by a care actor to be a problem

Note 1 to entry: Health problems can be single observations but are usually more compound as a summary of several observations. Single observations are often criteria for the more compound health condition considered to be a health problem

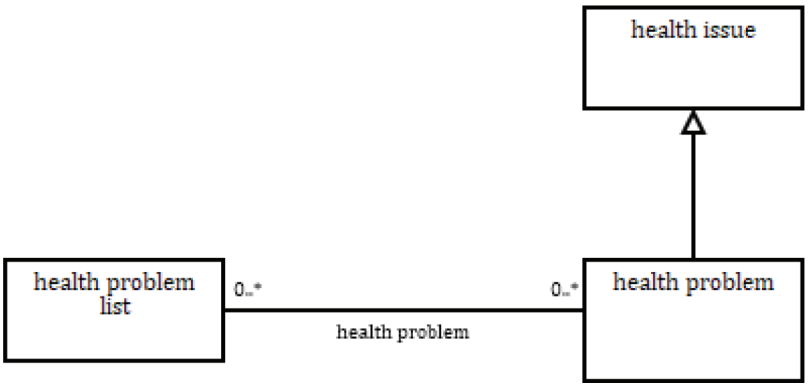


Figure 11 — health problem (UML Representation)

3.2.11
health thread
defined association between care matters as determined by one or more care actors

EXAMPLE 1 A low back pain, known for many years by the subject of care's GP, treated several times by the physiotherapist who labelled it a scoliosis and currently a candidate for a specific orthopaedic intervention.

EXAMPLE 2 Type 2 diabetes treated by a GP, a nurse, an endocrinologist and a vascular surgeon.

EXAMPLE 3 The health conditions included in a care process.

Note 1 to entry: A health thread reconciles a range of health matters reflecting the variety of scopes of care actors, particularly of care providers.

Note 2 to entry: A health thread may be established by a team (e.g. a coordination committee).

Note 3 to entry: A health thread can be built step-by-step, by allowing each care professional to add their perspective into a common health thread

Note 4 to entry: Under the responsibility of a designated care actor a health thread linking several health matters can describe an episodes of care bundle for instance, a partial or comprehensive synthesis of care actor related episodes of care

Note 5 to entry: A collective decision (before, during or after the care interventions) may define a health thread and so the idea of the 'episode' accepted by all the care professionals involved.

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Note 6 to entry: Two health conditions may sometimes only be recognized as belonging to the same health thread late in the process of care Conversely, two health conditions thought initially to belong to the same health thread may need to be separated later.

Note 7 to entry: A health thread may be considered an aggregation of health matters and/or health threads.

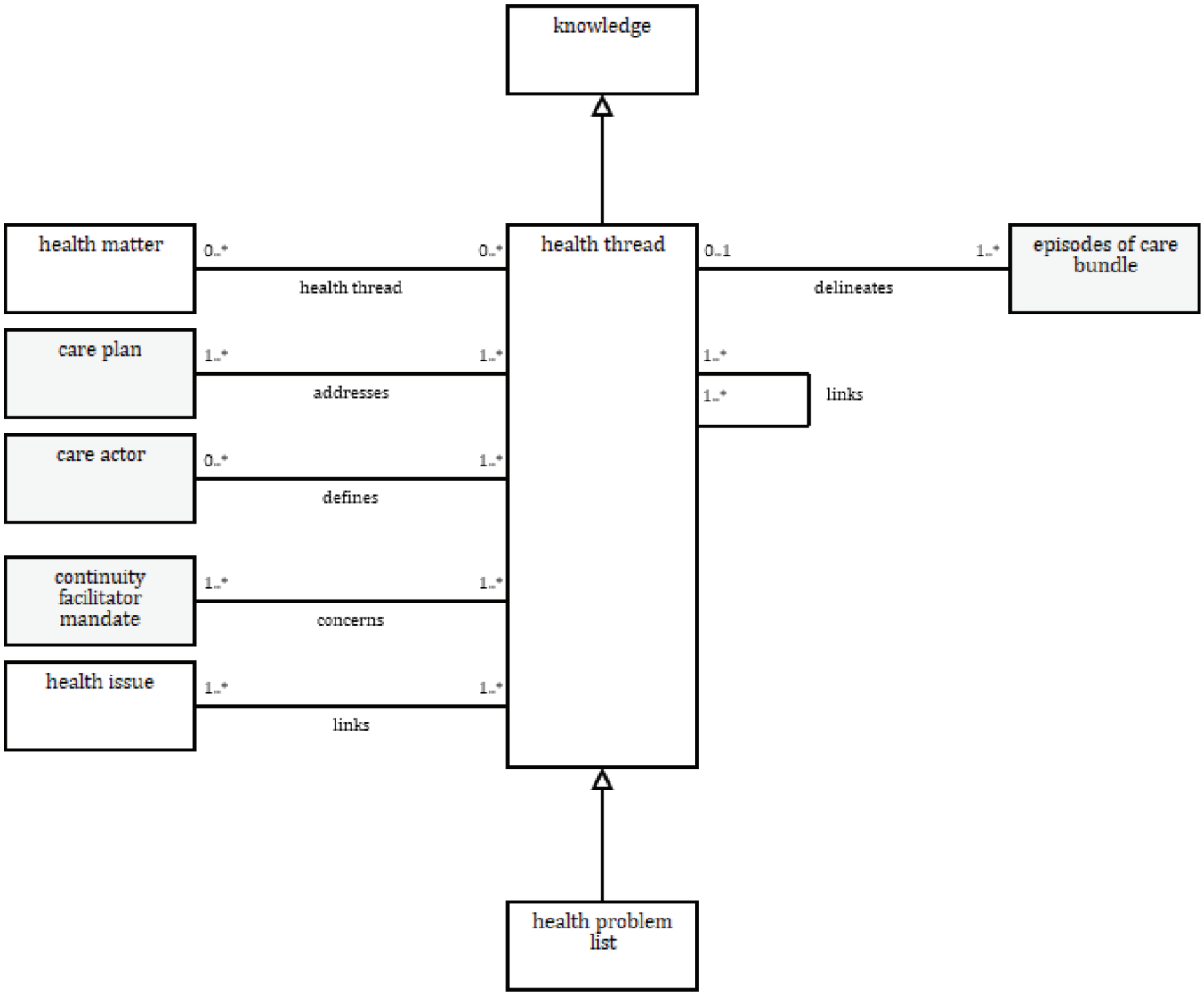


Figure 12 — health thread (UML Representation)

3.2.12
health problem list
care problem list
health thread linking a set of health problems

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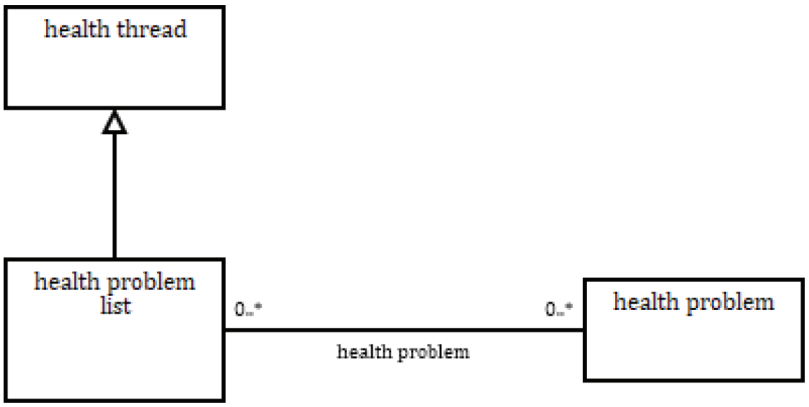


Figure 13 — health problem list (UML Representation)

3.2.13
potential health condition
possible future or current health condition described by a care actor

Note 1 to entry: A potential health condition is not yet observed, but represents an imagined, possible observation of aspects of a current or future health state

Note 2 to entry: A potential health condition can only be fully supported using one of its specializations.

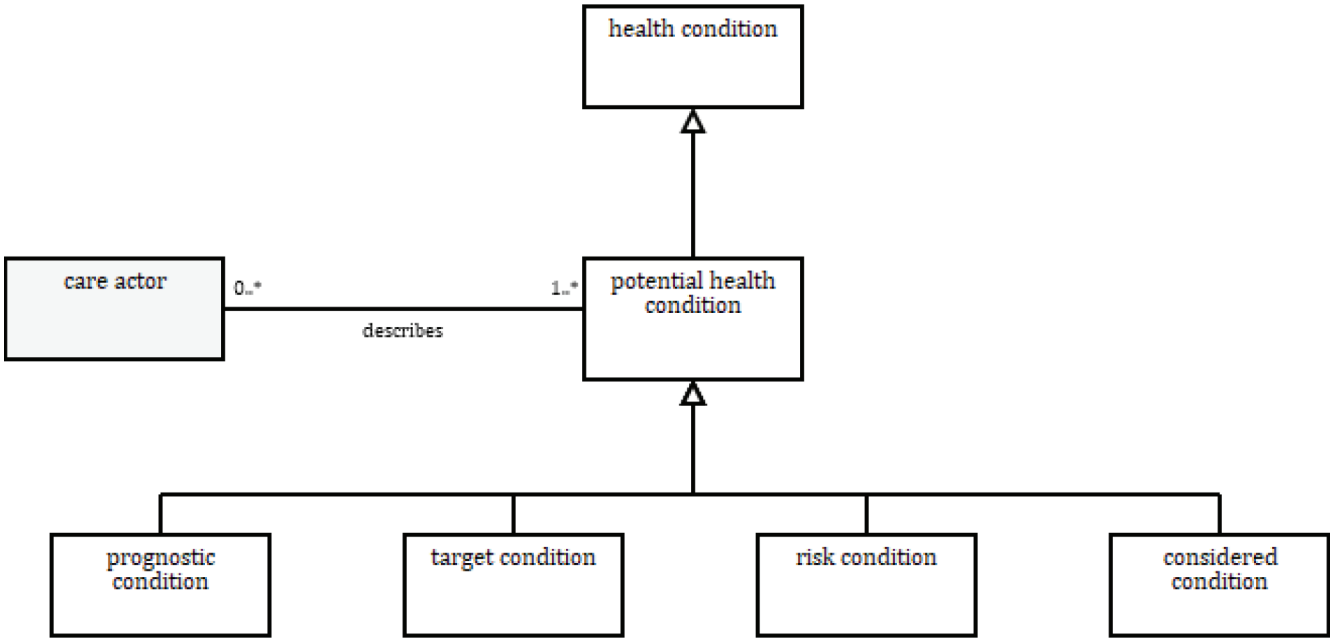


Figure 14 — potential health condition (UML Representation)

3.2.14
observed condition
health condition observed by a care actor

EXAMPLE A blood pressure, a swelling in the abdomen, tachycardia, body weight, lung infiltration on x-ray, a haemoglobin value, pale skin.

