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]

3.4.6
quality objective
something sought, or aimed for, related to quality

[SOURCE: ISO 9000:2005, 3.2.5]

3.4.7
quality plan
document specifying which procedures and associated resources shall be applied by whom and when to a specific project, product process or contract

Note 1 to entry: Quality plans should be structured and contain requirements that can be verified using procedures that provide objective evidence.

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

3.4.8
quality procedure
specified way to carry out an activity or process to manage quality

[SOURCE: ISO 9000:2005, 3.4.5, modified]

3.4.9
requirement
need or expectation that is stated, generally implied or obligatory

[SOURCE: ISO 9000:2005, 3.1.2]

3.5 Risk

3.5.1
residual risk
risk remaining after risk treatment

[SOURCE: ISO 31000:2009, 2.27]

3.5.2
risk
effect of uncertainty on objectives

[SOURCE: ISO 31000:2009, 2.1]

3.5.3
risk analysis
process to comprehend the nature of risk and to determine the level of risk

[SOURCE: ISO 31000:2009, 2.21]

3.5.4
risk assessment
overall process of risk identification, risk analysis, and risk evaluation

[SOURCE: ISO 31000:2009, 2.14]

3.5.5
risk criteria
terms of reference against which the significance of a risk is evaluated

[SOURCE: ISO 31000:2009, 2.22]

3.5.6
risk evaluation
process of comparing the results of risk analysis with risk criteria to determine whether the risk and/or its magnitude is acceptable or tolerable

[SOURCE: ISO 31000:2009, 2.24]

3.5.7
risk identification
process of finding, recognizing, and describing risks

[SOURCE: ISO 31000:2009, 2.15]

3.5.8
risk management
coordinated activities to direct and control an organization with regard to risk

[SOURCE: ISO 31000:2009, 2.2]

3.5.9
risk management process
systematic application of management policies, procedures, and practices to the activities of communicating, consulting, establishing the context, and identifying, analyzing, evaluating, treating, monitoring, and reviewing risk

[SOURCE: ISO 31000:2009, 2.8]

3.5.10
risk treatment
process to modify risk

[SOURCE: ISO 31000:2009, 2.25]

3.6 Telehealth

3.6.1
ICT
information and communication technology, sometimes also referred to as information technology

3.6.2
telehealth
information and communications technologies to deliver healthcare and transmit health information over both long and short distances

EXAMPLE Telehealth may use information and communications technologies to transmit video, voice, data, images, and other forms of information.

Note 1 to entry: Telehealth may be used to bridge short or long distances. It is also possible that differences in time are bridged, using asynchronous communications.

Note 2 to entry: It is possible that prior to, or following transmission, data or information is processed in order to enhance the telehealth service.

3.6.3
telehealth service
healthcare activity undertaken using telehealth

EXAMPLE It is possible that the subject of care is not directly involved in a telehealth service, e.g. in the case of teledermatology where one physician consults another physician who is at a distant location.

Note 1 to entry: Telehealth services may support treatment, preventive (educational) and curative aspects of healthcare, the performance of administrative functions.

Note 2 to entry: A healthcare organization or healthcare supporting organization may use telehealth to provide or support healthcare.

4 Conformance

This Technical Specification provides guidance and recommendations and is not intended to be used for certification, regulatory, or contractual purposes.

The design and implementation of risk management, safety, and quality management frameworks specific to telehealth should take into account the varying needs of a specific organization, its particular objectives, context, structure, operations, processes, functions, projects, products, services, or assets and specific practices employed. This Technical Specification provides generic quality objectives and guidelines for telehealth services that can be adapted as required for application across very different organizations and services.

This Technical Specification should be used to supplement existing international and national standards and guidelines for safety, quality, and risk management in the health sector. In particular, the use of other standards, when applicable in telehealth settings is encouraged including ISO 13485 and IEC/ISO 80001.

In addition to the below-mentioned standards, general legislation, quality and safety practices that may be applicable in certain countries, whether or not specific to the domain of healthcare should be taken into account when implementing quality objectives and guidelines.

5 Quality and risk management

5.1 Telehealth risk, safety and quality assessment

Many *healthcare organizations* have put in place *quality management systems* to actively manage patient safety and healthcare quality. These systems draw upon the quality management principles and processes described in ISO 9000, ISO 9001 and ISO 9004. This Technical Specification recommends the application of ISO 9000, ISO 9001 and ISO 9004 processes in telehealth services. In particular, this Technical Specification adopts the recommendation in ISO 9004 to use ISO 31000 to help organizations identify, assess and manage risks when developing appropriate quality objectives for telehealth services.

