

Practice Standard

for the Quality and Safety of Virtual Care in
Rural and Remote communities

Document Control

Document Information

Document Owner	Jane Connolly – ACRRM Digital Health Program Coordinator
Issue Date	01/05/2026

Document History

Version	Issue Date	Changes
0.4	19/02/2026	Review ACRRM Quality and Safety Council
0.6	31/03/2026	Review ACRRM Digital Health Committee
0.6	24/04/2026	Review ACRRM Quality and Safety Council
1.0	Date	Board approval

Document content and review was provided by the following groups, organisations and individuals with thanks from the Australian College of Rural and Remote Medicine.

1. ACRRM Telehealth Working Group

A/Prof Chris Pearce PhD, MFM, MBBS, FRACGP, FACRRM, FACHI, FAIDH, General Practitioner specialising in anaesthetics and emergency, Chair ACRRM Digital Health Committee

Dr John Kelly MBBS, MPH, FACRRM, FRACGP, DRANZCOG (adv), General Practitioner. ACRRM Medical Educator (NT) and ACRRM Digital Health Committee member

Dr Thomas Drake-Brockman MD AACEM(F), ACRRM Rural Generalist Trainee, ACRRM Digital Health Committee member

A/Prof Eugene Wong MBBS, FRACGP, FACRRM, FACHSM, FRACMA, GCCS, MIPH, MHSM, LCAM, GAICD; GP and Rural Generalist, with advanced credentials in Anaesthesia and Retrieval Medicine. ACRRM Digital Health Committee member

Dr Shaun Francis FACRRM, ACRRM Digital Health Committee member

Dr Alan Taylor PhD, CEng MIET, RPEng (IT&T). eDevelopment Solutions

Jane Connolly BSC (Hons), CHIA, ACRRM Program Coordinator Digital Health

2. ACRRM Digital Health Committee

Table of Contents

Introduction	6
General	6
Intended Audience	6
Background	6
Requirements for virtual care	7
Aim of a management system for the quality of virtual care	7
Virtual care quality planning	7
Application of this document	8
Scope	8
Related standards or guidelines	9
Terms and definitions	10
Quality management	10
Risk management	10
Improvement	11
People	11
Organisational matters	12
Health matters	12
1 Context of the organisation	14
1.1 Understanding the organisation and its context	14
1.2 Understanding the needs and expectations of interested parties	14
1.2.1 Partnering with interested parties	14
1.2.2 Service level agreements	14
1.3 Determining the scope of the virtual care management system	14
1.4 Virtual care management system	15
1.4.1 Quality and safety management	15
1.4.2 Quality management	15
1.4.3 Risk management	15
1.4.4 Safety, adverse event and incident management	15
1.4.5 Safety and quality training	15
2 Leadership	16
2.1 Leadership and Governance	16
2.2 Virtual care governance	16
2.3 Clinical governance	17
2.4 Virtual care policy	17
2.5 Roles, responsibilities and authorities	17
3 Planning	18
3.1 Actions to address risks and opportunities	18
3.2 Virtual care quality and safety objectives and planning to achieve them	18
3.3 Planning of implementation	18
3.4 Planning of changes	18
3.5 Service design	18
3.5.1 Model of care - organisation	18
3.5.2 Diversity of needs	19
3.5.3 Accessibility	19
3.5.4 Availability	19

4 Support	20
4.1 Human Resources	20
4.2 Workforce Competence	20
4.3 Awareness	20
4.4 Communication	20
4.4.1 Internal and external communications	20
4.4.2 Person centred services	20
4.4.3 Feedback and complaints management	20
4.4.4 Care recipient communication	21
4.4.5 Care recipients' expenses	21
4.4.6 Clinical communication	21
4.5 Safe environment	21
4.5.1 Safety by design	21
4.5.2 Organisational facilities	21
4.5.3 Care recipient facilities	22
4.6 Documented information	22
4.6.1 General	22
4.6.2 Creating and updating documented information	22
4.6.3 Control of documented information	22
4.7 Information management systems	22
4.7.1 General security	22
4.7.2 Privacy	23
4.7.3 Identity and confidentiality	23
4.7.4 Data quality	23
4.7.5 Health record management	23
4.7.6 Documentation of consultations	23
4.7.7 Information collection, sharing, and disposal management	24
4.7.8 Consent management	24
4.8 Technology systems management	24
4.8.1 Technology systems design	24
4.8.2 Technology service support	24
4.8.3 Technology infrastructure management	25
4.8.4 Deploying technology	25
4.8.5 Operating technology	25
4.8.6 Device management	25
5 Operation	26
5.1 Obtaining consent	26
5.1.1 Gaining informed consent	26
5.1.2 Understanding care recipient preferences	26
5.1.3 Care recipient identity	26
5.2 Appropriate care	26
5.2.1 Medical history confirmation	26
5.2.2 Providing appropriate healthcare services	26
5.2.3 Managing care recipient safety	27
5.3 Care planning	27
5.3.1 Factors in providing virtual care	27
5.3.2 Guidelines and protocols	27
5.4 Healthcare continuity	27
5.4.1 Alternative care plans	27
5.4.2 Shared care	27
5.4.3 Health record continuity	27

6 Performance evaluation	28
6.1 Monitoring, measurement, analysis, and evaluation	28
6.2 Internal audit	28
6.2.1 General	28
6.2.2 Internal audit programme	28
6.3 Management review	28
6.3.1 General	28
6.3.2 Management review inputs	28
6.3.3 Management review results	28
7 Improvement	29
7.1 Continual improvement	29
7.2 Nonconformity and corrective action	29
Bibliography	30
Annex 1	
Guidelines for risk management according to ISO 31000	31
1 Risk management	31
1.1 Service risk, quality and safety assessment	31
1.2 Risk assessment - Identification	31
1.2.1 General	31
1.2.2 Guidelines for risk assessment	32
1.3 Risk assessment - analysis	32
1.3.1 General	32
1.3.2 Guidelines for risk analysis	32
1.4 Risk assessment - evaluation	32
1.4.1 General	32
1.4.2 Guidelines for risk evaluation	32
1.5 Risk treatment	32
1.5.1 General	32
1.5.2 Guidelines for risk treatment	32
Annex 2	
Guidance for the safety and quality of procedural and advanced care in rural and remote locations	33

Introduction

General

This document provides requirements for quality and safety management systems for virtual care, as provided to rural and remote communities.

Intended Audience

The intended audience for this standard is broad, including any healthcare system, organisation, or entity that aims to increase the quality of its healthcare delivery and care outcomes. This includes public and private healthcare systems, hospitals, clinics, non-governmental organisations and agencies that provide telehealth and virtual care, and more.

Background

Virtual care services can assist people in rural and remote communities access healthcare in a timely and cost effective manner, that is both safe and delivered to a standard by ensuring digital technologies strengthen - not replace - in-person care. Rural and remote Australians deserve the same quality of healthcare as people living in cities, and developments in virtual care can help deliver this.

This standard sets out how virtual care can be used safely, effectively, and securely to connect people to the care they need, in ways that are culturally appropriate and respectful of individual and community priorities.

“The health status of rural and remote people lags behind that of metropolitan citizens. Morbidity rates for cancer are higher and outcomes for mental health poorer.

The dislocation from family and community in order to seek care delays recovery and has financial, social and emotional impacts that simply cannot be compensated for.”

Dr Ewen McPhee
ACRRM President 2019-2020

Healthcare activities rely on communication between participants in healthcare, whether they are healthcare professionals or care recipients. When the point of care is geographically separated from healthcare resources and participants 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 and monitoring;
- assessment, and evaluation;
- provision of resources including devices and medication;
- documentation and
- education.

Virtual healthcare may rely on many technologies including, cameras, mobile phones and devices, health status monitors, diagnostic devices and communications services including email, telephony, video conferencing, online interactive services, local health records and national systems such as My Health Record to store and convey health information between healthcare professionals.

All these information and communication technology modalities can support virtual care or remote consultation activities. These activities can include but are not limited to telemedicine, telecare, mobile health applications (mHealth: healthcare supported by mobile devices), remote use of medical applications, remote patient monitoring, tele-diagnostics and virtual care.

Other virtual care activities that directly or indirectly support care recipients include but are not limited to teleconsultation, telephone advice, remote consultation, and health status monitoring at home. Virtual care supports real time healthcare activities using synchronous communications services such as a telephone or video conversation, or delayed health care activities using asynchronous communications services such as videos, image transfer, messaging and online interactive services.

Within the healthcare industry, virtual care is supported by digital health or ehealth (electronic health) products and systems. 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 virtual care. Use of these products and systems in virtual care require quality management of clinical, technology and administrative process to ensure their safety and quality.

Requirements for virtual care

This document contains the requirements used to assess conformity. An organisation that wishes to demonstrate conformity with this document can do so by:

- making a self-determination and self-declaration;
- seeking confirmation of its conformity by parties having an interest in the healthcare organisation, such as care recipients;
- seeking confirmation of its self-declaration by a party external to the organisation; or
- seeking certification/registration of its management system for quality in the healthcare organisation by an external organisation.

In this document, the following verbal forms are used:

- “shall” indicates a requirement;
- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

Information marked as “NOTE” is intended to assist the understanding or use of this document.

Aim of a management system for the quality of virtual care

The aims of a management system for the quality of virtual care include the following:

- create a culture of quality starting with strong top management;
- embrace a healthcare system based on people-centred care, respect, compassion, co-production, equity and dignity;
- identify and address risks;
- ensure patient and workforce safety and wellbeing;
- control service delivery through documented processes and documented information;
- monitor and evaluate clinical and non-clinical performance;
- continually improve its processes and results.

Virtual care quality planning

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

1. Plan: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organisation's policies, and identify and address risks and opportunities;
2. Do: implement what was planned;
3. Check: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;
4. Act: take actions to improve performance as necessary (ISO 9001).

Mapping of the PDCA cycle to virtual care provision considers risks that occur to care 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.
- ‘Do phase’ applies the healthcare processes designed for virtual care to assess the healthcare needs of a care recipient and conduct appropriate healthcare activities.
- ‘Check phase’ monitors the health status and evaluates the health outcomes for care recipients.
- ‘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.

The same PDCA cycle should also be applied to management of information and technology systems that support virtual care.

