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Health informatics — System of concepts to support continuity of care

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

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ISO copyright office
Ch. de Blandonnet 8 • CP 401
CH-1214 Vernier, Geneva, Switzerland
Tel. +41 22 749 01 11
Fax +41 22 749 09 47
copyright@iso.org
www.iso.org

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Foreword

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

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

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

0 Introduction

0.1 General

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

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

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

0.2 Aims for this International Standard

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

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

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

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

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

0.3 About the concept of health

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

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

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

0.4 Healthcare versus social care

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

0.5 Intended users for this International Standard

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

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

0.6 Architecture of this system of concepts

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

- Healthcare/clinical processes
- Management
- Support

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

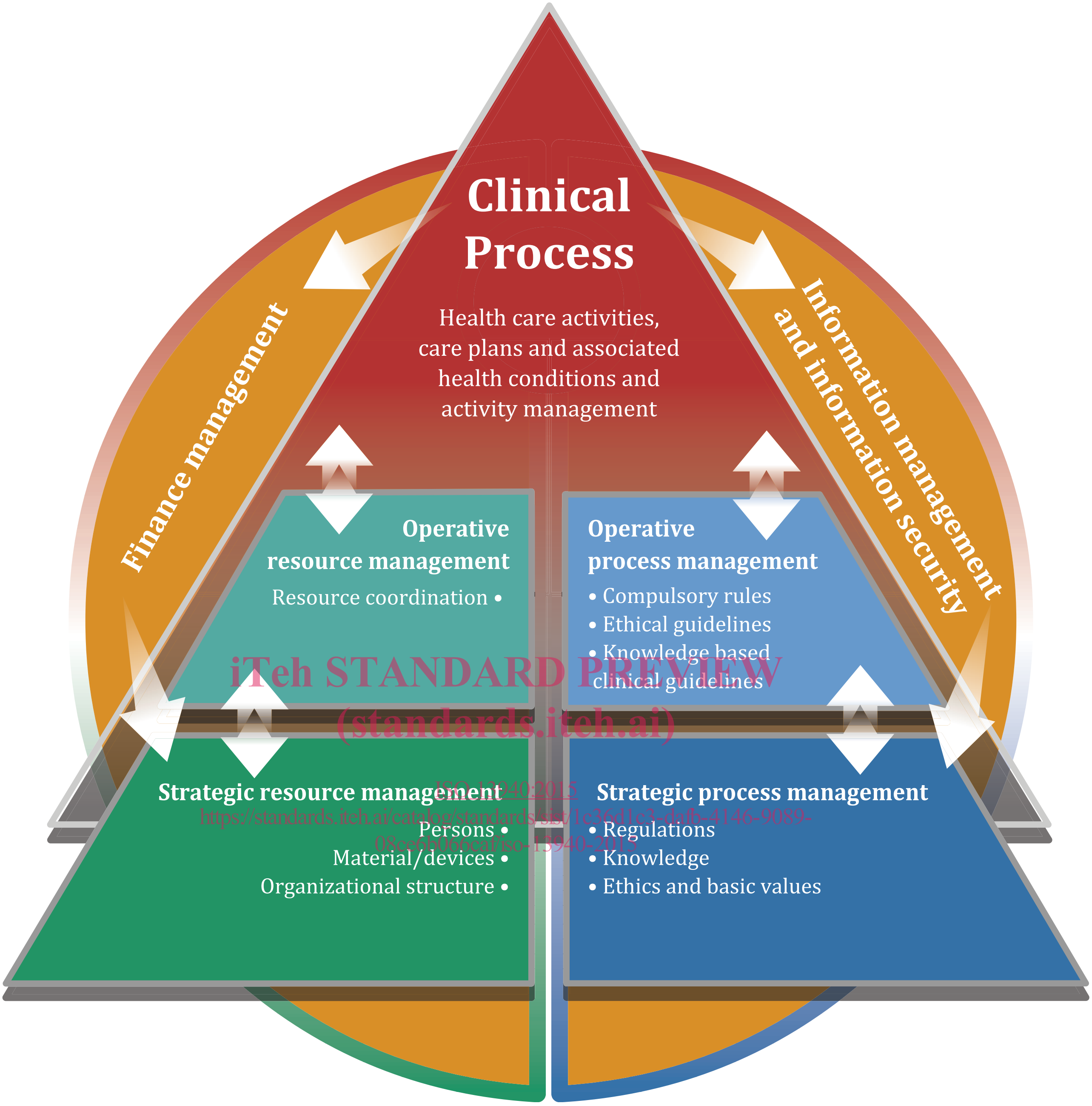
Clinical Process
Health care activities, care plans and associated health conditions and activity management
Finance management
Information management and information security
Operative resource management
Resource coordination •
Operative process management
• Compulsory rules
• Ethical guidelines
• Knowledge based clinical guidelines
Strategic resource management
Persons •
Material/devices •
Organizational structure •
Strategic process management
• Regulations
• Knowledge
• Ethics and basic values