Organizational objectives, strategies, scope and parameters of the services provided by an organization shall be established in accordance with ISO 31000. The risks that may then prevent the achievement of organizational objectives can be identified by analysing factors external to and internal to the organization.

ISO 31000 guidelines require these risks to be analysed, prioritized, and risk treatments established. In a quality management system, these risk treatments can then become the basis for quality objectives that are used to control the identified risks.

ISO 9004 recommends that an organization should identify the internal and external resources that are needed for the achievement of the organization's objectives in the short and long term. This Technical Specification supports the use of this recommendation when deriving generic quality objectives and guidelines for telehealth services. The objectives and guidelines in this Technical Specification support quality and financial management, service planning, workforce planning, healthcare planning, healthcare organization responsibilities, facilities, technology, and information management to deliver healthcare and transmit health information. This Technical Specification does not provide advice for the full implementation of ISO 9004 in a telehealth context.

5.2 Telehealth quality characteristics

Telehealth can support a broad range of healthcare activities that are not restricted to only to recipients receiving health treatments. In general, telehealth services aim to support healthcare quality characteristics that improve the quality of life and quality of care for care recipients. The quality characteristics considered by this Technical Specification include: accessibility, accountability,

appropriateness, competency, confidentiality, continuity, dependability, effectiveness, efficiency, inclusivity, safety, transparency, and usability.

In general, the quality characteristics desirable for health services delivery without the use of telehealth should also apply in situations where telehealth is used. Some quality characteristics can become more important to consider when telehealth is used for delivering health services.

5.3 Management of quality characteristics

An organization should have a quality management system in place to define and monitor the required quality characteristics of telehealth services.

The processes that impact quality and financial management, service planning, workforce planning, healthcare planning, healthcare organization responsibilities, facilities, technology, and information management should be analysed for identifiable risks that may impact a range of quality characteristics such as accessibility, accountability, appropriateness, competency, confidentiality, continuity, dependability, effectiveness, efficiency, inclusivity, safety, transparency, and usability.

Usually only a small number of these characteristics will be relevant to the development of an individual quality guideline.

The process to derive quality objectives and guidelines for the organization, people, facilities, and information used in telehealth service provision should follow the risk assessment process described in ISO 31000:2009, Clause 5 as shown in Figure 1.

