Applying International Guidelines for Telehealth Services – a case study

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Abstract

Recently the International Standards Organisation, TC215 Health Informatics Committee has developed a new Technical Specification, ISO/TS 13131 Health informatics — Telehealth services — Quality planning guidelines (ISO/TS 13131) based on a risk and quality management approach. This paper provides examples of the application of this new international specification to the generation of guidelines for a telehealth in the home service. To date most guidelines for telehealth have been developed for use within limited clinical contexts. In contrast ISO/TS 13131 specification allows a broader approach by focusing on quality and risk management methods able to generate the level of detailed guidelines required by a particular service. This specification belongs to a class of standards that provide flexible, general guidelines that support innovation in healthcare. The ISO/TS 13131 specification proposes guidelines for quality and financial management, service planning, workforce planning, healthcare planning, healthcare organisation responsibilities, facilities, technology and information management.

Keywords: telehealth, quality, safety, risk, innovation, healthcare, information, communications, technology

1 Introduction

1.1 Aims

This paper has three aims: Firstly to review international and national standards or guidelines that can inform the development of a telehealth initiative including standards for safety, quality and risk in health. The second aim is to describe the development of the telehealth service guidelines in the recent ISO/TS 13131 specification and their relationship to existing guidelines. The third aim is to describe though a case study how these guidelines and standards were informed by and applied to the chosen case study.

The Flinders University Telehealth in the Home: - Palliative and Aged Care (including rehabilitation) in South Australia pilot (FTH pilot) was chosen as the case study.

1.2 The international standardisation context

Health informatics is an intensely multi-disciplinary field, spanning Information and Communications Technology (ICT), Health and Healthcare. Multiple standards organisations cover the ICT, Health and Health Informatics fields. Interest groups continually form new standards organisations in their efforts to capture ground in emerging fields.

Standards have a role in overcoming barriers to the sharing of knowledge and placing the promotion of community interest ahead of sectional interests.

Standards organisations have to contend with complex and evolving health information systems that are continually re-creating silos of information, expertise, conflicting business models, intellectual property and policies. Standards organisations need to balance local needs against national and global interests.

In a bid to partially reconcile these interests at the international level, the Joint Initiative Council (JIC) for Global Health Informatics Standardisation was formed in 2007 (Joint Initiative Council, 2014). It aims to foster:

- greater collaboration to facilitate achievement of coherent, coordinated and usable global health informatics standards;
- coordinated standards processes and work programs;
- resolution of gaps, overlaps and counter-productive standardization efforts;
- improved standards availability; and
- greater communication and engagement with stakeholder communities.

Current JIC members include the International Standards Organisation (ISO) TC 215 Health Informatics Technical Committee (ISO/TC 215), CEN/TC 251 Health Informatics Committee, Health Level Seven International, Clinical Data Interchange Standards Consortium, International Health Terminology, Identification of products and services, Integrating the Healthcare Enterprise, the mHealth Alliance and the DICOM Standards Committee. Other collaborating organisations include the IEEE, IEC/TC62, ITU/T and the Continua Alliance.

The ISO/TC 215 Health informatics committee produces standards, technical specifications and reports to encourage standardisation, interoperability, compatibility and consistency for health information and data. A working group of this committee has produced a new ISO specification ISO/TS 13131:—, Health informatics —

Telehealth services — Quality planning guidelines (ISO/TS 13131) to provide high level guidelines for the implementation of telehealth services. The author was project leader for development of the ISO/TS 13131 specification during its later development stages.

1.3 Regional and national telehealth guidelines

In many countries specific guidelines have been developed for clinical specialties or industry segments using telehealth. Examples are the Canadian Telestroke Action Implementation Kit (Canadian Heart & Stroke Foundation, 2013), and the European Code of Practice for Telehealth Services (TeleSCoPE 2014), which focuses on supporting monitoring and alarm services for people at home.

The American Telemedicine Association (ATA) has made the development of standards and guidelines a priority. The ATA has developed general operational and many clinically specific guidelines for a range of disciplines including pathology, mental health and rehabilitation.

1.4 Australian telehealth guidelines

Australian telehealth guidelines mirror the diversity of standards and guidelines found in other countries. A number of Australian organisations have produced guidelines for telehealth activities relate to specific areas of professional clinical activity. Examples include:

- The Australian College of Rural and Remote Medicine (ACRRM) Telehealth Guidelines (ACRRM 2012);

- The Royal Australian College of General Practitioners (RACGP) Guidelines for inter-professional collaboration between general practitioners and other medical specialists providing video consultations (RACGP 2013);

- The Australian Health Practitioner Regulation Agency (AHPRA) Guidelines for technology based patient consultations (AHPRA 2012).

