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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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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC *215*, *Health informatics*.

This first edition cancels and replaces the ISO/TS 13131:2014, which has been technically revised.

The main changes compared to the previous edition are as follows:

— alignment with ISO 9000:2015, ISO 9001:2015, ISO 31000:2018 and ISO 13940:2015;

— addition of informative annexes providing use cases illustrating applications of this document;

— improvement in the clarity of the clauses on quality management and risk management.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Healthcare activities rely on communication between healthcare actors. When the point of care is geographically separated from healthcare resources and healthcare actors are geographically separated, technology enabled services can support healthcare activities. There are diverse forms of healthcare activity, including care by a health professional, self-care activity, treatment, investigation, management, assessment, and evaluation, provision of resources, documentation and education. (For an explanation of these terms, refer to ISO 13940). Health services rely on many technical devices and services including, but not limited to facsimile machines, telephones, cameras, mobile phones, mobile devices, health state monitors, diagnostic scanners and communications services including email, telephony, video conferencing, image transmission and electronic messaging to convey health information and data between healthcare actors.

These services can be described as telehealth services because information and communication technology services are being used to support healthcare activities. Telehealth services can include but are not limited to telemedicine, telecare, mhealth (healthcare supported by mobile devices), remote use of medical applications, tele-monitoring, tele-diagnostics and virtual care[30]. Examples of health services include but are not limited to tele-pathology, tele-dermatology, tele-cardiology, tele-rehabilitation, tele-oncology, and tele-orthopaedics. Healthcare activities that directly or indirectly support care recipients include but are not limited to teleconsultation, telephone advice, health alarm systems and health status monitoring at home. Telehealth services can support immediate healthcare activities using synchronous communications services such as a telephone or video conversation, or delayed health care activities using asynchronous communications services such as messaging services.

Within the healthcare industry, these services are described as digital health or ehealth (electronic health) products provided to support healthcare activity. Electronic health information systems are an example of products that support the capture, storage and transmission of healthcare information and data, which may or may not be used for telehealth services. It is expected that telehealth services will improve the quality of health and healthcare. For example, healthcare professionals can 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 consult a health advisor or healthcare professional as well as having easier access to healthcare information and education to support self-care.

Health informatics — Telehealth services — Quality planning guidelines

1 Scope

This document provides processes that can be used to analyze the risks to the quality and safety of healthcare and continuity of care when telehealth services are used to support healthcare activities. Using risk management processes, quality objectives and procedures are derived which provide guidelines for the operations of telehealth services. These include but are not limited to the following domains:

— management of telehealth quality processes by the healthcare organization;

— strategic and operational process management relating to regulations, knowledge management (best practice) and guidelines;

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

— management of financial resources to support telehealth services;

— management of information management and security used in telehealth services;

— processes related to the planning and provision of human resources, infrastructure, facilities and technology resources for use by telehealth services.

This document provides a set of example guidelines containing quality objectives and procedures for each domain. Organizations can apply the quality and risk management processes described in Clauses 5 and 6 to develop quality objectives and procedures appropriate to the telehealth services they provide.

This document does not provide guidance for the manufacture, assembly, configuration, interoperability or management of devices, products or technical systems.

Annex A provides procedures for the implementation of telehealth services by a large organization. Annex B provides use cases for the application of quality planning guidelines in different types of real-world telehealth services.

2 Normative references

There are no normative references in this document.

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

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 care recipients.

[SOURCE: ISO 9241-20:2008, 3.1, modified — Notes to entry removed and example added.]

3.1.2
accountability
state of being answerable for decisions and activities to the organization's governing bodies, legal authorities and, more broadly, its stakeholders

[SOURCE: ISO 26000:2010, 2.1]

EXAMPLE Accountability for healthcare activities delivered by a healthcare organization.

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

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

[SOURCE: ISO/IEC 17021-1:2015, 3.7]

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

3.1.5
confidentiality
property that information is not made available or disclosed to unauthorized individuals, entities, or processes

[SOURCE: ISO/IEC 27000:2018, 3.10]

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

3.1.6
continuity of care
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

[SOURCE: ISO/TR 18307:2001, 3.42]

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

3.1.7
dependability
ability to perform when and as required

EXAMPLE Dependability of healthcare for care recipients.

[SOURCE: ISO 9000:2015, 3.6.14]

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

[SOURCE: ISO 9000:2015, 3.7.11]

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

3.1.9
efficiency
relationship between the results achieved and the resources used

[SOURCE: ISO 9000:2015, 3.7.10]

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

3.1.10
inclusivity
intention or policy of including people who might otherwise be excluded or marginalized, such as people with physical disabilities, learning disabilities, or racial and sexual minorities

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

EXAMPLE Inclusivity of the care recipient in society or social life

3.1.11
safety
freedom from unacceptable risk or harm

EXAMPLE Safety measures that maintain the health of care recipients.

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

[SOURCE: ISO 26000:2010, 2.24]

EXAMPLE Transparency of healthcare activities.

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

[SOURCE: ISO 9241-420:2011, 3.42]

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

3.2 Actors

3.2.1
carer
caregiver
person who provides care

Note 1 to entry: A carer can be a healthcare professional or an informal caregiver.

3.2.2
care recipient
patient
client
subject of care
service user
subject of healthcare
healthcare actor with a person role; who seeks to receive, is receiving or has received healthcare

Note 1 to entry: In applying this document it is possible that the subject of care is considered to be a group of people

[SOURCE: ISO 13940:2015, 5.2.1]

3.2.3
care team
group of collaborating carers who provide care to a care recipient

EXAMPLE A group of caregivers who collaborate to support a diabetic child; the care team includes his parents (informal caregivers), a primary healthcare professional, a community nurse (healthcare professionals), a teacher and a sport coach (other professionals).

3.2.4
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: ISO 13940:2015, 5.2]

3.2.5
healthcare organization
healthcare provider having an organization role

[SOURCE: ISO 13940:2015, 5.2.3.1]

EXAMPLE A care team, a group practice, a hospital department, a hospital care unit, a self-employed healthcare professional, a service providing healthcare advice.

3.2.6
healthcare third party
healthcare actor other than a healthcare provider or the subject of care

[SOURCE: ISO 13940:2015, 5.2.4]

3.2.7
healthcare personnel
individual healthcare actor having a person role in a healthcare organization

[SOURCE: ISO 13940:2015, 5.2.3.3]

3.2.8
healthcare professional
healthcare personnel having a healthcare professional entitlement recognized in a given jurisdiction

[SOURCE: ISO 13940:2015, 5.2.3.3.1]

3.2.9
informal caregiver
person, other than healthcare professional, who provides care

EXAMPLE A family member, a neighbour.

3.2.10
organization
persons or groups of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives

Note 1 to entry: An organization may in some cases be a single health professional

[SOURCE: ISO 9000:2015, 3.2.1, modified — Note 1 to entry replaced and note 2 to entry removed.]

3.2.11
subject of care proxy
healthcare third party having a person role with the right to take decisions on behalf of the subject of care

[SOURCE: ISO 13940:2015, 5.2.4.3]

3.2.12
supporting organization
organization that provides services to healthcare organization but that does not provide healthcare services

EXAMPLE Healthcare financing bodies such as insurance institutions, suppliers of pharmaceuticals and other goods. Internet and application service providers. Manufacturers and suppliers of devices not related to the health of an individual.

