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Zdravstvena informatika - Sistem pojmov za podporo neprekinjeni oskrbi - 2. del: Proces zdravstevene oskrbe in potek dela

Health informatics - System of concepts to support continuity of care - Part 2: Health care process and workflow

Medizinische Informatik - Begriffssystem zur Unterstützung der Versorgungskontinuität - Teil 2: Gesundheitsfürsorge-Prozess und Arbeitsablauf

Informatique de la santé - Système de concepts en appui de la continuité des soins - Partie 2: Processus de soins et flux des tâches

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Health informatics - System of concepts to support continuity of care - Part 2: Health care process and workflow

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

Management Centre: Avenue Marnix 17, B-1000 Brussels

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Foreword

This document (prEN 13940-2:2010) has been prepared by Technical Committee CEN/TC 251 “Health informatics”, the secretariat of which is held by NEN.

This document is currently submitted to the CEN Enquiry.

The two-part standard 13940 under the general heading Health informatics – System of concepts to support Continuity of care" consists of the following parts:

Part 1: Basic concepts.

Part 2: Health care process and workflow.

0 Introduction

0.1 General

Continuity of care is increasingly invoked nowadays as one of the most important issues in health care. What is in perspective is both an improvement of the quality of care, and a reduction of costs. Continuity of care is now seen as prerequisite to improve at the same time efficacy, effectiveness and efficiency of health care.

Thus there is a need for clinicians, private and public health care providers, health managers, and funding organisations to base their decisions, in terms of re-organisation of services, on a good understanding of the concepts involved.

This European Standard defines the classes of concepts and their descriptive terms, regarding all processes of care, especially considering patient-centred continuity of care, shared care and seamless care.

Continuity of care depends on the effective transfer and linkage of data and information about both the clinical situation and the health care provided to a subject of care, between different parties involved in the process, within the framework of ethical, professional and legal rules. The description and formalisation of continuity of care in information systems implies that the related concepts and descriptive terms be defined, so establishing a common conceptual framework across national, cultural and professional barriers.

This part standard defines a set of concepts reflecting phenomena that are basically part of the processes in health care concerning an individual subject of care. The health care process reflects the interaction between the subject of care and health care professionals in general. The clinical process is defined by a clinical context to cover the continuity aspects from the subject of care perspective. The actual focus of that process is the health state of a subject of care. This document focuses the concepts related to the health care and the clinical processes as well as the workflow of the clinical process. This second part of the two-part standard supplements the first part from this perspective. With the aim to further clarify and give traceability to the concepts, this document also includes an informative part with generic models of the clinical process and the workflow of that process.

0.2 Target groups

The system of concepts and the terms defined in this European Standard are designed to support the management of health care related information over time and the delivery of care by different health care actors who are working together. This includes primary care professionals and teams, health care funding organisations, managers, patients, secondary and tertiary health care providers, and community care teams.

This harmonised system of concepts will be used to facilitate clinical and administrative decision making, and to enhance relationships between health care professionals and their patients.

Among other applications, the content of this European Standard should have importance for the development of well designed clinical networks, either at regional — possibly cross-border —, or at local level, either including hospital settings or not; it will help the correct management of personal health data. It provides a clear conceptual framework to establish the terms of reference of health information systems, to be used for tenders.

The system of concept as well as the process and workflow descriptions are meant as tools for the development of information systems. They may also be used for business analysis as a basis for organisational decisions and more widely in organisational developments that are not inherently tied to the use of ICT.

0.3 Health

In 1948 WHO defined health as "... a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity". We interpret this definition as being the one of 'good health', which means that any harm to the physical, mental or social condition of a person has the effect that health is no longer present. This definition by WHO does not include any incompleteness of "health", meaning that the presence of any disease or (health) problem, calling or not for health care activities causes the subject of care not to possess health. To our eyes, WHO defines something that most people would consider to be "good health" or even "best possible health", the ultimate target for any intervention meant to restore, maintain or stabilise an individual's or a population's welfare. 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". Thus health still includes several quality perspectives and is not just inherent characteristics of an individual.