Figure 1 — Architecture of the concept areas

0.7 Description and display of concepts

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

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

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

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

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

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

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

Health informatics — System of concepts to support continuity of care

1 Scope

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

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

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

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

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

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

2 Normative references

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

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

3 Terms and definitions

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

3.1 Healthcare

3.1.1
healthcare
care activities, services, management or supplies related to the health of an individual

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

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

3.1.2
continuity of care
efficient, effective, ethical care delivered through interaction, integration, co-ordination and sharing of *information* (3.9.5) between different healthcare actors over time

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

3.2 Concepts and terms

3.2.1
concept
unit of knowledge created by a unique combination of characteristics

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

3.2.2
system of concepts
DEPRECATED: concept system
set of *concepts* (3.2.1) structured according to the relations among them

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

3.2.3
deprecated term
term rejected by an authoritative body

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

3.3 Actors

3.3.1
organization
unique framework of authority within which a *person* (3.3.4) or persons act, or are designated to act towards some purpose

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

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

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

3.3.2
organizational pattern
relationships between the various parts of an *organization* (3.3.1)

3.3.3
party
person or group performing a *role* (3.3.5) in relation to the business of a specific community or domain

[SOURCE: ISO 8459:2009, 2.33]

3.3.4
person
human being regarded as an individual

3.3.5
role
function or position

[SOURCE: ISO/HL7 21731:2006]

3.3.6
person role
role (3.3.5) of a *person* (3.3.4)

3.3.7
organization role
role (3.3.5) of an *organization* (3.3.1)

3.4 Resources

3.4.1
resource
asset that is utilized or consumed during the execution of a *process* (3.6.1)

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

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

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

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

3.4.2
medical device
any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of

— diagnosis, prevention, monitoring, treatment or alleviation of disease,

— diagnosis, monitoring, treatment, alleviation of or compensation for an injury,

— investigation, replacement, modification, or support of the anatomy or of a physiological process,

— supporting or sustaining life,

— control of conception,

— disinfection of medical devices,

— providing *information* (3.9.5) for medical purposes by means of *in vitro* examination of specimens derived from the human body,

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

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

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

— aids for disabled/handicapped people,

— devices for the treatment/diagnosis of diseases and injuries in animals,

— accessories for medical devices (see Note 3),

— disinfection substances,

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

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

[SOURCE: ISO 14971:2007, 2.9]

3.4.3
medicinal product
any substance or combination of substances that can be administered to human beings for treating or preventing disease, with the view to making a medical diagnosis or to restore, correct, or modify physiological functions

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

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

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

[SOURCE: ISO 11615:2012, 3.1.49]

3.5 Management

3.5.1
quality in healthcare
degree to which *healthcare* (3.1.1) fulfils requirements related to defined quality characteristics

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

3.5.2
quality management
management with regard to quality

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

[SOURCE: ISO 9000:2015, 3.3.4]

3.5.3
quality assurance
part of *quality management* (3.5.2) focused on providing confidence that quality requirements will be fulfilled

[SOURCE: ISO 9000:2015, 3.3.6]

3.5.4
quality control
part of *quality management* (3.5.2) focused on fulfilling quality requirements

[SOURCE: ISO 9000:2015, 3.3.7]

3.5.5
risk
combination of the probability of an event and its consequences

[SOURCE: ISO Guide 73:2009, 1.1]

3.5.6
unintended event
phenomenon that is not part of the normal course of a *process* (3.6.1) but might influence it

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

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

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

3.6 Process management

3.6.1
process

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

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

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

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

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

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

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

[SOURCE: ISO 9000:2015, 3.4.1]

3.6.2
process model
representation of a *process* (3.6.1)