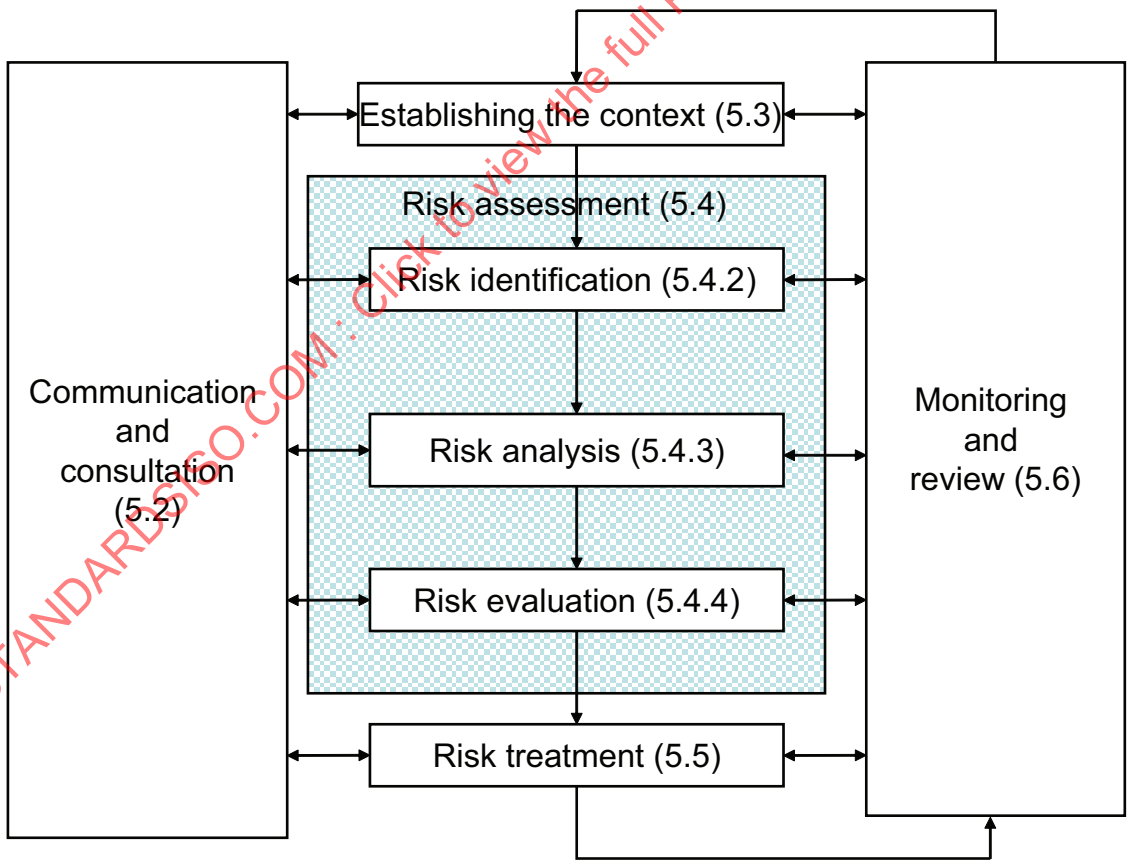

Figure 1 — Risk management process in ISO 31000:2009

5.4 Establishing the context for telehealth services

The organization should establish the context in which a telehealth service will operate in the external environment, in the internal organizational environment and the desired quality characteristics for the service.

Telehealth refers to scenarios in which healthcare actors at various locations actively cooperate in a particular health or healthcare process. Telehealth is concerned with processes and sub-processes in which at least two healthcare actors are actively involved. It is also possible for one of the actors to be the supervisor of a technical application, as in the case of a remote operation, or a digital analysis system.

It is expected that telehealth will improve the quality of health and healthcare, for example because healthcare professionals will have health information about the care recipient available in the right place at the right time, and they will have easier access to support from medical specialists. The care recipient can be monitored in his or her home, and receive advice without the need to travel to a health advisor, a healthcare professional or organization as well as having easier access to healthcare information and education to support self-care.

5.5 Risk assessment — Identification

Risk identification is the process of finding, recognizing, and identifying the risks that can prevent the achievement of the required quality characteristics for a telehealth service by analysing the healthcare processes external to and internal to the telehealth organization.

Risk identification requires the analysis of the processes occurring in management of quality, strategy, policy, and resources including financial management, service planning, workforce planning, healthcare planning, healthcare organization responsibilities, facilities, technology and information management. Some illustrative examples are provided Annex A.

5.6 Risk assessment — Analysis

Risk analysis is a process used to comprehend the nature of a risk and to determine the level of risk to the desired quality characteristics of the telehealth service.

ISO 31000:2009, 5.4.3 states that: *"risk analysis involves consideration of the causes and sources of risk, their positive and negative consequences, and the likelihood that those consequences can occur. Factors that affect consequences and likelihood should be identified. Risk is analyzed by determining consequences and their likelihood, and other attributes of the risk. An event can have multiple consequences and can affect multiple objectives. Existing controls and their effectiveness and efficiency should also be taken into account."*

5.7 Risk assessment — Evaluation

Risk evaluation is process of assessing the results of a risk analysis for the possible impact of a risk on the organization in order to determine whether the risk and/or its magnitude is acceptable or tolerable. The purpose of risk evaluation is to decide and identify, based on the outcomes of the risk analysis, which risks need treatment and their priority.

When establishing the priority order of the risks that have been identified, the following factors should be taken into account:

a) probability of a risk materializing;

b) consequences that can be expected for a desired quality characteristic if the risk materializes;

c) possible measures or processes to reduce the probability that the risk materializes;

d) expected effect of these measures or processes.

5.8 Risk treatment and quality

Risk treatment requires the selection of one or more processes (risk treatments) to modify risks. Risk treatment processes should manage the risks that have been identified and prioritized against quality characteristics that can be documented in quality plans.

Risk treatment in ISO 31000:2009 involves a cyclical process of

— assessing a risk treatment,

— deciding whether residual risk levels are tolerable,

— if not tolerable, generating a new risk treatment, and

— assessing the effectiveness of that treatment.

The resulting quality plan that will mitigate the prioritized risks should contain

a) quality characteristics: describing which quality characteristic is affected when the risk materializes (e.g. safety),

b) quality objectives: each quality characteristic should be supported by at least one quality objective (e.g. improved patient safety), and

c) quality procedures: for each quality objective there should be at least one quality procedure (e.g. identify patients at an increased risk of harm)

Each quality plan should include a statement of who should be responsible for implementing, monitoring, and reviewing the plan. Quality plans should be structured and contain requirements that can be verified through the provision of objective evidence. (Derived from ISO 9000:2005, 3.8.4.)

Quality plans for telehealth services can relate to the management of resources and/or activities by a healthcare organization, healthcare professional, healthcare organization, or healthcare supporting organization. Each quality plan should be documented in a quality manual.

6 Quality management of telehealth services

6.1 Quality characteristics

The *quality characteristics* relevant to the derivation of quality plans for the management of quality by an organization include accountability, effectiveness, safety, and transparency.