Risk-based thinking enables the development of quality plans that address potential risks to care recipient safety when healthcare is provided by virtual care. 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 organisations identify, assess and manage risks when developing appropriate quality objectives for virtual care.

Virtual care, technology and Information systems management Plan-Do-Check-Act cycle

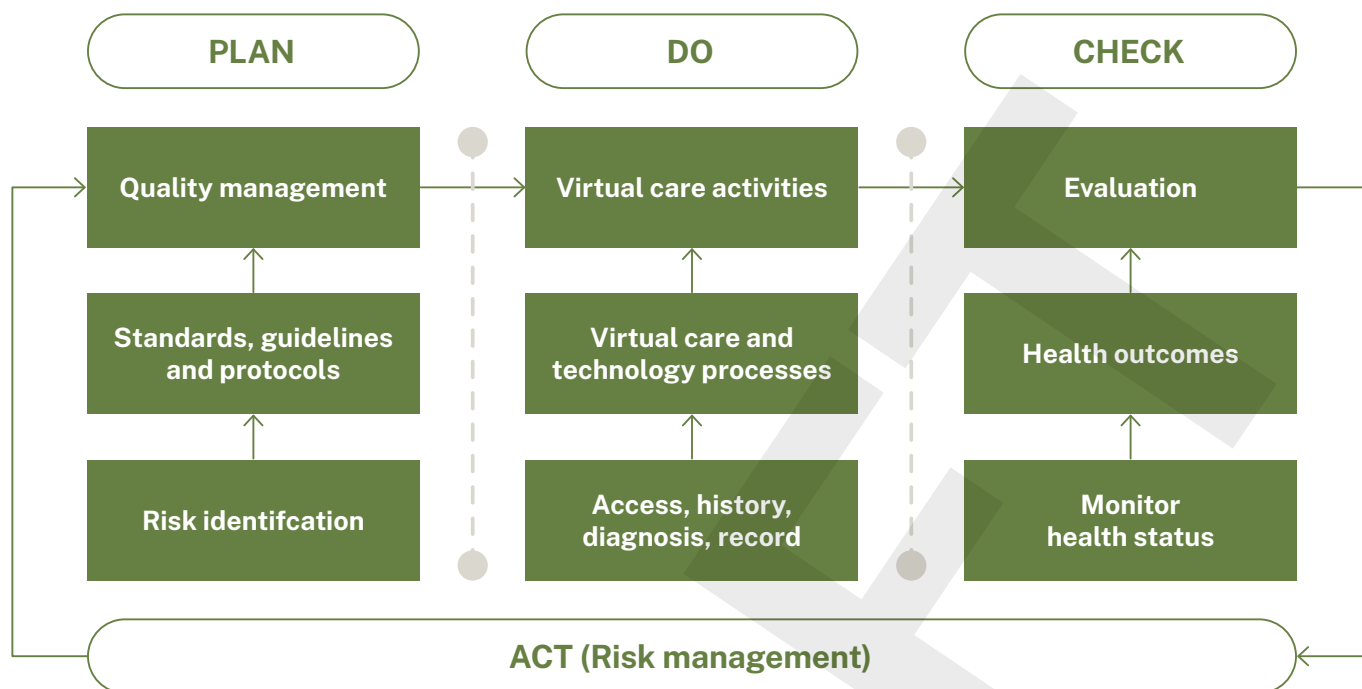


Figure 1 — Mapping the PDCA cycle to virtual care service provision

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

Virtual care can support a broad range of healthcare activities that are not restricted to persons receiving health treatments. In general, virtual care aims to support healthcare quality characteristics that improve the quality of life and quality and safety of care for care recipients.

Application of this document

This document provides requirements for virtual care in Australia – with a particular emphasis on rural and remote contexts and the quality and safety of:

- Rural hospitals using virtual care providers (usually to reduce the workload or impact on local GPs, or where coverage is absent).
- At rural practices, care recipients and health professionals looking for reassurance that a virtual care service, either by the practice itself or an external provider supports high quality and safe care or for particular health needs.
- Organisations, public or private including hospitals, primary care practices, emergency departments planning to provide virtual care, either as a standalone service or combined with in-person care which meets a high standard for quality and safety.

Scope

This document provides requirements for quality management systems that identify and address the risks to the quality and safety of healthcare and continuity of care when using virtual care and remote consultations. These requirements include but are not limited to the following domains:

- management of virtual care quality processes by the healthcare organisation;
- 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 virtual care;
- management of information management and security used in virtual care;
- processes related to the planning and provision of human resources, infrastructure, facilities and technology resources for use by virtual care.

All the requirements of this document are generic and are intended to be applicable to any organisation, regardless of its type or size, or the products and services it provides.

These requirements do not substitute or modify any legal requirements in the form of legislation regulations or legal authorisations which may apply to healthcare organisations or healthcare professionals.

Related standards or guidelines

Many Australian organisations, professional associations and government or regulatory entities have developed guidelines for virtual care in the form of remote consultations. The following documents were consulted during the development of this standard because they provided the most comprehensive guidance relevant to the quality and safety of healthcare services when delivered at a distance (virtual care).

- Australian College of Rural and Remote Medicine. (2020a). Risk management for video consultations. https://www.acrrm.org.au/docs/default-source/all-files/acrrm_risk-management_clinical-video-consultations-factsheet_final.pdf?sfvrsn=dfb6190a_6
- Australian College of Rural and Remote Medicine. (2020b). Telehealth Framework and Guidelines. https://www.acrrm.org.au/docs/default-source/all-files/telehealth-framework-and-guidelines.pdf?sfvrsn=ec0eda85_4
- Australian College of Rural and Remote Medicine. (2022). Defining safe and quality procedural and advanced care in rural and remote locations. Australian College of Rural and Remote Medicine. https://www.acrrm.org.au/docs/default-source/all-files/college-position-statement-defining-safe-and-quality-procedural-and-advanced-care.pdf?sfvrsn=53ba09ac_20
- Australian College of Rural and Remote Medicine. (2025). Practice Standard for Digitally Connected Rural and Remote Communities. Australian College of Rural and Remote Medicine. <https://www.acrrm.org.au/resources/digital-health/digital-health-standards-and-guidelines>
- Australian Commission on Safety and Quality in Health Care. (2017). National Model Clinical Governance Framework. <https://www.safetyandquality.gov.au/sites/default/files/migrated/National-Model-Clinical-Governance-Framework.pdf>
- Australian Commission on Safety and Quality in Health Care. (2020). National Safety and Quality Digital Mental Health Standards. <https://www.safetyandquality.gov.au/standards/national-safety-and-quality-digital-mental-health-standards>
- Australian Commission on Safety and Quality in Health Care. (2021). National Safety and Quality Health Service Standards (second edition). <https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-safety-and-quality-health-service-standards-second-edition>
- Australian Digital Health Agency. (2023). Clinical Governance Framework for Digital Health. https://www.digitalhealth.gov.au/sites/default/files/documents/clinical_governance_framework-2023.pdf
- ISO. (2016). ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes. <https://www.iso.org/standard/59752.html>
- ISO. (2018a). ISO 31000:2018 — Risk management — Guidelines. <https://www.iso.org/standard/65694.html>
- ISO. (2018b). ISO/IEC 20000-1 Information technology — Service management Part 1: Service management system requirements. <https://www.iso.org/standard/70636.html>
- ISO. (2022). ISO/IEC 27001 Information security, cybersecurity and privacy protection — Information security management systems — Requirements. <https://www.iso.org/standard/27001>
- ISO. (2023). ISO 7101:2023 Healthcare organization management — Management systems for quality in healthcare organization — Requirements. <https://www.iso.org/standard/81647.html>
- Royal Australian College of General Practitioners. (2019). Telehealth video-consultations guide. <https://www.racgp.org.au/getmedia/764ab82e-7dea-434e-94ca-cab808f7b5eb/Telehealth-video-consultations-guide.pdf.aspx>
- Standards Australia. (2022). AS ISO 13131:2022 Health informatics — Telehealth services — Quality planning guidelines. https://infostore.saiglobal.com/en-au/standards/as-iso-13131-2022-99279_saig_as_as_3177359

Terms and definitions

Quality management

documented information

information required to be controlled and maintained by an organisation and the medium on which it is contained

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to:

- the management system, including related processes;
- information created in order for the organisation to operate (documentation);
- evidence of results achieved (records).

[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

management system

set of interrelated or interacting elements of an organisation to establish policies) and objectives, as well as processes to achieve those objectives

Note 1 to entry: A management system can address a single discipline or several disciplines.

Note 2 to entry: The management system elements include the organisation's structure, roles and responsibilities, planning and operation.

objective

result to be achieved

Note 1 to entry: An objective can be strategic, tactical, or operational.

Note 2 to entry: Objectives can relate to different disciplines (such as finance, health and safety, and environment). They can be, for example, organisation-wide or specific to a project, product, service or process (3.8).

Note 3 to entry: An objective can be expressed in other ways, e.g. as an intended result, as a purpose, as an operational criterion, as an XXX objective or by the use of other words with similar meaning (e.g. aim, goal, or target).

Note 4 to entry: In the context of virtual care management systems (3.4), objectives are set by the organisation (3.1), consistent with the policy (3.5), to achieve specific results.

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.]

quality characteristic

inherent characteristic of an object related to a requirement
[SOURCE: ISO 9000:2015, 3.10.2, modified — Notes to entry removed.]

quality management

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

quality objective

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

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.]

Risk management

adverse event

unintended event that has a negative influence on healthcare processes
[SOURCE: ISO 13940:2015, 8.2.4]

incident

unplanned interruption to a service a reduction in the quality of a service or an event that has not yet impacted the service to the customer or user
[SOURCE: ISO/IEC 20000-1 modified]

risk management

coordinated activities to direct and control an organisation with regard to risk
[SOURCE: ISO 31000:2018, 3.2]

risk

effect of uncertainty

Note 1 to entry: An effect is a deviation from the expected — positive or negative.

Note 2 to entry: Uncertainty is the state, even partial, of deficiency of information related to, understanding or knowledge of, an event, its consequence, or likelihood.

Note 3 to entry: Risk is often characterized by reference to potential events and consequences, or a combination of these.