In ICF (the International Classification of Functioning, Disability and Health) of WHO, the concept of health is described in a more specified way. The theoretical model in ICF identifies five health components; body function, body structure, activity and participation, personal and environmental factors respectively. And it is noteworthy that in the introduction of an article published on Saturday 22 March 2003 in the Health Care Financing Review[1], Tevfik Bedirhan Üstün et al. also write: *"The health state of a person can be described in terms of capacity to carry out a set of tasks or actions. In addition, the health state also includes changes in body functions and/or structures arising from a health condition. The impact of the health state on a person's life can be understood by measuring performance of tasks and actions in the person's real-life or actual environment. The full picture of the health experience can further be appreciated by taking into cognisance the value that people place on levels of functioning in given domains in association with a health condition. Plainly, the concept of functional status is integral to health and its achievement. Two individuals with identical diagnoses may have utterly different levels of functioning that determine their actual health status."*

In this European 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's of care health state or health condition, often in relation to a health care/clinical process. To describe, for example, a body function, a mental state, a degree of general well-being, and causes for interventions in the domain of health care, this European Standard uses the terms *"health state"*, *"health condition"* and *"health issue"*. The *health state* is a concept reflecting a holistic view of the health of a human being. The *health condition* is a perception of an aspect or part of the health state and it may be good or bad. The *health issue* is the reason for the request for health care and it may or may not encompass a disease but it is always subject to assessment with respect to whether *health care activities* are needed, including medical statements, immunisation and other activities performed for a person in good *health state*.

[1] "*WHO's ICF and functional status information in health records*", Health Care Financ Rev. 2003 Spring;24(3):77-88.

0.4 Notes

0.4.1 General

These notes apply to this European Standard in general.

0.4.2 Subject of care

In this European Standard, 'subject of care' refers to an individual. It is assumed that in those cases where a health care activity addresses a group of more than one individual (e.g. a family, a community), and where a single health record is used to capture the health care activities provided to the group, each individual within the group will be referenced explicitly within that health record.

0.4.3 Health care versus social care

Health care as well as social care has the objective to restore, maintain, and keep health in the WHO sense. Health care is not limited to clinical activities with influence on body function or body structure. All kinds of activities having the potential to influence any one of the five components of health mentioned in ICF can be part of health care. Activities interacting with intellectual functions may have the purpose to improve the health state; such activities include informative and supportive talk as well as psychotherapy. Provision of a walking cane may be an act of rehabilitation and is considered to be within the scope of health care. In social care oral information as well as provision of physical aid may contribute to the restoration of health. There is an obvious overlap between health care activities and social care activities. This standard is focussed on the part of health care that does not include social care. The role of the subject of care is defined out from that health care domain and the terms chosen are from that sector. However many of the concepts are relevant for the social care sector and in the cooperation of the different domains of health care this standard should be applicable, though it is not the primary aim of this standard to directly be applied in social care.

0.4.4 Description and display of concepts

This European Standard aims to identify and describe concepts important to continuity of care, and to establish a system of concepts that is to be used when setting up information systems, especially when dealing with health record communication. The primary focus of the standard is terminology and ontology.

Descriptions framed in tables having the same pattern of rubrics are systematically provided for all the concepts presented in Clauses 7 to 12. Whenever not felt relevant to a given concept, some of these rubrics may intentionally be left blank. In the headings of these tables, the names of those concepts that are purely abstract constructs and therefore are not instantiable but through their specialisation, are shown in italic characters.

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

In order to help the readers understand more easily the relationships between these concepts, diagrams have been introduced based on UML conventions. Thus, for each one of the concepts described in Clauses 6 to 11, a subset of the general and comprehensive diagram is provided as an illustrative part of the monograph, 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 proposed at the beginning of each one of Clauses 6 to 11. These diagrams are focused on the topic addressed in the corresponding clause. For instance: actors, or health data management. For a better clarity, they only show the relationships between the concepts defined in that clause and, except for Clause 6, all relationships between those concepts and concepts defined in other clauses of this European Standard. For Clause 6 the relationship with a number of concepts that are not defined in this standard is shown. For clarity of reading, concepts defined in the clause the diagram is a part of are shown in white. Concepts defined in other clauses of the standard are shown in

grey, concepts defined in part 1 (see EN 13940-1) are shown in yellow while concepts not defined in this standard is light grey, without frames.

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

Besides, there are related features and other related entities which may be considered as concepts in their own right. They are usually of a generic nature, and do not belong to the system of concepts which is the focus of this European Standard. As a consequence, they are not described any further. An example of this is: a subject of care may have an undefined number of addresses, and an address may be associated with an undefined number of subjects of care. The resolution of this 'many to many' relationship is not within the scope of this European Standard.

