TECHNICAL SPECIFICATION

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Health informatics — Telehealth services — Quality planning guidelines

Informatique de santé — Services de télésanté — Lignes directrices pour la planification de la qualité

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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*.

Introduction

Aging populations are driving the demand for healthcare in many countries. Extended life expectancy will bring increased health issues for many people. Health systems are seeking to lower the demand for hospital beds by shortening the periods of hospitalization and providing more health care outside of the acute sector. The acute sector can also be geographically concentrated in capital cities which increases the potential demand for health services in primary care, community care settings, and preventative health care. Despite such measures, the demand for healthcare professionals and resources is likely to increase across all these care settings.

The use of information and communication technologies (ICT) is growing within the healthcare sector. The applications for ICT include devices and equipment that have embedded software. Originally, ICT was mainly used only within larger healthcare organizations, but has now spread throughout the healthcare sector. Applications and devices that use many types of information and communication technologies, including embedded software are now widely available for use in hospital clinics and the homes of patients or clients.

Healthcare organizations and healthcare supporting organizations can provide or support healthcare services using information and communications technologies (ICTs) to deliver health services and transmit health information over both long and short distances. The use of ICT in this way is known as telehealth or telemedicine services.

Although the use of ICT applications to deliver health care in community settings, in patient's homes, and connect healthcare professionals is seen as advantageous, there are additional risks to the quality of health care services when delivered at a distance using ICT. This Technical Specification provides guidelines on the development of quality plans to manage these risks. These guidelines are intended for use by healthcare organizations and healthcare supporting organizations.

A quality plan identifies the desired quality characteristics, related quality objectives, and quality procedures. This Technical Specification provides examples of generally applicable quality plans applicable to telehealth services.

Health informatics — Telehealth services — Quality planning guidelines

1 Scope

A growing number of initiatives in various countries around the world, most of them small-scale, are described as telehealth or telemedicine or m-health projects. It is not yet clear when the term telehealth or telemedicine should be used to describe such initiatives, because these terms can be described and interpreted in different ways in the absence of a unifying concept.

Telehealth is the use of information and communications technologies to deliver healthcare and transmit health information over both long and short distances. Telehealth is a form of care provision that extends the reach of care, reduces the need for care recipient or client travel and mobility, supports choice in healthcare service delivery, preventative care, individual self-care, and may also increase the efficiency of care. Currently telemedicine is seen as a providing a subset of a broader suite of telehealth services. Telehealth also includes ICT applications that support a wider set of activities including educational and administrative use.

This Technical Specification provides advice and recommendations on how to develop quality objectives and guidelines for telehealth services that that use information and communications technologies (ICTs) to deliver healthcare over both long and short distances by using a *risk management process*. The following key requirements are considered when developing quality objectives and guidelines for telehealth services:

— management of telehealth quality processes by the healthcare organization;

— management of financial resources to support telehealth services;

— processes relating to people such as workforce planning, healthcare planning, and responsibilities;

— provision of infrastructure and facilities resources for telehealth services;

— management of information and technology resources used in telehealth services.

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 31000:2009, *Risk management — Principles and guidelines*

3 Terms and definitions

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

3.1 Quality characteristics

3.1.1
accessibility
usability of a product, service, environment, or facility by people within the widest range of capabilities

EXAMPLE Accessibility of healthcare for recipients.

[SOURCE: Based on ISO 9241-20]

3.1.2
accountability
responsibility of an organization for its decisions and activities, and state of being answerable to its governing bodies, legal authorities, and, more broadly, its other stakeholders regarding these decisions and activities

EXAMPLE Accountability for healthcare activities delivered by a healthcare organization.

[SOURCE: ISO 26000, 2.1, modified]

3.1.3
appropriateness
extent to which healthcare activities enable care recipients to achieve specified objectives

EXAMPLE Appropriateness of a healthcare activity for care recipients and healthcare organizations.

[SOURCE: ISO/IEC 25010, modified]

3.1.4
competency
ability to apply knowledge and skills to achieve intended results

EXAMPLE Competency to participate in healthcare activities of care recipients or healthcare professionals.

[SOURCE: ISO/IEC 17021:2011, 3.7]

3.1.5
confidentiality

extent to which information is not made available or disclosed to unauthorized entities

Note 1 to entry: In this context, entities include individuals, processes, and healthcare actors.

EXAMPLE Confidentiality of information to maintain the privacy of the care recipient in society or social life.