NOTE 1 This Clause does not present comprehensive guidelines for telehealth quality planning.

NOTE 2 Unless otherwise specified, the responsible organization is a healthcare organization or healthcare supporting organization.

6.2 Services description

Quality characteristic: transparency
Quality objective: The telehealth services offered by the organization are described.
Quality procedure: The organization defines in the quality manual the purposes of the services it offers, how those purposes can be achieved and how to evaluate the extent to which the purposes are achieved.

6.3 Processes description

Quality characteristic: accountability
Quality objective: The healthcare processes that use telehealth are described by the organization.
Quality procedure: The organization develops a document in that a) describes the healthcare and telehealth processes, and b) defines the responsibilities and mandates of the actors involved.
NOTE 1 This should be a complete process description, including all parties that are needed to establish the telehealth service as well as their relationships, both in terms of healthcare activity and the formal/legal aspects. NOTE 2 Telehealth services can include as actors one or more healthcare organizations, professionals, and a care recipient, for example when telehealth is used for case conferencing there may be several health professionals involved.

6.4 Quality planning

Quality characteristic: effectiveness
Quality objective: The organization has a quality plan to improve the effectiveness of telehealth services.
Quality procedure: The organization implements and maintains a quality management system for telehealth services which includes a) a description of organizational requirements, identified risks, prioritized risks and required quality plans to treat each risk as outlined in Clause 5, and b) a description of the objective evidence required to verify that a quality plan has been implemented.

6.5 Risk assessment

Quality characteristic: accountability
Quality objective: The key risks to telehealth services have been identified by the organization.
Quality procedure: The organization implements an accountable process for risk assessment that a) follows a documented risk assessment process such as that outlined in ISO 31000 for assessing the priority risks to manage, and b) makes explicit which factors influenced the assessed risks.
NOTE 1 This procedure is based on the risk analysis and risk evaluation process in ISO 31000. NOTE 2 One can use ISO 14971 and ISO 31000 as a guideline for the risk management.

6.6 Risk treatment

Quality characteristic: effectiveness
Quality objective: The organization has quality plans that contain effective risk treatments for managing risks to the quality objectives of the organization.
Quality procedure: Quality plans are derived systematically by the organization according to the processes outlined in Clause 5 and recorded in a quality manual.

6.7 Service improvement

Quality characteristic: effectiveness
Quality objective: The organization has effective healthcare processes that use telehealth.
Quality procedure: The organization ensures that it regularly reviews the description, quality planning and risk management of healthcare processes that use telehealth and revises its quality manual and plans.

6.8 Safety improvement

Quality characteristic: safety
Quality objective: The organization has safety measures for all healthcare actors in the healthcare processes that use telehealth.
Quality procedure: The organization documents a process for the management of safety in a quality and safety manual that ensures a) the risks to care recipient safety have been considered for all telehealth processes and are documented in a quality manual, b) mechanisms are in place and documented in quality plans to identify care recipients at an increased risk of harm and take early action to reduce these risks, and c) systems exist and are documented in quality plans to escalate the level of care when there is an unexpected deterioration in health status.

7 Financial management

7.1 Quality characteristics

Healthcare organizations should provide sustainable funding for telehealth services.

The *quality characteristics* relevant to the derivation of quality plans for the management of financial resources by the organization include accountability and transparency.

NOTE 1 This Clause does not present comprehensive guidelines for telehealth quality planning.

NOTE 2 Unless otherwise specified the responsible organization is a healthcare organization or healthcare supporting organization.

7.2 Sustainability

Quality characteristic: accountability
Quality objective: The organization has provided sustainable funding for telehealth services.
Quality procedure: The organization has developed a business case and implemented a financial plan that considers the costs, benefit, affordability and sustainability of telehealth services.

7.3 Healthcare funds

Quality characteristic: transparency
Quality objective: Healthcare professionals are familiar with the available healthcare funds applicable to telehealth services.
Quality procedure: The organization regularly informs healthcare professionals about the available reimbursements, funding and charges for telehealth services.

8 Service planning

8.1 Quality characteristics

Healthcare organizations are responsible for the design of telehealth services, the establishment of service levels and service durations.

NOTE 1 The plans described below refer to the delivery of care at a distance. For services that aim at delivery of health advice at a distance, education of healthcare professionals, professional-to-professional consultation, education of care recipients or informal caregivers, etc., similar plans can be derived.

The *quality characteristics* relevant to the derivation of quality plans for the management of organizationally related people resources by the organization include accessibility, appropriateness, continuity, dependability, effectiveness, and inclusivity.

NOTE 2 This Clause does not present comprehensive guidelines for telehealth quality planning.

NOTE 3 Unless otherwise specified, the responsible organization is a healthcare organization or healthcare supporting organization.