Note 1 to entry: Care professionals and subjects of care are examples of care actors that can perceive the observed aspect of a health state

Note 2 to entry: An observed condition is a health issue and as such is a representation of aspect(s) of the health state

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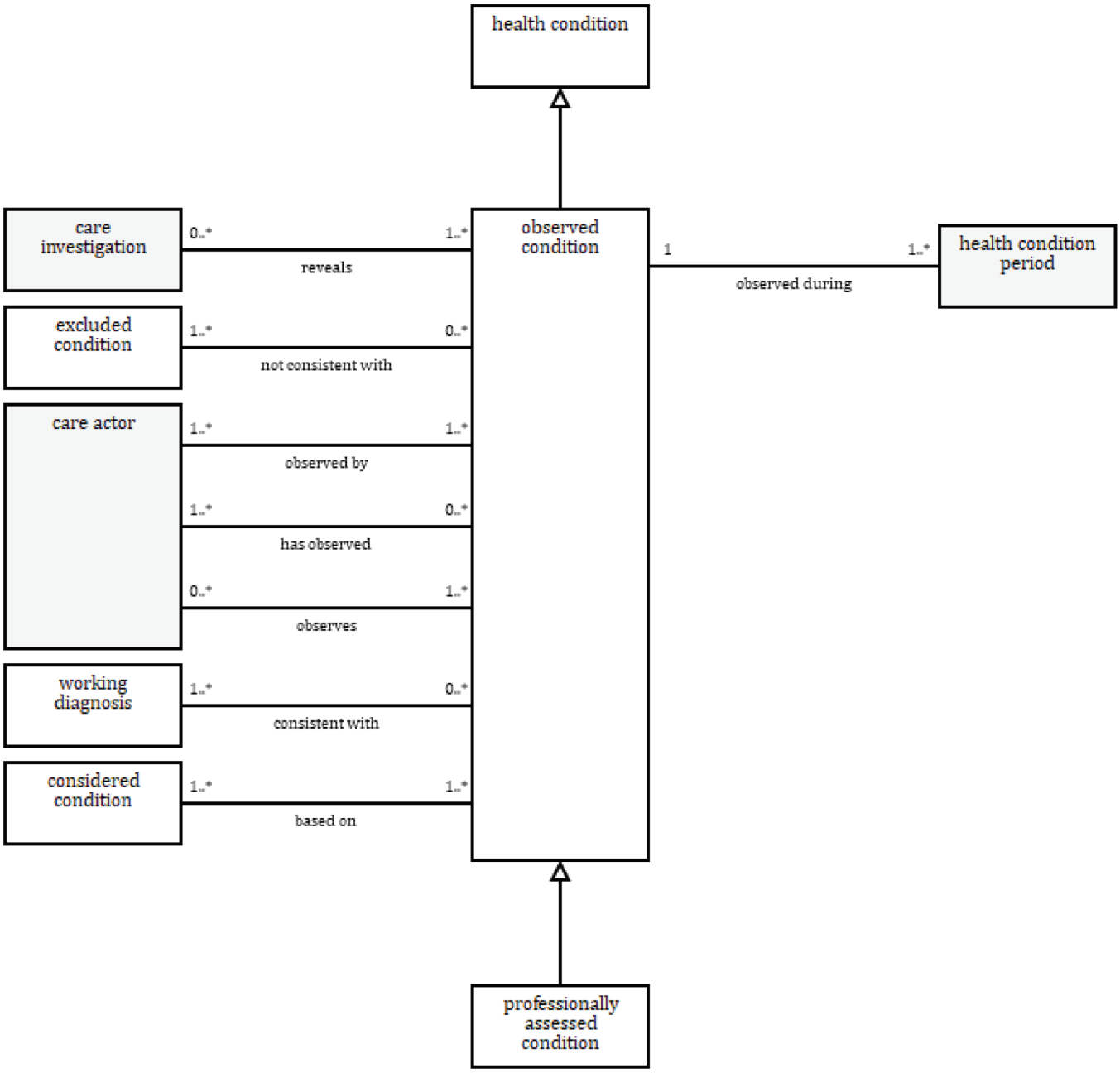


Figure 15 — observed condition (UML Representation)

3.2.15
considered condition
considered health condition
potential health condition considered by a care actor based on one or more observed conditions

Note 1 to entry: A request for care normally includes a health condition or symptom observed by the subject of care and also a question about what the reason for that symptom might be. It is the potential health condition in this question (the health condition behind the symptom) that is called a considered condition

Note 2 to entry: A referral within a continuity of care process is normally motivated by one or several observed conditions and/or professionally assessed conditions. However the referral also normally includes a question that the care investigation is supposed to get an answer to. The question formulated as a potential condition is a considered condition

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Note 3 to entry: A considered condition remains considered until the associated observed conditions are changed or completed. Care investigation or care treatment can result in new observations that can verify or not verify the considered condition When a considered condition is verified it becomes an observed condition or professionally assessed condition that may be a working diagnosis If a considered condition is discounted it is transformed into an excluded condition

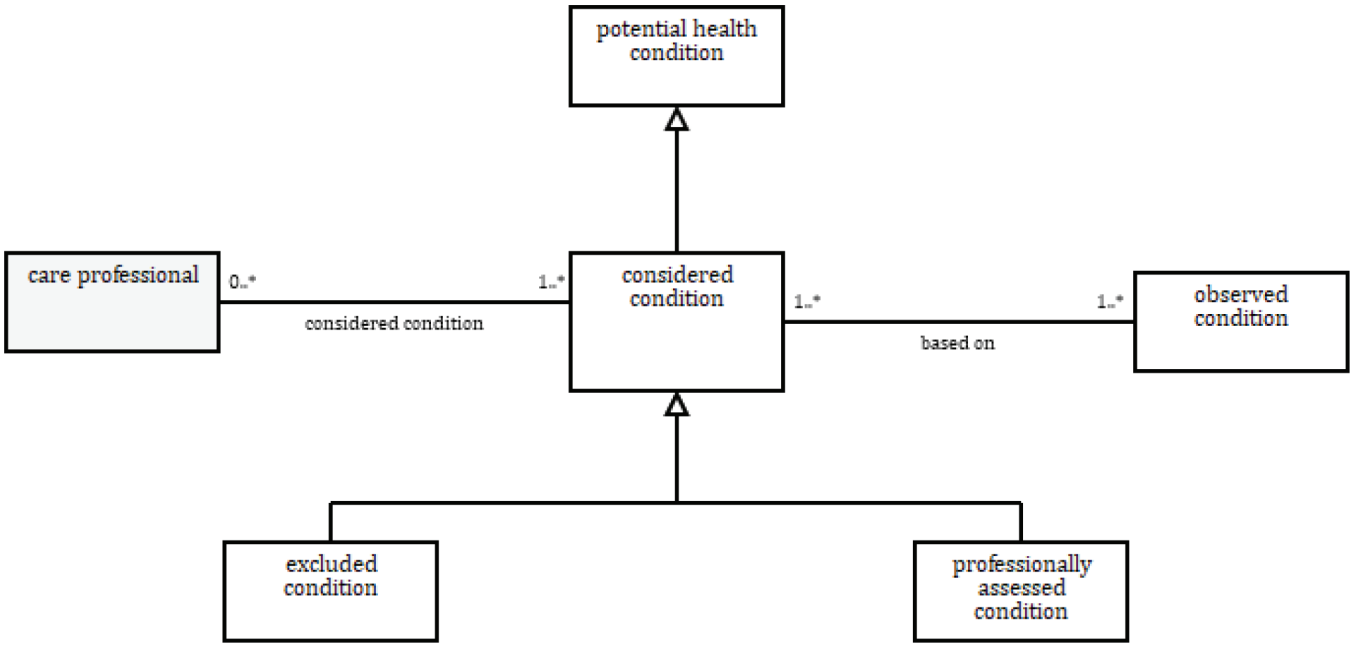


Figure 16 — considered condition (UML Representation)

3.2.16
professionally assessed condition
observed condition assessed by a care professional

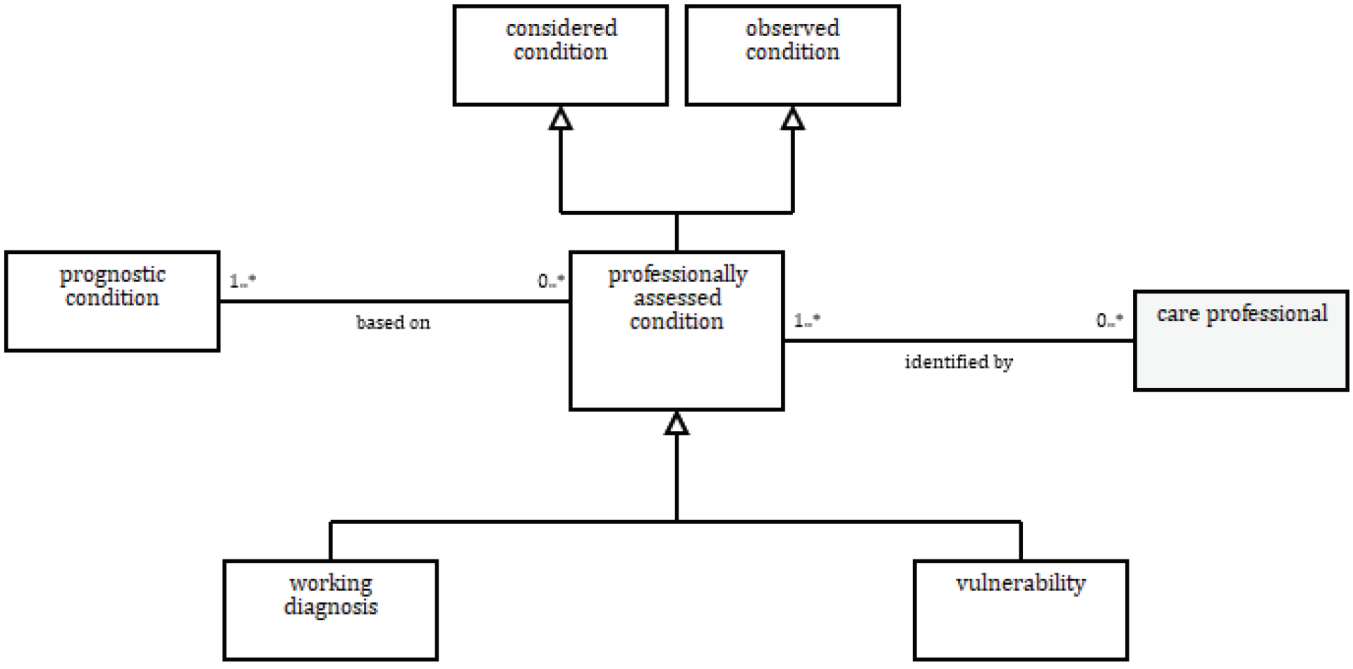


Figure 17 — professionally assessed condition (UML Representation)

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3.2.17
vulnerability
health condition that is an exposure to the risk of harm

EXAMPLE 1 Released from prison

EXAMPLE 2 Drug addiction

EXAMPLE 3 Loss of employment

EXAMPLE 4 Lives up a steep flight of stairs leading to increased risk of falls

EXAMPLE 5 Immunosuppressed leading to risk of infection

Note 1 to entry: In the perspective of health care and wellbeing the term vulnerable condition is often used to label frail citizens and/or socio-economic and education conditions (e.g. housing, job, disability) that motivate certain social care provider activity interventions, generally addressing a target population (e.g. older persons, children, families, homeless, refugees).

Note 2 to entry: The potential harm is a risk condition.