Note 4 to entry: Risk is often expressed in terms of a combination of the consequences of an event (including changes in circumstances) and the associated likelihood of occurrence.

safety

freedom from risk which is not tolerable
[SOURCE: ISO/IEC Guide 51:2014, 3.14]

Improvement

audit

systematic and independent process for obtaining evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled

Note 1 to entry: An audit can be an internal audit (first party) or an external audit (second party or third party), and it can be a combined audit (combining two or more disciplines).

Note 2 to entry: An internal audit is conducted by the organisation (3.1) itself, or by an external party on its behalf.

Note 3 to entry: “Audit evidence” and “audit criteria” are defined in ISO 19011.

effectiveness

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

competence

ability to apply knowledge and skills to achieve intended results

conformity

fulfilment of a requirement

continual improvement

recurring activity to enhance performance

corrective action

action to eliminate the cause(s) of a nonconformity and to prevent recurrence

measurement

process (3.8) to determine a value

monitoring

determining the status of a system, a process or an activity

Note to entry: To determine the status, there can be a need to check, supervise or critically observe.

nonconformity

non-fulfilment of a requirement

performance

measurable result

Note 1 to entry: Performance can relate either to quantitative or qualitative findings.

Note 2 to entry: Performance can relate to managing activities, processes (3.8), products, services, systems or organisations

requirement

need or expectation that is stated, generally implied or obligatory

Note to entry: “Generally implied” means that it is custom or common practice for the organisation (3.1) and interested parties that the need or expectation under consideration is implied.

People

care recipient

healthcare recipient

- patient
- client
- subject of care
- service user
- subject of healthcare
- participant in healthcare; who seeks to receive, is receiving or has received healthcare?

[SOURCE: ISO 13940:2015, 5.2.1]

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

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).

carer

caregiver

person who provides care

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

consumer

an individual member of the general public, purchasing or using goods, property or services, for private purposes
[SOURCE: ISO/IEC Statement on Consumer Participation in Standardization Work]

healthcare professional

individual healthcare provider

healthcare personnel having a healthcare professional entitlement recognized in a given jurisdiction
[SOURCE: ISO 13940:2015, 5.2.3.3.1]

Example: In Australia a healthcare professional has Healthcare Provider Identifier-Individual (HPI-I) number registered with Services Australia

informal caregiver

person, other than healthcare professional, who provides care

Example: A family member, a neighbour.

interested party (preferred term)

stakeholder (admitted term)

person or organisation that can affect, be affected by, or perceive itself to be affected by a decision or activity

rural generalist

doctor who has specific expertise in providing medical care for rural and remote or isolated communities.

Note: A Rural Generalist medical practitioner understands and responds to the diverse needs of rural communities: this includes applying a population approach, providing safe primary, secondary and emergency care, culturally engaged Aboriginal and Torres Strait Islander peoples' health care as required, and providing specialised medical care in at least one additional discipline.

top management

person or group of people who directs and controls an organisation at the highest level

Note 1 to entry: Top management has the power to delegate authority and provide resources within the organisation.

Note 2 to entry: If the scope of the management system covers only part of an organisation, then top management refers to those who direct and control that part of the organisation.

Organisational matters

healthcare organisation

healthcare provider organisation

healthcare provider having an organisation role

[SOURCE: ISO 13940:2015, 5.2.3.1]

Example 1: A care team, a group practice, a hospital department, a hospital care unit, a self-employed healthcare professional, a service providing healthcare advice.

Example 2: EXAMPLE In Australia a healthcare professional has Healthcare Provider Identifier-Organisation (HPI-O) number registered with Services Australia

organisation

person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives

Note 1 to entry: The concept of organisation includes, but is not limited to, sole-trader, company, corporation, firm, enterprise, authority, partnership, charity or institution, or part or combination thereof, whether incorporated or not, public or private.

Note 2 to entry: If the organisation is part of a larger entity, the term "organisation" refers only to the part of the larger entity that is within the scope of the virtual care management system (3.4).

partnership

a collaborative association with another community, organisation, company, institution or agency, that usually shares a common interest.

Note: A partnership may be legally binding or informally endorsed.

policy

intentions and direction of an organisation as formally expressed by its top management

process

set of interrelated or interacting activities that uses or transforms inputs to deliver a result

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

service

output of an organisation with at least one activity necessarily performed between the organisation and the customer

supporting organisation

organisation that provides services to healthcare organisation 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.

[SOURCE: Australian Indigenous Governance Institute (<https://aigi.org.au/toolkit/relationships>)]

Health matters

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]

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]

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.]

healthcare activity

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

[SOURCE: ISO 13940:2015, 7.2]

health record

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

[SOURCE: ISO 13940:2015, 12.2]

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 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 Organisation defines health as a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity.

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]

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.

Note to entry: For the definition of a “medical device” under Australian legislation, refer to the Therapeutic Goods Act.

[SOURCE: ISO 81001-1:2021(en), Clause 3.3.13 modified by substitution of Note to entry specific to Australia.]

protocol

customized clinical guideline

[SOURCE: ISO 13940:2015, 9.2.4.1]

virtual care

telehealth

remote consultation

healthcare activity supported at a distance by information and communication technology

Note 1: Virtual care includes all forms of care delivered by what is known as telehealth in Australia

Note 2: It is possible that the subject of care is not directly involved in a virtual care service, e.g. in the case of tele-dermatology where one health professional consults another health professional who is at a distant location.

Note 3: 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 4: Healthcare activities may include both synchronous (real-time) and asynchronous (delayed) interactions using audio, video or messaging technologies between a patient and clinician or clinicians.

1 Context of the organisation

1.1 Understanding the organisation and its context

The organisation shall determine external and internal issues that are relevant to its purpose and that affect its ability to achieve the intended result(s) of its virtual care. This information should be documented in the virtual care management system.

Note 1: External context can include factors related to legal, political, technological, clinical, ethical, cultural, religious, socioeconomic conditions, and social determinants of health, whether international, national, regional or local.

Note 2: Internal context can include factors relating to the organisational vision, values, goals and objectives, workforce values, culture, power structures, religion, knowledge, and access to resources.

Note 3: The available resources (government funded, privately funded or general practice), and location (regional or metropolitan), of the organisation should be considered

Note 4: The sector within which the organisation operates (public, private, health care or social care) may influence the external context

1.2 Understanding the needs and expectations of interested parties

The organisation shall determine:

- the interested parties that are relevant to the virtual care;
- the relevant requirements of these interested parties;
 - > which of these requirements will be addressed through the virtual care management system.

1.2.1 Partnering with interested parties

The organisation shall ensure that virtual care, and associated processes, align with the needs and wants of consumers and care recipients which can be confirmed through partnering and consultation with representative organisations.

The organisation shall ensure partnerships with First Nation people's organisations to support shared decision-making with First Nation peoples in the design, implementation, monitoring and evaluation of the Closing the Gap Framework (or any government policy that succeeds Closing the Gap), which is essential to closing the gap in life outcomes between First Nation peoples and other Australians.

The organisation shall:

- a. partner with consumers, carers and families from the intended care recipient groups in the governance, planning, design, measurement and evaluation of the services;
- b. involve a mix of people in process design that are reflective of the diversity of care recipients and their support people;

- c. provide orientation, support and education to care recipients, consumers, carers, families and support people who are partners in the governance, planning, design, measurement and evaluation of the service;
- d. partner with care recipients and their support people to incorporate their views and experiences into training and education for the workforce;
- e. consider that care recipients and partners' digital health literacy levels are critical to meeting their care needs;
- f. incorporate the principles of person-centredness, partnership and evidence-based practice in service design and operation;
- g. use a charter of rights that is consistent with the Australian Charter of Healthcare Rights;

1.2.2 Service level agreements

The healthcare organisation shall have wherever possible, service level agreements with all healthcare and supporting organisations supporting virtual care services which include.

- a. the desired quality characteristics, quality objectives and required quality procedures to ensure the quality objectives of the virtual care 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.

Note: In some cases, the healthcare organisation can be unable to reach service level agreements with all supporting organisations to ensure service quality (such as internet or application organisations). In this case, they should rely on the information that has been provided by the manufacturer or organisation, for determining the quality of the device or service used in the virtual care and undertake a risk assessment of the suitability of the device or service for application in a virtual care.

1.3 Determining the scope of the virtual care management system

The organisation shall determine the boundaries and applicability of the virtual care management system to establish its scope.

When determining this scope, the organisation shall consider:

- a. the external and internal issues referred to in 4.1;
- b. the requirements referred to in 4.2.
- c. The scope shall be available as documented information.

1.4 Virtual care management system

1.4.1 Quality and safety management

The organisation shall establish, implement, maintain and continually improve quality and safety management systems for virtual care, including the processes needed and their interactions, in accordance with the requirements of this document.

Note 1: This section provides requirements for organisations to implement appropriate clinical governance and management systems for quality, risk, safety and adverse events and to ensure patient safety, uphold care standards, and support continuous quality improvement with suitable training.

Note 2: Where the organisation has established quality, risk, safety and adverse event management systems for other activities these systems should be used to meet the requirements stated in the following sections

Note 3: Annex 1 provides guidelines for risk management according to ISO 31000

Note 4: Annex 2 provides guidance for the safety and quality of procedural and advanced care in rural and remote locations

1.4.2 Quality management

The organisation shall implement a quality management approach to:

- a. set out, review and maintain the currency and effectiveness of policies, procedures and protocols;
- b. monitor and act to improve adherence to policies, procedures and protocols;
- c. review compliance with legislation, regulations and jurisdictional requirements.

Note: AS ISO 13131:2022 Health informatics - Telehealth services - Quality planning guidelines provides guidance to organisations in the development of quality plans.

1.4.3 Risk management

The organisation shall:

- a. identify and document service risks;
- b. use clinical, technical, research evidence and other data collections to support risk assessments;
- c. regularly review and act to improve the effectiveness of the risk management system;
- d. report on risks to the workforce, and care recipients and their support people;
- e. plan for and manage internal and external emergencies and disasters, including cybersecurity risks and threats.