In order to differentiate them both from normal attributes and from concepts with which direct relationships are explicitly mentioned, these features are shown apart, in a rubric called "features or related entities not described in this document".

0.4.5 Concept modelling vs. information modelling

[The concepts designated by terms printed in italic in this sub-section are defined in ISO 1087:2002].

Concept modelling may be used for two purposes. The main purpose is to graphically describe a *concept system* within a *subject field*. This description can clarify the relationships between the *concepts*, and illustrate some of their *definitions*. The other purpose is to let a concept modelling tool set up a data base organising the *concept system*, in order to keep track of its *concepts* and relationships, as well as check its consistency.

Information modelling has the purpose of organising the information objects, each one representing knowledge about a concept. There is however additional information in an information model about the properties of the information objects, shown as attributes to the objects, and operations describing behaviour of the objects.

All *concepts* have the same degree of integrity, and in a concept model all *concepts* should be modelled in the same way. In UML this means that a *concept* is represented by a class. There are no attributes or operations in the classes. A *characteristic* of a *concept* is also a *concept*, and its function as *characteristic* is therefore modelled as a relation to the core *concept*. Relations may be *generic* making the *specific concept* inherit all *characteristics* of its *generic concept*. The *specific concept* has additional *characteristics* modelled as *concepts* associated to the *specific concept*.

Beside *associative relations* and *generic relations* there are *partitive relations* describing *partitive concepts* being parts of a *comprehensive concepts*.

If a relation between two *concepts* denotes an *essential characteristic* of the core concept, this relation can probably be used when the core *concept* is to be textually defined. Also *concepts* not being *characteristics* of another *concept* may be related, and it may be clarifying to show this relation graphically. Equally, not all *characteristics* used in a *definition* have to be shown in the graph.

In an information model a lot of information objects should be added. They are often modelled as attributes. The relations between the information objects, drawn as classes in the UML are often the same as in the concept model. Some related *concepts* are not necessary to show as classes of their own, and they may then be represented as attributes of their class. Even some *characteristics of concepts* may be better represented as attributes than as separate classes in the information model. The information model needs to be a robust template for a data model, which can be used in the creation of a data base keeping information of those objects which have been conceptually analysed in the concept model.

In this European Standard *concepts* are described in text and models. The models comply with the principles described here above. The tables list the relationships of each *concept*, but they also list those attributes that are considered important to be included in an information model though they are not necessary to describe the *concept system*.

0.4.6 Frequent use of the term 'care' instead of 'health care'

The scope of this European Standard regards topics related to continuity of health care. However, in this document the shorter term 'care' is often used and is to be understood as a synonym for the longer term 'health care'. Examples of this are: 'continuity of care', 'subject of care', 'episode of care', 'period of care', 'care plan'... Would the concepts hereby described be used in another context, the complete phrase 'health care' might have to be systematically used wherever relevant in order to provide full consistency in that context.

1 Scope

1.1 Main purpose

This part standard supplements Part 1(EN 13940-1). Its specific purpose is to define a system of concepts for the provision of care in clinical processes to an individual subject of care and the corresponding workflow. Furthermore the concepts aim to enable the management, including communication, so as to support continuity of care, taking into consideration data handling, decision making, quality control, and resource management. It provides the terminology for planning, delivery and follow-up of the activities and health conditions that form the overall health care and clinical process. An additional aim is to enable the reuse of clinical data for other purposes than the direct care of an individual subject of care at group level for follow up and knowledge management.

This part standard identifies the most common objects processed that can be identified in clinical processes. It also takes into consideration the resource aspects, the responsibilities of health care providers and means for subject's of care participation. Whenever continuity of health care delivery implies social interventions as part of, or in support to, the health care process towards health recovery, these are to be mentioned wherever relevant in the process and workflow descriptions; but addressing those social interventions in depth is not within the scope of this European Standard.

1.2 Topics outside the scope

This European Standard does not mean to be prescriptive with regard to the performance or not of any health care activities or to the clinical content of the specific processes of health care; neither does it prescribe a specific method or language for process modelling.