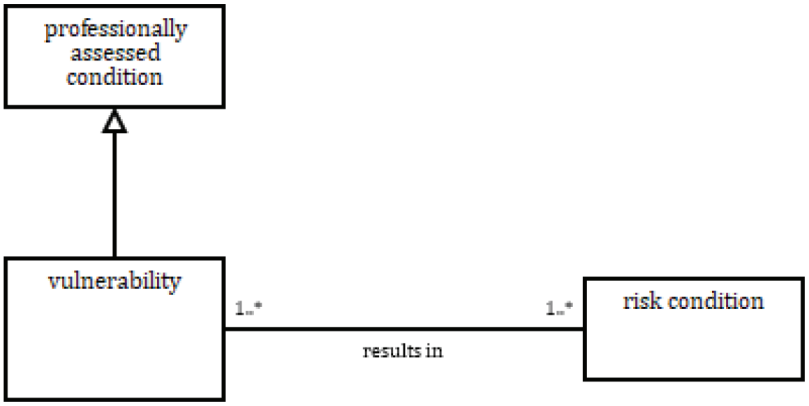


Figure 18 — vulnerability (UML Representation)

3.2.18
excluded condition
discounted condition, non-verified condition, ruled out condition, ruled out considered condition

considered condition that one or more care professionals have determined not to be consistent with the known observed conditions

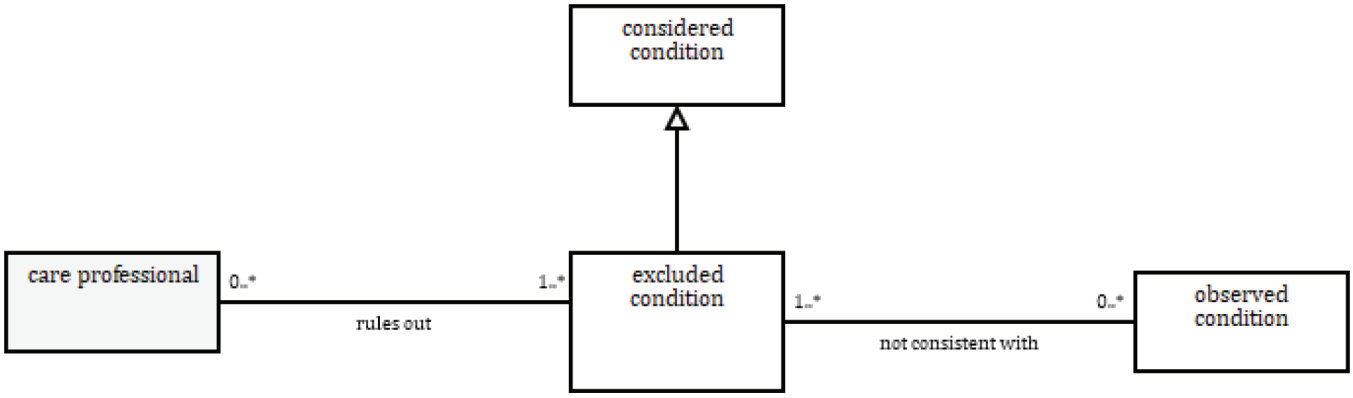


Figure 19 — excluded condition (UML Representation)

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3.2.19
working diagnosis
working hypothesis
considered condition that one or more care professionals have determined to be the most consistent with observed conditions

Note 1 to entry: A working diagnosis is used as a label for the considered condition that one or more care professionals assess as the most probable health condition and that could be concluded after further observations. The basis for such assessments is the already observed conditions.

Note 2 to entry: Different care professionals may make different interpretations and assessments of the observed conditions and thereby come to different conclusions and different working diagnosis

Note 3 to entry: A working diagnosis is often identified in the continuity of care process as a summary after the planned care investigation are completed. A working diagnosis in this stage is often called a diagnosis. An excluded condition could correspondingly be called a negation of a working diagnosis

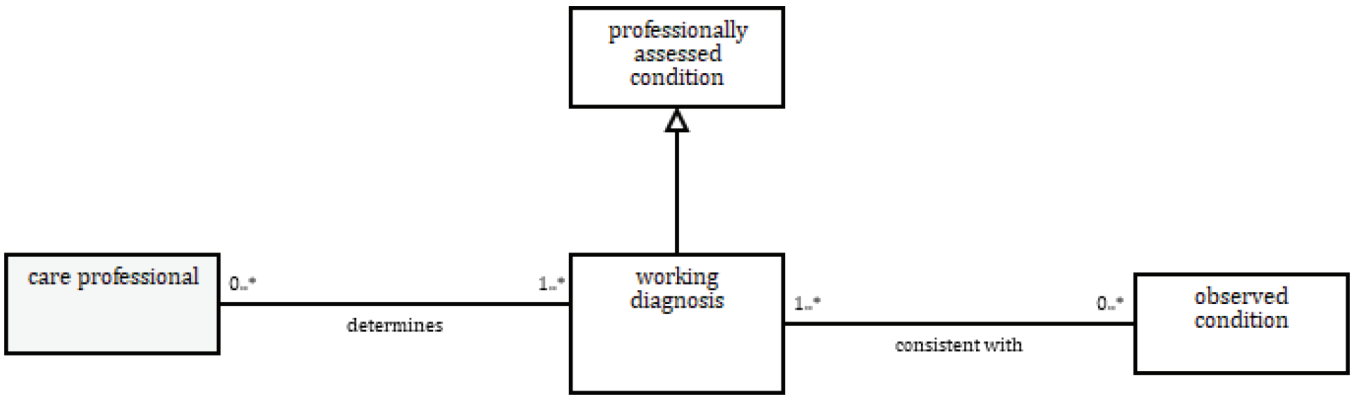


Figure 20 — working diagnosis (UML Representation)

3.2.20
prognostic condition
potential health condition representing the expected course of a health state as assessed by care professionals

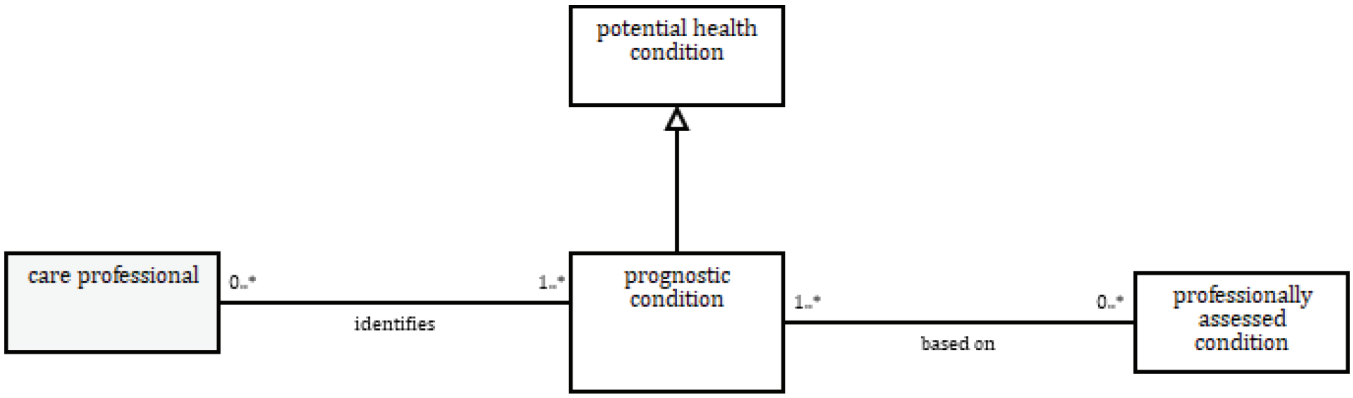


Figure 21 — prognostic condition (UML Representation)

3.2.21
resultant condition
observed condition representing an output health state

EXAMPLE Care process result, care activity result

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Note 1 to entry: A resultant condition can represent the output health state after a single care activity a bundle of care investigations and/or care treatments in a care process and also the outcome after a complete continuity of care process

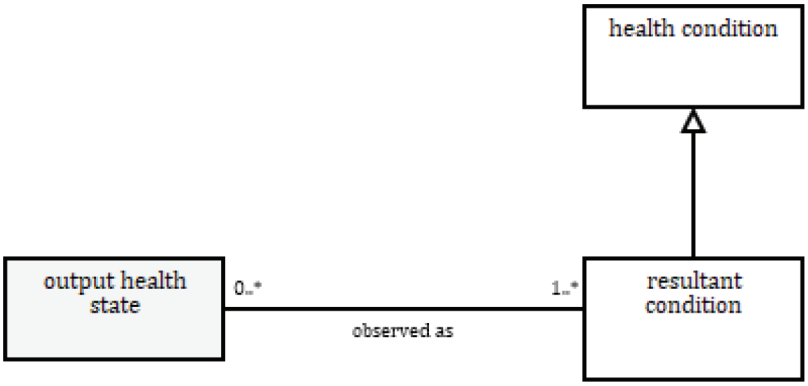


Figure 22 — resultant condition (UML Representation)

3.2.22
target condition
target health condition, intended outcome

potential health condition representing either health objectives or care goals

EXAMPLE 1 The target condition for a worker that arrived at the Emergency Room with a broken arm is to be fully functional for work in the shortest period.

EXAMPLE 2 The target condition of a newly diagnosed diabetic adolescent boy is maintenance of his HbA1c at less than 48 mmol/mol. (HbA1c is a lab test that shows the average level of blood sugar (glucose) over the previous 3 months; it shows how well diabetes is being controlled).

Note 1 to entry: Assessment of needs for care activities includes identification of health objectives and/or care goals. These inform decisions about relevant activities to create or update the care plan

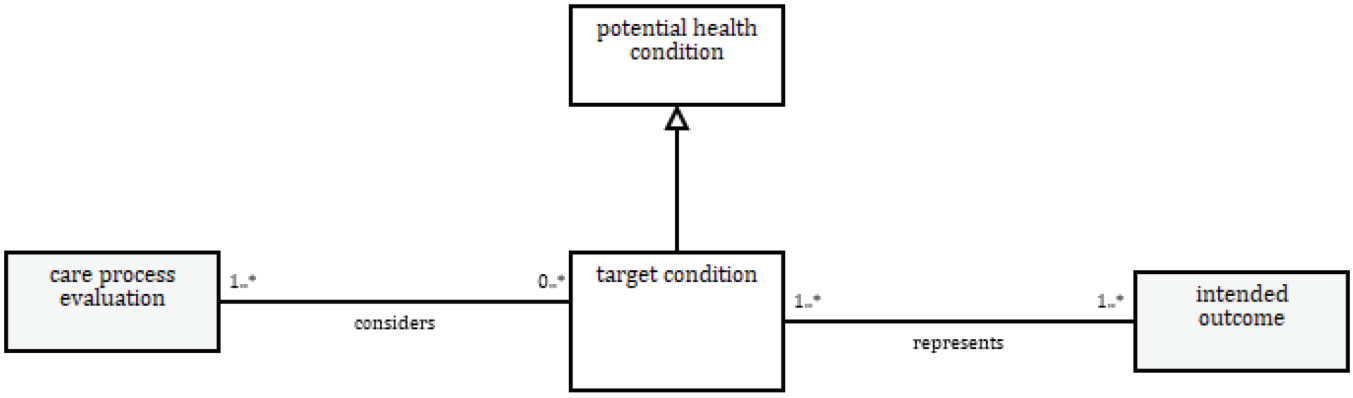


Figure 23 — target condition (UML Representation)

3.2.23
risk condition
risk health condition
health condition representing a potential undesired future health state

Note 1 to entry: While a risk is defined as the combination of a probability of an event and its consequences, the risk condition deals only with the consequences.

Note 2 to entry: A risk condition can be a result of a current vulnerability.

