Australasian
TELE||HEALTH
Society

22nd February 2021

Dear Sir/Madam,

Re: ADHA Trial of consultative Process to Recommend Appropriate Technical Standards for Telehealth Consultations

The Australian Telehealth Society (ATHS) was formed in 2008, with a vision to deliver a united 'voice' for telehealth advancement and covering a broad range of domains including the health sector, academic institutions, government and industry partners. Our society has a membership representing all states and territories in Australia.

Attached is the ATHS response to the ADHA consultation on possible standards for telehealth.

Telehealth is not a discrete way of delivering healthcare and hence, existing standardisation efforts for healthcare should also apply to telehealth services. It is therefore important to identify the areas where telehealth-specific standards are needed and focus effort on these alone, rather than duplicate effort.

There is a need understand the difference between standards, guidelines, regulations and policy. It is important not to attempt to standardise technologies used in telehealth services which are already widely used in other healthcare services.

The peak bodies representing clinical disciplines such as the medical colleges should continue to be supported to develop clinical guidelines for telehealth services.

The ATHS response contains 17 recommendations to the six questions posed in the consultation documents. The ATHS

Sincerely,
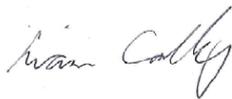
Dr Liam Caffery
Vice President
Australian Telehealth Society
l.caffery@uq.edu.au

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AUSTRALIAN TELEHEALTH SOCIETY RESPONSE TO ADHA CONSULTATION ON STANDARDS, FEBRUARY 2021

This response references the following documents provided by the ADHA Trial of Consultative Process to Recommend Appropriate Technical Standards for Telehealth:

1) Stage 2 consultation document February 2021, Introduction and background

2) Technical Standards to Categories Mapping for Consultation and Feedback

3) Feedback Form

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AUSTRALIAN TELEHEALTH SOCIETY RESPONSE TO ADHA CONSULTATION ON STANDARDS, FEBRUARY 2021

Summary

Telehealth is not a discrete way of delivering healthcare and hence, existing standardisation efforts for healthcare should also apply to telehealth services. It is therefore important to identify the areas where telehealth-specific standards are needed and focus effort on these alone, rather than duplicate effort.

There is a need understand the difference between standards, guidelines, regulations and policy. It is important not to attempt to standardise technologies used in telehealth services which are already widely used in other healthcare services.

The peak bodies representing clinical disciplines such as the medical colleges should continue to be supported to develop clinical guidelines for telehealth services.

The ATHS response to the ADHA consultation on possible standards for telehealth contains 17 recommendations contained in the responses to the six questions posed in the consultation documents.

Question 1: What do you think of the 9 key themes from the stage 1 consultation in Nov/Dec 2020?

Theme 1: Language is important.

Telehealth has many meanings. It is important that telehealth should primarily be viewed as a service or a way of delivering health care. A telehealth service is a "healthcare activity supported at a distance by information and communication technology service(s)" (ISO/FDIS 13131). Telehealth services depend on a wide range of standards, guidelines, codes of practice, protocols, which originate from a wide range of industries, including the health sector.

It is important not to restrict discussion on telehealth services to the item numbers in the Medicare Benefits Schedule which provide rebates for the use of audio (telephone) and video supported consultations in Australia. Many other technology modalities support healthcare activities performed at a distance.

> **Recommendation 1**. The ATHS recommends that a single definition of telehealth is used for this project and that the definition emphasises that telehealth is a mode of service using multiple technologies.

The use of term standards is often used synonymously for product codes, terminologies, testing regulations, service charters, process definitions and management systems. (See ISO/IEC GUIDE 2:2004 Standardization and related activities — General vocabulary). Note that a 'technology' or 'technical' standard is not defined at the international level but is instead covered by the above categories of standards.