State based health services have guidelines for a number of telehealth activities. For instance the South Australian Health Department (SA Health) through the Statewide Rehabilitation Clinical Network has developed Guidelines for Sub-acute Services offering Digital Telehealth Network Consultations (SA Health 2013) which focusses on consultation held between practitioners and patients in hospital settings.

1.5 The case study

The Flinders University Telehealth in the Home: - Palliative and Aged Care (including rehabilitation) in South Australia pilot (FTH pilot) was an action-research initiative to test and evaluate the impact of inclusion of telehealth services and broadband access technologies on:

1. Palliative care patients living in the community and the willingness of patients and carers to participate in self-reporting and video reviews. Palliative care patients and carers at home have received access to video-conferencing services with a palliative care nurse or carer support facilitator using a tablet device (iPad), a self-

assessment application to record their health status, use of activity tracking devices and scales to monitor their physical activity and weight.

2. Home-based rehabilitation services for the elderly at home and the extent to which their recovery can be supported. Rehabilitation patients in the community have been provided with access to video-conferencing services with a rehabilitation therapist using a tablet device (iPad), a self-assessment application to record their health status and use of an exercise tracking device to monitor their physical activity.

3. Aged care services for the elderly in residential aged care facilities and the possibilities for tracking and stabilising increasing frailty and risk in this group. Elderly residents received video-conferencing services with a geriatrician, rehabilitation, and medication advice.

The author was responsible for the implementation of an FTH pilot described above. Because the author was also project leader for the ISO/TS 13131 specification it became possible for the guidelines in the draft specification to be tested in a real telehealth service to confirm their value to telehealth service development and telehealth in the home services in particular.

1.6 Quality and safety and in healthcare

Most countries have national Safety and Quality Health Service Standards. In Australia ten National Safety and Quality Health Service (NSQHS) Standards have been developed by the Australian Commission on Safety and Quality in Health Care (ACSQHC) in consultation and collaboration with jurisdictions, technical experts, health professionals and patients. The first of these standards "Governance for Safety and Quality in Health Service Organisations" (ACSQHC 2012), describes the quality framework required for health service organisations to implement safe systems. This standard provides:

- a quality assurance mechanism that tests whether relevant systems are in place to ensure minimum standards of safety and quality are met; and

- a quality improvement mechanism that allows health service organisations to realise developmental goals.

The Australian NSQHS Standard 1 establishes several criteria to support governance for safety and quality in health including:

- governance and quality improvement systems to ensure there are integrated systems of governance to actively manage patient safety and quality risks;

- advice to ensure care provided by the clinical workforce is guided by current best practice;

- performance and skills management to assist managers and the clinical workforce have the right qualifications, skills and approach to provide safe, high-quality healthcare;

- incident and complaints management for patient safety and quality incidents to be recognised, reported and analysed and ensure this information is used to improve safety systems; and

- patient rights and engagement benchmarks to ensure patient rights are respected and their engagement in their care is supported.

The Australian NSQHS Standard 1 is explicitly linked to international standards such as:

- ISO 9000:2005, Quality management systems— Fundamentals and vocabulary (ISO 9000:2005); and
- ISO 31000:2009, Risk management— Principles and guidelines (ISO 31000:2009).

1.7 Quality and risk in telehealth

Many healthcare organisations have put in place quality management systems to actively manage patient safety and healthcare quality for face to face healthcare. These systems rely on quality management principles and processes described in ISO 9000:2005 and draw upon other quality management standards such as:

- ISO 9001:2008, Quality management systems — Requirements (ISO 9001:2008); and
- ISO 9004:2009, Managing for the sustained success of an organisation — A quality management approach (ISO 9004:2009).

The ISO 9004:2009 Standard recommends use of ISO 31000-2009 Risk management — Principles and Guidelines to help organisations identify, assess and manage risks when developing quality objectives.

The ISO 9004:2009 Standard recommends that an organisation should identify the internal and external resources that are needed for the achievement of the organisation's objectives in the short and long term.

The ISO 31000-2009 risk management process requires that the objectives, strategies, scope and parameters of the services provided by an organisation be established. Risks that may then prevent the achievement of organisational objectives can be identified by analysing factors external to and internal to the organisation.

