INTERNATIONAL STANDARD

ISO 13131

First edition
2021-05

Health informatics — Telehealth services — Quality planning guidelines

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 13131:2021
https://standards.iteh.ai/catalog/standards/sist/0b4001ae-92a6-4927-963d-2e84bd5beed5/iso-13131-2021

Reference number
ISO 13131:2021(E)

© ISO 2021

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 13131:2021
https://standards.iteh.ai/catalog/standards/sist/0b4001ae-92a6-4927-963d-2e84bd5beed5/iso-13131-2021

COPYRIGHT PROTECTED DOCUMENT

© ISO 2021

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

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

Published in Switzerland

© ISO 2021 – All rights reserved

Contents

Page

Foreword ..... **vi**
Introduction ..... **vii**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
3.1 Quality characteristics 2
3.2 Actors 3
3.3 Care 5
3.4 Quality and risk 7
3.5 Services 10
3.6 Devices 10
4 Application of these guidelines **10**
5 Quality management of telehealth services **11**
5.1 Quality management 11
5.1.1 Telehealth service quality planning 11
5.1.2 Guidelines for quality and risk management 12
5.2 Management of quality characteristics 12
5.2.1 General 12
5.2.2 Guidelines for quality characteristics 13
5.3 Description of service scope and context 13
5.3.1 General 13
5.3.2 Guidelines for description of services 13
5.4 Description of healthcare processes 14
5.4.1 General 14
5.4.2 Guidelines 14
5.5 Evaluation and monitoring 14
5.5.1 General 14
5.5.2 Guidelines for evaluation and monitoring 14
6 Risk management **15**
6.1 Telehealth service risk, quality and safety assessment 15
6.2 Risk assessment - Identification 16
6.2.1 General 16
6.2.2 Guidelines for risk assessment 16
6.3 Risk assessment - analysis 17
6.3.1 General 17
6.3.2 Guidelines for risk analysis 17
6.4 Risk assessment - evaluation 17
6.4.1 General 17
6.4.2 Guidelines for risk evaluation 17
6.5 Risk treatment 18
6.5.1 General 18
6.5.2 Guidelines for risk treatment 18
7 Financial management **18**
7.1 Quality characteristics 18
7.1.1 General 18
7.1.2 Guidelines for sustainability 19
7.1.3 Guidelines for healthcare funds 19
7.1.4 Guidelines for service payment 19
8 Service planning **19**
8.1 Quality characteristics 19
8.1.1 General 19

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 13131:2021
https://standards.iteh.ai/catalog/standards/sist/0b4001ae-92a6-4927-963d-2e84bd5beed5/iso-13131-2021

© ISO 2021 – All rights reserved

8.1.2 Guidelines for service design 19
8.1.3 Guidelines for service availability 20
8.1.4 Guidelines for duration of care 20
8.1.5 Guidelines for service level agreements 20

9 Human resources planning 21
9.1 Quality characteristics 21
9.1.1 General 21
9.1.2 Guidelines for human resources skills and training 21
9.1.3 Guidelines for consultation with human resources 22

10 Care planning 22
10.1 Quality characteristics 22
10.1.1 General 22
10.1.2 Guidelines for healthcare processes 22
10.1.3 Guidelines for care plans 22
10.1.4 Guidelines for healthcare continuity 22
10.1.5 Guidelines for emergency procedures 23
10.1.6 Guidelines for when clinical guidelines and protocols are unavailable 23
10.1.7 Guidelines for adverse event management 23
10.1.8 Guidelines for professional health record management 23

11 Responsibilities 24
11.1 Quality characteristics 24
11.1.1 General 24
11.1.2 Guidelines for healthcare mandates 24
11.1.3 Guidelines for informed consent 24
11.1.4 Guidelines for care recipient preferences 25
11.1.5 Guidelines for care recipients' expenses 25
11.1.6 Guidelines for providing appropriate healthcare services 25
11.1.7 Guidelines for ensuring competence of care recipients 26
11.1.8 Guidelines for design of telehealth services 26
11.1.9 Guidelines for execution of care plans 26

12 Facilities management 27
12.1 Quality characteristics 27
12.1.1 General 27
12.1.2 Guidelines for healthcare organization facilities 27
12.1.3 Guidelines for care recipient facilities 27