> **Recommendation 2**. The ATHS recommends that use of the term "standards" be restricted to documents published by Standards Australia, or the International Standards Organization and for healthcare services by the Australian Safety and Quality Commission. Other documents should be described as guidelines, regulations or specifications as appropriate.

Theme 2: Avoiding duplication

Given the wide range of technologies, clinical applications, organisational contexts, and patient situations the potential for overlap and over-specification is immense. It should be noted that codification of processes and practices for the broader health care delivery is likely to be more mature than those used when healthcare activities are supported at a distance and efforts should be concentrated on extending the applicability of existing codes The best way to avoid duplication is to improve awareness of existing resources.

> **Recommendation 3**. The ATHS recommends that the scope of work for this project is limited to recommending where existing processes and practices require modification in order to avoid duplication of effort.

Theme 3: Supporting consumer experience

Standards and best practice guides for consumer services can be drawn from outside the health sector. Duplication or re-invention of best practice should be avoided. The consumer experience is important. While supporting the intent of supporting a person-centred approach to healthcare the ATHS is of the view that person-centred healthcare will be driven in the first instance by reform of the healthcare system, rather than standards or guidelines.

Theme 4: Supporting a broad range of health professionals and services

The ATHS agrees that the diverse needs of health professionals and services need to be broadly supported. A risk-based approach to developing performance outcomes for telehealth service is best able to meet these needs. (see Appendix 2)

> **Recommendation 4**. The ATHS recommends that needs of health professionals and services are best served by encouraging the use of a risk-based approach to developing performance outcomes which can be applied within and by each speciality or area of healthcare.

Theme 5: Future proofing and flexibility

This paragraph on future proofing and flexibility conflates many issues that should be independently considered. An increasing range of guidelines are already becoming available for new areas of healthcare activity. In order to support future proofing and flexibility, it is a rule of standardisation that, wherever possible, requirements should be performance based (i.e. defined by required outputs) rather than being prescriptive or design based (i.e. specifying how the product/service is to be constructed/delivered). This is to allow innovation and support a diversity of solutions and marketplaces (See ISO/IEC 17007:2009 Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment).

> **Recommendation 5**. The ATHS recommends that performance-based guidelines based on safety and quality objectives will encourage innovation.

> **Recommendation 6**. The ATHS recommends that to ensure future proofing and flexibility, periodic review of standards and guidelines should be encouraged

> **Recommendation 7**. The ATHS recommends that to support future proofing and flexibility, the application of standards and guidelines should be separated from conformance activities. The two domains are very different (See ISO/IEC 17007).

Theme 6: Integration and interoperability

Integration and interoperability is important is certain contexts, services and business scenarios, but is not required in the same form in every situation. The form integration and interoperability takes is achieved through design practices. Interoperability requires

appropriate agreement on the many aspects, including business processes, terminology, and specifications for communications and interfaces between systems. It should be noted that there is a considerable body of international work, to which Australia has contributed to develop specification that health organisations and vendors of products and service can adopt.

Theme 7: Supporting multiparty telehealth consultations

Multiparty healthcare activities depend on the design of technology for integration and interoperability and the availability of commercial connectivity services. Multi-party video or audio consultations are just one example where audio conferencing and video conferencing services are already available. Common specifications and services are available for many technology modalities to support the exchange healthcare information. However, the use of technologies for shared care are very dependent on organisational business needs, scope of service and models of care.

> **Recommendation 8.** The ATHS recommends that standardisation of multi-party "telehealth" (video) consultations are not an immediate priority.

Theme 8: Need for complimentary clinical standards across digital health

A wide range of clinical guidelines and more generic guidelines for telehealth services already exist. See the ATHS website http://www.aths.org.au/resources/.

> **Recommendation 9.** The ATHS recommends that further work on clinical guidelines should complement existing guidelines and not override existing guidelines.

Theme 9: Creating and maintaining a national standards governance framework for digital health

In 2011, the Australian Government provided resources to a number of organisations to develop guidelines for telehealth services. These guidelines are still in existence, are useful and some have been updated.