Risks are required to be analysed, prioritised and risk treatments established. In a quality management system these risk treatments can then become the basis for quality objectives that are used to control the identified risks.

The application of the above international standards in the telehealth use case has been undertaken in a new ISO specification ISO/TS 13131:—, Health informatics — Telehealth services — Quality planning guidelines for information and communications technologies to deliver healthcare and transmit health information over both long and short distances. The ISO/TS 13131 specification provides guidance for quality and financial management, service planning, workforce planning, healthcare planning, healthcare organisational responsibilities, facilities, technology and information management. Guidelines in the specification focus on quality and risk management methods at a high level. These guidelines can readily be used to generate the detailed guidelines required by a particular telehealth service.

2 Development of guidelines for telehealth services in the ISO/TS 13131 specification

2.1 Method

The ISO/TC 215 Health informatics committee manages the production of standards through an extensive, and often lengthy process of consultation. New standards initiatives review existing international and national standards in the health and informatics domains and justify the need for a new standard to bi-annual meetings of the committee. International standards are often based on existing standards and the ISO/TS 13131 specification was based on an early draft from the a Dutch standards organisation.

International consultation is undertaken through a series of ballots which collect comments from international experts working with national standards bodies, such as Standards Australia. Following two ballots it was agreed that further review of the specification would be undertaken by Australia to address the comments that had been received, and road test the proposed guidelines.

Comments received during the balloting process highlighted the need for:

- improved linkages to the ISO 9000 Quality management and ISO 31000:2009 Risk management standards for derivation of quality plans;
- greater clarification of the role of the ISO/TS 13131 specification;
- clarification of the relationship with some national and international standards; and
- refinement of unclear and prescriptive guidelines.

2.2 Telehealth quality characteristics

Quality characteristics can be used to manage organisational risks, and improve the reliability and quality of patient care. Usually only a small number of these characteristics will be relevant to the development of an individual quality plan.

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

Telehealth services aim to support healthcare quality characteristics that improve the quality of life and quality of care for care recipients. The quality characteristics considered by the ISO/TS 13131 specification include: accessibility, accountability, appropriateness, competency, confidentiality, continuity, dependability, effectiveness, efficiency, inclusivity, safety, transparency and usability.

According to the ISO 9000:2005 standard organisations should have a quality management system in place to define and monitor the required quality characteristics of telehealth services.

To provide a better linkage with ISO quality and risk management standards the specification was redrafted to follow the terminology in ISO 9000:2005 and the risk

assessment process described in the ISO 31000:2009 standard specifically:

- definition of quality characteristics: describing which quality characteristic is affected by a risk (eg safety);

- use of quality objectives: each quality characteristic should be supported by at least one quality objective (eg improved patient safety);

- provision of quality procedures: for each quality objective there should be at least one quality procedure. (eg identify increased risk of patient harm)

Each quality plan in ISO/TS 13131 specification is designed to include a statement of who should be responsible for implementing, monitoring and reviewing the plan. Each plan contains requirements that can be verified through the provision of objective evidence.

2.3 The role of standards in telehealth

A review of American Telemedicine Association (ATA) standards activities (Krupinski, 2014) included a survey of people requesting access to ATA standards. One survey question asked why telemedicine should have guidelines. Respondents gave the top three reasons as being that standards add credibility, standardise approaches and decrease liabilities. Another question requested information on the use of guidelines and respondents indicate that standards were used when starting a new program, training staff and in clinical practice.

The above responses to the ATA survey indicate a desire for standards that assist in the management of risk, the establishment of new services and improving practice. In considering the desirable features of standards, one European study (Hanseth et al, 2012) identified three strategies evident in standardisation activities:

1. Anticipated standardisation.

2. Integrated solutions.

3. Flexible "generification".

In this classification scheme anticipated standardisation is defined as a top-down process involving many parties that make detailed compromises to arrive at a prescriptive form of Standards.

Integrated solutions arise when projects create Standards as part of their requirements. The introduction of the Australian personal electronic health record (NEHTA, 2014) is perhaps an example of a project where a national Standards body drove the creation of requirements for suppliers based on specifications.

Flexible "generification" is a Standards strategy where work process actually use and determine Standards, which can be adapted pragmatically. The ISO/TS 13131 specification was designed to belong to this third class of Standards by providing flexible, general guidelines that support innovation in healthcare.

2.4 The scope of ISO/TS 13131

The ISO/TS 13131 specification was designed not to supplant national and regionally specific requirements, or address access to and provision of health information as part of a wider eHealth agenda, or apply to general purpose ICT services, software application, operating systems and medical devices.