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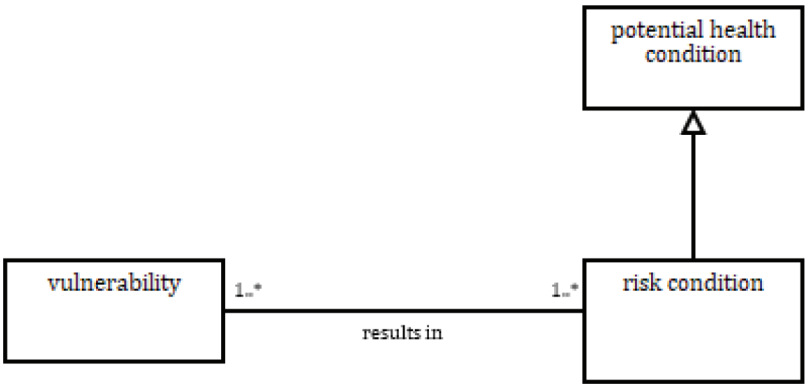


Figure 24 — risk condition (UML Representation)

3.2.24
social environment
milieu
immediate physical and social setting in which a subject of care lives and interacts

[SOURCE: Barnett et al, *A Definition of "Social Environment"* (102)]

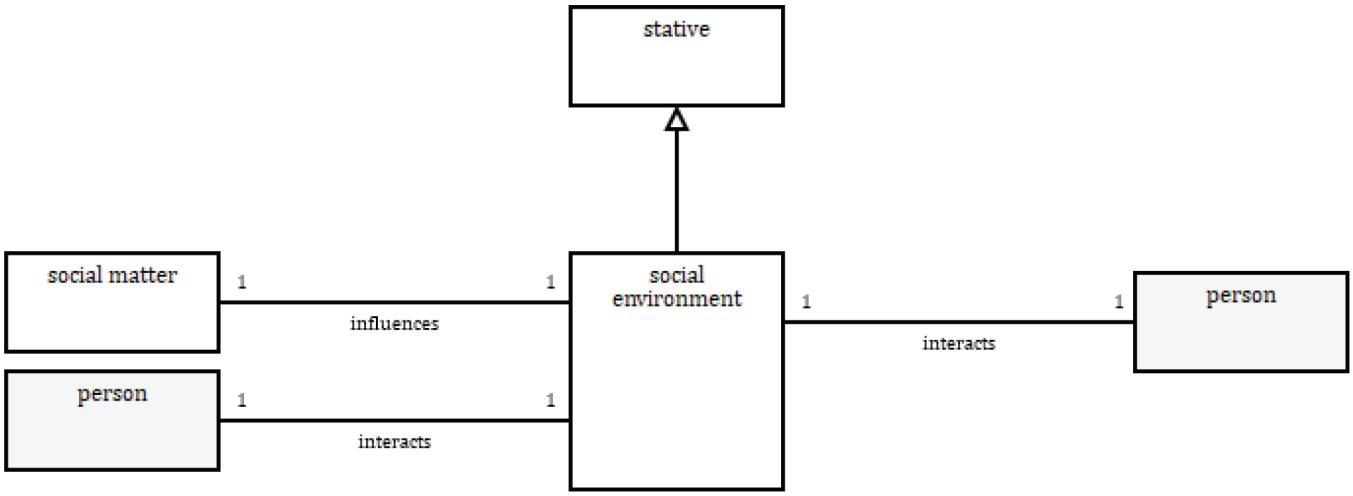


Figure 25 — social environment (UML Representation)

3.2.25
health need
health matter causing a deficit in the current health state compared to aspects of a desired future health state

Note 1 to entry: The desired future health state can be a health objective expressed as target conditions.

Note 2 to entry: The health need can be identified and formulated by the subject of care or by any other care actor

Note 3 to entry: Health needs are the motivations/indications for care activities and are the basic input to care needs assessments.

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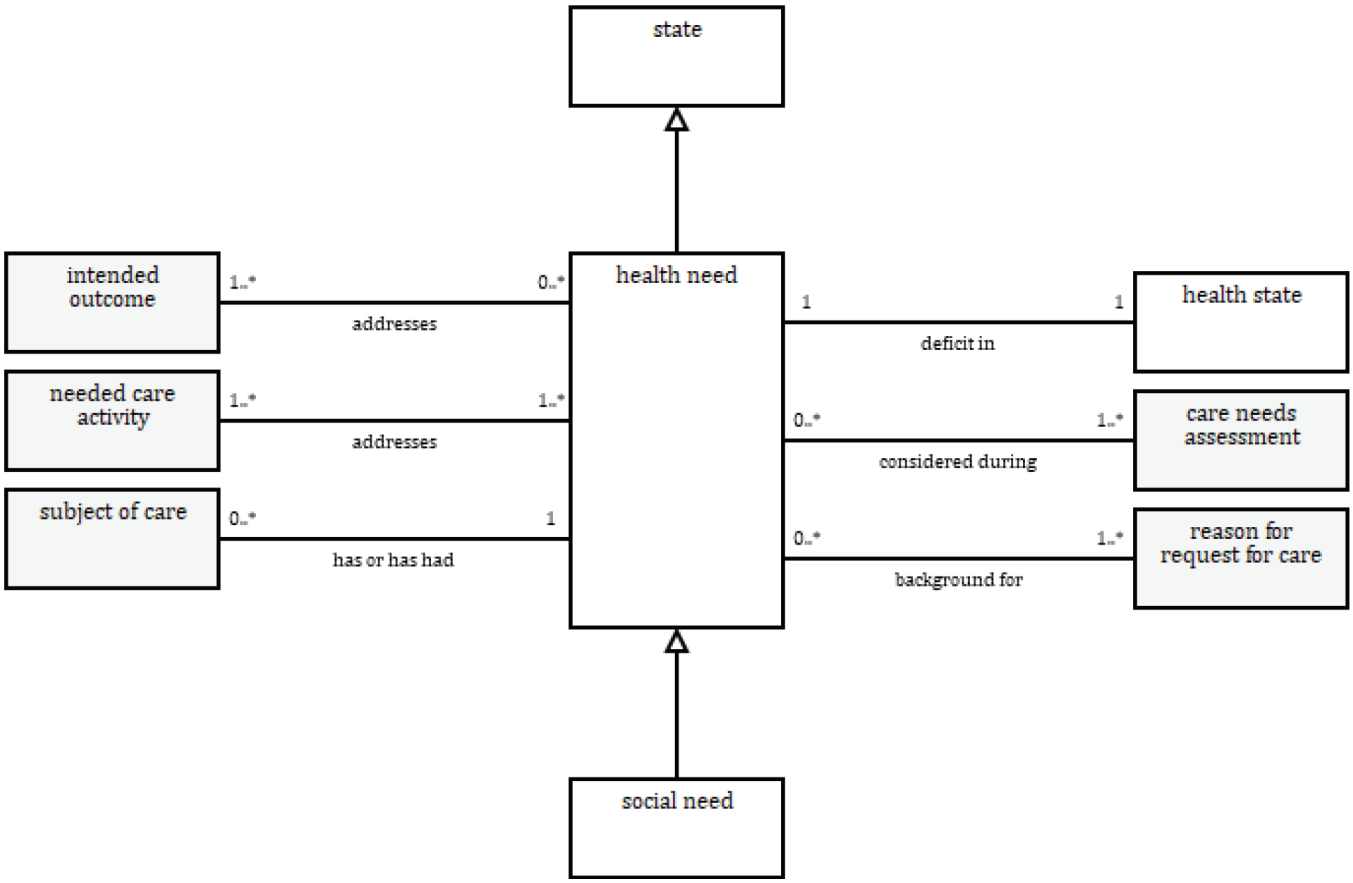


Figure 26 — health need (UML Representation)

3.2.26
social need
health need related to social determinants of health

EXAMPLE 1 loss of job

EXAMPLE 2 gambling addiction

EXAMPLE 3 loss of personal autonomy

EXAMPLE 4 physical or mental disability

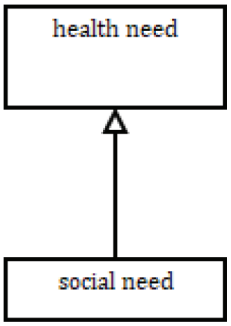


Figure 27 — social need (UML Representation)

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3.2.27
clinical need
health need related to the body or mind

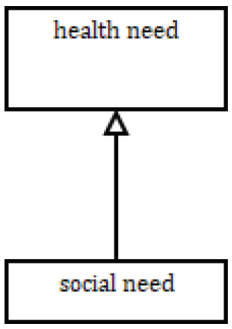


Figure 28 — clinical need (UML representation)

3.3 Actors, performers and resources

3.3.1
care actor
organization or person participating in care

Note 1 to entry: The involvement of the care actor can either be direct (for example, the actual provision of care or indirect (for example, at organizational level).

Note 2 to entry: According to this definition, people or organizations responsible for the funding, payment, or reimbursement of care provision are care actors, as well as organizations responsible for care delivery.

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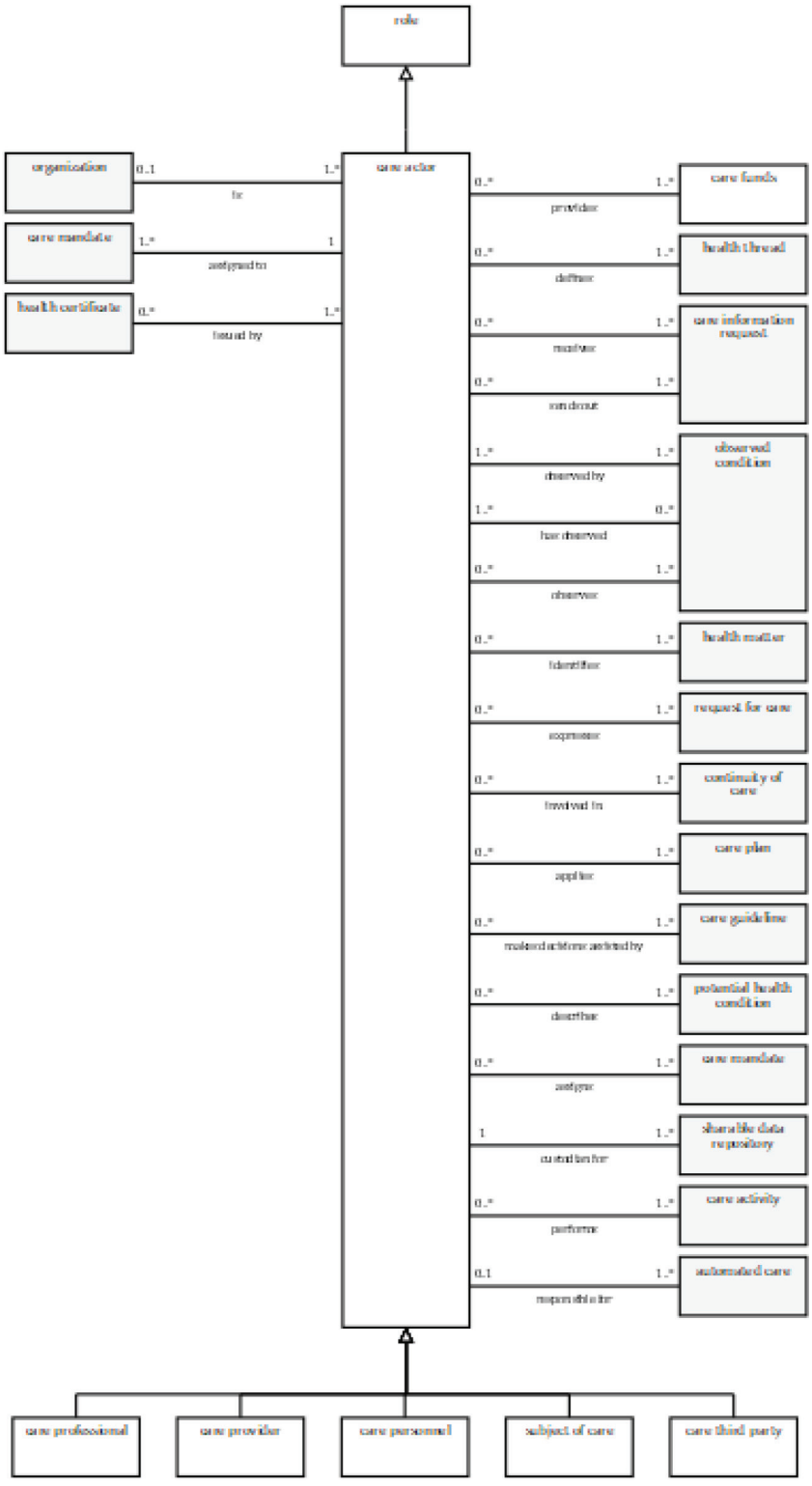


Figure 29 — care actor (UML Representation)

3.3.2
subject of care
patient, client, service user, consumer

person seeking to receive, receiving, or having received care

EXAMPLE 1 A treated patient

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EXAMPLE 2 A client of a physiotherapist

EXAMPLE 3 Each member of a target population for screening

EXAMPLE 4 Each member of a group of diabetic people attending a session of medical education

EXAMPLE 5 A person seeking health advice

Note 1 to entry: A fœtus may be considered as a subject of care when receiving care.

Note 2 to entry: Subject of care is a person role.