> **Recommendation 10.** The ATHS recommends that the most appropriate roles for government agencies are:

a) Department of Health should resource, where a need is identified by a health organisation, the development of additional guidelines for the use of telehealth services in healthcare.
b) Australian Commission on Safety and Quality in Health Care should be asked to consult throughout the health sector as to how existing ACSQH standards should be enhanced to cover healthcare activities performed at a distance.
c) The Department of Health should resource Standards Australia to develop Australian implementation guidelines which complement ISO/FDIS 13131, Health informatics — Telehealth services — Quality planning guidelines, AS ISO 13131:2017 | Health informatics Telehealth services - Quality planning guidelines and other Australian or international standards.

All the above activities should be undertaken with the maximum transparency to ensure widespread stakeholder engagement, including publicly available repositories, submissions, documented processes, evidence trails and responsive communications with stakeholders.

Observations on outcomes from January discussions with the ADHA project

The key issue is not the embedding of telehealth services in the Australian digital health landscape but is instead how to embed support of healthcare at a distance within the Australian healthcare system. In this context, the ATHS notes that telehealth services employ

multiple technologies. Integration of these technologies to meet specific health service needs will always be a challenge. Similarly, exchanging information across health services will remain difficult. Progress on resolving these issues will require changes in models of care to support of healthcare at a distance and improvements in the technical interoperability of information systems.

On the question of video and telephone consultations, intuitively some health care activities would seem to have the potential to benefit more from the use of video instead of audio communications. However, there is no real evidence that different modalities of telehealth services, video, audio, remote monitoring, online interactions, messaging etc., produce different health outcomes for the management of similar conditions.

> **Recommendation 11.** The ATHS recommends that within the current Australian health system, rather than prioritising one modality (e.g. video) over another for regulation and MBS funding, that funding be made available to improve infrastructure, infostructure training and education for use of telehealth services including use of video modalities.

Some other important issues are:

- Technology needs to be widely available. How do patients and carers access telehealth services if they don't have devices or reliable, equitable access to the network infrastructure.
- Design of technology based services should support workflows which include the needs of the patient, the clinician, the organisation, and the funder.
- Technology needs to be easy to use. Doctors have not always embraced the more complex technologies. No one solution may fit all needs, for instance, sometimes Zoom and FaceTime are what works best for the clinician and the patient
- Clinicians need support to develop competence and confidence in technologies.
- Services and technologies should support interactions between clinicians without a patient consultation taking place.

Question 2: What do you think of the 5 proposals listed on pages 3 and 4 of the paper?

Q 2(a) Are there additional Categories to the 5 listed on page 3 that you believe should form part of the initial focus for recommended technical IT telehealth standards?

The ADHA project has proposed an initial focus for recommended technical IT telehealth standards on security, privacy compliance, interoperability and integration and audit trails. For each of these categories ISO/FDIS 13131 provides quality objectives and procedures for telehealth services

> **Recommendation 12.** The ATHS recommends an additional foundation category for the safety and quality of telehealth services. (see Recommendation 11).

Q 2(b) Do you support the concept of developing and maintaining a list of future focus desirable capabilities and features?

A future focus list desirable capabilities and features should be led by healthcare needs rather than a technology wish list. The desirable capabilities may be context, profession, and organisation specific. For instance, the requirements of rural and remote may be different to metropolitan contexts.

> **Recommendation 13.** The ATHS recommends that identification of desirable capabilities and features for technologies and services supporting healthcare at a

distance should be undertaken under governance mechanisms that ensure maximum transparency to ensure widespread stakeholder engagement, including publicly available repositories, submissions, documented processes, evidence trails and responsive communications with stakeholders.

Q 2(c) While clinical standards are not within the Project scope, do you support a recommendation from the Project for requesting the Australian Commission on Safety Quality in Health Care to develop comprehensive Australian Telehealth Clinical Standards?