3.3 Care

3.3.1
adverse event
unintended event that has a negative influence on healthcare processes

[SOURCE: ISO 13940:2015, 8.2.4]

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

[SOURCE: ISO 13940:2015, 11.2.9]

3.3.3
care
interactions between a care recipient and a healthcare actor to benefit the health state of the care recipient

Note 1 to entry: The term 'care' is frequently used in combination with other words, such as 'healthcare' or 'care recipient'.

Note 2 to entry: Care also includes interactions between carers who are not healthcare professionals such as informal caregivers.

3.3.4
care plan
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 13940:2015, 9.2]

3.3.5
clinical guideline
set of systematically developed statements to assist the decisions made by healthcare actors about healthcare activities to perform with regard to specified health issues

[SOURCE: ISO 13940:2015, 9.2.4]

3.3.6
consent competence
capability of the subject of care and/or the subject of care proxy to give informed consent or dissent

[SOURCE: ISO 13940:2015, 11.2.8]

3.3.7
health record
data repository regarding the health and healthcare of a subject of care

[SOURCE: ISO 13940:2015, 12.2]

3.3.8
healthcare
care activities, services, or supplies related to the health of an individual

[SOURCE: ISO 13940:2015, 3.1.1, modified — "management" removed from definition and note to entry removed.]

3.3.9
healthcare activity
activity intended directly or indirectly to improve or maintain a health state

[SOURCE: ISO 13940:2015, 7.2]

3.3.10
healthcare funds
financial resources provided for healthcare delivery

[SOURCE: ISO 13940:2015, 7.2.10]

3.3.11
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 his or her involvement in healthcare processes performed for a specific subject of care

[SOURCE: ISO 13940:2015, 11.2]

3.3.12
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 13940:2015, 7.2.7.5]

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

[SOURCE: ISO 13940:2015, 8.2]

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

[SOURCE: ISO 13940:2015, 8.2.6]

3.3.15
health state
physical and mental functions, body structure, personal factors, activity, participation, and environmental aspects as the composite health of a subject of care

[SOURCE: ISO 13940:2015, 6.5]

Note 1 to entry: The WHO International Classification of Functioning, Disability and Health identifies five health components; body function, body structure, activity, participation and environmental factors which form the basis for this entry. The Constitution of the World Health Organization defines health as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

3.3.16
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 13940:2015, 11.2.6]

3.3.17
procedure
specified way to carry out an activity or process

[SOURCE: ISO 9000:2015, 3.4.5, modified — Note to entry removed.]

3.3.18
process
set of interrelated or interacting activities that use inputs to deliver an intended result

[SOURCE: ISO 9000:2015, 3.4.1, modified — Notes to entry removed.]

3.3.19
professional health record
health record held under the responsibility of one healthcare provider and maintained by one or several healthcare professionals

[SOURCE: ISO 13940:2015, 12.2.1]

3.3.20
protocol
customized clinical guideline

[SOURCE: ISO 13940:2015, 9.2.4.1]

3.4 Quality and risk

3.4.1
procedure
specified way to carry out an activity or process to manage quality

[SOURCE: ISO 9000:2015, 3.4.5, modified — Note to entry removed.]

3.4.2
process
set of interrelated activities that use inputs to deliver an intended result

[SOURCE: ISO 9000:2015, 3.4.1, modified — "or interacting" removed from definition and notes to entry removed.]

3.4.3
quality
degree to which a set of inherent characteristics of an object fulfils requirements

[SOURCE: ISO 9000:2015, 3.6.2, modified — Notes to entry removed.]

3.4.4
quality characteristic
inherent characteristic of an object related to a requirement

[SOURCE: ISO 9000:2015, 3.10.2, modified — Notes to entry removed.]

3.4.5
quality management
management with regard to quality

[SOURCE: ISO 9000:2015, 3.3.4, modified — Note to entry removed.]

3.4.6
quality management system
part of a management system with regard to quality

[SOURCE: ISO 9000:2015, 3.5.4]

3.4.7
quality manual
specification for the quality management system of an organization

[SOURCE: ISO 9000:2015, 3.8.8, modified — Note to entry removed.]

3.4.8
quality objective
objective related to quality

[SOURCE: ISO 9000:2015, 3.7.2, modified — Notes to entry removed.]

3.4.9
quality plan
specification of the procedure and associated resources to be applied when and by whom to a specified object

[SOURCE: ISO 9000:2015, 3.8.9, modified — Notes to entry removed.]

3.4.10
requirement
need or expectation that is stated, generally implied or obligatory

[SOURCE: ISO 9000:2015, 3.6.4, modified — Notes to entry removed.]

3.4.11
risk
combination of the probability of occurrence of harm and the severity of that harm

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

Note 2 to entry: In certain applications of this term, it can be positive, negative or both, and can address, create or result in opportunities and threats.

[SOURCE: ISO/IEC Guide 51:2014, 3.9, modified — Note 1 to entry modified and note 2 to entry added.]

3.4.12
risk analysis
process to comprehend the nature of risk and its characteristics including, where appropriate, the level of risk

Note 1 to entry: The process of risk analysis is described in ISO 31000:2018, 6.4.3.

3.4.13
risk assessment
overall process of risk identification, risk analysis and risk evaluation

Note 1 to entry: The process of risk assessment is described in ISO 31000:2018, 6.4.1.

3.4.14
risk criteria
terms of reference against which the significance of a risk is evaluated

Note 1 to entry: The use of risk criteria is described in ISO 31000:2018, 6.3.4.

3.4.15
risk evaluation
process of comparing the results of risk analysis with the established risk criteria to determine whether additional action is required

Note 1 to entry: The process of risk analysis is described in ISO 31000:2018, 6.4.4.

3.4.16
risk identification
process of finding, recognizing and describing risks

Note 1 to entry: The process of risk identification is described in ISO 31000:2018, 6.4.2.

3.4.17
risk management
coordinated activities to direct and control an organization with regard to risk

[SOURCE: ISO 31000:2018, 3.2]

3.4.18
risk management process
systematic application of management policies, procedures and practices to the activities of communicating, consulting, establishing the context, and identifying, analysing, evaluating, treating, monitoring and reviewing risk

Note 1 to entry: The process of risk management is described in ISO 31000:2018, 6.1.

3.4.19
risk treatment
process to select and implement options for addressing risk

Note 1 to entry: The process of risk treatment is described in ISO 31000:2018, 6.5.

3.5 Services

3.5.1
service
output of an organization with at least one activity necessarily performed between the organization and the customer

[SOURCE: ISO 9000:2015, 3.7.7, modified — Notes to entry removed.]

Note 1 to entry: In the case of healthcare the customer may be a care recipient, subject of care or patient or other healthcare actor

3.5.2
telehealth service
healthcare activity supported at a distance by information and communication technology service(s)

Note 1 to entry: It is possible that the subject of care is not directly involved in a telehealth service, e.g. in the case of tele-dermatology where one physician consults another physician who is at a distant location.

Note 2 to entry: Healthcare activities may include healthcare provider activities such as diagnosis, treatment, review or advice, and self-care activities as prescribed or recommended by a health professional, preventive (educational) advice and management of healthcare processes.

Note 3 to entry: Healthcare activities may include both synchronous (real-time) and asynchronous (delayed) interactions between actors. For example, a radiology examination can be transmitted and subsequently reported by a radiologist over a communications network. A discussion on the diagnostic findings can occur in real time over a telephone or video conferencing connection between a patient and health professionals.