Note 1: Annex 1 summarises the risk management framework of ISO 31000:2018

Note 2: Annex 2 explains the ACRRM risk management framework for safe and quality procedural and advanced care suitable for use by virtual care services provided in rural and remote applications

Note 3: Other risk management frameworks can be developed to suit the organisational context

1.4.4 Safety, adverse event and incident management

The organisation shall implement an adverse event management and investigation systems which:

- a. assists the workforce to recognise and report adverse events and incidents;
- b. assist care recipients and their support people to communicate concerns or adverse events and incidents;
- c. involve the workforce, consumers, carers and families in the review of adverse events and incidents;
- d. provide timely feedback on the analysis of adverse events and incidents to the governing body, the workforce, and care recipients and their support people;
- e. uses the information from the analysis of adverse events and incidents to improve safety and quality;
- f. incorporate risks identified in the analysis of adverse events and incidents into the risk management system;
- g. regularly reviews and acts to improve the effectiveness of the adverse event management system;
- h. use an open disclosure program that is consistent with the Australian Open Disclosure Framework;
- i. monitor and act to improve the effectiveness of open disclosure processes.

Note 1: Clause 7 states that the organisation shall continually improve the suitability, adequacy and effectiveness of the virtual care service management system.

1.4.5 Safety and quality training

The organisation shall:

- a. identify needs for training in safety and quality;
- b. assess the safety and quality competency and training needs of its workforce;
- c. provide access to training to meet its safety and quality training needs;
- d. monitor the workforce's participation in the training.

2 Leadership

2.1 Leadership and Governance

Top management shall demonstrate leadership and governance of the virtual care management system by:

- a. ensuring that the virtual care policy and objectives are established and are compatible with the strategic direction of the organisation;
- b. ensuring the integration of the virtual care management system requirements into the organisation's business processes;
- c. ensuring that the financial, human and technology resources needed for the virtual care management system are available;
- d. communicating the importance of effective virtual care management and of conforming to the virtual care management system requirements;
- e. ensuring that the organisation's management system achieves the virtual service objectives;
- f. directing and supporting persons to contribute to the effectiveness of the virtual care management system;
- g. promoting continual improvement of the safety and quality of virtual care services – based on evidence-based practice;
- h. supporting other relevant roles;
- i. promoting a person-centred approach to service design and operation;
- j. ensuring the workforce has the appropriate qualifications, skills, orientation, training, experience, attributes, cultural awareness and competency and oversight to ensure clinical safety and quality in service delivery;
- k. promoting the physical and psychological safety and wellbeing of the workforce;
- l. promoting risk-based thinking and risk assessment.

Note: This section provides requirements for the leadership of the organisation to commit to a management system for virtual care, establish a governance framework supported by appropriate policies and define roles and responsibilities to drive improvements in service safety, quality, performance and effectiveness. A clear line of accountability and authority for clinical and information technology services should be implemented to facilitate review at all levels of the organisation.

2.2 Virtual care governance

The governing body of the organisation shall:

- a. provide leadership to develop a culture of safety and quality improvement, and satisfies itself that this culture exists within the organisation;
- b. focus on the needs of rural and remote communities;
- c. provide leadership to ensure partnering with other healthcare organisations, care recipients and their support people;
- d. set priorities and strategic directions for ethical, safe and high-quality care, and ensure that these are communicated effectively to the workforce and care recipients and their support people;
- e. ensure that roles and responsibilities are clearly defined for the governing body, management, clinicians, care teams, technicians and other members of the virtual care service;
- f. monitor the action taken from the analysis of clinical adverse events and information technology incidents and trends in relation to the quality and safety of virtual care;
- g. review reports and monitor the organisation's progress on safety, quality, performance and effectiveness;
- h. establish principles and practices within governance frameworks that support the organisation's ability to adapt to technology as it changes;
- i. establish and maintain clinical and information technology governance frameworks and use the processes within these frameworks to drive improvements in safety, quality, performance and effectiveness;
- j. implement and monitors strategies to meet its priorities for diverse population groups, including First Nation peoples, and inclusion of care recipients and where relevant, their support people;
- k. apply ethical principles to its business decision-making about the design, development and delivery of services.

Note 1: Where the organisation has established governance arrangements for other activities these systems should be used to meet the requirements stated in the following sections

Note 2: The Australian Commission on Safety and Quality in Health Care, National Model Clinical Governance Framework (2017) states that clinical governance is an integrated component of (overall) organisational governance. For virtual care, clinical governance and information technology governance are key component of organisational governance

Note 3: For examples of good practice see

- National Model Clinical Governance Framework (Australian Commission on Safety and Quality in Health Care, 2017)
- Clinical Governance Framework for Digital Health (Australian Digital Health Agency, 2023)

2.3 Clinical governance

In addition to general governance, organisations shall have in place a comprehensive clinical governance framework, intended to inform the design, implementation, operation and evaluation of healthcare services, as well as having a role in clinical safety (see clause 1.4.1) which includes:

- a. rural generalists, and other stakeholders with experience in rural and remote communities;
- b. First Nation peoples.

2.4 Virtual care policy

Top management shall establish a virtual care quality and safety and an information technology services policies that:

- a. is appropriate to the purpose of the organisation;
- b. provides a framework for setting virtual care objectives;
- c. includes a commitment to meet applicable requirements;
- d. includes a commitment to continual improvement of the virtual care management system;
- e. addresses affordability and accessibility of its services, while minimising health, safety and financial risks to care recipients;
- f. considers economically challenged underprivileged and vulnerable populations;
- g. considers input from stakeholders;
- h. expresses a commitment to people-centred care;
- i. Is available and maintained as documented information throughout the organisation;
- j. is available to interested parties, as appropriate;
- k. can be communicated, understood and applied within the organisation.

Note 1: For further guidance on health policy see ISO 7101:2023. Healthcare organisation management — Management systems for quality in healthcare organisations — Requirements, Clause 5.2

Note 2: For further guidance on information technology policy see ISO/IEC 20000-1:2018. Information technology — Service management, Part 1: Service management system requirements, Clause 5.2

2.5 Roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned and communicated within the organisation including for members of the governing body, clinicians; technicians and other members of the workforce.

Top management shall assign the responsibility and authority for:

- a. ensuring that the virtual care management system conforms to the requirements of this document;
- b. reporting on the performance of the virtual care management system to top management.
- c. reporting on the performance and status of quality objectives and health indicators at all levels of the healthcare organisation and/or healthcare system including primary, secondary, tertiary, quaternary care, and private providers (as appropriate to the healthcare system structure);
- d. ensuring the effective functioning of the risk management program;
- e. ensuring effective functioning of technology systems supporting virtual care;
- f. ensuring transparency of reporting;
- g. promoting and improving care recipient experience;
- h. proposing and implementing modifications to improve the quality management system;
- i. allocating resources and empowering the workforce to carry out their roles and responsibilities in the quality management system.

Note 1: For further guidance on health policy see ISO 7101:2023. Healthcare organisation management — Management systems for quality in healthcare organisations — Requirements, Clause 5.2

Note 2: For further guidance on information technology policy see ISO/IEC 20000-1:2018. Information technology — Service management, Part 1: Service management system requirements, Clause 5.2

3 Planning

3.1 Actions to address risks and opportunities

When planning for the virtual care management system, the organisation shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to:

- give assurance that the virtual care management system can achieve its intended result(s);
- prevent, or reduce, undesired effects;
- achieve continual improvement.

The organisation shall plan:

- actions to address these risks and opportunities;
- how to
 - integrate and implement the actions into its virtual care management system processes;
 - evaluate the effectiveness of these actions.

3.2 Virtual care quality and safety objectives and planning to achieve them

The organisation shall establish virtual care quality and safety objectives at relevant functions and levels.

Virtual care objectives shall:

- be consistent with the virtual care service policy;
- be measurable (to the fullest extent practicable);
- take into account applicable requirements;
- be monitored;
- be communicated;
- be updated as appropriate;
- be available as documented information.

When planning how to achieve its virtual care quality and safety objectives, the organisation shall determine:

- the objectives of the virtual care service;
- what will be done;
- what resources will be required;
- who will be responsible;
- when it will be completed;
- how the results will be evaluated.

3.3 Planning of implementation

The organisation shall implement virtual care in a planned manner, including:

- developing or utilising a business case i.e. considering the costs, benefits and sustainability of virtual care;
- consulting with the staff about the workflow and other changes virtual care will introduce;

- making a formal decision to use virtual care, and then supporting the changes needed for implementation;
- assessing the need for staff training or professional development in the use of virtual care and enabling this to occur.
- including virtual care in its continuous quality improvement program;
- ensuring that virtual care is covered by insurance and professional indemnity;
- consulting with local stakeholders and shared care providers;
- providing instructions in plain language on how to use the virtual care service;
- assessing the digital health literacy of the local community using the virtual care service;
- assessing the availability of technology in the community to support virtual care. assessing the availability of the in the community to support the virtual care service

3.4 Planning of changes

When the organisation determines the need for changes to the virtual care management system, the changes shall be carried out in a planned manner by:

- establishing criteria for the processes;
- implementing control of the processes in accordance with the criteria.

Documented information shall be available to the extent necessary to have confidence that the processes have been carried out as planned.

The organisation shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organisation shall ensure that externally provided processes, products or services that are relevant to the virtual care management system are controlled.

3.5 Service design

3.5.1 Model of care - organisation

The organisation shall ensure that the model of care for each virtual care service is based on best available evidence, best practice, supporting policies and can achieve the stated outcomes of care for care recipients.

The organisation shall:

- document the purpose and intent of the model of care for each service and the context in which it will operate;
- define the intended care recipient demographic and match the model of care to the care recipients and their support people;
- establish a set of criteria about which care recipients are suitable for virtual care;

- d. monitor and evaluate the performance and effectiveness of the virtual care service's model of care;
- e. assign accountability for maintaining and improving the effectiveness of the virtual care service's model of care;
- f. ensure products and services are designed, developed, delivered and continually improved on the basis of effective and appropriate use of data, evidence and existing research to drive clinical safety and quality;
- g. when designing, developing and delivering virtual care, consider consumer journeys, shared care arrangements and clinical workflows through partnership with other health professionals, communities, consumers, care recipients and their representatives;
- h. ensure that the delivery of care has access to experts in rural generalism for guidance and context;
- i. include staff and other stakeholders in consultations about changes to workflow, workloads, required skills, training or other changes a service can require.