> **Recommendation 14.** The ATHS recommends that the Department of Health continues to support professional bodies to develop clinical guidelines for telehealth services where healthcare activities are performed at a distance.

Q 2(d) Do you support the Australian Privacy Commissioner developing guidance on compliance with the Australian Privacy Principles when using telehealth

> **Recommendation 15.** The ATHS recommends the OAIC Guide to health privacy https://www.oaic.gov.au/privacy/guidance-and-advice/guide-to-health-privacy/   be extended to include telehealth content as opposed to developing a separate guidance. This approach recognises that many transactions for in-person and telehealth are similar and further, it supports integrating telehealth as a service for delivering health care.

Question 3. Technical standards to categories mapping for consideration and comments

A wide range of international and national standards can support telehealth services. Some of these are listed in the Bibliography to this response. The applicability of standards or sections within standards should be assessed for the degree to which they support the quality objectives of each type of telehealth service. We expect that quality objectives and suitable standards or guidelines will vary according to the type of health organisation, speciality and the overall context for the healthcare provider and recipient of healthcare. For an example of this issue, see the Australian College of Rural and Remote Medicine. (2018). ACRRM position statement on defining safe and quality, available online at: https://www.acrrm.org.au/docs/default-source/all-files/quality-safety-for-rg-care-in-rural-remote-position-statement.pdf?sfvrsn=53ba09ac_6

The overarching quality objectives for each of the proposed foundation categories are contained in AS ISO 13131:2017, which is being updated to a full international standard ISO FDIS 13131 Health informatics — Telehealth services — Quality planning guidelines. ISO/FDIS 13131 provides quality objectives and procedures for telehealth services. The standard covers quality management, risk management, financial management, service planning, human resources planning, care planning, responsibilities, facilities management, technology management and information management.

- For *security and privacy* compliance, Clause 14 in ISO FDIS 13131 provides quality objectives and procedures.
- For *interoperability*, Clause 13 in ISO FDIS 13131 provides quality objectives and procedures. The ATHS also recommends that business and technical architectures for the most common use cases of telehealth services for be developed
- For *integration* of systems and information, Clauses 13 and 14 in ISO FDIS 13131 provides quality objectives and procedures.
- For *audit trails*, Clauses 11 and 14 in ISO FDIS 13131 provides quality objectives and procedures

Recommendation 16. The ATHS recommends that for each foundation category the overarching quality objectives for each of the proposed foundation categories contained in AS ISO 13131:2017 and the selection criteria listed in APPENDIX 1: Standards Document Assessment Criteria, be applied when selecting standards that may assist in meeting the relevant quality objectives.

Question 4: Please consider the list of categories for future consideration of recommended standards.

Video and Audio Quality of Consultations

Healthcare providers conducting a telehealth consultation should assess the quality of all information accessible to them and provided by the healthcare recipient, including image, video and audio information to ensure it is fit for clinical purpose. This assessment needs to be based on a risk management process. The outcomes of a risk assessment will depend on clinical judgements and vary across medical discipline, the situation of the care recipient and the contexts within which care is being provided. For instance, the required information quality may vary between different locations, different specialities (e.g. sonography, mental health, dermatology, orthopaedics, out-patient follow-up), and the point at which the information is used in a care session which may extend over several encounters between a person and a health professional. See AS ISO 13131:2017, Clause 14.

Consumer Experience

Standards and best practice guides can be drawn from outside the health sector. Duplication or re-invention of best practice should be avoided. Inclusion of consumer experiences should be part of an organisation's quality plan. See AS ISO 13131:2017, Clause 6.