2 Conformance

2.1 Full conformance

In order to be declared fully conformant with the current European standard, an information system shall:

1. implement all the concepts which the current European standard defines in its normative provisions;

2. implement all the relationships between these concepts, as defined in this European standard, including their relationship type;

3. keep the multiplicity of these relationships within the intervals defined by this European standard.

Additionally:

4. Whenever any term used in this European standard to designate a concept is used in the description of the information system, it shall refer to the same concept, and therefore bear the same meaning.

5. Symmetrically, if a term other than the one used in this European standard is proposed to designate a concept which would nevertheless strictly match the same description as per this European standard, its synonymy shall be explicitly stated.
This requirement applies particularly to all languages other than English, French, and German, in which this European standard is officially translated.

2.2 Partial conformance

Partial conformance shall only be declared if the parts of this European standard with which the conformance of an information system is claimed are precisely and accurately stated.

3 Normative references

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

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

ISO 704, *Terminology work – Principles and methods*

ISO 10241, *International terminology standards – Preparation and layout*

ISO/TR 24156, *Guidelines for using UML notation in terminology work*

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

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

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

4 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 1087-1, EN 12264 and EN 13940-1 and the following apply.

4.1
commitment
acceptance of a request or of an assignment

4.2
consent
agreement, approval, or permission as to some act or purpose given voluntarily by a competent person

[ISO 18308:2009]

4.3
unintended event
phenomenon which is not part of the normal course of a *process* but may influence it

NOTE 1 An unintended event can be either expected or unexpected.

NOTE 2 activities in a process are deliberate and have its purpose(s). 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.

EXAMPLES 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.

4.4
health care activity management
actions to organise, allocate resources and schedule *health care activities* in a *care plan*

4.5
health care assessment activity
action, based on *knowledge* and information, to create an opinion related to *health conditions* and/or *health care activities*

4.6
health care evaluation activity
action where the result or effect of a *health care activity* is analysed and compared to what was expected

4.7
health care investigating activity
health care activity with the intention to clarify one or several *health conditions* of a *subject of care*

4.8
health care planning activity
action aiming to include and/or change *health care activities* in a *care plan*

4.9
knowledge
facts, information, and skills acquired through experience, reasoning or education

4.10
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

[EN ISO 14971:2009]

NOTE 1 This definition has been developed by the Global Harmonization Task Force (GHTF)

NOTE 2 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 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.

NOTE 4 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 704. The meaning is simply, that a device used for service of a medical device is included in the definition.

4.11
process
set of interrelated or interacting activities which transforms inputs into outputs

[ISO 9000:2000, 3.4.1]

NOTE 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 sometimes be considered as resources in a process.

4.12
quality in health care
degree to which health care fulfil requirements related to defined quality characteristics

Note Quality is defined in ISO 9000:2005, 3.11 as “degree to which a set of inherent characteristics fulfil requirements”

4.13
quality management
coordinated activities to direct and control an organisation with regard to quality

[ISO 9000:2005, 3.2.8]

4.14
quality assurance
part of *quality management* focused on providing confidence that quality requirements will be fulfilled

[ISO 9000:2005, 3.2.11]

4.15
quality control
part of *quality management* focused on fulfilling quality requirements

[ISO 9000:2005, 3.2.10]

4.16
quality management system
management system to direct and control an organisation with regard to quality

[ISO 9000:2005, 3.2.3]

4.17
resource
entity available, or potentially available for use in a process

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

4.18
responsibility
duty to adequately execute a mission in the framework of assigned entitlement and resources

NOTE A mission can be executed only if the appropriate resources are at disposal and the one having the mission has got an appropriate entitlement to perform the activities necessary within the mission. The responsibility can never reach beyond the entitlement and what is possible with the available resources. As long as the resources are available, the entitlement is effective and the mission lasts, the responsibility cannot be renounced.

4.19
risk
the combination of the probability of an event and its consequences

[ISO-IEC Guide 73]

4.20
risk factor
personal characteristic --genetic or acquired-- that increases the probability that a person's health state be harmed

EXAMPLE Life style, behaviour, exposure, health issue.

4.21
task
activity which does not need to be further broken down into smaller activities

5 Symbols and abbreviations

The following abbreviations are used for the terms defined in this European standard:

DRG Diagnosis-Related Group

EHR Electronic Health Record

ICF The International Classification of Functioning, Disability and Health