3.6 Devices

3.6.1
medical device
instrument, apparatus, implement, machine, appliance, implant, reagent for in vitro use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

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

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

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

— supporting or sustaining life;

— control of conception;

— disinfection of medical devices;

— providing information by means of in vitro examination of specimens derived from the human body;

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

[SOURCE: ISO 13485:2016, 3.11, modified — Note to entry removed.]

4 Application of these guidelines

The design and implementation of risk management, quality and safety management systems specific to telehealth services 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 document provides generic guidelines for telehealth services that can be adapted as required for application across different organizations and services.

This document should be used to supplement existing international, national standards and guidelines for quality, safety, and risk management in the health sector. In particular, the use of other International Standards, when applicable in telehealth settings is encouraged including: ISO 9000, ISO 9001, ISO 9004, ISO 21298, IEC 31010, ISO 13485, ISO/TS 21564, ISO 25237, ISO/IEC 27000, ISO/IEC 27001, ISO/IEC 27002, ISO 27799, IEC 80001-1, ISO 81001-1, ISO 14971, ISO/IEEE 11073 (all parts), ISO/TS 21564, IEC 62304, IEC 82304-1 and ISO 13940.

5 Quality management of telehealth services

5.1 Quality management

5.1.1 Telehealth service quality planning

According to ISO 9001:2015, quality management depends on the adoption of a process approach to enhance customer satisfaction. The process approach advocated by ISO 9001:2015 depends on the application of a Plan-Do-Check-Act (PDCA) cycle and risk-based thinking. According to ISO 9001:2015, the PDCA cycle consists of four phases:

Plan: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies, and identify and address risks and opportunities;

Do: implement what was planned;

Check: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;

Act: take actions to improve performance as necessary (ISO 9001:2015).

Mapping of the PDCA cycle to telehealth service provision considers risks that occur to a service during the plan, do and act phases. Figure 1 illustrates that during the 'Plan phase' standards, guidelines and protocols establish the objectives of the service and identify key risks and benefits for care recipients. The 'Do phase' applies the healthcare processes designed for the telehealth service to assess the healthcare needs of a care recipient and conduct appropriate healthcare activities. The 'Check phase' monitors the health status and evaluates the health outcomes for care recipients. The 'Act phase' is a continuous process occurring across all of the first three phases during which the quality plan controls risks to the service and risk-based thinking enables continuous quality improvement.

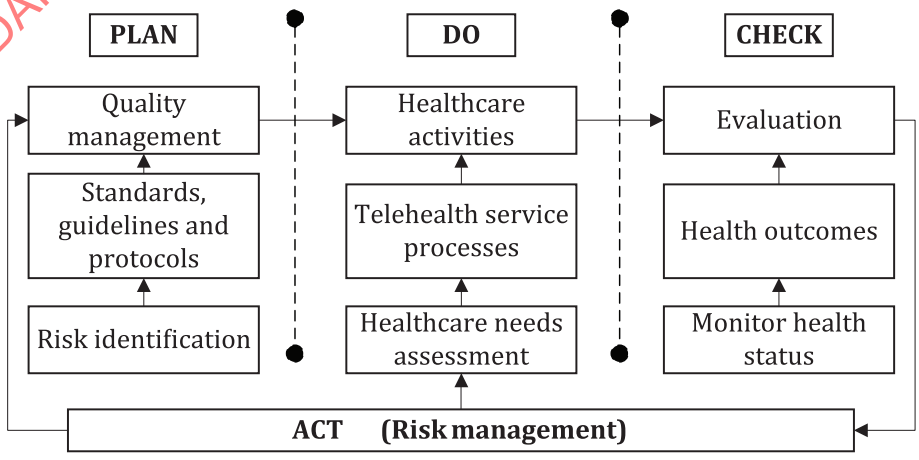

Figure 1 — Mapping the PDCA cycle to telehealth service provision

Risk-based thinking enables the development of quality plans that address potential risks to care recipient safety when healthcare is provided by telehealth services. In particular, this document recommends the adoption of 'risk based thinking' as described in ISO 9001:2015, 0.3.3, supported by ISO 31000:2018, to help organizations identify, assess and manage risks when developing appropriate quality objectives for telehealth services.

Quality plans for telehealth services should be formulated for the management of resources and activities by a healthcare professional, healthcare organization or supporting organization. Quality plans should be structured and contain requirements that can be verified through the provision of objective evidence and describe the following:

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 care recipient safety);

c) quality procedures: for each quality objective, there should be at least one quality procedure.

(e.g. identify care recipients at an increased risk of harm); and include who should be responsible for implementing, monitoring and reviewing the plan.

Telehealth services can support a broad range of healthcare activities that are not restricted to persons 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 document include accessibility, accountability, appropriateness, competence, confidentiality, continuity, dependability, effectiveness, efficiency, inclusivity, safety, transparency and usability.

5.1.2 Guidelines for quality and risk management

Quality characteristic: effectiveness.

Quality objective: The healthcare organization has a quality plan to improve the effectiveness of telehealth services.

Quality procedures: The healthcare organization implements and maintains a quality management system for telehealth services which includes the following:

a) a description of organizational requirements, identified risks, prioritized risks and required quality plans to treat each risk as outlined in Clause 6;

b) a description of the objective evidence required to verify that a quality plan has been implemented.

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

NOTE 2 An introduction to quality management can be found in Reference [29].

5.2 Management of quality characteristics

5.2.1 General

The quality characteristics desirable for health services delivery without the use of telehealth services should also apply in situations where telehealth services are used. Some quality characteristics can become more important to consider when telehealth services are used for delivering health services. An organization should have a quality management system in place to define and monitor the required quality characteristics of telehealth services.

The quality characteristics relevant to the derivation of plans for the management of quality of telehealth services by a healthcare organization or by a non-healthcare organization by way of a service level agreement include accountability, effectiveness, safety and transparency.

5.2.2 Guidelines for quality characteristics

Quality characteristic: effectiveness.

Quality objective: The healthcare organization has defined the required quality characteristics of the telehealth services it provides.

Quality procedures: The healthcare organization maintains in a quality management system for telehealth services:

a) a description of the quality characteristics that are appropriate to each offered service;

b) a description of the procedures that will be used to monitor the achievement the attainment of quality characteristics.

NOTE This procedure does not present comprehensive guidelines for telehealth service quality planning.

5.3 Description of service scope and context

5.3.1 General

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.

Healthcare actors providing telehealth services at various locations actively cooperate in health or healthcare processes. Telehealth services depend on 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 diagnostic system.

Telehealth services are provided by healthcare organizations who, in turn, can rely on healthcare professionals, healthcare personnel, and supporting organizations. There are three scenarios for the involvement of healthcare and non-healthcare actors in a telehealth service:

a) The healthcare organization is solely responsible for providing telehealth services to healthcare actors (e.g. healthcare professionals or care recipients)

b) The healthcare organization relies to a greater or lesser extent on supporting organizations, organizations supplying non-healthcare services (e.g. technology services) or manufacturers of devices for use in telehealth services by healthcare actors (e.g. healthcare professionals or healthcare recipients)

c) In some cases, persons (consumers) can purchase a service or device from a supporting organization that does not provide services, or supplies related to the health of an individual (e.g. technology services and manufacturers of devices). Subsequently that service (e.g. internet provision) or device (computer) can be used in a telehealth service provided by a healthcare organization.

NOTE A healthcare organization can provide services, or supplies related to the health of an individual with or without the direct involvement of a healthcare professional.

5.3.2 Guidelines for description of services

Quality characteristic: transparency.

Quality objective: The telehealth services offered by the healthcare organization are described.