Technical Infrastructure

Healthcare organisations must design telehealth services to be delivered over a variety of technical infrastructure. Improving access to and use of technical infrastructures is a political, policy, strategic and regulatory and funding problem. Standardisation of technical infrastructure lies outside of the health sector domain. However, it may be useful for the health sector to lobby for certain infrastructure features such as low latency communications networks, or the ability to form meaningful service level agreements with infrastructure service providers which better support the needs of healthcare. See AS ISO 13131:2017, Clause 13 and ISO/IEC 20000, Information Technology-Service management.

Emergency

Emergency and adverse event management is the responsibly of health professionals and health organisations. Guidelines and protocols for this area are already included in many clinical guidelines and protocols. See AS ISO 13131:2017, Clauses 10.

Documentation of Consultation and Outcomes

The responsibility for documentation of consultations, procedures and clinical outcomes lies with health professionals. The requirements for documentation vary tremendously according to the medical discipline. See AS ISO 13131:2017, Clause 10.

Multi-party Consultation

The ATHS does not see this as a priority. See response to Theme 7. Also see AS ISO 13131:2017, Clause 10. A greater priority is to fund multi-party remote consultations and develop technologies that support this model of care.

Communication Tools During Consultations

A wide range of technologies are readily available to support healthcare activities at a distance. The problem health professionals face is how to integrate these tools into their work practices before, during and after a consultation. The ATHS believes that more attention should be given to designing interoperable technical systems that integrate into work practices and are easy to use in various healthcare contexts and workflows.

Use of Other Devices and Tools

There are current standardisation efforts for use of consumer orientated devices, apps and tools in telehealth services. The ATHS believes that that any work in this area should complement and not duplicate current national and international standardisation efforts.

Training and Support

Training and support is important and contributes to the quality and safety of telehealth services. However, the ATHS does not see this as a stand-alone area requiring standardisation. See AS ISO 13131:2017, Clauses 9 and 13.

Review and Quality Improvement

ISO/FDIS 13131 provides quality objectives and procedures for telehealth services. The standard covers quality management, risk management, financial management, service planning, human resources planning, care planning, responsibilities, facilities management, technology management and information management. See Recommendation 11.

Q4 Categories for future consideration

Q4 (a) Are there any additional categories you would propose at this stage?

No

Q4 (b) Are there any categories listed that you do not believe warrant future consideration of recommended standards at this stage?

Please refer Recommendation 13.

Q4 (c) Which categories do you believe need to have a recommended technical standard determined over the next 2-3 years?

Given the variety of use cases in healthcare activities, the ATHS does not expect that it will be possible to recommend the use of a single technical standard in any of one the categories listed.

Question 5: Please review the future focus set of desirable capabilities and features
What comments do you have on this list?

We agree it is important to maintain a focus on the desirable "future state", encouraging the development of enhanced features and capabilities, adopted and adapted over time as appropriate to the needs and sophistication of the participants (both providers and consumers), the clinical situation and the evidence on outcomes, quality, cost effectiveness and participant satisfaction.

In general, the ATHS does not support extensive standardisation of capabilities and features for telehealth services with some exceptions listed in Table 1. The requirements for many

capabilities and features vary tremendously across services and the ATHS believes that the industry should be able to innovatively develop solutions to the requirements of organisations and services, without an unnecessary level of standardisation being required. The ATHS believes that as organisations evolve their technical and non-technical capabilities and services some generic requirements may emerge and considered for possible standardisation.

Question 5a: Please review list of other desirable capabilities and features

Our observations about possible future features suggest by the ADHA project are listed below in Table 1. Many of these possible future features are not telehealth-specific and care should be taken not to duplicate work on these being undertaken in the wider healthcare context

Table 1. Observations of the ATHS on possible future features for telehealth services