For instance, the manufacturing, design and use of medical devices are provided for by specific international Standards such as IEC 80001-1:2010, Application of risk management for IT-networks incorporating medical devices -- Part 1: Roles, responsibilities and activities (IEC 80001-1:2010).

The specification was designed to be compatible with the quality and risk management processes used in national safety and quality Standards such as the Australian NSQHS Standard 1.

The guidelines in the ISO/TS 13131 specification have been designed to support telehealth service design by a health or healthcare organisation, healthcare professionals using telehealth and health and safety assessors of telehealth. The specification contains guidelines describing quality requirements for telehealth services, methods and examples for development of quality objectives for telehealth. Importantly the specification is intended to be used as a tool that can apply to each healthcare setting and derive quality criteria specific to that setting.

2.5 Refining the guidelines in ISO/TS 13131

The experiences gained during the execution of the FTH pilot informed refinement of the draft guidelines in the ISO/TS 13131 specification.

For example an early draft of the guidelines proposed a quality indicator requiring that there are "criteria for the skills the healthcare provider should have for providing care with the aid of telehealth". Review of this statement showed that the objective evidence required to satisfy these criteria was inadequately specified and difficult to obtain by clinicians working in the FTH pilot.

Subsequently this statement was rewritten to provide the quality objective that "The organization has a workforce that is competent to deliver effective telehealth services", which could be objectively verified using a quality procedure to ensure that:

a) the healthcare professional, or healthcare third party is required to possess the competencies that are necessary for providing healthcare by means of telehealth;

b) appropriate minimum professional standards are applied in the assessment of the required competencies for providing healthcare by means of telehealth; and

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

Examples of the application of the ISO/TS 13131 guidelines in the management of processes, activities and resources in the FTH pilot are provided below.

3 Application of guidelines in ISO/TS 13131

3.1 Case study method

The FTH pilot provided an opportunity for a case study in the application of the draft ISO/TS 13131 specification to

a real telehealth initiative. This permitted early drafts of the guidelines in the specification to provide guidance to the FTH pilot in developing its telehealth services.

The case study considers risks to safety and quality in service, workforce and healthcare planning and the responsibilities of healthcare actors. The second part of this evaluation considers new safety and quality risks that may arise when using telehealth.

The case study the discusses the quality objectives and guidelines which are generically applicable to most telehealth services using specific examples from the experiences of the FTH pilot to illustrate the applicability of the guidelines contained in the specification.

4 Service, workforce, healthcare and responsibility risk management

4.1 Service planning

Australian NSQHS Standard 1 proposes that patients and carers, in partnership with health service organisations, are involved in making decisions for service planning. The use of telehealth raises significant new service planning issues. Service planning guidelines in the ISO/TS 13131 specification cover service design, service levels and duration of care.

The objective of service design is to ensure an organisation provides accessible, appropriate and inclusive telehealth services. This requires consideration of the ability of a care recipient to travel, clinical objectives and model(s) of care or shared care, availability of specialists, local clinical staff and facilities. While these considerations will in most cases already be part of service planning there are new issues raised when telehealth is used. Examples include care recipient and provider access to computers or telecommunications and the need to cater for care recipients who may wish to choose how to access healthcare services.

Service planning needs to take into account the technical availability of telehealth services which may not be supported for 24 hours a day and 7 days a week, and may not be totally reliable. In the FTH pilot technical support was limited to business hours. Note that in some cases telecommunications services could not be provided to care recipients.

4.2 Workforce planning

Australian NSQHS Standard 1 sets out criteria that support the workforce planning needed to ensure managers and the clinical workforce have the right qualifications, skills and approach to provide safe, high quality healthcare.

Healthcare organisations are responsible for workforce planning and consultation with the workforce to support telehealth services. In particular, the organisation needs to ensure that the workforce is competent to deliver effective telehealth services. In many cases, the competencies required by a workforce using telehealth have yet to be defined and training has still to be provided. The FTH pilot found that the existing training materials were often not appropriate or specific enough for use in a telehealth in the home service and consequently developed a suite of new materials.

When planning a telehealth service which requires new workforce skills it is important to include staff in consultations about changes to service design including workflow, workloads, training or other changes a telehealth service may require. The FTH pilot staff developed new services, tested service delivery processes and technology, refined processes and retested the resulting solutions until satisfactory outcomes were achieved. Since staff members were responsible for the design and development of the telehealth services from the outset, minimal formal change management activities were required.