13 Technology management 28
13.1 Quality characteristics 28
13.1.1 General 28
13.1.2 Guidelines for safety and quality 29
13.1.3 Guidelines for service support 29
13.1.4 Guidelines for service delivery 29
13.1.5 Guidelines for infrastructure management 30
13.1.6 Guidelines for deployment management 30
13.1.7 Guidelines for operations management 30
13.1.8 Guidelines for technical support 31
13.1.9 Guidelines for device management 31

14 Information management 32
14.1 Quality characteristics 32
14.1.1 General 32
14.1.2 Guidelines for privacy 32
14.1.3 Guidelines to protect care recipient identity 32
14.1.4 Guidelines for confidentiality of health records 32
14.1.5 Guidelines for consultations, ordering and prescribing 33
14.1.6 Guidelines for coordination and scheduling 33
14.1.7 Guidelines for data quality 33

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 13131:2021
https://standards.iteh.ai/catalog/standards/sist/0b4001ae-92a6-4927-963d-2e84bdfbaad5/iso-13131-2021

 © ISO 2021 – All rights reserved

Annex A (informative) **Procedures for the implementation of telehealth services by a large organization** **35**
Annex B (informative) **Using quality planning guidelines in real-world telehealth services** **37**
Bibliography **46**

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 13131:2021
https://standards.iteh.ai/catalog/standards/sist/0b4001ae-92a6-4927-963d-2e84bd5beed5/iso-13131-2021

© ISO 2021 – All rights reserved

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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

ISO 13131:2021
https://standards.iteh.ai/catalog/standards/sist/4f0c1e23-c64f-4927-96d1-2e84bd5beed5/iso-13131-2021

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.

© ISO 2021 – All rights reserved

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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.

ISO 13131:2021
https://standards.iteh.ai/catalog/standards/sist/0f4d0e1e-e6d1-4327-943e-3e9b5f1ddf5e/iso-13131-2021

© ISO 2021 – All rights reserved

iTeh STANDARD PREVIEW
(standards.iteh.ai)

ISO 13131:2021
https://standards.iteh.ai/catalog/standards/sist/0b4001ae-92a6-4927-963d-2e84bd5beed5/iso-13131-2021

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)
ISO 13131:2021
https://standards.iteh.ai/catalog/standards/sist/0b4001ae-92a6-4927-965d-2c84bd5bced5/iso-13131-2021

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/

© ISO 2021 – All rights reserved

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]

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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

3.1.5
confidentiality

ISO 13131:2021
https://standards.iteh.ai/catalog/standards/sist/0b4001ae-92a6-4927-963d-

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]

© ISO 2021 – All rights reserved

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

3.1.11
safety
freedom from unacceptable risk or harm

EXAMPLE Safety measures that maintain the health of care recipients.

ISO 13131:2021
https://standards.iteh.ai/catalog/standards/sist/0b4001ae-92a6-4927-963d-2e84bd5beed5/iso-13131-2021

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.

© ISO 2021 – All rights reserved

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.

iTeh STANDARD PREVIEW
(standards.iteh.ai)

[SOURCE: ISO 13940:2015, 5.2]

ISO 13131:2021
https://standards.iteh.ai/catalog/standards/sist/0b4001ae-92a6-4927-963d-2e84bd5beed5/iso-13131-2021

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.

© ISO 2021 – All rights reserved

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

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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

ISO 13131:2021
https://standards.iteh.ai/catalog/standards/sist/0b4001ae-92a6-4927-963d-2e84bd5beed5/iso-13131-2021

[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]

© ISO 2021 – All rights reserved

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.]

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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

[SOURCE: ISO 13940:2015, 7.2]

ISO 13131:2021
https://standards.iteh.ai/catalog/standards/sist/0b4001ae-92a6-4927-963d-2e84bd5beed5/iso-13131-2021

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]

© ISO 2021 – All rights reserved

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]

iTeh STANDARD PREVIEW
(standards.iteh.ai)

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.]

ISO 13131:2021
https://standards.iteh.ai/catalog/standards/sist/0b4001ae-92a6-4927-963d-2e84bd5beed5/iso-13131-2021

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.]

© ISO 2021 – All rights reserved