Feature or capability	Comment	Standardise
Online bookings for telehealth consultations	This is a feature. Requirements will vary across organisations and services.	Not at present
Secure consultation invitations and links and ability	This is a feature. Requirements will vary across organisations and services.	Not at present
Able to import scheduled event into calendar systems	This is a feature. Requirements will vary across organisations and services.	Not at present
Access management, participant identity verification and consent	This is a current feature of health services. Requirements to implement this feature electronically will vary across organisations and services. See AS ISO 13131:2017, Clauses 11 and 14	Not at present
Virtual waiting rooms and management	This is a feature. Requirements will vary across organisations and services.	Not at present
Multiparty and multipoint consultation (both providers and consumers)	This is a feature. Requirements will vary across organisations and services.	Not at present
Case conferencing and group video therapy	This is a feature. Requirements will vary across organisations and services.	Not at present
Ability to launch a telehealth consultation without scheduled event	This is a feature. Requirements will vary across organisations and services.	Not at present
Ability to undertake video consultations across a variety of settings and locations (including consumer access across devices and portals)	Universal access to telehealth services depends on policy, regulatory and resource mechanisms which require system reform measures	Not at present.
Electronic messaging, sharing screens and files and bi-directional communication tools during telehealth consultation	Some standards exist. Electronic messaging between providers is available. Other capabilities are features, which are device and application dependent and not required in all contexts	Review the use of and requirements for electronic messaging between providers when sharing care.
Interoperability with codec-based videoconferencing systems and peripheral devices	Review existing standards and products. This is a feature, which is device and application dependent and not required in all contexts. See AS ISO 13131:2017, Clause 13	Not at present. Dependant on results of review
Video quality with audio default options	This is a feature, which is device and application dependent and not required in all contexts	Not at present.
Access for consumers with special needs	This is a feature. Existing guidelines should be reviewed.	Dependant on results of review

Access to technical support during telehealth consultations	This would be a service offered by some organisations. It may not be usable in many contexts	Not at present.
Use of different audio and video sources during consultation	This is a feature, which is device and application dependent and not required in all contexts	Not at present
Use of other digital diagnostic devices and tools	Review existing standards	Dependant on results of review
Associated "e services" (e.g. prescribing, referrals, clinician to clinician consults)	Some standards exist. Review. The requirements for many of these services are very dependent on organisational, clinical, regulatory, and funding contexts	Dependant on results of review
System, equipment, and connectivity testing	This is already covered by existing guidelines. See AS ISO 13131:2017, Clause 13	Not at present
Development of connectivity with other digital systems and devices through APIs	Many standards exist in the health sector. Review existing standards	Dependant on results of review
Data exchange, data content and terminology standards	Many standards exist in the health sector. Review existing standards	Dependant on results of review
Recording, back up, recovery and storage management	This is already covered by existing guidelines. See AS ISO 13131:2017, Clause 14	Not at present
Reporting on telehealth consultation outcomes and user satisfaction	This should be part of a quality plan. See AS ISO 13131:2017, Clause 6	Not at present

Question 5b: **Are there other capabilities and features you would add?**

None

Question 5c: What would be your top 3 or 5 desirable capabilities and features that might warrant early attention?

> **Recommendation 17.** The ATHS recommends the following capabilities warrant early attention
>
> a) Use of and requirements for electronic messaging between providers when sharing care.
> b) Data exchange, data content and terminology standards applicable to shared care
> c) Requirements for access to telehealth services for consumers with special needs
> d) Reliable and equitable access to high quality health care using telehealth services for all, including those disadvantaged through lack of choice, cost, reliability and digital skills.
> e) Development of technologies to facilitate the sharing of devices used to access telehealth services
> f) Funding for telehealth services that employ store and forward or monitoring technologies

Question 6: We would very much value your feedback on the process to date?

Question 6a: What worked well for you?

The intent of the project is welcomed

Question 6b: What did not work at all?

The structure of the project did not permit participants to access the submissions received by the project. Participants were unable to access information that provided an evidence base for the decisions made by the project. The consultation did not include key organisations with a track record in developing guidelines for telehealth services.

Question 6c: How could the process have been undertaken better?