8.2 Service design

Quality characteristic: accessibility, appropriateness, continuity, inclusivity
Quality objective: The organization has accessible, appropriate and inclusive telehealth services.
Quality procedure: The organization has included in a telehealth service design document consideration of a) the ability of a care recipient to travel, their family, work and cultural situation when determining the telehealth services to be offered, b) appropriate clinical objectives and model(s) of care or shared care, c) the availability of specialists, local clinical staff and facilities required to provide service continuity when determining the telehealth services to be offered, d) potential barriers (such access to computers or telecommunications) to the inclusion of care recipients, and e) care recipients who may choose which healthcare services they consider appropriate to access, whether delivered using telehealth or not.

8.3 Service levels

Quality characteristic: continuity, dependability
Quality objective: The organization provides dependable telehealth services.
Quality procedure: The organization has included in a telehealth service design document consideration of a) at what times of day the care recipient can expect to be able to access the service, and b) for a service operating 24 h a day and 7 days a week, the expected duration of service outages.

8.4 Duration of care

Quality characteristic: appropriateness, effectiveness
Quality objective: The total duration for the healthcare activities provided by the organization using telehealth are appropriate and enable the effective delivery of healthcare.
Quality procedure: The organization specifies in a telehealth service design document the durations of the healthcare activities that are required to deliver appropriate and effective healthcare to the care recipient.

9 Workforce planning

9.1 Quality characteristics

Healthcare organizations are responsible for workforce planning to support telehealth services.

The *quality characteristics* relevant to workforce planning include competency and inclusivity.

NOTE 1 This Clause does not present comprehensive guidelines for telehealth quality planning.

NOTE 2 Unless otherwise specified, the responsible organization is a healthcare organization or healthcare supporting organization.

9.2 Workforce skills and training

Quality characteristic: competency
Quality objective: The organization has a workforce that is competent to deliver effective telehealth services.
Quality procedure: The organization ensures that a) the healthcare professional, or healthcare third party is required to possess the competencies that are necessary for providing healthcare by means of telehealth, b) appropriate minimum professional standards are applied in the assessment of the required competencies for providing healthcare by means of telehealth, and c) opportunities to complete appropriate training courses in the provision of telehealth services are made available.

9.3 Consultation with workforce

Quality characteristic: inclusivity
Quality objective: The organization has consulted with the workforce about the design of telehealth services.
Quality procedure: The organization includes staff in consultations about changes to workflow, workloads, required skills, training or other changes a telehealth service may require.

10 Healthcare planning

10.1 Quality characteristics

Healthcare organizations are responsible for healthcare plans that support healthcare activities based on clinical guidelines and protocols.

The *quality characteristics* relevant to healthcare planning include accountability, appropriateness, continuity, effectiveness, safety, and transparency,

NOTE 1 This Clause does not present comprehensive guidelines for telehealth quality planning.

NOTE 2 Unless otherwise specified, the responsible organization is a healthcare organization or healthcare supporting organization.

10.2 Healthcare processes

Quality characteristic: effectiveness, efficiency
Quality objective: Healthcare processes for telehealth services are planned and coordinated by the organization.
Quality procedure: The organization defines the clinical guidelines and protocols that support collaboration among healthcare organizations and healthcare professionals and that describe, among other things a) processes that are part of the care provision, b) roles and responsibilities of the actors in each process, and c) which elements of the professional health record are required to support the collaboration.

10.3 Healthcare plans

Quality characteristic: effectiveness, safety
Quality objective: Healthcare delivered by the organization using telehealth is effective and safe.
Quality procedure: The organization bases healthcare plans and healthcare activities on clinical guidelines and protocols a) which demonstrate evidence of their effectiveness and safety, and/or b) are recognized by a professional society. NOTE A healthcare organization may also define and maintain local clinical protocols for treatment, nursing, and care.

10.4 Healthcare continuity

Quality characteristic: continuity, safety
Quality objective: The organization can continue to provide safe healthcare if there is a failure of information and communications technology.
Quality procedure: The organization has comprehensive and layered backup healthcare plan to enable continuity of healthcare if there is a failure of information and communications technology.

10.5 Unavailable clinical guidelines and protocols

Quality characteristic: accountability, appropriateness, transparency
Quality objective: There are accountable, appropriate, and clear procedures for the delivery of healthcare using telehealth when clinical guidelines and protocols are not provided by the organization.
Quality procedure: The organization ensures when healthcare is delivered using telehealth in situations for which there are no guidelines or protocols, the following procedures should be used: a) a healthcare plan is established and healthcare activities are performed according to that plan; b) the healthcare organization is informed by the healthcare professional that a clinical guideline or protocol is lacking for that situation; c) the care recipient is informed that no clinical guideline or protocol exists for the current situation.