[SOURCE: ISO/TR 14292:2012, 2.32][5]

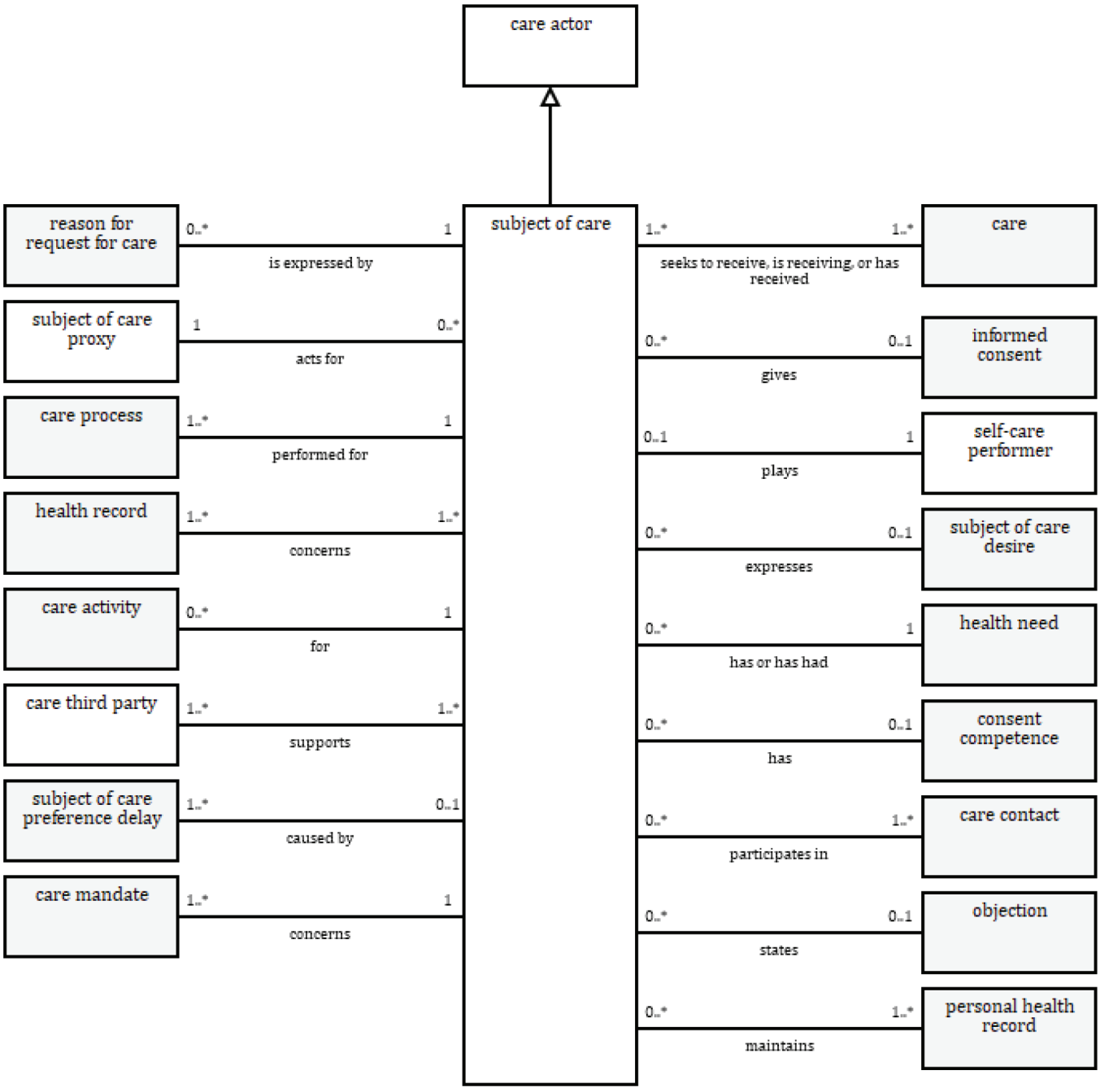


Figure 30 — subject of care (UML Representation)

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3.3.3
care provider
care actor that is able to be assigned one or more care period mandates

Note 1 to entry: The personnel of a care organization that is a care provider may be care professionals and other care personnel who participate in the provision of care

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

Note 3 to entry: According to this definition, organizations solely responsible for the funding, payment, or reimbursement of care provision are not care providers; for the purpose of this document, they are considered as care third parties.

[SOURCE: ISO 27269:2021, 3.2.2, modified “healthcare” changed to “care”][6]

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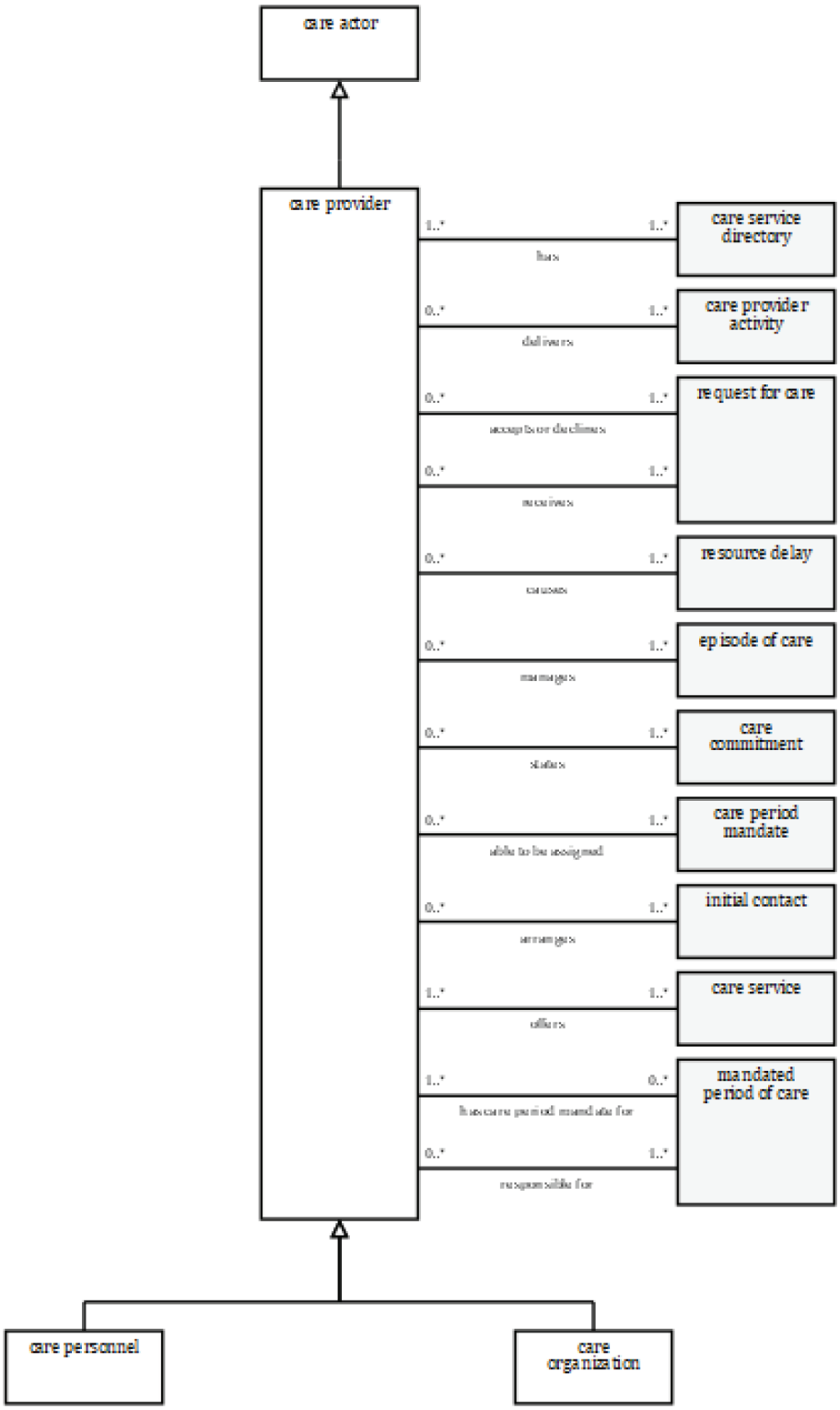


Figure 31 — care provider (UML Representation)

3.3.4
care third party
care actor other than a care provider or the subject of care

EXAMPLE Funder of care

Note 1 to entry: Care third party is an abstract concept. It is fully supported by one of the specific subordinate parties.

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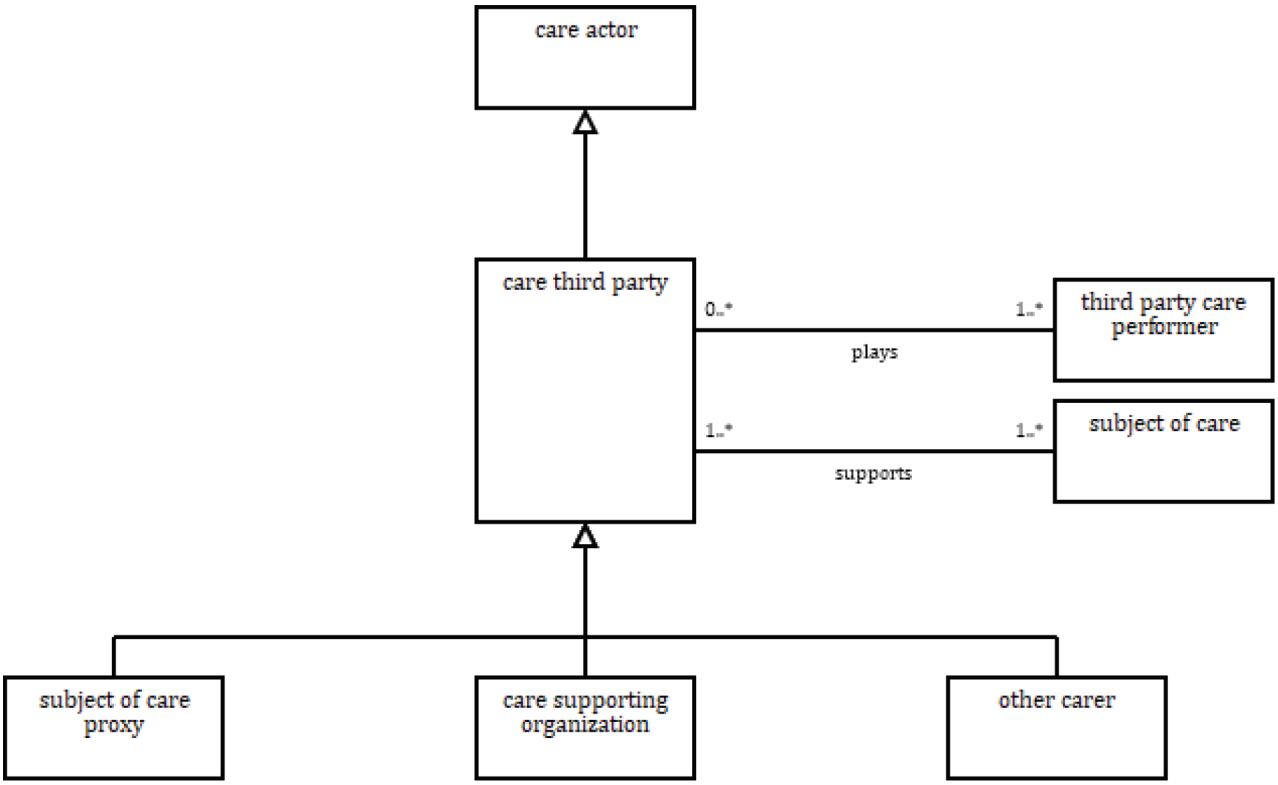


Figure 32 — care third party (UML Representation)

3.3.5
care organization
healthcare delivery organization

organization being a care provider

EXAMPLE 1 A care team

EXAMPLE 2 A group practice or a self-employed general practitioner

EXAMPLE 3 A hospital, a hospital department, or a hospital care unit

EXAMPLE 4 A social department or a municipality providing care (including social care)

EXAMPLE 5 A non-governmental organisation or a voluntary association providing care (including social care)

Note 1 to entry: 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 as a standalone organization or as a superstructure containing departments and sub-departments, for instance, other lower-level organizations. A care organization represents the role any such organization plays when it is involved in the direct provision of care activities.