4.3 Healthcare planning

Healthcare planning guidelines in the ISO/TS 13131 specification include process design, plans, continuity planning, clinical guidelines and protocols, adverse event management and record management. Most of these healthcare planning processes are provided for in the Australian NSQHS Standard 1.

In executing healthcare plans, an organisation needs to cater for a failure of information and communications technology. FTH pilot palliative care staff developed a protocol to mitigate a failure in a video conferencing connection that employed use of an alternative video conferencing system, the telephone and if required a home visit.

Situations may also arise in which a procedure which may work well in a face to face consultation is not suitable for use at a distance. In this case it is important that a health professional takes action to reassure the healthcare recipient and initiates action to develop a suitable alternative procedure. For instance, the FTH pilot rehabilitation staff developed an exercise application for prescribing exercises that could be displayed on a care recipients tablet device to provide clear examples of how rehabilitation exercise should be performed.

4.4 Responsibilities of healthcare actors

Many responsibilities of actors in the healthcare process are discussed in the Australian NSQHS Standard 1 but the use of telehealth extends the range of responsibilities that require consideration.

Most healthcare organisations have well established processes to obtain consent. When using telehealth it may not be possible to obtain written consent. Instead health professionals may have to record verbal consent. Delivery of healthcare by telehealth requires appropriate informed consent but additional care may be needed to ensure that a recipient fully understands that aspects of the proposed healthcare plan may be delivered by telehealth, especially if written information and physical cues may be missing. The FTH pilot operated as a research project so written consent was obtained from all care recipients for legislated ethical reasons. In a normal telehealth service consent mechanisms may require modification.

In operating the FTH pilot service it was found that not all care recipients wished to receive care using telehealth. It is therefore important that care recipients can make informed choices from the available options for healthcare whether or not delivered by telehealth. It follows that once a choice is made regarding the type of

service delivery, a recipient should be free to change their preferences and switch to another mode of healthcare delivery. This issue has important consequences for health services, because the availability of a telehealth mode of healthcare delivery does not obviate the need to offer other (face to face) modes.

Factors influencing the choice of telehealth as a delivery mode include the possibility of expense for healthcare recipients (e.g. telecommunications costs) and the availability of reimbursements for telehealth services from government or insurance companies.

Healthcare organisations also become responsible for considering whether the use of telehealth is appropriate for a particular care recipient. Clinical pathways need to document the inclusion or exclusion criteria for receipt of care via telehealth. Quality procedures may need to include the availability of telecommunications services. For instance, the FTH pilot found instances where mobile data services were not available within a home.

A new dimension arising from the use of telehealth to deliver healthcare is ensuring that the care recipient and/or the informal care giver are competent to use the devices used to deliver a telehealth service. This is an additional organisational responsibility to those contained in current safety and quality procedures. For instance some recipients in the FTH pilot were assessed as not being confident enough or being too ill to learn how to use the provided tablet devices.

5 New safety and quality risks in the use of telehealth

The second part of this evaluation considers four new areas of risk not identified by Australian NSQHS Standards which are of particular concern to telehealth services in their present stage of development.

- financial management to ensure organisations provide sustainable funding for telehealth services;
- facilities management to ensure telehealth services use adequate facilities, including buildings and accommodation;
- technology management to ensure that telehealth services gain access to the information and communications technologies to deliver healthcare and transmit health information; and
- information management for processes related to privacy, security and data.

5.1 Financial management

Currently the development of existing telehealth funding and reimbursement models may not provide sufficient financial compensation for organisations or care recipients to effectively provide telehealth services.

It is therefore important for an organisation to develop a business case and implement a financial plan that considers the costs, benefit, affordability and sustainability of telehealth services. Additionally, healthcare professionals need to be familiar with the available healthcare funds applicable to telehealth services.

Many telehealth services are small scale. The FTH pilot demonstrated that small scale telehealth implementations may be very useful in establishing a service, but are not sustainable in the longer term.

5.2 Facilities management

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

Appropriate facilities are required for a telehealth service to operate successfully in a healthcare facility and in the home. The FTH pilot set up custom-designed consulting rooms to provide appropriate physical environment and privacy for consultations.

Telehealth services require equipment that can effectively transmit and receive an appropriate quality of audio or video and other information. The FTH pilot found through extensive testing that not all devices, applications and services can deliver comparable levels of technical quality, and that there is a continual need to review these factors as the available technology changes.