Note 1: Virtual care services should demonstrate that their clinicians deliver care aligned with community needs, health service availability, best-practice guidelines, professional ethics, and legal obligations. Clinicians should prioritise patient safety, risk management and clinician accountability while remaining conscious of context and cultural safety.

Note 2: The RACGP Telehealth video-consultations guide provides guidance on getting started with video consultations.

Note 3: The ACRRM Telehealth Framework and Guidelines provides guidance on selecting appropriate care recipients for health care using telehealth services

3.5.2 Diversity of needs

The organisation shall include in a design document consideration of:

- a. groups of care recipients who are at higher risk of harm when using information technologies to provide virtual care;
- b. the diversity of care recipients and their support people, and higher-risk groups into the planning and delivery of the service;
- c. communication mechanisms tailored to the diversity of care recipients and their support people;
- d. processes to assess and optimise the usability of each virtual care service;
- e. barriers to accessing virtual care services associated with the hardware, software, data requirements and platform of the services, or the language, location, age, culture and ability of the care recipients and their support people;
- f. compatibility of virtual care services with commonly used assistive technologies;
- g. the needs and preferences of First Nations peoples, culturally and linguistically diverse communities and people with particular needs including people with:

- > Mental health conditions and psychosocial impairment;
- > Developmental and cognitive impairment;
- > Vision impairment or blindness Hearing impairment;
- > Speech difficulties;
- > Mobility impairments.

3.5.3 Accessibility

The organisation shall provide accessible, appropriate and inclusive virtual care which considers.

- a. the ability of a care recipient to travel, their family, work and cultural situation when determining the services to be offered;
- b. the availability and capability of specialists, local clinical staff and facilities required to provide service continuity;
- c. the availability and capability of specialists, local clinical staff, pathology or imaging services and facilities required to provide service continuity when in-person services are subsequently required as a result of the virtual care based assessment;
- d. potential barriers such as access to computers or adequate telecommunications;
- e. care recipients who may choose which healthcare services they consider appropriate to access, whether or not delivered using virtual care.

Note: The ACRRM Telehealth Framework and Guidelines has adopted the ARTS framework which health and medical colleges, clinicians and health care organisations can use to develop risk based guidelines for the establishment of high quality telehealth services. ACRRM recommends that the attendant risks of health services should be assessed in the context of the patient situation, the health professional and the community.

3.5.4 Availability

The organisation shall include in a 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;
- d. provision of alternative services that can be accessed when usual services are unavailable;
- e. contact, booking arrangements and instructions for using the service.

The healthcare organisation shall specify in a design document the durations of the healthcare activities that are required to deliver appropriate and effective healthcare to the care recipient.

4 Support

4.1 Human Resources

The organisation shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the virtual care management system.

4.2 Workforce Competence

The organisation shall:

- a. determine and take actions to acquire the necessary competence of person(s) doing work under its control that affects its virtual care service design, operation and performance;
- b. maintain a documented process for recruitment that defines the requirements for competence, education, qualification, training, technical knowledge, skills, and experience in a virtual care delivery;
- c. where relevant, shall ensure recruitment includes doctors with experience in rural generalism;
- d. ensure that these persons are competent on the basis of appropriate professional standards, education, training, or experience;
- e. provide orientation to all workforce at the time of joining the organisation which shall include but not be limited to organisation's services, rules and regulations, processes, policies and procedures;
- f. provide ongoing education and training necessary to maintain the required level of performance and competency within a defined scope of clinical practice.;
- g. develop and implement a documented performance evaluation system;
- h. provide training where required on respecting care recipients' preferences and choices, including their options for care and treatment, components of co-production and compassionate care, and obtaining informed consent;
- i. specify the key skills, and competencies required by personnel involved in technology and information management services are specified by the healthcare organisation or supporting organisation;
- j. retain documented information as evidence of competence for all workforce members.

Appropriate documented information shall be available as evidence of competence.

Note 1: Applicable actions can include, for example: the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

Note 2: Virtual care services should demonstrate that their clinicians deliver care aligned with best-practice guidelines, professional ethics, and legal obligations; and prioritise patient safety, risk management and clinician accountability while remaining conscious of context and cultural safety.

4.3 Awareness

Persons doing work under the organisation's control shall be aware of:

- a. the virtual care quality and safety policy and the objectives applicable to their role;
- b. their contribution to the effectiveness of the virtual care management system for quality and safety in the organisation, including the benefits of improved healthcare quality and safety performance;
- c. the implications of not conforming with the virtual care management system requirements.

4.4 Communication

4.4.1 Internal and external communications

The organisation shall determine the internal and external communications relevant to the virtual care management system including:

- a. on what it will communicate;
- b. when to communicate;
- c. with whom to communicate;
- d. how to communicate.

4.4.2 Person centred services

The organisation shall provide person-centred services by

- a. listening to people's needs, goals, values, preferences and experiences to ensure the design and delivery of clinically safe, quality products and services;
- b. creating an environment of co-production that encourages care recipients to participate in their care;
- c. working with care recipients to ensure their cultural safety;
- d. considering the social emotional and cultural wellbeing of communities.

4.4.3 Feedback and complaints management

The organisation shall:

- a. have processes to seek regular feedback from care recipients and their support people about their experiences of the service and outcomes of care
- b. use this information to improve safety, quality, performance and effectiveness;
- c. have a complaints management system;
- d. encourage and assist care recipients and their support people to report complaints;
- e. involve care recipients and their support people in the review of complaints;
- f. resolve complaints in a timely way;
- g. provide timely feedback to the governing body, the workforce, and care recipients and their support people on the analysis of complaints and actions taken;

- h. record the risks identified from the analysis of complaints in the risk management system, the actions taken and the controls implemented;
- i. regularly review and act to improve the effectiveness of the complaints management system.

Note: The Australian Commission on Safety and Quality in Health Care provides Complaints Management Handbook for Health Care Services.

4.4.4 Care recipient communication

Communication processes with care recipients for telehealth or virtual care shall include:

- a. providing information relating to services, rights and responsibilities;
- b. handling enquiries, agreements or requests, including any actions taken;
- c. obtaining care recipient feedback relating to services, including complaints;
- d. ensuring that feedback mechanisms are accessible, understandable, and appropriate to the care recipient's education level and access to resources (e.g. computer, telephone, literacy level);
- e. provision of current product and service information;
- f. promoting and educating the care recipient on how to access their own My Health Record.

The organisation shall ensure that in-product sales or advertising:

- a. complies with Australian Consumer Law and regulatory requirements;
- b. is appropriate for care recipients.

Note: The Australian Commission on Safety and Quality in Health Care provides a digital mental health services product information template.

4.4.5 Care recipients' expenses

Care recipients shall be informed by the organisation of their expenses for virtual care and how and by whom these expenses will be met including:

- 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 organisations, such as the Australian Government Medicare rebates, insurance companies that can reimburse the costs of healthcare provision.

4.4.6 Clinical communication

The organisation shall have processes in place to ensure effective clinical communication which:

- a. safeguard the security and privacy of care recipients' personal information during referrals and transfers between healthcare workers, at shift change, between hospitals and care networks;
- b. ensure that oral and telephone orders, and communication of clinical results, are controlled and verified for accuracy;

- c. demonstrate the use of comprehensive clinical records that allow for proper tracking of communication between different professionals and service sites;
- d. demonstrate that all communications containing personal health information follow national or international standards of privacy;
- e. maintain documented information as evidence of employee training on proper clinical communication and privacy requirements.

4.5 Safe environment

4.5.1 Safety by design

The organisation shall ensure the safety and quality of care through the design of services and information technology by:

- a. providing terms and conditions for use of services are fair and transparent and do not mislead care recipients and where relevant, their support people;
- b. providing devices, infrastructure and facilities that are fit for purpose, well maintained and accessible for people with a disability or particular needs;
- c. designing systems and processes which minimises the risk of abuse or exploitation of care recipients and their carers;
- d. preserving the dignity of care recipients and where relevant, their carers.

4.5.2 Organisational facilities

Virtual care activities shall take place in accommodation that is appropriate for the healthcare professional to effectively deliver virtual care and / or the care recipient to effectively participate in the activity.

The organisation shall ensure the following:

- a. adequate physical space is available to conduct consultations or activity;
- b. an appropriate level of comfort and privacy is available for the healthcare professional and if required, a care recipient(s);
- c. the physical space has good lighting, little or no background noise, and can accommodate use of a camera;
- d. equipment can effectively transmit and receive an appropriate quality of audio, video or other information;
- e. equipment can be used in a safe manner;
- f. adequate internet connectivity and capacity (acknowledging local availability may be limiting);
- g. the availability of a system for coordinating and booking the people, equipment and facilities needed for consultations using virtual care.

4.5.3 Care recipient facilities

The organisation shall provide advice to care recipients receiving virtual care outside of the organisational facility regarding:

- a. adequate physical space should be available to conduct consultations;
- b. an appropriate level of comfort and privacy should be available for the care recipient and an informal care giver if required;
- c. equipment and software should be able to effectively transmit and receive an appropriate quality of information including audio or video information;
- d. equipment, including mobile medical devices, health and wellness devices should be used in a safe manner;
- e. there is adequate internet connectivity and capacity;
- f. presence of carers and use of any required assistive technology, for example those used for hearing and vision impairments;
- g. The adequacy, effectiveness and safety of any monitory devices (whether or not these are approved medical devices) that the care recipient may have or be provided with.

Note: Standards Australia AS 4891 Health informatics – Provision of guidance for users of a telehealth or virtual care service' provides further guidance on the information that should be provided to care recipients and consumers.

4.6 Documented information

4.6.1 General

The organisation's virtual care management system shall include:

- a. documented information as required by this document;
- b. documented information determined by the organisation as being necessary for the effectiveness of the virtual care management system.

Note: The extent of documented information for a virtual care management system can differ from one organisation to another due to:

- the size of organisation and its type of activities, processes, products and services;
- the complexity of processes and their interactions;
- the competence of persons.

4.6.2 Creating and updating documented information

When creating and updating documented information, the organisation shall ensure appropriate:

- a. identification and description (e.g. a title, date, author, or reference number);
- b. format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
- c. review and approval for suitability and adequacy.