Quality procedures: The healthcare organization defines in a quality management system

a) the scope, context and purposes of the services it offers, how those purposes can be achieved and how to evaluate the extent to which the purposes are achieved, and

b) the actors who will be responsible for any part of the services including other healthcare organizations, supporting organizations, manufacturers, suppliers and other healthcare actors such as care recipients, carers and informal caregivers.

NOTE Unless otherwise specified, the responsible organization is a healthcare organization(s).

5.4 Description of healthcare processes

5.4.1 General

A number of processes are used by telehealth services for quality and financial management, service planning, human resources planning, care planning, healthcare organization responsibilities, facilities, technology and information management. These processes should be analysed for risks that influence the provision of telehealth service against a range of quality characteristics. Usually only a small number of these characteristics will be relevant to the development of an individual quality guideline.

5.4.2 Guidelines

Quality characteristics: accountability and safety.

Quality objective: The healthcare processes that use telehealth services are described by the healthcare organization.

Quality procedures: The healthcare organization develops a document that does the following:

a) describes the healthcare and telehealth service processes;

b) defines the responsibilities and mandates of the healthcare actors involved;

c) defines the responsibilities for the maintenance of processes, protocols and guidelines;

d) defines the required service level agreements with supporting organizations (see Clause 8);

e) defines the processes for mapping the information exchanged between health actors.

This should be a complete process description, including all parties that are needed to establish the telehealth service as well as their relationships, in terms of both healthcare activity and the formal/legal aspects.

NOTE Telehealth services can include one or more healthcare organizations, professionals, a care recipient and informal carer, for example when telehealth services are used for case conferencing there can be several health professionals involved.

5.5 Evaluation and monitoring

5.5.1 General

A robust evaluation framework is needed to appropriately assess the effects of a telehealth service within the health care system. To ensure that telehealth services are functioning appropriately and effectively, it is important to design data collection systems and evaluation metrics appropriate to the type of telehealth service deployment.

5.5.2 Guidelines for evaluation and monitoring

Quality characteristics: effectiveness, appropriateness.

Quality objective: Evaluation frameworks for telehealth services take account of the telehealth service type and the purpose for which they are employed.

Quality procedures: The organization develops a document that does the following:

a) describes how the services will be evaluated;

b) describes whether the services are being evaluated for specific clinical outcomes and/or their contribution to overall health service objectives;

c) identifies the quality indicators and evaluation metrics to be used for each service;

d) describes how the evaluations of multiple telehealth services will be aggregated;

e) describes how the data collection system will enable the evaluation of each service.

Data collection systems should be designed prior to telehealth service deployment. If this is not possible, evaluation frameworks should be compatible with existing data collection systems. Data collection and analysis should occur within the context of the specific telehealth service being measured. For example, metrics used to collect data for and evaluate tele-nephrology or tele-psychiatry will be different than those used for tele-trauma.

Data management systems should have the ability to collect relevant data and analyse many types of telehealth service. Data collection systems should be designed at the outset of service deployment. If organizations are evaluating multiple telehealth systems, service-specific evaluation analysis and benchmarks should inform the synthesis of knowledge about the efficacy and safety of telehealth services within the context of the whole health system.

6 Risk management

6.1 Telehealth service risk, quality and safety assessment

Many healthcare organizations have put in place quality management systems for care recipient safety and healthcare quality. These systems draw upon the quality management principles and processes described in ISO 9000, ISO 9001 and ISO 9004. ISO 9000 and ISO 9001 require an organization to establish the organizational objectives, strategies, scope, processes and characteristics of the services the organization offers. The risks that can then prevent the achievement of organizational objectives and desired service characteristics can be identified in accordance with ISO 31000 by evaluation of factors external to and internal to the organization followed by prioritization of the established risks. Options for the treatment of the prioritized risks can then become the basis for quality procedures that are used to control the identified risks and ensure quality objectives are met.

This document supports the use of the International Standards referred to in this clause when deriving generic quality objectives and procedures for telehealth services. Note that this document does not provide advice for the full implementation of ISO 9004 in a telehealth service context.

The example quality objectives and procedures in this document provide guidelines for quality and financial management, service planning, human resources planning, care planning, healthcare organization responsibilities, facilities, technology and information management to deliver healthcare and transmit health information.

The process to derive quality objectives and procedures for the organization, people, facilities and information used in telehealth service provision should follow the risk assessment process described in ISO 31000:2018, Clause 6 and ISO 31000:2018, Figure 4, as shown in Figure 2.

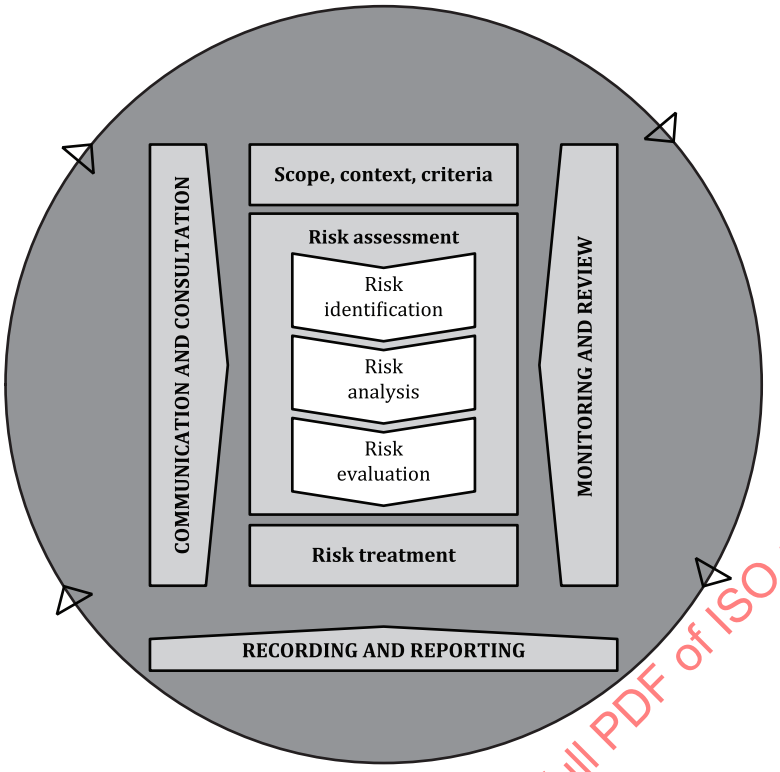

Figure 2 — Risk management process in ISO 31000:2018

6.2 Risk assessment - Identification

6.2.1 General

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 healthcare organization that could influence the quality characteristics of the telehealth service.

A structured approach to identification of risks requires the analysis of the processes for management of quality, strategy, policy, and resources including financial management, service planning, human resources planning, care planning, healthcare organization responsibilities, facilities, technology management, and information management. External contextual influences on a telehealth service, such as legislative, regulatory, standards, guideline and licensing compliance, should be considered. Risks arising from healthcare activities may be identified by considering the following:

— clinical guidelines, protocols, and processes;

— healthcare needs assessments for subjects of care;

— monitoring of the health status of subjects of care;

— healthcare outcomes and possible adverse events.

The explicit identification and documentation of risks ensures that the organization is accountable if a risk eventuates.

6.2.2 Guidelines for risk assessment

Quality characteristic: accountability.

Quality objective: The key risks to telehealth services have been identified by the healthcare organization.

Quality procedures: The healthcare 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 identification of each risk.