5.3 Technology management

Telehealth services depend on information and communications technologies to deliver healthcare and transmit health information. Since these technologies are part of the healthcare process, quality objectives should be established for information and communication technology service support, service delivery, infrastructure management, deployment management, operations management, and technical support.

Technology management is not simply about operation of a particular piece of equipment. Technology equipment, applications and services are heavily dependent on the service management capabilities of a healthcare organisation or technology provider.

Guidance on the management of information technology services can be found in ISO/IEC 20000-1:2011 - Information technology -- Service management -- Parts 1 to 5 (ISO/IEC 20000-1:2011). This provides guidance on the application of service management systems. The ISO/IEC 20000-1:2011 Standard is closely aligned with the Information Technology Infrastructure Library (ITIL®).

The FTH pilot was only able to implement a few service management aspects, since it was small scale pilot project with limited resources. However effective technology management based on best practices, such as those contained in the ISO/IEC 20000-1:2011 Standard is key to delivering healthcare on a large scale using telehealth.

Some organisations providing health services using telehealth may rely on information technology management services from an external ICT provider or a large internal ICT provider. In these cases, quality characteristics must be defined in service level agreements with those providers.

General purpose ICT infrastructure, including equipment, software and communications may be used to support telehealth services. In this case, the healthcare

organisation should define appropriate service level agreements with the relevant providers.

It should be noted that special provisions may apply to medical devices such as those defined in ISO 13485:2003 Medical devices — Quality management systems — Requirements for regulatory purposes. The IEC/TR 80001-2-1:2012-Part 2-1: Step-by-step risk management of medical IT-networks – Practical applications and examples series also provide useful guidance for medical devices and medical IT networks

5.3.1 Service support

Service support provides procedures to maintain telehealth continuity and dependability using:

- incident management of changes to services;
- problem management identification and resolution of issues whose cause is unknown;
- change management to manage necessary alterations to services; and
- release management for new services.

For instance, when a problem occurs with equipment used in the delivery of the care by telehealth, procedures should specify how problems can be diagnosed, communicated and resolved.

The FTH pilot initially relied on reactive problem solving by technical staff. However by the end of the pilot a number of guides had been developed such as a troubleshooting guide for the Tele-Rehabilitation Conference Room, a Patient Troubleshooting Guide and an iPad Setup Guide that enabled users to resolve many issues.

5.3.2 Service delivery

Service delivery procedures should include:

- service level agreements specifying the levels of telehealth service required for continuity of care;
- financial arrangements that account for the costs and charges to users of telehealth;
- capacity management to ensure that IT infrastructure resources are in place to effectively meet planned demand for telehealth;
- availability management to ensure systems are dependable and available for use in accordance with the service level agreements provided to users of telehealth; and
- service continuity management to provide recovery plans for telehealth in case of a significant failure.

Initially the FTH project was not able to provide any service level agreements to clinicians because technical solutions were in development. Subsequently a service catalogue was published for hours of service, fault management and escalation processes and service costs.

5.3.3 Infrastructure management

Infrastructure management for telehealth includes video-conferencing equipment, personal computers, servers, applications and telecommunications services. This infrastructure must be managed to support the longer term needs of telehealth services. Planning, design and technical support should be designed to ensure interoperability using appropriate Standards with other telehealth services, reliable communications and financial viability over a period of time.

The FTH pilot was fortunate to be able to leverage the technology infrastructure of both Flinders University and SA Health (which was a partner in the project). Some of the required service delivery procedures were already in place (such as maintenance of network availability). Even so health professionals were sometimes forced to use telephone communications when video conferencing failed, or to visit a care recipient in person.

5.3.4 Deployment management

Deployment management procedures can ensure that the configuration, testing and roll-out of telehealth services meet clinical needs for a timely provision of healthcare. Procedures should confirm that the equipment or software is safe and usable for telehealth services, installation of equipment complies with the guidelines of the manufacturer or supplier, and a process for removal of the equipment exists when a clinical service ceases.

Management of service and equipment deployment proved to be one of the most challenging aspects of the FTH pilot. To meet this challenge a customised asset and service management database was developed that tracks configuration of equipment (iPads, activity monitors) and services (telecommunications, application access) for each new patient.

5.3.5 Operations management

Operations management provides key behind the scenes technology services. For instance day-to-day technical supervision of ICT infrastructure includes:

- backup storage and restoration services;
- network monitoring and management;
- system monitoring and management; and
- management of diverse systems that may not interoperate well across facilities and organisational boundaries.