[SOURCE: ISO/IEC 27000:2014, modified]

3.1.6
continuity
component of patient care quality consisting of the degree to which the care needed by a patient is coordinated among practitioners and across organizations and time

EXAMPLE Continuity of healthcare especially when several healthcare professionals or organizations share the delivery of services to a single care recipient.

[SOURCE: ISO/TR 18307:2001]

3.1.7
dependability
collective term used to describe the availability performance and its influencing factors, reliability performance, maintainability performance, and maintenance support performance

EXAMPLE Dependability of healthcare for care recipients and healthcare organizations.

[SOURCE: ISO 9000:2005, 3.5.3]

3.1.8
effectiveness
extent to which planned activities are realized and planned results achieved

EXAMPLE Effectiveness of healthcare activities in improving the quality of life and health outcomes of care recipients and their informal caregivers.

[SOURCE: ISO 9000:2005, 3.2.14]

3.1.9
efficiency
relationship between the results achieved and how well the resources have been used

EXAMPLE Efficiency of healthcare activities in improving the quality of life and health outcomes of care recipients and healthcare providers.

[SOURCE: ISO/IEC 27000:2014, 2.14]

3.1.10
inclusivity
intention or policy of including people who might otherwise be excluded or marginalized, such as the handicapped, learning-disabled, or racial and sexual minorities

EXAMPLE Inclusivity of the care recipient in society or social life.

Note 1 to entry: Refer to ISO 26000 for further discussion of this concept.

[SOURCE: The Oxford Pocket Dictionary of Current English, 2009]

3.1.11
safety
freedom from unacceptable risk or harm

EXAMPLE Safety measures that maintain the health of care recipients and healthcare professionals.

[SOURCE: ISO/IEC Guide 51:1999, modified]

3.1.12
transparency
openness about decisions and activities that affect the care recipient, and willingness to communicate these in a clear, accurate, timely, honest, and complete manner

EXAMPLE Transparency of healthcare activities.

[SOURCE: ISO 26000:2010, 2.1.24, modified]

3.1.13
usability
extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency, and satisfaction in a specified context of use

EXAMPLE Usability of the systems providing healthcare for care recipients and healthcare professionals.

[SOURCE: ISO 9241:2011]

3.2 Actors

3.2.1
care recipient
person seeking to receive, receiving, or having received healthcare

Note 1 to entry: Based on ISO 13940:—, 5.2.1 definition of subject of care

3.2.2
client
person seeking to receive, receiving, or having received healthcare

EXAMPLE A client may have a contract or agreement for the provision of healthcare using telehealth. If the subject of care is not capable of engaging in an agreement, a subject of care proxy or a legally authorized proxy may act on behalf of the client.

[SOURCE: Based on ISO 13940:—, 5.2.1]

3.2.3
healthcare actor
organization or person participating in healthcare

Note 1 to entry: An individual person may be regarded as a legal entity in some situations depending on the service being delivered and the relevant national legislation.

[SOURCE: Based on ISO 13940:—, 5.2]

3.2.4
healthcare organization
organization whose healthcare personnel participate in the direct provision of healthcare

EXAMPLE A care team, a group practice, a hospital department, a self employed healthcare professional.

[SOURCE: ISO 13940:—, 5.2.2.1]

3.2.5
healthcare professional
healthcare personnel having a healthcare professional entitlement in a given jurisdiction

[SOURCE: ISO 13940:—, 5.2.3.2]

3.2.6
healthcare supporting organization
healthcare third party having organizational role

EXAMPLE Public health organization, organization that focus on wellness, fitness, and/or prevention, a homecare service organization, a health insurance fund, the operator of a telehealth service.

[SOURCE: ISO 13940:—, 5.2.4.2]

3.2.7
healthcare third party
healthcare actor other than a healthcare organization, professional, or the subject of care

EXAMPLE Spouse, neighbour, family members, and friends.

Note 1 to entry: This Technical Specification may use the following term as a synonym: informal caregiver.

[SOURCE: ISO 13940:—, 5.2.3, modified]

3.2.8
informal care giver
healthcare third party having person role

EXAMPLE A relative (family member), a neighbour.

[SOURCE: ISO 13940:—, 5.2.3.1, modified]

3.2.9
organization
group of people and facilities with an arrangement of responsibilities, authorities, and relationships

[SOURCE: ISO 9000:2005, 3.3.1]

3.2.10
person
human being regarded as an individual

Note 1 to entry: An individual person is not intended to also be regarded as a legal entity for legislative purposes.

[SOURCE: The Oxford Pocket Dictionary of Current English, 2009]

3.2.11
subject of care
person seeking to receive, receiving, or having received healthcare

Note 1 to entry: This Technical Specification may use the following terms as synonyms: subject of healthcare, patient, client, care recipient

Note 2 to entry: In applying this Technical Specification, it is possible that the subject of care may be considered to be a group of people.