NOTE 1 This procedure is based on the risk analysis and risk evaluation process in ISO 31000.

NOTE 2 One can use ISO 14971, ISO 31000 and national standards as guidelines for the risk management process.

6.3 Risk assessment - analysis

6.3.1 General

Risk analysis is a process to comprehend the nature of risk and its characteristics including, where appropriate the level of risk is mapped to the desired quality characteristics of the telehealth service especially its effectiveness. See ISO 31000:2018, 6.4.3.

6.3.2 Guidelines for risk analysis

Quality characteristic: effectiveness.

Quality objective: The healthcare organization has analysed the healthcare processes that use telehealth services.

Quality procedure: The healthcare organization ensures that it regularly analyses the description, quality planning, service experience, outcomes, risk management of healthcare processes for telehealth services and revises its quality plans for these services.

6.4 Risk assessment - evaluation

6.4.1 General

Risk evaluation is the overall process of risk identification and risk analysis for the possible impact of a risk on the organization to determine whether the risk and/or its magnitude is acceptable or tolerable when considering the safety of care recipients. 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. According to ISO 31000:2018, 6.4.4, this can lead to either of the following decisions:

a) do nothing further;

b) consider risk treatment options;

c) undertake further analysis to better understand the risk;

d) maintain existing controls; or reconsider objectives.

6.4.2 Guidelines for risk evaluation

Quality characteristic: safety.

Quality objective: The healthcare organization has evaluated the risks for all healthcare actors in the healthcare processes that use telehealth services.

Quality procedures: The healthcare organization documents a process for the management of safety in a quality and safety management system that ensures the following:

a) the risks to care recipient safety have been considered for all telehealth service 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;

c) systems exist and are documented in quality plans to escalate the level of care when there is an unexpected deterioration in health status or an expected increased risk of such a deterioration.

6.5 Risk treatment

6.5.1 General

Risk treatment requires the selection of one or more processes (risk treatments) to modify risks to the effectiveness of a telehealth service. Risk treatment processes should manage the risks that have been identified and prioritized against documented quality characteristics.

Risk treatment in ISO 31000:2018, 6.5 involves an iterative process consisting of the following:

a) formulating and assessing risk treatment options;

b) planning and implementing risk treatment;

c) assessing the effectiveness of that treatment;

d) balancing the potential benefits derived in relation to the achievement of objectives;

e) deciding whether the remaining risk is acceptable;

f) if not acceptable, taking further treatment.

6.5.2 Guidelines for risk treatment

Quality characteristic: effectiveness.

Quality objective: The healthcare 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 healthcare organization according to the processes outlined in Clause 5 and recorded in a quality management system.

7 Financial management

7.1 Quality characteristics

7.1.1 General

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 service quality planning.

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

7.1.2 Guidelines for 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.

7.1.3 Guidelines for 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.

7.1.4 Guidelines for service payment

Quality characteristic: accountability.

Quality objective: Payment and reimbursement processes for telehealth services are managed in accordance with consumer protection and accounting standards.

Quality procedure: The organization is able to collect payments and refund subsidies to payments when telehealth services are not provided free of charge to the care recipient.

8 Service planning

8.1 Quality characteristics

8.1.1 General

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 accountability, accessibility, appropriateness, continuity, dependability, effectiveness and inclusivity.

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

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

8.1.2 Guidelines for service design

Quality characteristics: accessibility, appropriateness, continuity, and inclusivity.

Quality objective: The healthcare organization has accessible, appropriate and inclusive telehealth services.

Quality procedures: The healthcare organization has included in a telehealth service design document consideration of the following:

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 telehealth service continuity;

d) the availability of specialists, local clinical staff and facilities required to provide service continuity when in-person services are subsequently required as a result of the telehealth based assessment;

e) potential barriers (such access to computers or telecommunications) to the inclusion of care recipients;

f) care recipients who may choose which healthcare services they consider appropriate to access, whether or not delivered using telehealth services.

8.1.3 Guidelines for service availability

Quality characteristics: continuity, and dependability.

Quality objective: The healthcare organization provides dependable telehealth services.

Quality procedures: The healthcare organization has included in a telehealth service design document consideration of the following:

a) at what times of day the care recipient can expect to be able to access the service;

b) the times and days that the service will be intentionally unavailable;

c) the expected maximum duration of unanticipated service outages.

8.1.4 Guidelines for duration of care

Quality characteristics: appropriateness, and effectiveness.

Quality objective: The total duration for the healthcare activities provided by the healthcare organization using telehealth services are appropriate and enable the effective delivery of healthcare.

Quality procedure: The healthcare 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.

8.1.5 Guidelines for service level agreements

Healthcare organization should take responsibility for the quality of the telehealth service. The healthcare organization can rely on service level agreements with supporting organizations to ensure service quality. This document is concerned with processes required to define service level agreements or where they do not exist, to ensure that healthcare actors are aware of and accept the limitations of a telehealth service.

Quality characteristic: accountability, continuity, and dependability.

Quality objective: The healthcare organization has wherever possible, service level agreements with all healthcare and supporting organizations supporting telehealth services.

Quality procedures: The healthcare organization has included in service level agreements the following:

a) the desired quality characteristics, quality objectives and required quality procedures to ensure the quality objectives of the telehealth service;

b) quality characteristics for the service, including non-medical aspects such as privacy;

c) responsibilities and liability;

d) documentation and auditing processes;

e) financial management arrangements.

In some cases, the healthcare organization can be unable to reach service level agreements with supporting organizations to ensure service quality (such as internet or application service providers). In this case, they should rely on the information that has been provided by the manufacturer or service provider, for determining the quality of the device or service used in the telehealth service (see Clause 13) and undertake a risk assessment of the suitability of the device or service for application in a telehealth services.

9 Human resources planning

9.1 Quality characteristics

9.1.1 General

Healthcare organizations are responsible for human resources planning to support telehealth services. The quality characteristics relevant to human resources planning include competency and inclusivity.

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

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

9.1.2 Guidelines for human resources skills and training

Quality characteristic: competency.

Quality objective: The organization has human resources that are competent to deliver effective telehealth services.

Quality procedures: The organization ensures the following:

a) the healthcare professional, and/or informal caregivers have the competencies that are necessary for providing healthcare by means of telehealth services including clinical, cultural, communications or language specific competencies;

b) appropriate minimum professional standards in compliance with the jurisdiction of all actors are applied in the assessment of the required competencies for providing healthcare by means of telehealth services;

c) sufficient knowledge of local environment, health threats and clinical infrastructure at the patient location;

d) opportunities to complete appropriate training courses in the provision of telehealth services are made available;

e) specifies the key skills, and competencies required by personnel involved in technology and information management services in the healthcare organization or supporting organization.

9.1.3 Guidelines for consultation with human resources

Quality characteristic: inclusivity.

Quality objective: The organization has consulted with employees and other stakeholders 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 can require.

10 Care planning

10.1 Quality characteristics

10.1.1 General

Healthcare organizations are responsible for care plans that support healthcare activities based on clinical guidelines and protocols. The quality characteristics relevant to care planning include accountability, appropriateness, continuity, effectiveness, efficiency, 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.

10.1.2 Guidelines for healthcare processes

Quality characteristics: effectiveness, and efficiency.

Quality objective: Healthcare processes for telehealth services are planned and coordinated by the organization.

Quality procedures: The organization defines clinical guidelines and protocols that support collaboration among healthcare organizations and healthcare professionals and describe the following:

a) the processes that are part of the healthcare provision;

b) the roles and responsibilities of the actors in each process;

c) which elements of the professional health record are required to support the collaboration.