The FTH pilot was able to benefit from many operational management services from Flinders University. The exception was management of video conferencing. Interoperability of video conferencing systems is not seamless and manual intervention was often required to establish video calls between the FTH and the SA Health systems.

5.3.6 Technical support

Technical support for telehealth is not just about fixing faults. Technology for telehealth application is continually evolving and requires ongoing research, evaluation, market intelligence-gathering and documentation management.

The FTH pilot found that effective technical support was best provided by technical staff who worked alongside health professionals on a continuous collaborative basis, rather than via a remote call centre or help desk arrangement. This type of customer intimate service helped build confidence and capacity among the health professionals using telehealth and contributes

significantly to the sustainability of services by avoiding situations where equipment is put in a cupboard when, in the clinicians' perceptions, it "does not work".

5.4 Information management

Telehealth services depend on many information related processes related to privacy, identity management, security and information management. Provision, transmission and care of information is an important part of the healthcare process, and elementary quality objectives should be established for information management.

A minimum requirement is that organisations should notify the care recipient about the privacy regulations of the organisation, obtain agreement to these regulations and define processes to audit the compliance of healthcare professionals and healthcare third parties with the privacy regulations that may apply to the telehealth service. To meet this requirement the FTH pilot operated under the consent and privacy regulations of SA Health.

Electronic health records are increasingly associated with telehealth and in many settings are key tools for health professionals. Healthcare professionals should apply the guidelines of the healthcare organisation to protect the confidentiality of health records and confirm that information and communication technologies protect health records in electronic storage or transmission.

The FTH pilot supported the extension of clinical services from a hospital based service to the patients' home. Consequently the existing electronic health care record could be accessed from dedicated and secure laptop computer or iPad during a consultation, providing the health professional was working from within the hospital.

Coordination and scheduling of people, equipment and accommodation is often a major problem for telehealth services. The healthcare organisation should have a system for coordinating and booking the people, equipment, software licences and facilities needed for consultations using telehealth.

Coordination and scheduling proved a difficult issue for the FTH pilot that was never successfully solved. Preliminary work to provide a scheduling application accessible to patients and clinicians was undertaken. This application was intended to provide clinicians in a team with a patient centred view of a care plan, the patient with the ability to receive reminders of appointments, and family members access to add events to a calendar. Ideally a scheduling application should also be able to book video conferencing rooms and calls, but this did prove possible.

The quality of the collected or transmitted data provided by telehealth must be sufficient to safely support healthcare activities. For instance, the quality of textual, numerical, video or voice information may reduce the dependability and effectiveness of the health information leading to poor or unsafe decisions. The required levels of quality may also differ depending on the type of clinical service. For instance the FTH pilot found that the quality of audio during a video conference for use by a speech therapist was much higher than needed for a rehabilitation therapist.

6 Discussion

While developing the guidelines in the ISO/TS 13131 specification and considering the applicability of existing Australian safety and quality Standards to telehealth, it was found that there are areas of these Standards that require extension to cover the delivery of healthcare using telehealth. In the context of the telehealth pilot reviewed in this instance, the SA Health Guidelines for Sub-acute Services Offering Digital Telehealth Network Consultations were found to be the most relevant of all the existing Standards to the delivery of rehabilitation services to the home, but had some limitations because the guidelines were written for consultations taking place within the hospital system.

A key finding from the application of ISO/TS 13131 specification to creation of guidelines for telehealth in the home services is that safety and quality health service Standards may require extension to cover new risks introduced by telehealth healthcare delivery. In particular the guidelines provide a new emphasis for the application of many existing criteria contained in the Australian NSQHS Standards including:

- changes in service planning for clinical practice to take account of the difference between physical face to face healthcare settings and telehealth;

- new aspects of workforce planning in order to ensure managers and the clinical workforce have additional telehealth related competencies including qualifications and skills to provide safe, high quality healthcare;

- adaptation of healthcare planning to take account of improved systems for sharing patient care, and changes in the processes used in face to face care for use at a distance; and

- extended and new responsibilities of healthcare professionals to determine if the use of telehealth to deliver a healthcare service is appropriate.

Four new areas of risk not identified in Australian safety and quality Standards mediate the delivery of healthcare when using telehealth. These risk areas are the financial management needed to ensure telehealth becomes a sustainable mode of healthcare delivery, facilities management to provide an appropriate environment, technology management to underpin the delivery of services using telehealth and information management to safeguard information privacy, security and health information.