4.6.3 Control of documented information

Documented information required by the virtual care management system and by this document shall be controlled to ensure:

- a. it is available and suitable for use, where and when it is needed;
- b. it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

For the control of documented information, the organisation shall address the following activities, as applicable:

- a. distribution, access, retrieval and use;
- b. storage and preservation, including preservation of legibility;
- c. control of changes (e.g. version control);
- d. retention and disposal.

Documented information of external origin determined by the organisation to be necessary for the planning and operation of the virtual care management system shall be identified as appropriate, and controlled.

Note: Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

4.7 Information management systems

4.7.1 General security

The organisation's information management system(s) shall be validated for its functionality, including the proper functioning of interfaces within the organisation information management system, by the organisation before use.

Whenever there are changes, including organisation software configuration, they shall be authorised, documented, tested, and validated before implementation.

The information management system shall:

- a. be protected from unauthorised access;
- b. be safeguarded against tampering and loss;
- c. be maintained in a manner that ensures the integrity of data and information;
- d. include adverse events and incidents of any malfunctioning in the recording system;
- e. have provisions for backup;
- f. have contingency plans so that services are not disrupted;
- g. address cybersecurity risk protections.

Note: This section provides requirements for data protection and security including general security, privacy access, identity, confidentiality, data quality for management of healthcare records, information collection sharing and disposal, consent for consultations, ordering and prescribing,

4.7.2 Privacy

The organisation shall:

- a. ensure privacy policies are readily available to care recipients and their support people before accessing and while using the services;
- b. ensure privacy policies are easy to understand and transparent for care recipients and their support people;
- c. ensure privacy policies are compliant with privacy laws, privacy principles and best practice;
- d. notify the care recipient and obtains agreement to the privacy regulations of the organisation providing the services, including possible updates and/or modifications to the regulations;
- e. implement a system for obtaining and recording the permissions provided by care recipients regarding the use of data and information based on the principles of informed consent, and
- f. define processes to audit the compliance of healthcare professionals and healthcare supporting organisations with the privacy regulations of the healthcare organisation and any national regulations or legislation that can apply to the service.

4.7.3 Identity and confidentiality

The organisation shall implement processes which:

- a. ensure the confidentiality and availability of health records whether generated by a healthcare organisation, an individual or a device, that are in electronic storage or transmission is protected by the healthcare organisation;
- b. confirm that the information and communication technologies meet justifiable standards for the protection of health records in electronic storage or transmission;
- c. confirm that healthcare professionals apply the guidelines of the healthcare organisation to protect the confidentiality of health records, and
- d. ensure the semantic interoperability of health records used 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.

4.7.4 Data quality

The organisation shall ensure that processes are

- a. implemented to ensure the dependability of data representation, generation, collection, transmission, exchange and use by services, and
- b. documents the decisions made when designing these processes.

Note 1: These requirements are 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 2: The quality of textual, numerical, video or audio information can reduce the dependability and effectiveness of the information leading to poor or unsafe decisions.

4.7.5 Health record management

The organisation's health records systems shall:

- a. support the creation and maintenance of accurate healthcare records;
- b. be configured and used in a manner than maximises the capture and use of structured and coded data instead of unstructured text;
- c. comply with security and privacy legislation and regulations;
- d. support the systematic audit of clinical information and the technical operation of the healthcare record;
- e. integrate multiple information systems, where they are used;
- f. use national patient, provider and organisation identifiers;
- g. use standard national terminologies;
- h. describe access to the system by the workforce, to comply with legislative requirements;
- i. maintain the accuracy and completeness of the clinical information the organisation uploads into other health record systems.

Note: Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

4.7.6 Documentation of consultations

The organisation and the healthcare professional shall determine the following:

- a. how and by which professional or professionals a consultation using virtual care services is documented;
- b. the means by which the consultation is documented;
- c. the elements of the consultation that should be documented and shared.

4.7.7 Information collection, sharing, and disposal management

The organisation has systems for the collection, use, disclosure, storage, transmission, retention and destruction of data that provide care recipients and where relevant, their support people with:

- Where data collected is stored, who has access to it, and how it is protected from unauthorised access;
- information on the types of data collected and how the information is used;
- information on who has access to their data, including through data sharing agreements, provision or sale to third parties, and if transfer of data outside of Australia occurs;
- timely information about requests to access data by external parties (sharing of data) are provided by the organisation;
- protection of their data that was provided anonymously or using a pseudonym;
- prevention against the unauthorised re-identification of anonymous or de-identified data;
- information on where their data will go if the service ceases to operate or changes ownership.

Note 1: Virtual care services should ensure clinical systems interface with external systems, such as real-time prescription monitoring and My Health Record, to support informed care and reduce risk.

Note 2: A Virtual care service should work to actively uphold the principles of interoperability, including through the relevant and appropriate sharing of clinical information with digital patient repositories, such as My Health Record

Note 3: When a patient commences treatment the service should ask the care recipient for consent to communicate with their regular medical practitioner or other nominated community clinician. If the patient provides consent, the virtual care service should prepare a patient summary record.

4.7.8 Consent management

The organisation shall implement mechanisms for care recipients to be provided with information that will enable them to make informed decisions to:

- consent to the use of personal data including written information, photos and videos for any purpose beyond direct care;
- consent before any personal data and records are used in research;
- withdraw or withhold consent for the collection, storage or distribution of their personal data and records;
- opt-out from the sharing of their personal data and records;
- access, copy and amend their personal data and records;
- request deletion of their personal data and records;
- consent to the use of audio or video recordings of remote consultations;
- consent to an artificial intelligence supported scribe software being used to record and provide notes of a virtual consultation;

- Consent to the storage of their personal data and records in a known location and information system.

Note: All care recipients should provide informed consent before receiving treatment (including being prescribed medication).

4.8 Technology systems management

4.8.1 Technology systems design

The organisation shall ensure that procedures are in place for the following:

- service level agreements with technology providers which specify the levels of service required to support the agreed availability of care;
- capacity management ensures that technology system resources are in place to effectively meet planned demand for virtual care services;
- availability management to ensure systems are dependable and available for use in accordance with the service level agreements provided to users of virtual care services;
- service continuity management to provide recovery plans for virtual care when there is a significant failure;
- ensure security of systems are achieved using a 'secure by design' methodology where security is considered at all stage of the system lifecycle.

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 organisation to inform the supplier about deficiencies of equipment and devices can be defined in service level agreements.

Note 3: This section provides requirements for designing technology solutions, supporting and managing infrastructure, technology infrastructure management, deploying and operating technology and management of devices. Virtual care platforms and should be reliable, private and secure. Infrastructure should support high-quality video, voice, text, and diagnostic tools, and accommodate patient preferences for how services are delivered.

Note 4: ISO/IEC 20000-1 Information technology – Service management Part 1: Service management system requirements provides further guidance for the support of technology systems.

4.8.2 Technology service support

The organisation shall ensure that procedures are in place to maintain virtual care service continuity and dependability using the following:

- incident management unplanned interruption to technology services or a reduction in the quality of a service;
- problem management to undertake root cause analysis and determine potential actions to prevent the occurrence or recurrence of technology based incidents;
- change management to manage the technology based risks, health and safety risks, business benefits, feasibility and financial impact for existing

services when technology changes occur release management for the deployment of new or changed technology services and service components into the live environment. A release shall be verified against documented acceptance criteria and approved before deployment.

Note 1: When a problem occurs with the equipment that is necessary for the delivery of the care by virtual care, procedures should specify how problems can be diagnosed, communicated and resolved. Healthcare organisations 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.

Note 2: 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®)2) and ISO/IEC/TR 20000-11 provides guidance on their relationship.

(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 of the product named)

4.8.3 Technology infrastructure management

The organisation shall ensure that the infrastructure used for virtual care which is provided by a healthcare or supporting organisations is:

- a. based on an accountable requirements analysis and planning process covering design, deployment, operations and technical support;
- b. interoperable with other health systems using appropriate standards with other virtual care services;
- c. sufficiently redundant to enable continuity of service should one component fail;
- d. usable and fit for purpose;
- e. designed to communicate reliably over the available telecommunications services;
- f. secured against cyber attacks according to justifiable standards. and
- g. financially efficient over the whole of the infrastructure life cycle.

Note 1: Infrastructure can consist of equipment, software, telecommunications and computer networks.

Note 2: Equipment should work reliably and well over the locally available network and bandwidth.

Note 3: The equipment should be compatible with the equipment used at the other locations

Note 4: Suitability of peripheral devices should be jointly determined by the patient-end clinician and the distant specialist.

4.8.4 Deploying technology

The organisation shall ensure that procedures are in place for the following:

- a. design, build, test and roll-out of equipment, software and devices for virtual care using an appropriate project management methodology;
- b. confirmation that the equipment or software is usable for virtual care;

- c. confirmation that the equipment or software is safe to operate;
- d. installation of equipment and devices for virtual care according to the guidelines of the manufacturer or supplier;
- e. repair or replacement of defective equipment and devices;
- f. removal and secure destruction of the equipment or devices.

4.8.5 Operating technology

The organisation shall ensure that operations management can provide day-to-day technical supervision of information and communication technology infrastructure used for virtual care 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 information and communication technologies infrastructure;
- h. management of technical diversity arising from the use of multiple technologies or suppliers.

4.8.6 Device management

The organisation shall ensure that the devices used for virtual care

- 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 virtual care systems;
- d. communicate dependably over the available telecommunications services, and
- e. are accompanied by internal technical support arrangements, downtime procedures, availability of spare parts and 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 provides useful guidance for medical devices and medical IT networks.

Note 4: 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 and the Australian Therapeutic Goods Administration). 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 organisations, suppliers of non-healthcare services (e.g. technology services) and manufacturers of devices to provide virtual care.

5 Operation

5.1 Obtaining consent

5.1.1 Gaining informed consent

The organisation shall obtain informed consent for virtual care activities that confirms that the care recipient has:

- a. been informed about the available virtual care;
- b. understood the relative advantages and disadvantages of receiving care virtual care;
- c. understands that some services cannot be delivered by virtual care and will require an in-person service;
- d. been informed about any anticipated out of pocket expenses;
- e. easy access to plain language information about virtual care.
- f. understood the information provided;
- g. been given the option to read the provided information later;
- h. been informed that the organisation complies with the relevant national legislation and standards to protect their privacy and data security;
- i. understood the need to exchange information with other health professionals in their care team;
- j. understood how and where to make a complaint about the service.