10.6 Adverse event management

Quality characteristic: safety, transparency
Quality objective: Any limitations or risks resulting from the use of telehealth that may increase the risk of adverse events have been identified by the organization.
Quality procedure: The organization clearly records in the healthcare plan any possible limitations and risks to healthcare activities due to the use of telehealth and takes measures to reduce such limitations or risks. NOTE This quality objective is merely a statement of duty of care, which applies for any kind of care delivered with or without the use of telehealth.

10.7 Professional health record management

Quality characteristic: appropriateness
Quality objective: Records that contain all appropriate information observed during a healthcare activity using telehealth have been kept by the organization. NOTE A healthcare activity may include a healthcare investigation and needs assessment for a care recipient.
Quality procedure: The organization develops healthcare plans that include a description of the information arising from a healthcare activity and ensures that information is recorded in the professional health record during a healthcare activity that uses telehealth. NOTE The information that will be recorded during the healthcare activity should be based on clinical guidelines. The format in which it is recorded and transmitted should be based on appropriate technical standards.

11 Responsibilities

11.1 Quality characteristics

Healthcare organizations, professionals and healthcare supporting organizations are responsible for obtaining a mandate (agreement) from a care recipient based on a commitment and either an informed consent or an authorization by law, to provide healthcare to the recipient.

The *quality characteristics* relevant to the responsibilities of healthcare organizations are: accountability, appropriateness, competency, transparency.

NOTE 1 This Clause does not present comprehensive guidelines for telehealth quality planning.

NOTE 2 Unless otherwise specified, the responsible organization is a healthcare organization or healthcare supporting organization.

NOTE 3 For further information on the concept of responsibilities in healthcare and a healthcare mandate, see ISO 13940:—, Clause 11.

11.2 Healthcare mandate

Quality characteristic: accountability, appropriateness, transparency
Quality objective: A mandate (agreement) from a care recipient to become involved in healthcare processes performed for the care recipient has been obtained by the organization and the healthcare professional.
Quality procedure: The organization ensures that healthcare mandates from all care recipients considering healthcare provision using telehealth services are based on a) informed consent from the care recipient giving permission to perform healthcare activities, voluntarily given by a care recipient 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, or b) authorization by law under a provision in legislation that in certain circumstances may overrule the need for informed consent,

c) a healthcare commitment consisting of a promise by the care recipient to perform healthcare activities this also means that the healthcare professional accepts and confirms the pending healthcare mandate contained in the proposed healthcare plan, and

d) a healthcare needs assessment during which a healthcare professional considers a care recipient's health needs and determines the required healthcare activities to be recorded in a healthcare plan.

NOTE 1 A healthcare mandate should be recorded in the professional health record.

NOTE 2 All applicable legal regulations for setting up a care provision relationship without telehealth between a healthcare professional and a care recipient continue to apply.

11.3 Informed consent

Quality characteristic: accountability, transparency
Quality objective: Informed consent from care recipients to perform healthcare activities has been obtained by the organization and the healthcare professional.
Quality procedure: The organization and the healthcare professional obtains informed consent from the client that confirms a) permission to perform healthcare activities, voluntarily given by a care recipient 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, b) that the care recipient has understood the information provided, and c) the care recipient has been given the option to read the provided information at a later time. NOTE 1 Where the procedures for care delivery by means of telehealth are the same as those for the non-telehealth based delivery of care - it may suffice to have an informed consent statement (in writing or verbal) that the care recipient (or client) agrees with the use of telehealth. NOTE 2 The use of common technology should not be taken for granted, e.g. a care recipient may never have used a mobile phone or never have used text messaging. Hence in most cases there will be a difference between care delivery by telehealth and without telehealth.

11.4 Care recipient preferences

Quality characteristic: accountability, appropriateness, transparency
Quality objective: Care recipients can make informed choices from the available options for healthcare whether or not delivered by telehealth from the options that have been provided by the organization and the healthcare professional.
Quality procedure: Easy access to information that is needed to make appropriate choices among the various options of healthcare provision has been provided by the organization and healthcare professionals to enable the care recipient or subject of care proxy to a) express informed choices regarding the performance of certain healthcare activities, b) request the performance of healthcare activities that do not use telehealth, and c) refuse to permit specific healthcare activities to be performed including healthcare using telehealth. NOTE Once a choice is made regarding a kind of service or service delivery, the recipient should be free to change their preferences and switch to another mode of health care delivery.