[SOURCE: ISO 13940:—, 5.2.1, modified]

3.2.12
subject of care proxy
person having the right to take decisions on behalf of the subject of care

[SOURCE: ISO 13940:—, 5.2.3.3, modified]

3.3 Care

3.3.1
adverse event
unintended event that may negatively influence a healthcare process

[SOURCE: ISO 13940:—, 8.2.4]

3.3.2
authorization by law
provision in legislation that in certain circumstances may overrule the need for informed consent

[SOURCE: ISO 13940:—, 11.2.7]

3.3.3
clinical guidelines
set of systematically developed statements to assist the decisions made by healthcare actors about healthcare activities to be performed with regard to specified health issues

[SOURCE: ISO 13940:—, 9.2.4]

3.3.4
consent competence
capability of the subject of care and/or the subject of care proxy to give informed consent or dissent

[SOURCE: ISO 13940:—, 11.2.5.1]

3.3.5
guideline
systematically developed requirements to assist decisions

Note 1 to entry: Guidelines should be structured and contain requirements that can be verified through the provision of objective evidence.

[SOURCE: ISO 9000:2005, 3.8.4, modified]

3.3.6
health record
data repository regarding the health and healthcare of a subject of care

[SOURCE: ISO 13940:—, 12.2]

3.3.7
healthcare
care activities, services, or supplies related to the health of an individual

[SOURCE: ISO 13940:—, 3.1.1]

3.3.8
healthcare activity
activity performed for a subject of care with the intention of directly or indirectly improving or maintaining the health state of the subject of care

Note 1 to entry: See ISO 13940:—, 6.2.1.1.2 for a detailed definition of *health state*.

[SOURCE: ISO 13940:—, 7.2]

3.3.9
healthcare funds
funds provided for healthcare delivery

[SOURCE: ISO 13940:—, 5.2.4]

3.3.10
healthcare mandate
mandate (commission) based on a commitment and either an informed consent or an authorization by law, defining the rights and obligations of one healthcare actor with regard to their involvement in healthcare processes performed for a specific subject of care

[SOURCE: ISO 13940:—, 11.2]

3.3.11
healthcare needs assessment
healthcare assessment during which a healthcare professional considers a subject of care's health need and determines the needed healthcare activities

[SOURCE: ISO 13940:—, 7.2.4.4.1]

3.3.12
healthcare plan
dynamic, personalized plan including identified needed healthcare activities, health objectives, and healthcare goals, relating to one or more specified health issues in a healthcare process

[SOURCE: ISO 13940:—, 9.2]

3.3.13
healthcare process
set of interrelated or interacting healthcare activities which transform inputs into outputs

[SOURCE: ISO 13940:—, 8.2]

3.3.14
healthcare service
service that is the result of a healthcare process

[SOURCE: ISO 13940:—, 8.2.5]

3.3.15
informed consent
permission to perform healthcare activities, voluntarily given by a subject of care having consent competence or by a subject of care proxy, after having been informed about the purpose and the possible results of the healthcare activities

[SOURCE: ISO 13940:—, 11.2.5.1]

3.3.16
procedure
specified way to carry out an activity or process

[SOURCE: ISO 9000:2005, 3.4.5]

3.3.17
process
set of interrelated or interacting activities which transform inputs into outputs

[SOURCE: ISO 9000:2005]

3.3.18
professional health record
health record held under the responsibility of one healthcare organization and maintained by one or several healthcare professionals

[SOURCE: Based on ISO 13940:—, 12.2.1]

3.3.19
protocols
customized guidelines

[SOURCE: ISO 13940:—, 9.4.2.1]

3.4 Quality

3.4.1
quality
degree to which a set of inherent characteristics of a product, fulfils requirements

[SOURCE: ISO 9000:2005, 3.1.1]

3.4.2
quality characteristic
inherent characteristic of a product, process, or system related to a requirement

Note 1 to entry: Refer to ISO 9001:2005 for definitions of subsidiary terms.

[SOURCE: ISO 9000:2005, 3.5.2]

3.4.3
quality management
coordinated activities to direct and control an organization with regard to quality

[SOURCE: ISO 9000:2005, 3.2.8]

3.4.4
quality management system
management system to direct and control an organization with regard to quality

[SOURCE: ISO 9000:2005, 3.2.10]

3.4.5
quality manual
document specifying the quality management system of an organization

[SOURCE: ISO 9000:2005, 3.7.4]