10.1.3 Guidelines for care plans

Quality characteristics: effectiveness, and safety.

Quality objective: Healthcare delivered by the organization using telehealth is effective and safe.

Quality procedures: The organization bases care plans and healthcare activities on clinical guidelines and protocols

a) that demonstrate evidence of their effectiveness and safety, and/or

b) are recognized by an (or the) appropriate professional society/societies

NOTE A healthcare organization can also define and maintain local clinical guidelines and protocols for treatment, nursing and care.

10.1.4 Guidelines for healthcare continuity

Quality characteristics: continuity, and safety.

Quality objective: The organization can continue to provide safe healthcare if there is a failure of information and communications technology including devices, communications and services.

Quality procedure: The organization has comprehensive and layered alternative care plans to enable continuity of healthcare if there is a failure of information and communications technology.

10.1.5 Guidelines for emergency procedures

Quality characteristics: continuity, and safety.

Quality objective: The organization can ensure appropriate patient management in an emergency.

Quality procedure: The organization has comprehensive emergency protocols and escalation pathways to manage acute clinical situations that arise during the provision of telehealth services.

10.1.6 Guidelines for when clinical guidelines and protocols are unavailable

Quality characteristics: accountability, appropriateness, and transparency.

Quality objective: There are accountable, appropriate, and clear procedures for the delivery of healthcare using telehealth services when clinical guidelines and protocols are not provided by the organization.

Quality procedures: The organization ensures when healthcare is delivered using telehealth services in situations for which there are no guidelines or protocols, the following procedures should be used:

a) a care 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.

10.1.7 Guidelines for adverse event management

Quality characteristics: safety, and transparency.

Quality objective: Any limitations or risks resulting from the use of telehealth services that can increase the risk of adverse events have been identified by the organization.

Quality procedure: The organization clearly records in the care plan any possible limitations, risks to healthcare activities due to the use of telehealth services, 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 services

10.1.8 Guidelines for professional health record management

Quality characteristic: appropriateness.

Quality objective: Records that contain all appropriate information observed during a healthcare activity using telehealth services have been kept by the organization.

NOTE A healthcare activity can include a healthcare investigation and needs assessment for a care recipient.

Quality procedure: The organization develops care 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 services.

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

11.1.1 General

Healthcare organizations, professionals and 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 service quality planning.

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

NOTE 3 For further information on the concept of responsibilities in healthcare and a healthcare mandate, see ISO 13940:2015, Clause 11.

11.1.2 Guidelines for healthcare mandates

Quality characteristics: accountability, appropriateness, and 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 healthcare organization and the healthcare professional.

Quality procedures: The organization ensures that healthcare mandates from all care recipients 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 can 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 care plan;

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

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

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

11.1.3 Guidelines for informed consent

Quality characteristics: accountability, and transparency.

Quality objective: Informed consent from care recipients to perform healthcare activities has been obtained by the organization and the healthcare professional.

Quality procedures: The organization and the healthcare professional obtain informed consent from the care recipient, which confirms the following:

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) the care recipient has understood the relative advantages and disadvantages of receiving care via telehealth services;

c) the care recipient has understood the information provided;

d) the care recipient has been given the option to read the provided information later.

NOTE 1 Where the procedures for care delivery by means of telehealth services are the same as those for the non-telehealth service based delivery of care, an informed consent statement (in writing or verbal) that the care recipient agrees with the use of telehealth services can be obtained.

NOTE 2 The use of common technology cannot not be taken for granted, e.g. a care recipient who has never used a mobile phone or text messaging. Hence, in most cases, there will be a difference between care delivery by telehealth services and without telehealth services.

11.1.4 Guidelines for care recipient preferences

Quality characteristics: accountability, appropriateness, and transparency.

Quality objective: Care recipients can make informed choices from the available options for healthcare whether or not delivered by telehealth services from the options that have been provided by the organization and the healthcare professional.

Quality procedures: 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 do the following:

a) express informed choices regarding the performance of certain healthcare activities;

b) request the performance of healthcare activities that do not use telehealth services;

c) refuse to permit specific healthcare activities to be performed including healthcare using telehealth services;

d) change their preferences and switch to another mode of health care delivery.

11.1.5 Guidelines for care recipients' expenses

Quality characteristics: accountability, and transparency.

Quality objective: Care recipients are informed by the organization of their expenses for healthcare and how and by whom these expenses will be met.

Quality procedures: The organization clearly informs the care recipient using accountable procedures of the following:

a) financial details for the provision of the healthcare to be delivered;

b) provisions under which reimbursements for the cost of care can be claimed from other organizations, such as insurance companies, that can reimburse the costs of healthcare provision.

11.1.6 Guidelines for providing appropriate healthcare services

Quality characteristic: appropriateness.

Quality objective: Appropriate healthcare using telehealth services is provided by the organization and healthcare professionals.

Quality procedures: The organization ensures the following:

a) provision of healthcare using telehealth services is appropriate for the care recipients based on documented inclusion or exclusion criteria;

b) assessment of the appropriateness of healthcare provision using telehealth services by the healthcare professional continues during the healthcare activity.

EXAMPLE 1 The quality objective can be assessed using healthcare needs assessment.

EXAMPLE 2 The quality objective can be assessed using a complaint registry about the effectiveness of healthcare that uses telehealth services.

NOTE 1 The competency of the care recipient can be part of the assessment.

NOTE 2 Aspects of the physical environment and facilities available to the care recipient can be assessment criteria.

11.1.7 Guidelines for ensuring 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 care plan using telehealth services.

Quality procedures: The organization ensures the following:

a) care recipient and/or informal care giver have committed to perform their tasks required in the care plan using telehealth services;

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 services.

11.1.8 Guidelines for design of telehealth services

Quality characteristics: transparency, and inclusivity.

Quality objective: The organization has consulted with care recipients about the purpose and design of telehealth services.

Quality procedures: The organization includes care recipients and their representatives in the community in consultations about its plans for telehealth services, their purpose, design, operation, management and access to telehealth services.

11.1.9 Guidelines for execution of care plans

Quality characteristic: transparency.

Quality objective: A care 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 procedures: The organization ensures the following:

a) healthcare professional prior to the execution of the care 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 care plan, informs the care recipient 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;

d) healthcare professional at regular intervals during to the execution of the care plan, asks care recipients and possible involved informal care givers whether they understood and followed the advice and instructions given;

e) appropriate follow-up services for care recipients are coordinated in collaboration with the care recipient and healthcare professionals.

12 Facilities management

12.1 Quality characteristics

12.1.1 General

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, 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 clause does not present comprehensive guidelines for telehealth service quality planning.

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

12.1.2 Guidelines for healthcare organization facilities

Quality characteristics: appropriateness, effectiveness, and safety.

Quality objective: Consultations using telehealth services take place in accommodation that is appropriate for the healthcare professional to effectively deliver healthcare.

Quality procedures: The organization ensures the following:

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;

d) equipment can be used in a safe manner.

12.1.3 Guidelines for care recipient facilities

Quality characteristics: appropriateness, effectiveness, and safety.

Quality objectives: Consultations using telehealth services take place in accommodation that is appropriate for the care recipient to effectively participate in healthcare.

Quality procedures: The organization can demonstrate the following:

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 care giver if required;

c) equipment can be used effectively to transmit and receive an appropriate quality of information including audio or video information;

d) equipment can be used in a safe manner.