11.5 Care recipients expenses

Quality characteristic: accountability, transparency
Quality objective: Care recipients are informed by the organization of the expenses to themselves for healthcare and how and by whom these expenses will be met.
Quality procedure: The organization clearly informs the care recipient using accountable procedures of the a) financial cost for the provision of the healthcare to be delivered, and b) provisions under which reimbursements for the cost of care can be claimed from other organizations such as insurance companies that may reimburse the costs of healthcare provision.

11.6 Appropriate healthcare services

Quality characteristic: appropriateness
Quality objective: Appropriate healthcare using telehealth is provided by the organization and healthcare professionals.
Quality procedure: The organization ensures that a) provision of healthcare using telehealth is appropriate for the care recipients based on documented inclusion or exclusion criteria, and b) assessment of the appropriateness of healthcare provision using telehealth by the healthcare professional continues during the healthcare activity. EXAMPLE 1 The quality objective may be assessed by the use of healthcare needs assessment. EXAMPLE 2 The quality objective may be assessed through assessing complaints in a complaint registry about the effectiveness of healthcare that uses telehealth. NOTE 1 The competency of the care recipient may be part of the assessment. NOTE 2 Aspects of the physical environment and facilities available to the care recipient may be assessment criteria.

11.7 Competence of care recipients

Quality characteristic: competency
Quality objective: The organization and the healthcare professional can confirm that the care recipient and/or the informal caregiver are competent and motivated to perform the tasks that are part of their healthcare plan using telehealth.
Quality procedure: The organization ensures that the a) care recipient and/or informal caregiver have committed to perform their tasks required in the healthcare plan using telehealth, and b) healthcare professional regularly evaluates whether or not the care recipient and/or informal caregiver are still able and motivated to perform their tasks using telehealth.

11.8 Execution of healthcare plan

Quality characteristic: transparency
Quality objective: A healthcare plan is available from the organization and healthcare professional that transparently explains the roles, responsibilities, mandates, tasks and mutual expectations of all actors in the healthcare process.
Quality procedure: The organization ensures that the a) healthcare professional prior to the execution of the healthcare plan, informs the care recipient about the actors that will participate in the provision of healthcare and the various roles they have, b) healthcare professional prior to the execution of the healthcare plan, informs the client about which actor is responsible and therefore accountable for each part of the healthcare to be supplied, c) care recipients have been informed about how complaints about a telehealth service can be placed and will be dealt with, and d) healthcare professional at regular intervals during to the execution of the care plan, asks care recipients and possible involved informal caregivers whether they understood the advice and instructions given and whether that advice and instructions are being followed.

12 Facilities management

12.1 Quality characteristics

Telehealth services depend on using adequate facilities, including buildings and accommodation. Since the use of facilities is part of the healthcare process, quality objectives should be established for the facilities required by healthcare organizations, healthcare supporting organizations, and care recipients.

The *quality characteristics* relevant to facilities management for telehealth services by healthcare organizations are: appropriateness, effectiveness, and safety.

NOTE 1 This section does not present comprehensive guidelines for telehealth quality planning.

NOTE 2 Unless otherwise specified the responsible organization is a healthcare organization or healthcare supporting organization.

12.2 Healthcare organization facilities

Quality characteristic: appropriateness, effectiveness, safety
Quality objective: Consultations using telehealth take place in accommodation that is appropriate for the healthcare professional to effectively deliver healthcare.
Quality procedure: The organization ensures that a) adequate physical space is available to conduct consultations, b) an appropriate level of comfort and privacy is available for the healthcare professional and if required a care recipient(s), c) equipment can effectively transmit and receive an appropriate quality of audio or video, and d) equipment can be used in a safe manner.

12.3 Care recipient facilities

Quality characteristic: appropriateness, effectiveness, safety
Quality objective: Consultations using telehealth take place in accommodation that is appropriate for the care recipient to effectively participate in healthcare.
Quality procedure: The organization can demonstrate that a) adequate physical space is available to conduct consultations, b) an appropriate level of comfort and privacy is available for the care recipient and an informal caregiver if required, c) equipment can be used effectively to transmit and receive an appropriate quality of information including audio or video information, and d) equipment can be used in a safe manner.

13 Technology management

13.1 Quality characteristics

Telehealth services depend on information and communications technologies to deliver healthcare and transmit health information over both long and short distances.

Since these technologies are part of the healthcare process, quality objectives should be established for information and communication technology service support, service delivery, infrastructure management, deployment management, operations management, and technical support.

Some organizations providing health services using telehealth may rely on information technology management services from an external ICT provider or a large internal ICT provider. In these cases, the quality procedures in this Clause should include definition of service level agreements with those providers. For instance, the relationship between the healthcare organization and external ICT provider should be defined in a service level agreement that specifies that when a problem occurs with equipment, the healthcare organization should communicate this to the provider and the provider must have a system for post market surveillance to detect deficiencies that occur after deployment of the equipment or device.