5.1.2 Understanding care recipient preferences

The organisation shall ensure care recipients can make informed choices from the available options for healthcare whether or not delivered by virtual care from the options that have been provided by the organisation and the healthcare professional including being able to:

- a. express informed choices regarding the performance of healthcare activities;
- b. request access to healthcare activities that do not use virtual care;
- c. not provide consent for specific healthcare activities to be performed including healthcare using virtual care;
- d. change their preferences and switch to another mode of health care delivery.

Note: When a patient ceases to receive treatment from a telehealth or virtual care service, on request of the care recipient the service should prepare a handover document with a summary of the patient's treatment and clinical progress in a form useful to a another healthcare professional.

5.1.3 Care recipient identity

The organisation or healthcare professional shall verify the identity of each care recipient by one or more of the following methods:

- a. obtaining the care recipient's Medicare number or other healthcare identifier;
- b. reviewing a piece of photo identification; and
- c. communicating with the care recipient's regular general practitioner or healthcare professional.

5.2 Appropriate care

5.2.1 Medical history confirmation

The organisation or healthcare professional shall verify, by reference to appropriate sources of information, the most pertinent parts of the medical history stated by each patient before they may receive treatment by means of:

- a. questions posed during a phone consultation;
- b. a video consultation (if not already undertaken);
- c. prescribing, pathology, diagnostic imaging and immunisation history from My Health Record;
- d. communication with the patient's regular GP;
- e. external clinical records such as clinical records held in other portals - such as state based shared record systems and real time prescription monitoring systems.

5.2.2 Providing appropriate healthcare services

The organisation shall ensure virtual care activities are:

- a. appropriate for the care recipients based on documented inclusion or exclusion criteria;
- b. assessed to be appropriate by the healthcare professional during the healthcare activity;
- c. culturally safe services that meet the needs of its First Nations peoples and their support people.

5.2.3 Managing care recipient safety

When there are concerns about the quality of care available to the care recipient, or the safety of the care delivered, the organisation or healthcare professional shall notify the:

- relevant emergency service, health service, specialist or other healthcare professional;
- top management of the organisation;
- nominated carers for the care recipient.

in order that actions may be taken to ensure the safety of the care recipient.

5.3 Care planning

5.3.1 Factors in providing virtual care

The organisation or healthcare professional when deciding if virtual care is appropriate shall take into account:

- clinical factors such as continuity of care, shared care, and the best model of care for the individual patient;
- practical factors such as the availability of other healthcare services, specialists and local clinical staff should a referral be required;
- Care recipient factors such as the ability to travel, self-care, plus their family, work and cultural situation.

5.3.2 Guidelines and protocols

The organisation shall adopt organisational or professional clinical guidelines and protocols that support collaboration in healthcare delivery among healthcare organisations and healthcare professionals using a mix of in-person and virtual care that ensures the:

- care recipient understands who will participate in the provision of their healthcare and the various roles they have;
- healthcare professional at regular intervals during to the execution of the care plan, asks care recipients whether they understood and followed the advice and instructions given;
- appropriate follow-up services for care recipients are coordinated in collaboration with the care recipient and other healthcare professionals.

Note: A healthcare organisation can also define and maintain local clinical guidelines and protocols for treatment, nursing and care.

5.4 Healthcare continuity

5.4.1 Alternative care plans

The organisation shall have plans to enable continuity of healthcare, when there is a failure of information and communications technology or in an acute clinical situation including:

- appropriate care recipient management;
- comprehensive emergency protocols and escalation pathways to manage acute clinical situations that arise during the provision of services;
- structured referral pathways to a care recipient's general practice, specialist or local health system.

5.4.2 Shared care

When several health professionals or care teams use virtual care to participate in a healthcare activity with a care recipient the:

- referring health care professional shall confirm the identity of the patient to the distant specialist or health service, and confirm the identity and credentials of the distant specialist to the patient;
- referring health care professional, nurse or allied health worker shall be present (virtually or in-person) with the patient for some or all of the remote consultation with the specialist;
- participating health professionals shall agree and document who delivers which aspect of care, including who takes responsibility for ordering tests, preparing prescriptions and follow up;
- participating health professionals shall each document clinical notes of the activity.

Note: Methods by which a service consultation can be documented include written notes by a human or electronic scribe, 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 specialised electronic image store.

5.4.3 Health record continuity

When registering a care recipient in a virtual care service the organisation shall

- request permission from the patient to have their health information shared in their My Health Record for each relevant patient encounter unless otherwise specified by the patient, organisation, or has a policy that the healthcare encounter will be uploaded to the My Health Record unless the patient expressly declines;
- if the care recipient declines participating in My Health Record, ask patient for permission to share their health information with the care recipient's usual general practitioner or relevant healthcare professional, and
- if the care recipient declines participating in My Health Record or does not have a usual general practitioner, ask permission to share their health information with the last known health professional or General Practitioner that has treated the care recipient.
- assist the care recipient in understanding how to access their own My Health Record.

6 Performance evaluation

6.1 Monitoring, measurement, analysis, and evaluation

The organisation shall determine:

- what performance measures need to be monitored and measured;
- the methods for monitoring, measurement, analysis and evaluation, as applicable, to ensure valid results;
 - > the results from when the monitoring and measuring shall be performed;
 - > when monitoring and measurement shall be analysed and evaluated.

Documented information shall be available as evidence of the results.

The organisation shall evaluate the virtual care service performance and the effectiveness of the virtual care management system.

6.2 Internal audit

6.2.1 General

The organisation shall conduct internal audits at planned intervals to provide information on whether the virtual care management system:

- a. conforms to:
 - the organisation's own requirements for its virtual care management system;
 - the requirements of this document;
- b. is effectively implemented and maintained.

6.2.2 Internal audit programme

The organisation shall plan, establish, implement and maintain (an) audit programme(s), including the frequency, methods, responsibilities, planning requirements and reporting.

When establishing the internal audit programme(s), the organisation shall consider the importance of the processes concerned and the results of previous audits.

The organisation shall:

- a. define the audit objectives, criteria and scope for each audit;
- b. select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- c. ensure that the results of audits are reported to relevant managers.

Documented information shall be available as evidence of the implementation of the audit programme(s) and the audit results.

6.3 Management review

6.3.1 General

Top management shall review the organisation's virtual care management system, at yearly intervals, to ensure its continuing suitability, adequacy and effectiveness.

6.3.2 Management review inputs

The management review shall include:

- a. the status of actions from previous management reviews;
- b. changes in external and internal contexts that are relevant to the virtual care management system;
- c. changes in needs and expectations of interested parties that are relevant to the virtual care management system;
- d. information on the virtual care service performance, including trends in:
- e. nonconformities with the requirements of this document and corrective actions;
- f. monitoring and measurement results;
- g. audit results;
- h. opportunities for continual improvement.

6.3.3 Management review results

The results of the management review shall include decisions related to continual improvement opportunities and any need for changes to the virtual care management system.

Documented information shall be available as evidence of the results of management reviews.

7 Improvement

7.1 Continual improvement

The organisation shall continually improve the suitability, adequacy and effectiveness of the virtual care management system.

7.2 Nonconformity and corrective action

When a nonconformity with the requirements of this document occurs, the organisation shall:

- a. react to the nonconformity, and as applicable:
 - take action to control and correct it;
 - deal with the consequences;
- b. evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
 - reviewing the nonconformity;
 - determining the causes of the nonconformity;
 - determining if similar nonconformities exist, or can potentially occur;
- c. implement any action needed;
- d. review the effectiveness of any corrective action taken;
- e. make changes to the virtual care management system, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

Documented information shall be available as evidence of:

- the nature of the nonconformities and any subsequent actions taken;
- the results of any corrective action.

Bibliography

- Australian College of Rural and Remote Medicine. (2020a). Risk management for video consultations. https://www.acrrm.org.au/docs/default-source/all-files/acrrm_risk-management_clinical-video-consultations-factsheet_final.pdf?sfvrsn=dfb6190a_6
- Australian College of Rural and Remote Medicine. (2020b). Telehealth Framework and Guidelines. https://www.acrrm.org.au/docs/default-source/all-files/telehealth-framework-and-guidelines.pdf?sfvrsn=ec0eda85_4
- Australian College of Rural and Remote Medicine. (2022). Defining safe and quality procedural and advanced care in rural and remote locations. Australian College of Rural and Remote Medicine. https://www.acrrm.org.au/docs/default-source/all-files/college-position-statement-defining-safe-and-quality-procedural-and-advanced-care.pdf?sfvrsn=53ba09ac_20
- Australian College of Rural and Remote Medicine. (2025). Practice Standard for Digitally Connected Rural and Remote Communities. Australian College of Rural and Remote Medicine.
- Australian Commission on Safety and Quality in Health Care. (2017). National Model Clinical Governance Framework. <https://www.safetyandquality.gov.au/sites/default/files/migrated/National-Model-Clinical-Governance-Framework.pdf>
- Australian Commission on Safety and Quality in Health Care. (2020). National Safety and Quality Digital Mental Health Standards. <https://www.safetyandquality.gov.au/standards/national-safety-and-quality-digital-mental-health-standards>
- Australian Commission on Safety and Quality in Health Care. (2021). National Safety and Quality Health Service Standards (second edition). <https://www.safetyandquality.gov.au/publications-and-resources/resource-library/national-safety-and-quality-health-service-standards-second-edition>
- Australian Digital Health Agency. (2023). Clinical Governance Framework for Digital Health. https://www.digitalhealth.gov.au/sites/default/files/documents/clinical_governance_framework-2023.pdf
- International Organisation for Standardization. (2015). ISO 9001:2015 Quality management systems — Requirements. <https://www.iso.org/standard/62085.html>
- International Organisation for Standardization. (2018). ISO/IEC 20000-1 Information technology — Service management Part 1: Service management system requirements. <https://www.iso.org/standard/70636.html>
- International Organisation for Standardization. (2021). ISO 13131 Health informatics — Telehealth services — Quality planning guidelines. <https://www.iso.org/standard/75962.html>
- International Organisation for Standardization. (2022). ISO/IEC 27001 Information security, cybersecurity and privacy protection — Information security management systems — Requirements. <https://www.iso.org/standard/27001>
- International Organisation for Standardization. (2023). ISO 7101:2023 Healthcare organisation management — Management systems for quality in healthcare organisations — Requirements. <https://www.iso.org/standard/81647.html>
- International Organisation for Standardization. (2016). ISO 13485 Medical devices — Quality management systems — Requirements for regulatory purposes. <https://www.iso.org/standard/59752.html>
- ISO. (2018). International Organisation for Standardization. <https://www.iso.org/standard/65694.html>
- Royal Australian College of General Practitioners. (2019). Telehealth video-consultations guide. <https://www.racgp.org.au/getmedia/764ab82e-7dea-434e-94ca-cab808f7b5eb/Telehealth-video-consultations-guide.pdf.aspx>
- Standards Australia. (2022). AS ISO 13131:2022 Health informatics — Telehealth services — Quality planning guidelines. https://infostore.saiglobal.com/en-au/standards/as-iso-13131-2022-99279_saig_as_as_3177359/
- Standards Australia. (2025). AS 4891:202X Health informatics — Provision of guidance for users of a telehealth or virtual care service.