Development of guidelines should be undertaken with the maximum transparency to ensure widespread and public stakeholder engagement, including publically available repositories, submissions, documented processes, evidence trails and responsive communications with stakeholders.

Question 7: Please provide any additional comments here.

None

Appendix 1: Standards document assessment criteria

The assessment criteria for potential standards to be used by telehealth services should relate only to the quality and maturity of the standard. Suggested criteria are listed in Table 1.

Table 1. Criteria for the selection of standards documents.

#	Criteria	Description
1	**Quality of standard (ISO/IEC 17007:2009)**	The following criteria are fundamental requirements of standards.
1a	Scope of document	The scope of each standards document should clearly identify an "object of conformity assessment" - the product or service that is the subject of the standards document.
1b	Clarity	Standards documents should: • clearly specify each relevant characteristic needing to be standardized as a separate normative requirement - in a separate sentence (or list item) to facilitate reference • be divided into distinct, consistent and easily identifiable sections, • use direct, precise, objective, logical language, to enable accurate, uniform interpretation • use terms consistently and avoid subjective/ qualitative/ ambiguous expression • prefer verbs to nouns, and active voice to passive voice.
1c	Performance based outcomes	Wherever possible, normative requirements should be specified as "performance-based" outcomes, rather than using "prescriptive" or "design-based" criteria
1d	Traceability	When following requirements stated in another document, this should be done by specific reference, clearly indicating the referenced version (by year of publication).
1e	Conformance assessment	Specifications of test methods must simply outline the process and thresholds of testing – NOT who should undertake the test, NOR the conformity assessment structure
2	**Maturity**	**Maturity and evolution of standard**
2a	Development Status	The extent to which the standard is fully developed, has been endorsed via a recognized standardization process, is still current, and has ongoing maintenance and development.
2c	Level of Consensus	The extent to which the standard has been reviewed by all relevant stakeholder communities and has been accepted with a high level of consensus. Is the standard is to be adopted partially or entirely?
2c	Risk based	Contains guidance of management the quality of services and products using risk management processes
2d	Quality focused	Adopts internationally recognized quality management processes for services and products

Source: ISO/IEC 17007:2009 Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment

Appendix 2: Risk management for telehealth services and technologies

It is recommended that a risk management process be used to identify key risks related to the use of technology services and products by telehealth services. Risk management is a four step process:

- Risk assessment - identification, requires the key risks to telehealth services to be identified by the healthcare organization.
- Risk assessment - analysis, requires the healthcare organization to analysed the healthcare processes that use telehealth services.
- Risk assessment - evaluation, requires the healthcare organization to evaluate the risks for all healthcare actors in the healthcare processes that use telehealth services.
- Risk treatment requires the healthcare organization to create quality plans that contain effective risk treatments for managing risks to the quality objectives of the organization.

Sources: AS ISO 13131:2017, ISO 31000. The ACRRM position statement on defining safe and quality: Procedural and advanced care in rural and remote locations (2018) also provides guidance on risk management processes.

Bibliography of guidelines and standards relevant to telehealth services

For a list of key international and Australian telehealth guidelines please refer to the ATHS website: http://www.aths.org.au/resources/guidelines/

For a partial list of publications relating to clinical guidelines please refer to the ATHS website: http://www.aths.org.au/publications-on-clinical-guidelines/

A non-exhaustive list of international standards relevant to telehealth services is provided below.