General purpose ICT infrastructure, including equipment, software, and communications can be used to support telehealth services. In this case, the healthcare organization or healthcare supporting organization should define appropriate service level agreements with the relevant providers.

The *quality characteristics* relevant to management of equipment, devices and technology used for telehealth services by healthcare organizations are: accountability, continuity, dependability, effectiveness, efficiency, safety, transparency, and usability.

NOTE 1 This Clause does not present comprehensive guidelines for telehealth quality planning.

NOTE 2 Unless otherwise specified, the responsible organization is a healthcare organization or healthcare supporting organization.

NOTE 3 Further advice on information technology management can be found in ISO/IEC 20000-1:2011 that provide guidance on the application of service management systems. ISO/IEC 20000-1:2011 is closely aligned with the Information Technology Library (ITIL®) and provides guidance on their relationship. This Clause does not provide guidelines on the application of (ITIL®) to achieve conformance with ISO/IEC 20000-1:2011.

NOTE 4 This Clause is intended to apply to equipment or software specifically intended by the manufacturer, healthcare organization, or healthcare supporting organization to be used in the provision of telehealth services.

NOTE 5 Instruments that qualify as a medical device according to national legislation and regulations should meet the requirements of such regulations, for example the Medical Device Directive in Europe.

NOTE 6 ISO 13485 and IEC/TR 80001–2-1:2012 provide useful guidance for medical devices and medical IT networks.

13.2 Service support

Quality characteristic: continuity, dependability
Quality objective: Service support procedures are in place to manage telehealth.
Quality procedure: The organization ensures that procedures are in place to maintain telehealth continuity and dependability using a) incident management to manage changes in services, b) problem management identify and resolve issues whose cause is unknown, c) change management to manage necessary alterations to services, and d) release management for the introduction of new services. EXAMPLE When a problem occurs with the equipment that is necessary for the delivery of the care by telehealth, procedures should specify how problems can be diagnosed, communicated and resolved. NOTE Healthcare organizations should ensure that measures are put in place to mitigate the impact of failures of information and communications technology due to events beyond their control.

13.3 Service delivery

Quality characteristic: accountability, continuity, dependability
Quality objective: Service delivery procedures are in place to support telehealth.
Quality procedure: The organization ensures that procedures are in place for a) service level agreements specifying the levels of telehealth service required to support the agreed continuity of care, b) financial arrangements that account for the costs and charges to users of telehealth, c) capacity management ensures that IT infrastructure resources are in place to effectively meet planned demand for telehealth, d) availability management to ensure systems are dependable and available for use in accordance with the service level agreements provided to users of telehealth, and e) service continuity management to provide recovery plans for telehealth when there is a significant failure. NOTE 1 The obligations of suppliers of equipment and devices to rectify deficiencies, provide maintenance services in a timely manner and supply records of known problems are defined in service level agreements. NOTE 2 The obligations of the healthcare organization to inform the supplier about deficiencies of equipment and devices should be defined in service level agreements.

13.4 Infrastructure management

Quality characteristic: accountability, dependability, efficiency, usability
Quality objective: Infrastructure is managed to support the longer term needs of telehealth services.

Quality characteristic: accountability, dependability, efficiency, usability
Quality procedure: The organization ensures that infrastructure used for telehealth a) is based on an accountable requirements analysis and planning process covering design, deployment, operations and technical support, b) supports interoperability using appropriate standards with other telehealth services, c) is usable and fit for purpose, d) communicates dependably over the available telecommunications services, and e) is financially efficient of the whole of the infrastructure life cycle. NOTE Infrastructure can consist of equipment, software, telecommunications and computer networks.

13.5 Deployment management

Quality characteristic:, appropriateness, safety, usability
Quality objective: Deployment procedures are in place to provide telehealth.
Quality procedure: The organization ensures that procedures are in place for a) design, build, test and roll-out of equipment and devices for telehealth using an appropriate project management methodology, b) confirmation that the equipment or software is usable by for telehealth services, c) confirmation that the equipment or software and is safe to operate, d) installation of equipment and devices for telehealth according to the guidelines of the manufacturer or supplier, and e) removal of the equipment and devices.

13.6 Operations management

Quality characteristic: effectiveness, efficiency
Quality objective: Effective and efficient operational management procedures are in place to support telehealth.
Quality procedure: The organization ensures that ICT operations management can provide day-to-day technical supervision of the ICT infrastructure used for telehealth including a) backup and restore services, b) network monitoring and management, c) system monitoring and management, d) database monitoring and management, e) storage monitoring and management, f) a stable, secure ICT infrastructure, and g) management of technical diversity.