Annex 1 Guidelines for risk management according to ISO 31000

1 Risk management

1.1 Service risk, quality and safety assessment

Many healthcare organisations 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 organisation to establish the organisational objectives, strategies, scope, processes and characteristics of the services the organisation offers. The risks that can then prevent the achievement of organisational objectives and desired service characteristics can be identified in accordance with ISO 31000 (ISO, 2018) by evaluation of factors external to and internal to the organisation 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 when deriving generic quality objectives and procedures for services. Note that this document does not provide advice for the full implementation of ISO 9004 in a 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 organisation responsibilities, facilities, technology and information management to deliver healthcare and transmit health information. The process to derive quality objectives and procedures for the organisation, people, facilities and information used in 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.

1.2 Risk assessment - Identification

1.2.1 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 service by analysing the healthcare processes external to and internal to the healthcare organisation that could influence the quality characteristics of the service. A structured approach to identification of risks requires the analysis of the processes for management of quality, strategy, policy, and resources including financial

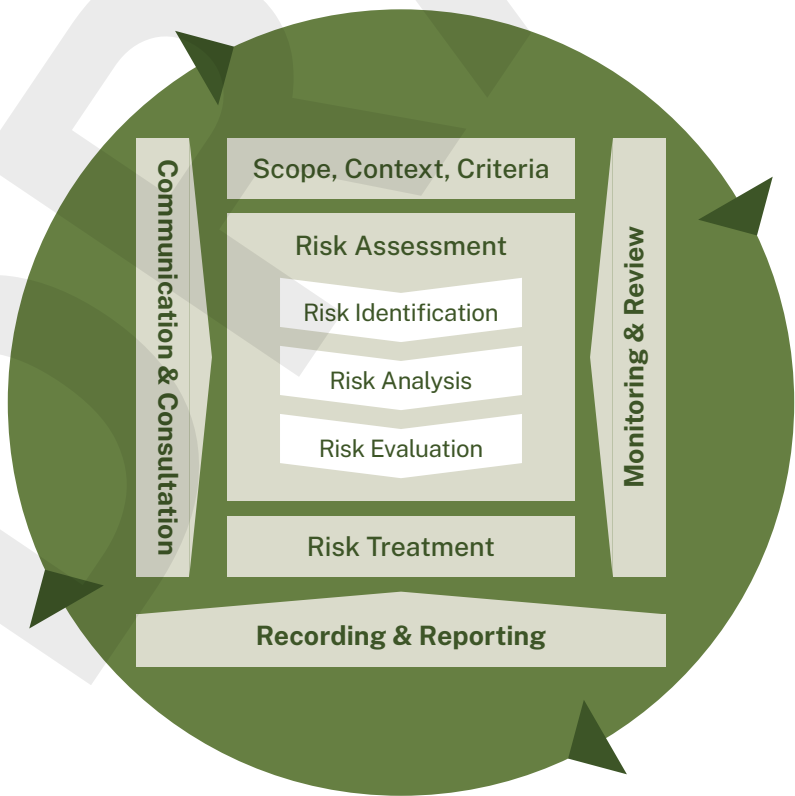


Figure 2 — Risk management process in ISO 31000:2018

management, service planning, human resources planning, care planning, healthcare organisation responsibilities, facilities, technology management, and information management. External contextual influences on a 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 organisation is accountable if a risk eventuates.

1.2.2 Guidelines for risk assessment

Quality characteristic: accountability.

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

Quality procedures: The healthcare organisation implements an accountable process for risk assessment.

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.

1.3 Risk assessment - analysis

1.3.1 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 service especially its effectiveness. See ISO 31000:2018, 6.4.3.

1.3.2 Guidelines for risk analysis

Quality characteristic: effectiveness.

Quality objective: The healthcare organisation has analysed the healthcare processes that use virtual care.

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

1.4 Risk assessment - evaluation

1.4.1 General

Risk evaluation is the overall process of risk identification and risk analysis for the possible impact of a risk on the organisation 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:

- do nothing further;
- consider risk treatment options;
- undertake further analysis to better understand the risk;
- maintain existing controls; or reconsider objectives.

1.4.2 Guidelines for risk evaluation

Quality characteristic: safety.

Quality objective: The healthcare organisation has evaluated the risks for all persons involved in the healthcare processes for virtual care.

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

- the risks to care recipient safety have been considered for all service processes and are documented in a quality manual;
- 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;
- 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.

1.5 Risk treatment

1.5.1 General

Risk treatment requires the selection of one or more processes (risk treatments) to modify risks to the effectiveness of a 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:

- formulating and assessing risk treatment options;
- planning and implementing risk treatment;
- assessing the effectiveness of that treatment;
- balancing the potential benefits derived in relation to the achievement of objectives;
- deciding whether the remaining risk is acceptable;
- if not acceptable, taking further treatment.

1.5.2 Guidelines for risk treatment

Quality characteristic: effectiveness.

Quality objective: The healthcare organisation has quality plans that contain effective risk treatments for managing risks to the quality objectives of the organisation.

Quality procedure: Quality plans are derived systematically by the healthcare organisation according to the processes outlined and recorded in a quality management system.

Annex 2 Guidance for the safety and quality of procedural and advanced care in rural and remote locations

The use of services may change the nature of the risks associated with health care activities for both clinicians and patients and influence the quality of health care. Clinicians constantly make judgements about their ability to make key clinical decisions in various contexts, and adjust their decision making accordingly. For example, they will moderate decisions according to the setting e.g. on the telephone compared to at the bedside or with whom they are communicating e.g. a patient, junior doctor or senior specialist. For many doctors, remote consultations present new challenges. Initially, they will need to be cautious in making critical decisions. Over time, it is expected that clinicians will become familiar with the characteristics of the required technologies such as video or phone conferencing, and increase the range of practice within which they are willing to make judgements.

For these reasons ACRRM recommends the use of a risk based framework for assessing the safety and quality of services. ACRRM upholds that measures of the safety and quality of health care services to people in rural and remote communities must factor in the distinctions of the rural and remote context. For this reason, ACRRM has published a position statement which discusses the safety and quality of procedural and advanced care in rural and remote locations (<https://www.acrrm.org.au/docs/default-source/all-files/quality-safety-for-rg-care-in-rural-remote.pdf>) to assist practitioners decide when services are appropriate for a specific patient or cohorts of patients in rural and remote medical practice (Australian College of Rural and Remote Medicine, 2022).

ACRRM recommends that the attendant risks of health services should be assessed in the context of the patient situation, the practitioner and the community.

The arts of rural and remote medicine (assessment, resources, transport, support)

Level of risk for patient (P), doctor (D), and community (C)

Risk Identification	P	D	C
assessment (situational analysis)			
complexity What risk of error does the clinical content and complexity result in? For example, is the clinical context acute or chronic, what speed of clinical response is required, are the diagnoses and treatment straight forward or are there multiple steps required? Are there complex communication needs?			
socioeconomic factors What risk will there be to the patient / family and community in relation to dislocation, cost, income and productivity?			
cultural and psychological factors This risk relates primarily to those resulting from the patient and community's belief systems around illness, treatment and expectations, and around communication. For the doctor, it revolves around medicolegal risk and the pressures on management decisions from nonclinical sources.			
public health issues This relates to infection control, occupational or environmental health issues, health promotion activities, and the risk to doctors, family, and team from contagious illness.			

resources			
Human Given the available local human resources, what risk is there for the patient in this clinical context? Will safety for patients, practitioners, and the community be compromised by the demands of this case on local resources?			
advice and information Is the availability of clinical information and specialist advice in this context adequate for patient safety or doctor support?			
technical What risk is there for the patient in this clinical context given the physical infrastructure (facilities, communications, etc.)?			
transport			
additional risks What additional risk is there for the patient, doctor, and other health personnel in this clinical context if transport is required?			
support			
psychological What are the risks to the patient and family, doctor, team and family, and community, in this clinical context given the psychological (and professional) supports available to each?			
management and organisational Are there systems in place that support the management of this case, or are they a barrier? Is the local (and distant) management supportive and enabling, or is it a battle to manage this case in the patient's best interest?			

From: McConnell F, Pashen D, McLean R. (2007) The ARTS of risk management in rural and remote medicine. Can J Rural Med. 12(4). Developed with the guidance and assistance of Dr Bruce Cameron.

Health care resources are scarce in rural and remote areas and every decision made by the practitioner impacts not only on the patient, but also on the clinician, the health service and the community. For example, if the patient needs to be transferred out of their locality, then the impact of this on their family and community needs to be considered.

The ARTS framework considers four domains important for clinical decision making in rural and remote areas; Assessment, Resources, Transport and Support. In rural and remote communities there are unique considerations:

- Practitioners have a broader scope of practice in a

more diverse range of settings, with greater on-call responsibilities; • Practitioners need advanced knowledge and skills; • Rural and remote practitioners often collaborate at a distance with specialty services, as the full range of specialty services may not be available locally. Practitioners often have close relations with individuals in their local community; • Adverse outcomes have implications for the doctor and the community. The ACRRM Framework for Services has adopted the ARTS framework that health and medical colleges, clinicians and health care organisations can use to develop risk based guidelines for the establishment of high quality services.