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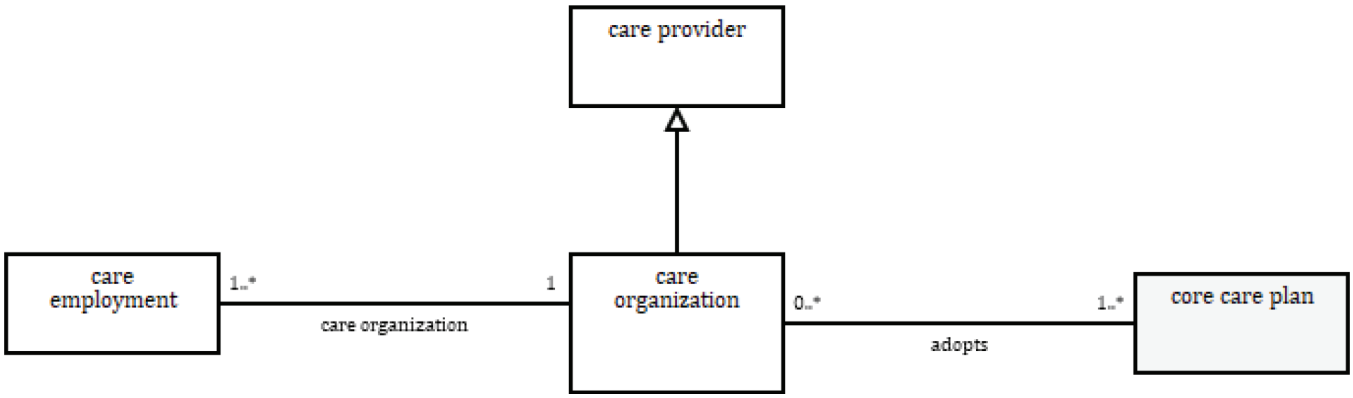


Figure 33 — care organization (UML Representation)

3.3.6
care employment
contractual framework between a care personnel and a care organization describing the roles and responsibilities assigned to that care personnel

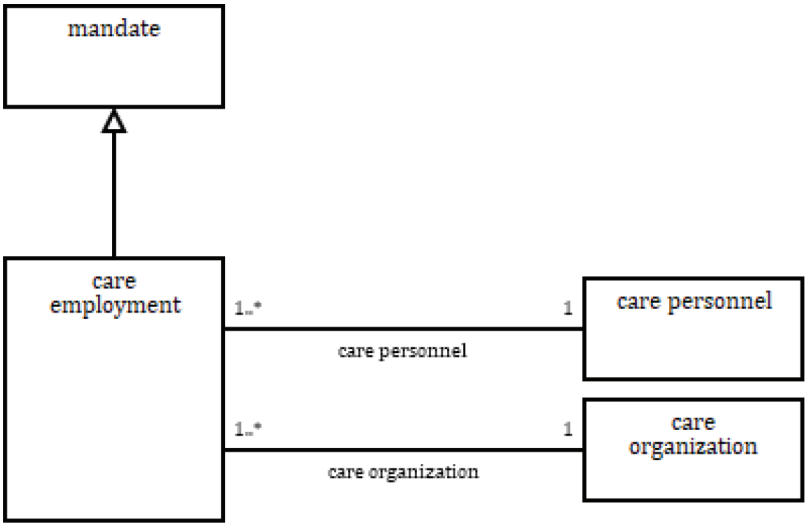


Figure 34 — care employment (UML Representation)

3.3.7
care personnel
person holding a care employment from a care organization

EXAMPLE nurse's assistant, head of department, medical secretary, receptionist

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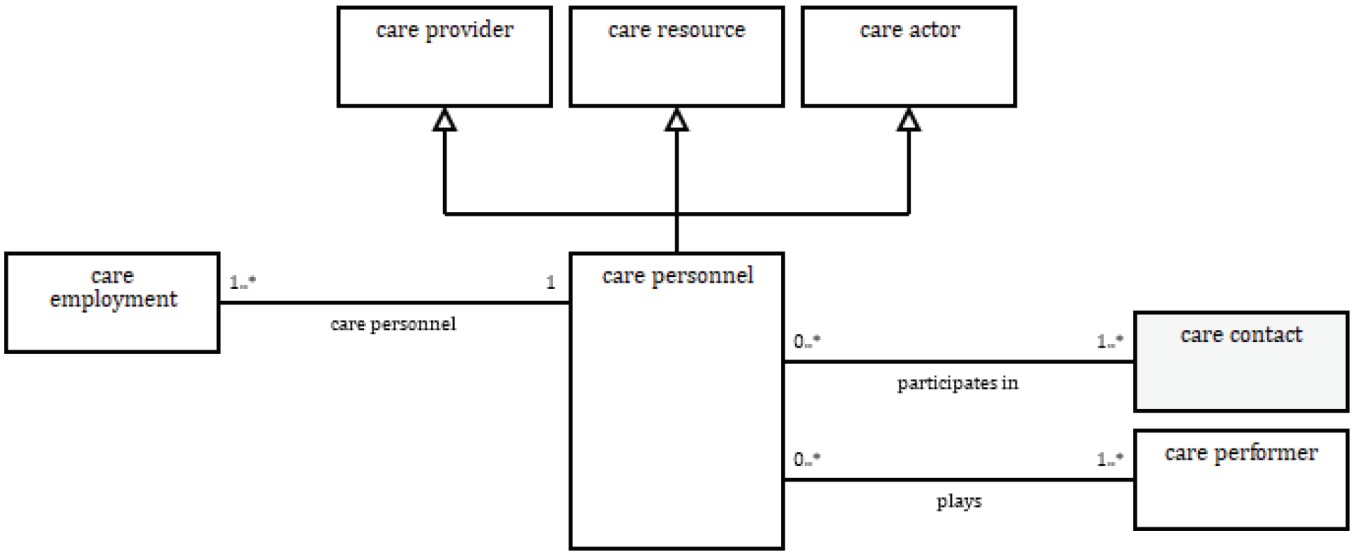


Figure 35 — care personnel (UML Representation)

3.3.8
care professional entitlement
professional mandate held by a person concerning specific roles in care

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

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

Note 2 to entry: The official entitlement of a care professional forms the foundation for his/her official duties and rights.

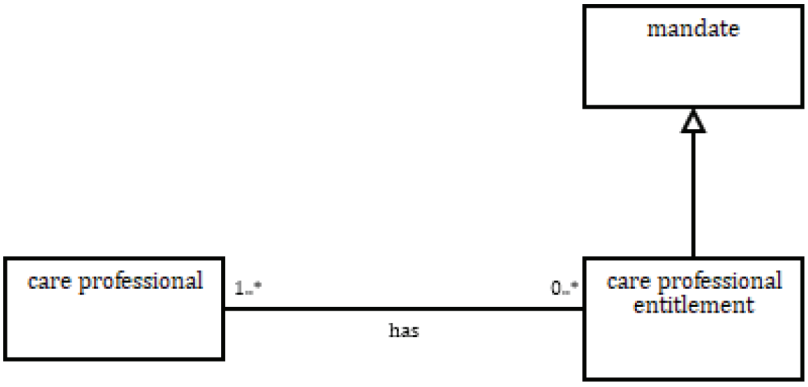


Figure 36 — care professional entitlement (UML Representation)

3.3.9
care professional
healthcare professional
DEPRECATED: health professional
person holding a care professional entitlement

EXAMPLE General practitioner, medical consultant, therapist, dentist, nurse, radiographer, social worker etc.

Note 1 to entry: The care professional entitlement entitles a care professional to provide care independent of a role in a care organization.

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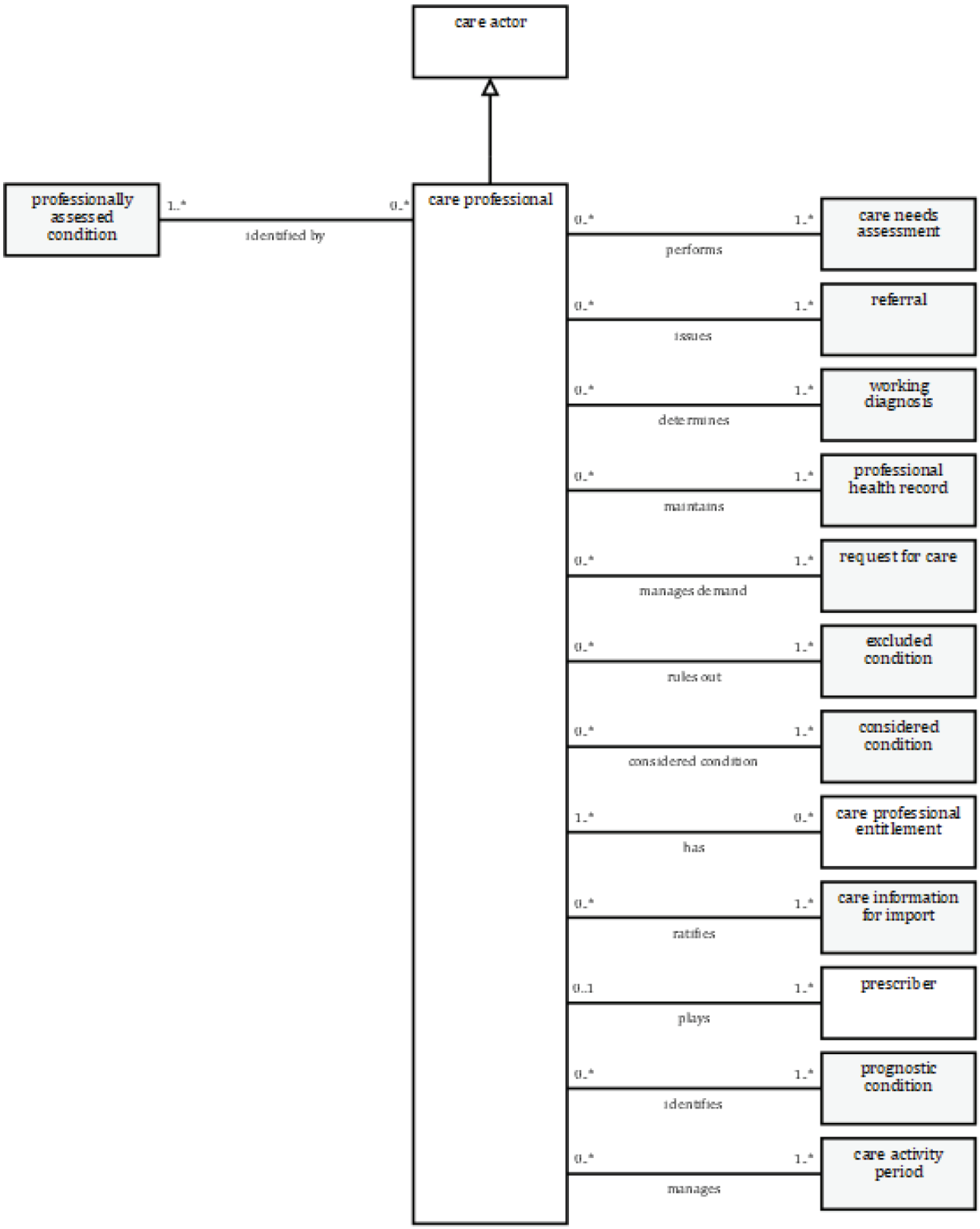


Figure 37 — care professional (UML Representation)

3.3.10
other carer
person being a care third party

EXAMPLE A relative (family member), a neighbour.