IEC 82304-1, Health software — Part 1: General requirements for product safety

IEC 82304-1:2016 Health software — Part 1: General requirements for product safety

IEC/ISO 80001-series (14 parts) Application of risk management for IT-networks incorporating medical devices

ISO 13485:2016, Medical devices — Quality management systems — Requirements for regulatory purposes

ISO 13940:2015, Health informatics — System of concepts to support continuity of care

ISO 14971, Medical devices — Application of risk management to medical devices

ISO/IEC 17007:2009 Conformity assessment — Guidance for drafting normative documents suitable for use for conformity assessment

ISO 25237, Health informatics — Pseudonymization

ISO 26000:2010, Guidance on social responsibility

ISO 27799, Health informatics — Information security management in health using ISO/IEC 27002

ISO 27799:2016 Health informatics — Information security management in health using ISO/IEC 27002

ISO 31000:2018, Risk management — Guidelines

ISO 81001-1 Health software and health IT systems safety, effectiveness and security — Part 1: Principles and concepts (currently in FDIS ballot before being finalised and submitted for publication)

ISO 9000:2015, Quality management systems — Fundamentals and vocabulary

ISO 9001:2015, Quality management systems — Requirements

ISO 9004, Quality management — Quality of an organization — Guidance to achieve sustained success

ISO 9241-11, Ergonomics of human-system interaction — Part 11: Usability: Definitions and concepts

ISO 9241-20:2008, Ergonomics of human-system interaction — Part 20: Accessibility guidelines for information/communication technology (ICT) equipment and services

ISO 9241-420:2011, Ergonomics of human-system interaction — Part 420: Selection of physical input devices

ISO/81001-11), Health software and health IT systems safety, effectiveness and security — Part 1: Principles and concepts

ISO/FDIS 13131 Health informatics—Telehealth services—Quality planning guidelines. ISO. Retrieved February 11, 2021, Available from https://www.iso.org/cms/render/live/en/sites/isoorg/contents/data/standard/07/59/75962.html

ISO/IEC 17021-1:2015, Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements

ISO/IEC 20000 (all parts), Information technology — Service management

ISO/IEC 27000:2018, Information technology — Security techniques — Information security management systems — Overview and vocabulary

ISO/IEC 27001, Information technology — Security techniques — Information security management systems — Requirements

ISO/IEC 27002, Information technology — Security techniques — Code of practice for information security management

ISO/IEC 31010, Risk management — Risk assessment techniques

ISO/IEC 62304, Medical device software — Software life cycle processes

ISO/IEC 80001-1, Application of risk management for IT-networks incorporating medical devices — Part 1: Roles, responsibilities and activities

ISO/IEC Guide 51:2014, Safety aspects — Guidelines for their inclusion in standards

ISO/IEC/TR 80001-2-1, Application of risk management for IT-networks incorporating medical devices — Part 2-1: Step by Step Risk Management of Medical IT-Networks; Practical Applications and Examples

ISO/IEEE 11073 (all parts), Health informatics — Device interoperability

ISO/TR 18307:2001, Health informatics — Interoperability and compatibility in messaging and communication standards — Key characteristics

ISO/TR 22696:2020 Health informatics — Guidance on the identification and authentication of connectable Personal Healthcare Devices (PHDs).-

In relation to personal healthcare devices, the Continua Guidelines (https://www.pchalliance.org/continua-design-guidelines) and IHE profiles for medical devices (https://www.ihe.net/ihe_domains/devices/) have been the most relevant source of standards, although there is also the ISO/IEEE 11073 series of standards on personal health device communications and some transitioning to HL7/FHIR is underway

ISO/TS 17975:2015 Health informatics — Principles and data requirements for consent in the Collection, Use or Disclosure of personal health information [OAIC guidelines and State/Territory legislation are probably more relevant].

ISO/TS 21564, Health Informatics — Terminology resource map quality measures (MapQual)

ISO/TS 82304-2 Health software — Part 2: Health and wellness apps—Quality and reliability (this document is nearing completion. It draws on UK/EU experience with PAS 277:2015 Health and wellness apps - Quality criteria across the life cycle - Code of practice, which was developed by BSI in the UK and is offered free of charge from the BSI webshop: https://shop.bsigroup.com/forms/PASs/PAS-2772015/.

Quality management principles. 2015. https:// www .iso .org/ files/ live/ sites/ isoorg/ files/ store/ en/ PUB100080 .pdf

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