13 Technology management

13.1 Quality characteristics

13.1.1 General

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 services can rely on external providers. Providers can be the manufacturer of a device for telehealth services. General-purpose ICT infrastructure, including equipment, software and communications can be used to support telehealth services. Information technology management services can be obtained 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 (see Clause 8).

For a device, the service level agreement in the purchase contract is subject to medical device standards when or if the device is intended by the manufacturer to be used, alone or in combination, for healthcare activities.

If the device qualifies as a 'medical device', the manufacturer should meet the requirements of medical device standards (e.g. ISO 13485 for the quality management system of the manufacturer and ISO 14971 for risk management). These International Standards aim to ensure the quality and safety of healthcare provided to the care recipients. Medical device standards are particularly important when a care recipient purchases a telehealth service or device for self-care activity they should rely to a greater or lesser extent on supporting organizations, suppliers of non-healthcare services (e.g. technology services) and manufacturers of devices to provide telehealth services.

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

This clause is intended to apply to equipment or software specifically intended by the manufacturer, healthcare organization or supporting organization for use in the provision of telehealth services.

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

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

NOTE 3 Further advice on information technology management can be found in the ISO/IEC 20000 series, which provide guidance on the application of service management systems. The ISO/IEC 20000 series is closely aligned with the Information Technology Library (ITIL®)[1)] and ISO/IEC/TR 20000-11 provides guidance on their relationship.

1) ITIL® is a registered trademark of AXELOS Limited. This information is given for the convenience of users of this document and does not constitute an endorsement by ISO of the product named. Equivalent products may be used if they can be shown to lead to the same results.

13.1.2 Guidelines for safety and quality

Quality characteristics: safety, continuity, and dependability.

Quality objective: The organization providing telehealth services ensures safety and quality of those services.

Quality procedures: The relationship between the care recipient, healthcare organization and any healthcare supporting organization should be defined in a service level agreement that

a) includes instructions for use from the provider and information on the intended use of the device and telehealth services,

b) includes the supporting clinical evidence,

c) ensures the information provided to the care recipient is understandable by the care recipient and informal caregivers,

d) provides a system for post-market surveillance to detect deficiencies that occur after deployment of the telehealth service including equipment or devices used by the care recipient, and

e) enables the care recipient to communicate problems with a service, equipment or device to the provider.

13.1.3 Guidelines for service support

Quality characteristics: continuity, and dependability.

Quality objective: Service support procedures are in place to manage telehealth services.

Quality procedures: The organization ensures that procedures are in place to maintain telehealth service continuity and dependability using the following:

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;

d) release management for the introduction of new services.

When a problem occurs with the equipment that is necessary for the delivery of the care by telehealth services, procedures should specify how problems can be diagnosed, communicated and resolved. 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.

13.1.4 Guidelines for service delivery

Qu**ality characteristics**: accountability, continuity, and dependability.

Quality objective: Service delivery procedures are in place to support telehealth services.

Quality procedures: The organization ensures that procedures are in place for the following:

a) service level agreements specifying the levels of service required to support the agreed continuity of care;

b) financial arrangements that account for the costs and charges to users of telehealth services;

c) capacity management ensures that IT infrastructure resources are in place to effectively meet planned demand for telehealth services;

d) availability management to ensure systems are dependable and available for use in accordance with the service level agreements provided to users of telehealth services;

e) service continuity management to provide recovery plans for telehealth services 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 can be defined in service level agreements.

NOTE 2 The obligations of the healthcare organization to inform the supplier about deficiencies of equipment and devices can be defined in service level agreements.

13.1.5 Guidelines for infrastructure management

Quality characteristics: accountability, dependability, efficiency, and usability.

Quality objective: Infrastructure is managed to support the longer-term needs of telehealth services.

Quality procedure: The organization ensures that the infrastructure used for telehealth services

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.

13.1.6 Guidelines for deployment management

Quality characteristics: appropriateness, safety, and usability.

Quality objective: Deployment procedures are in place to provide telehealth services.

Quality procedures: The organization ensures that procedures are in place for the following:

a) design, build, test and roll-out of equipment and devices for telehealth services using an appropriate project management methodology;

b) confirmation that the equipment or software is usable for telehealth services;

c) confirmation that the equipment or software is safe to operate;

d) installation of equipment and devices for telehealth services according to the guidelines of the manufacturer or supplier;

e) repair or replacement of defective equipment and devices;

f) removal of the equipment and devices.

13.1.7 Guidelines for operations management

Quality characteristics: effectiveness, and efficiency.

Quality objective: Effective and efficient operational management procedures are in place to support telehealth services.

Quality procedures: The organization ensures that ICT operations management can provide day-to-day technical supervision of the ICT infrastructure used for telehealth services including the following:

a) timely support for all users;

b) backup and restore services;

c) network monitoring and management;

d) system monitoring and management;

e) database monitoring and management;

f) storage monitoring and management;

g) a stable, secure ICT infrastructure;

h) management of technical diversity.

13.1.8 Guidelines for technical support

Quality characteristic: effectiveness.

Quality objective: Effective technical support is in place for telehealth services.

Quality procedures: The organization provides technical support for telehealth services that includes the following:

a) research and evaluation;

b) market intelligence gathering;

c) proof of concept and pilot engineering;

d) provision of specialist technical advice;

e) documentation management.

13.1.9 Guidelines for device management

Quality characteristics: dependability, effectiveness, and usability.

Quality objective: Devices can effectively support the healthcare activities of health professionals and care recipients.

Quality procedure: The organization ensures that the devices used for telehealth services

a) are usable and fit for purpose,

b) are supported by the relevant information, including the clinical evidence for the effectiveness of the device,

c) support interoperability using appropriate standards with other telehealth services,

d) communicate dependably over the available telecommunications services, and

e) are accompanied by service level agreements that can support the agreed continuity of care.

NOTE 1 Devices can consist of hardware, software and telecommunications elements.

NOTE 2 Devices can be used by health professionals, informal caregivers or care recipients

NOTE 3 ISO 13485 and IEC/TR 80001-2-1 provide useful guidance for medical devices and medical IT networks.

14 Information management

14.1 Quality characteristics

14.1.1 General

Telehealth services depend on many information-related processes related to privacy, identity management, security and information management. Since the provision, transmission and care of healthcare information and data is an important part of the healthcare process, quality objectives should be established for information management. The quality characteristics relevant to management of information for telehealth services by healthcare organizations are accountability, availability, confidentiality, dependability, effectiveness, efficiency and safety.

NOTE 1 This clause does not present a comprehensive list of quality plans.

NOTE 2 Further advice on information security management can be found in the ISO/IEC 27000.

NOTE 3 Further advice on information security management in health can be found in ISO 27799.

NOTE 4 Unless otherwise specified, the responsible organization is a healthcare organization or supporting organization.

NOTE 5 Further guidance is provided by ISO 81001-1.

14.1.2 Guidelines for privacy

Quality characteristic: confidentiality.

Quality objective: All actors involved in a telehealth service comply with any privacy regulations that can apply to the telehealth service.

Quality procedures: The organization

a) notifies the care recipient and obtains agreement to the privacy regulations of the organization providing the telehealth services, including possible updates and/or modifications to the regulations,

b) implements a system for obtaining and recording the mandates provided by care recipients regarding the use of data and information based on the principles of informed consent, and

c) defines processes to audit the compliance of healthcare professionals and healthcare supporting organizations with the privacy regulations of the healthcare organization and any national regulations or legislation that can apply to the telehealth service.