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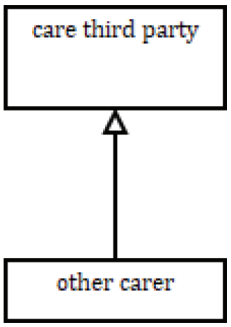


Figure 38 — other carer (UML Representation)

3.3.11
care supporting organization
organization that is a care third party

EXAMPLE 1 voluntary aid organization, homecare service organization, health insurance fund, family

EXAMPLE 2 health technology provider

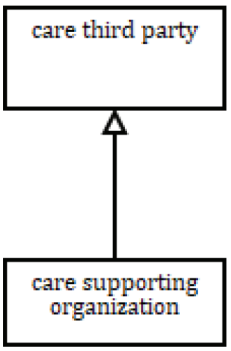


Figure 39 — care supporting organization (UML Representation)

3.3.12
subject of care proxy
subject of care agent
care actor exercising a proxy mandate

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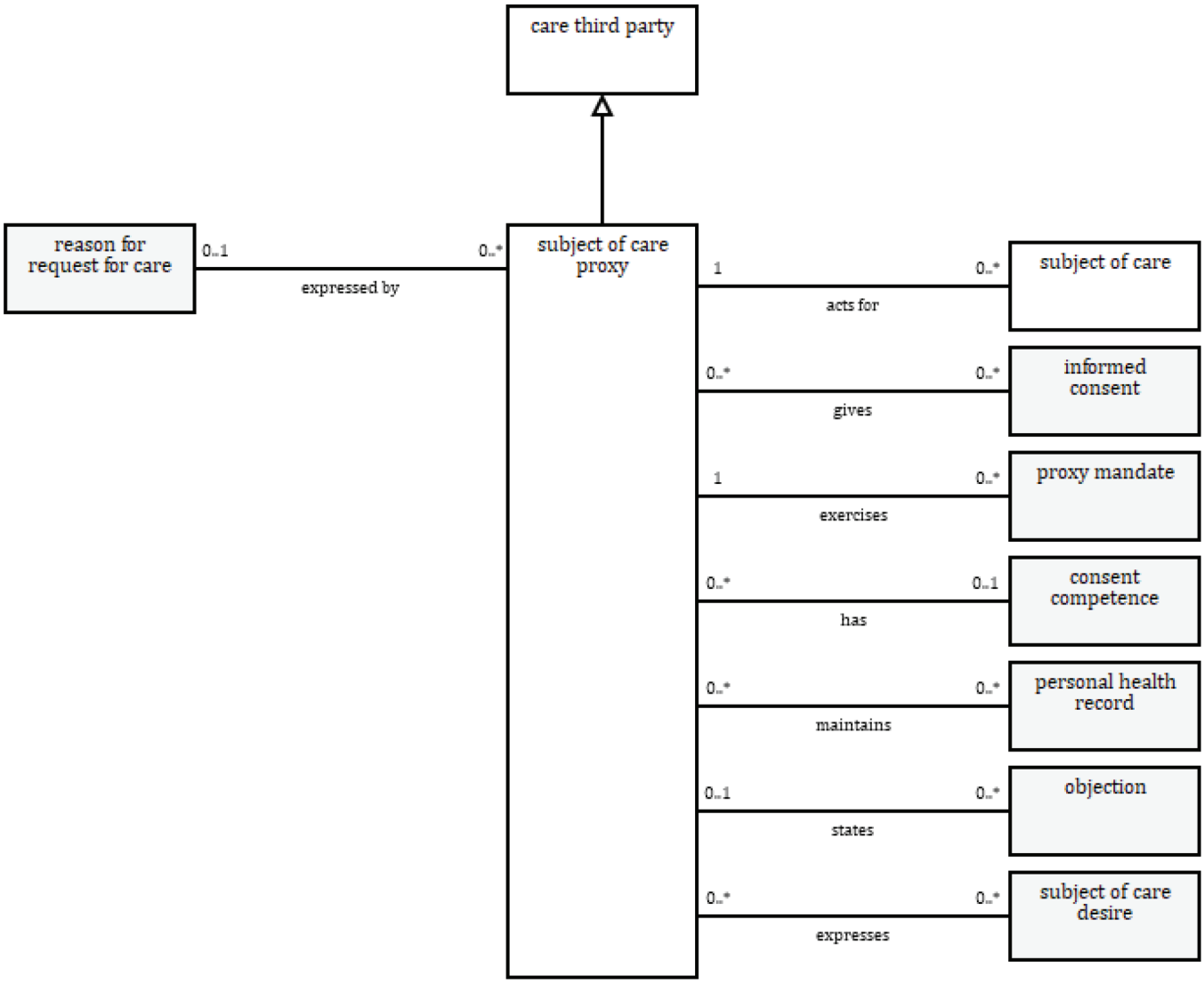


Figure 40 — subject of care proxy (UML Representation)

3.3.13
care performer
role adopted by care personnel when performing care

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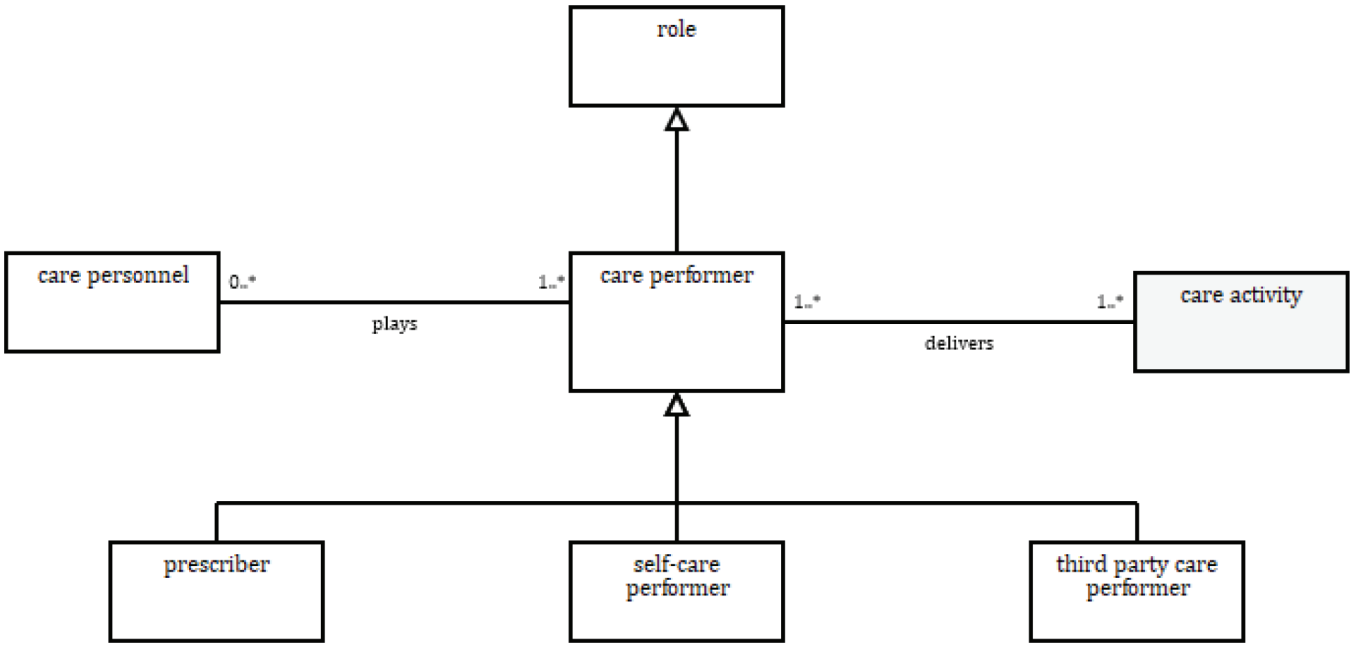


Figure 41 — care performer (UML Representation)

3.3.14
self-care performer
role played by a subject of care when performing self-care

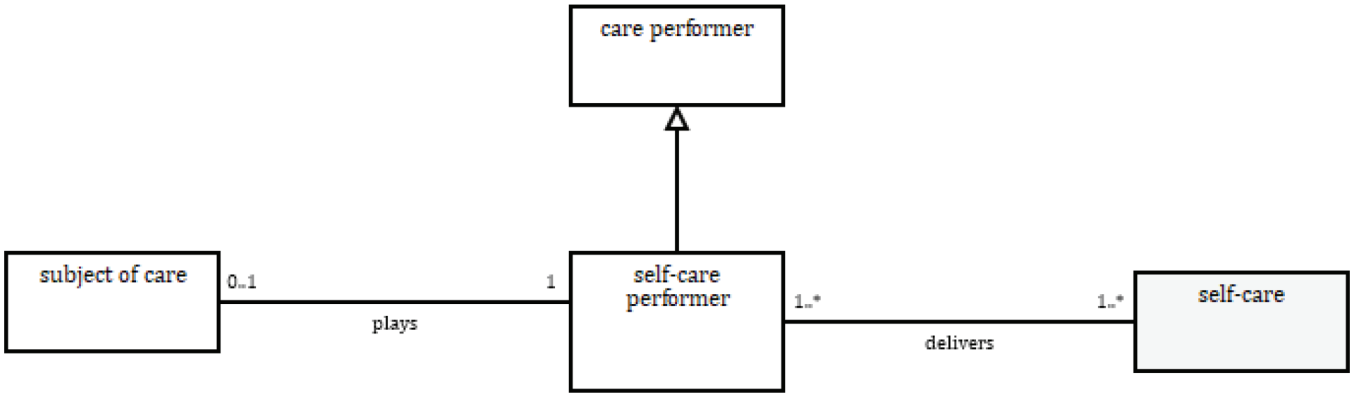


Figure 42 — self-care performer (UML Representation)

3.3.15
third party care performer
role performed by a care third party

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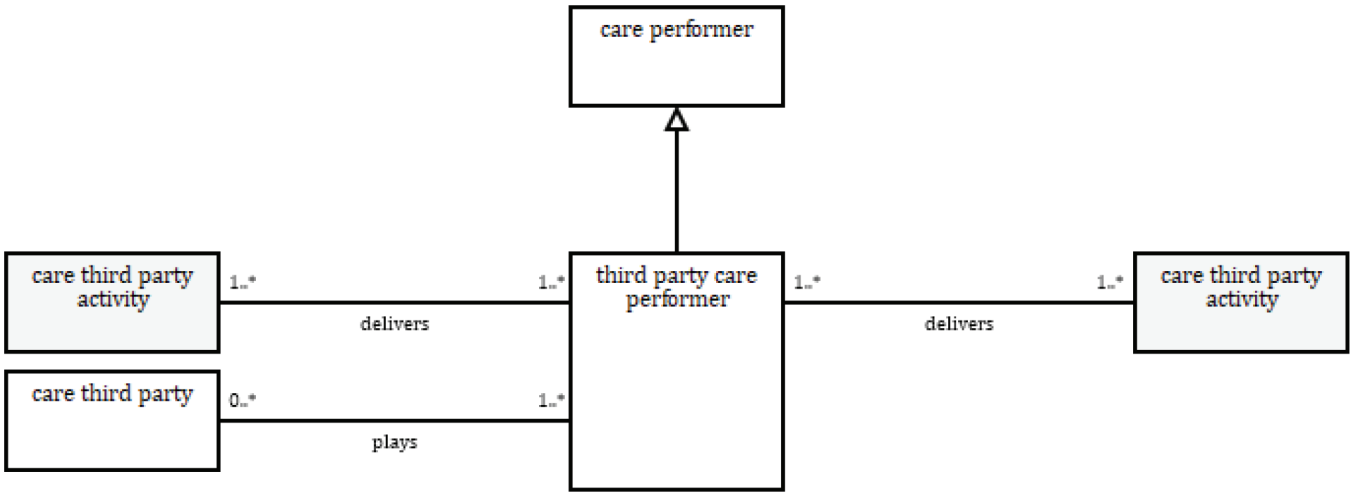