NOTE In the context of a care team that consists of collaborating carers, that is both informal caregivers and healthcare professionals from different organizations informed consent for the exchange of information between the carers in the care team can be obtained.

14.1.3 Guidelines to protect care recipient identity

Quality characteristics: confidentiality, and safety.

Quality objective: Healthcare actors can confirm each other's identity.

Quality procedure: The organization protects safety of healthcare actors and confidentiality of healthcare records by implementing processes that confirm the identity of the care recipient to the healthcare professional, and confirms the identity of the healthcare professional to the care recipient.

14.1.4 Guidelines for confidentiality of health records

Quality characteristics: availability, and confidentiality.

Quality objective: The confidentiality and availability of health records whether generated by a healthcare organization, an individual or a device, that are in electronic storage or transmission is protected by the healthcare organization.

Quality procedures:

The organization implements processes that

a) confirm that the information and communication technologies meet justifiable standards for the protection of health records in electronic storage or transmission,

b) ensure that the healthcare professional applies the guidelines of the healthcare organization to protect the confidentiality of health records, and

c) ensure the semantic interoperability of health records used in telehealth services with other healthcare services.

NOTE 1 ISO/IEC 27001 provides further advice on security techniques.

NOTE 2 ISO 25237 provides further advice on privacy protection using pseudonymization services for the protection of personal health information.

14.1.5 Guidelines for consultations, ordering and prescribing

Quality characteristic: accountability.

Quality objective: Consultations, orders and prescriptions for healthcare activities using telehealth services are documented in a health record.

Quality procedures: The organization and the healthcare professional determine the following:

a) how and by which professional or professionals a consultation using telehealth services is documented;

b) the means by which the consultation is documented;

c) the elements of the consultation that should be documented in or linked to a professional health record;

d) describe who is responsible for delivering each type of healthcare, including responsibilities for ordering tests, preparing prescriptions and follow up.

NOTE Methods by which a telehealth service consultation can be documented include written notes, an electronic health record, a still or moving image, or an audio recording.

EXAMPLE A diagnostic image and notes relating to that image can be kept in a paper-based file, electronic record system or a specialized electronic image store.

14.1.6 Guidelines for coordination and scheduling

Quality characteristic: efficiency.

Quality objective: The resources needed for healthcare activities using telehealth services are efficiently managed by the healthcare organization.

Quality procedure: The healthcare organization has a system for coordinating and booking the people, equipment and facilities needed for consultations using telehealth services.

14.1.7 Guidelines for data quality

Quality characteristics: dependability, effectiveness, safety, availability, and confidentiality.

Quality objective: The quality of the collected or transmitted data provided by telehealth services is sufficient to safely support healthcare activities.

Quality procedures: The organization ensures that processes are

a) implemented to monitor the dependability of data representation, generation, collection, transmission, exchange and use by telehealth services,

b) available to support effective and safe healthcare activities when telehealth service data quality exceeds control limits, and

c) documents the decisions made when designing these processes.

This quality objective is of particular importance in situations where actions are taken, based on remote measurements such as dietary and/or insulin intake advice for diabetics, based on glucose levels. There should be a process in place that can verify the received data is correct and advice based on best practice clinical evidence.

NOTE The quality of textual, numerical, video or audio information can reduce the dependability and effectiveness of the information leading to poor or unsafe decisions.

Annex A
(informative)

Procedures for the implementation of telehealth services by a large organization

A.1 General

This annex provides guidance on the procedures that can be used to confirm organizational and healthcare processes, infrastructure and information requirements for the implementation of telehealth services by a large organization. Other processes and requirements can be identified by application of quality and risk management processes described in Clauses 5 and 6.

This annex outlines a small selection of the quality procedures that should be undertaken by a large healthcare organization intending to implement a telehealth service. Undertaking these procedures can support the creation of guidelines containing quality objectives and procedures for telehealth services. Where appropriate the relevant clause number for each quality procedure is cross-referenced in brackets, for example (see 8.1.3) to associated clauses in this document.

A.2 Confirm organizational processes

The following procedures should be undertaken:

a) Establish if any changes to quality plans (see Clause 5), financial resources (see Clause 7), service planning (see Clause 8) or human resources planning (see Clause 9) are required to support a healthcare activity using telehealth services.

b) Undertake a risk assessment to identify (see 6.2.2), analyse (see 6.3.2), evaluate (see 6.4.2) and manage (see 6.5.2) any possible risks arising from use of a telehealth service to support healthcare activities.

c) Analyse the, scopes (see 5.3.2), responsibilities (see Clause 11) and tasks specific to telehealth services.

d) Design new processes, or changes in existing processes (see 8.1.2), and define the consequent skills, tasks and responsibilities required of healthcare actors (9.1.2).

Using telehealth services to support an existing healthcare activity can require changes in existing processes, new processes, skills, tasks and responsibilities. The impact on employee roles and the competencies required by healthcare actors to use telehealth services requires careful analysis.

A.3 Confirm healthcare processes

The following procedures should be undertaken:

a) Establish if any changes to healthcare processes such as admission (see 11.1.3), development or management of care plans (see 10.1.3) and treatment are required to deliver healthcare using telehealth services.

b) Confirm that the healthcare actors are able to communicate effectively (see 14.1.7) over a distance using information technology and telecommunication facilities.

c) Establish procedures and guidelines for triaging which care recipients should receive healthcare using telehealth services (see 11.1.8)

NOTE Since there is a physical distance between the healthcare actors, telecommunication technology is used for communication. In such a setting, certain visual or conversational clues that occur in a normal face-to-face communication can be missing or changed, which can alter the interpretation of the information exchanged.

A.4 Confirm infrastructure requirements

The following requirements should be confirmed:

a) Specify the facilities (see Clause 12), equipment, and technology (technical infrastructure and transmission media) (see Clause 13) needed to transmit information effectively and efficiently over a distance.

b) Ensure that resources are made available (see 13.1.6), and agreements are reached to ensure the continued operation (see 13.1.7) of information and communication technology required by a telehealth service.

EXAMPLE In tele-dermatology, a skin image is the main information exchanged. Data from the care recipient history and diagnostics can be required to complement the image to ensure the image can be linked with the care recipient.

A.5 Confirm information requirements

The following requirements should be confirmed:

a) Understand how identification of healthcare actors will occur when communicating at a distance (see 14.1.3). Healthcare professionals should be able to verify they are dealing with the correct care recipient and the care recipient should be able to verify he/she is communicating with the proper healthcare professional.

EXAMPLE 1 When the healthcare professional communicates with the care recipient via a voice or computer link, there is no face-to-face contact. The healthcare professional can to ask additional questions to obtain sufficient information.

b) Ensure the dependability, availability and confidentiality of the information (see 14.1.4) that is communicated by the healthcare actors is sufficient to undertake the defined healthcare activity.

EXAMPLE 2 When a person, other than the care recipient (such as an informal care giver) provides information at a distance, the healthcare professional can record the source of the information, ask further questions and make additional observations.

EXAMPLE 3 A remote monitoring system for diabetics can request a second blood sample to be taken when the glucose level is far outside the expected limits before transmitting the result to the responsible healthcare professional.

c) Confirm information can be efficiently and appropriately shared between healthcare actors (see 13.1.6) to undertake the defined healthcare activity.

EXAMPLE 4 When a care recipient is cared for by several healthcare professionals at a distance, each healthcare professional can require efficient access to different sets of information, such as pathology or radiology results and care plans.