Figure 43 — third party care performer (UML Representation)

3.3.16
prescriber
role performed by a care professional when recommending or authorising a care activity

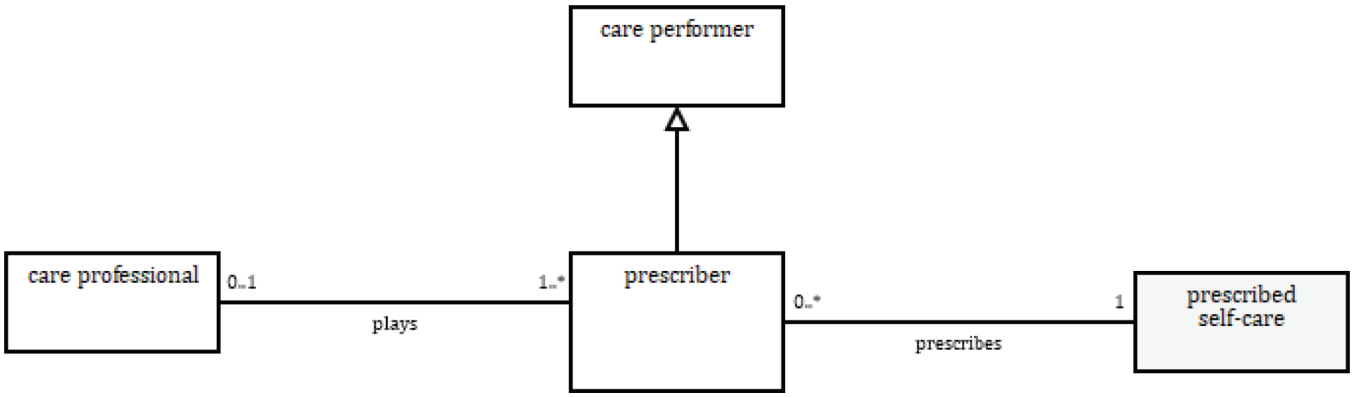


Figure 44 — prescriber (UML Representation)

3.3.17
care resource
resource needed to perform care activities

EXAMPLE 1 Care professional on duty

EXAMPLE 2 Operation theatre

EXAMPLE 3 Instruments ready to use

EXAMPLE 4 Consultation rooms

EXAMPLE 5 Bed in a ward

EXAMPLE 6 Prepared medicinal products

EXAMPLE 7 Electrocardiography-device

EXAMPLE 8 Blood sample

EXAMPLE 9 Donated kidney

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Note 1 to entry: As a care process develops, the care resources typically follow a life cycle. Examples of steps of such a life cycle are: 'available', 'booked', 'provided', 'in use', 'consumed', etc.

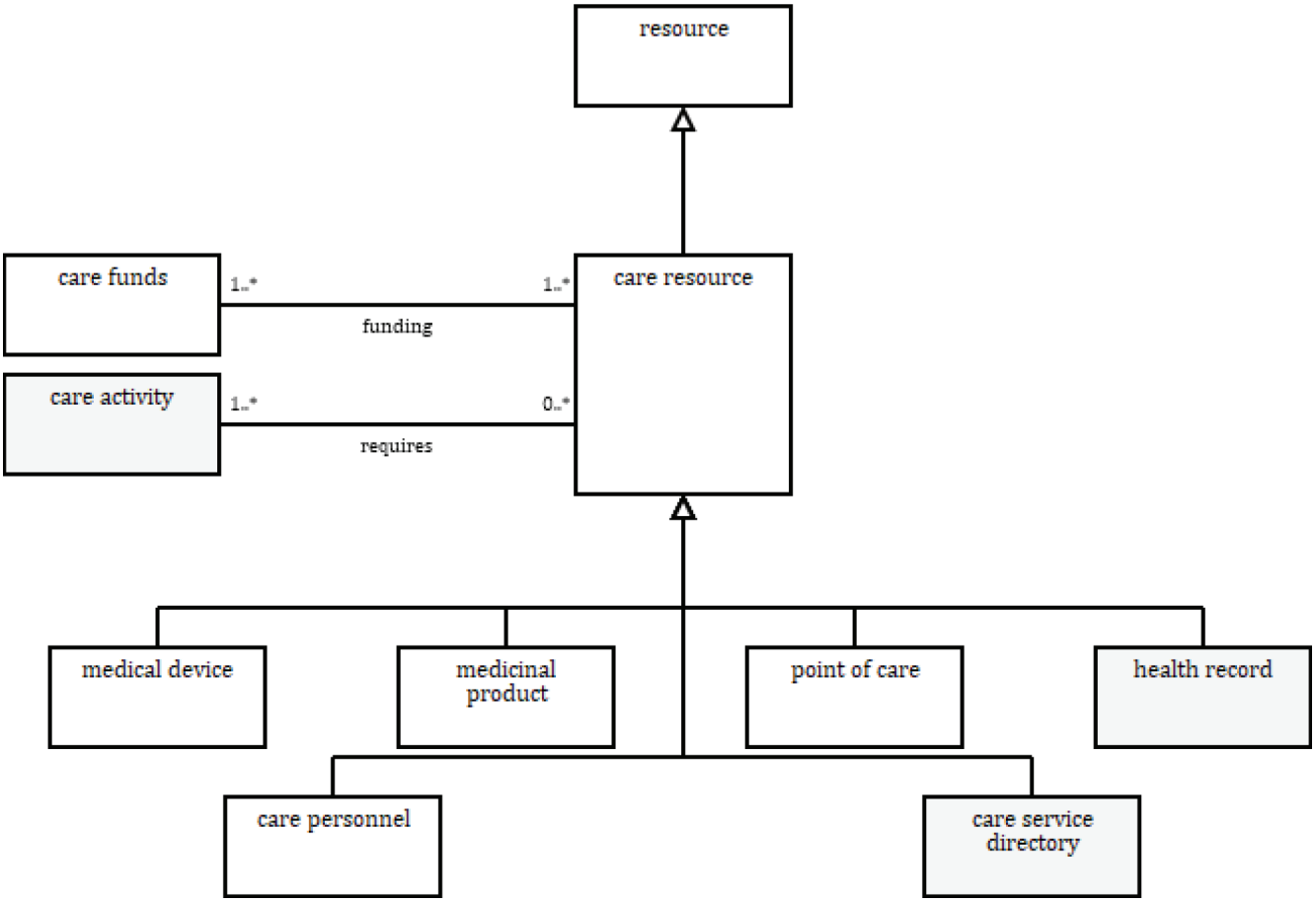


Figure 45 — care resource (UML Representation)

3.3.18
point of care
location where direct care activities are performed

EXAMPLE Surgery room, ward, ambulance, roadside, home of the subject of care, school, etc.

Note 1 to entry: Location refers to the geographical location of the subject of care not the body area of the subject of care that the treatment is applied to.

Note 2 to entry: Activities referred are not limited to care provider activities; self care activities are included.

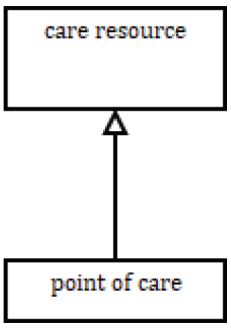


Figure 46 — point of care (UML Representation)

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3.3.19
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, 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 medical 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 by means of in vitro examination of specimens derived from the human body, and which does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which can be assisted in its intended function by such means

Note 1 to entry: Products which can be considered to be medical devices in some jurisdictions but not in others include:

— disinfection substances,

— aids for persons with disabilities,

— devices incorporating animal and/or human tissues,

— devices for in-vitro fertilization or assisted reproductive technologies.

[SOURCE: ISO/IEC Guide 63:2019, 3.7]

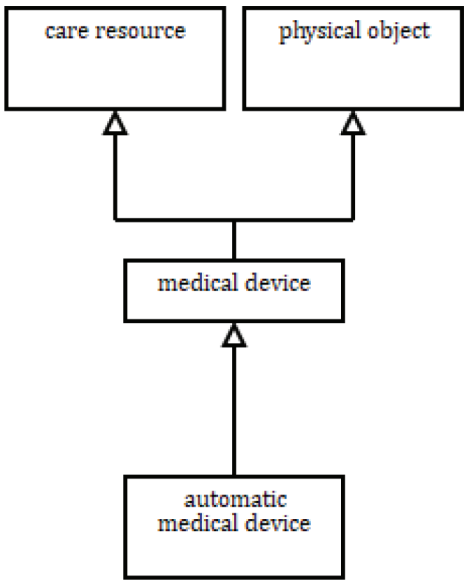


Figure 47 — medical device (UML Representation)

3.3.20
automatic medical device
medical device capable of performing care activities by itself or under human supervision

EXAMPLE 1 A specific identifiable electrocardiography machine

EXAMPLE 2 Electronic blood-sugar monitor

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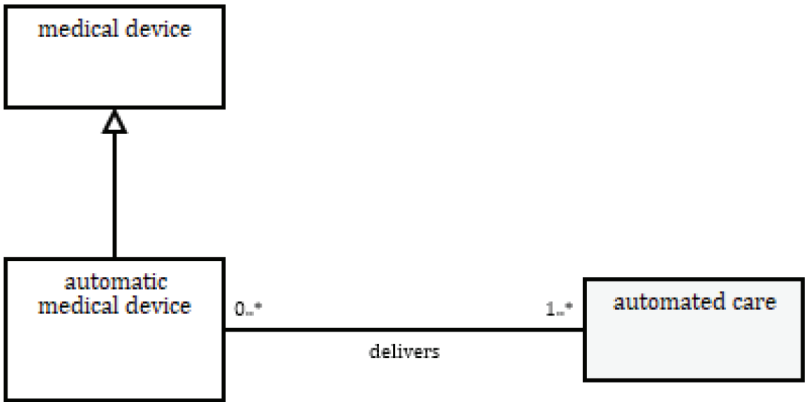


Figure 48 — automatic medical device (UML Representation)

3.3.21
medicinal product
pharmaceutical product or combination of pharmaceutical products that may be administered to human beings for treating or preventing disease, with the aim/purpose of making a medical diagnosis or to restore, correct or modify physiological functions

Note 1 to entry: A medicinal product may contain in the packaging one or more manufactured items and one or more pharmaceutical products. In certain regions, a medicinal product may also be defined as any substance or combination of substances which may be used to make a medical diagnosis.

Note 2 to entry: The provisions in this document apply to proprietary medicinal products for human use intended to be placed on the market and to be industrially manufactured medicinal products, the marketing of which has been authorised by a medicines regulatory agency. However, the provisions do not apply to: i) medicinal products prepared according to prescription (e.g. prepared in a pharmacy from a prescription intended for a specific patient), ii) medicinal products prepared in accordance with an official formula (e.g. prepared in a pharmacy in accordance with the instructions in a pharmacopoeia and intended to be given direct to the patient by the pharmacy), iii) medicinal products intended for research and development trials and to iv) intermediate products intended for subsequent processing by an authorised manufacturer.

[SOURCE: ISO 11615:2017, 3.1.50, revised: animals not included]

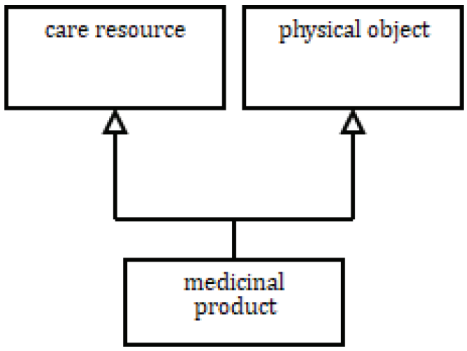


Figure 49 — medicinal product (UML Representation)

3.3.22
care funds
resource provided for funding care delivery

Note 1 to entry: Funds may be provided by, for example, a health insurance fund, a governmental agency, a national or local authority, a welfare programme, the subject of care or any other person or organization having a role in the funding of care.

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