The ability of the guidelines in the ISO/TS 13131 specification to support the generation of detailed service specific guidelines has been demonstrated by the development of a customised toolkit for telerehabilitation based on a risk and quality management approach informed by the guidelines. FTH pilot staff members used this toolkit to support the delivery of telehealth services to the home for rehabilitation care.

7 Conclusion

The ISO/TS 13131 specification provides useful guidelines to assist the development of telehealth services, but it remains the job of each organisation to develop appropriate guidelines for each health service.

Transitioning from face to-face delivery of health services to telehealth will require a shift in the way that health services conceive of and manage safety and quality.

Further research is required to assess the role of guidelines and Standards in the enabling a successful transition from healthcare delivered face to face to telehealth.

8 Acknowledgments

9 References

ACSQHC. (2012): *Australian Commission on Safety and Quality in Health Care. Safety and Quality Improvement Guide Standard 1: Governance for Safety and Quality in Health Service Organisations* (October 2012). Sydney.

ACRRM. (2012): *ACRRM Telehealth Guidelines,* http://www.ehealth.acrrm.org.au/system/files/private/ACRRM%20Telehealth%20Guidelines_v1.0_20120827.pdf. Accessed 23 August 2014.

AHPRA. (2012): *Guidelines for technology based patient consultations,* http://www.medicalboard.gov.au/Codes-Guidelines-Policies.aspx, Accessed 23 August 2014.

Canadian Heart & Stroke Foundation. (2013): *Telestroke Implementation Toolkit*, 4th Edition, http://www.strokebestpractices.ca/wp-content/uploads/2013/09/Telestroke-Best-Practice-Recs-and-Toolkit-2013-09_30_2013.pdf. Accessed 23 August 2014.

Hanseth, O, Bygstad, B, Ellingsen, G, Johannesen, LK and Larsen, E. (2012): *ICT Standardization Strategies and Service Innovation in Health Care*, In Thirty Third International Conference on Information Systems, Orlando, 2012.

IEC 80001-1:2010: *Application of risk management for IT-networks incorporating medical devices -- Part 1: Roles, responsibilities and activities* International Organization for Standardization, Geneva, Switzerland.

ISO/IEC 20000-1:2011: *Information technology -- Service management -- Parts 1 to 5,* International Organization for Standardization, Geneva, Switzerland.

IEC/TR 80001-2-1:2012: *Part 2-1: Step-by-step risk management of medical IT-networks – Practical applications and examples*, International Organization for Standardization, Geneva, Switzerland.

ISO/TC 215 *Health informatics technical committee*, http://www.iso.org/iso/iso_technical_committee%3Fcommid%3D54960. Accessed 23 August 2014.

ISO 13485:2003: *Medical devices — Quality management systems — Requirements for regulatory purposes,* International Organization for Standardization, Geneva, Switzerland.

ISO 9000:2005: *Quality management systems — Fundamentals and vocabulary,* International Organization for Standardization, Geneva, Switzerland.

ISO 9001:2008: *Quality management systems — Requirements,* International Organization for Standardization, Geneva, Switzerland.

ISO 9004:2009: *Managing for the sustained success of an organization — A quality management approach,* International Organization for Standardization, Geneva, Switzerland.

ISO 31000:2009: *Risk management — Principles and guidelines*, International Organization for Standardization, Geneva, Switzerland.

ISO/TS 13131. *Health informatics — Telehealth services — Quality planning guidelines*, http://www.iso.org/iso/home/store/catalogue_tc/catalogue_detail.htm?csnumber=53052. Accessed 23 August 2014.

ITIL®, http://www.itil-officialsite.com/. Accessed 23 August 2014.

Joint Initiative Council. (2014): *Joint Initiative on SDO Global Health Informatics Standardization*, http://www.jointinitiativecouncil.org/. Accessed 23 August 2014.

Krupinski EO, Bernard J, (2014): *Standards and Guidelines in Telemdicine and Telehealth*, Healthcare, Basel, Switzerland, 2014.

NEHTA. (2014): NEHTA Implementation Resources for National Infrastructure. http://www.nehta.gov.au/implementation-resources/national-infrastructure. Accessed 23 August 2014.

RACGP. (2103): *Guidelines for inter-professional collaboration between general practitioners and other medical specialists providing video consultations*, http://www.racgp.org.au/your-practice/guidelines/interprofessional/. Accessed 23 August 2014.

SA Health. (2013): *Guidelines for Sub-acute Services Offering Digital Telehealth Network Consultations,* http://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/health+reform/clinical+networks/rehabilitation+clinical+network. Accessed 23 August 2014.

TeleSCoPE. (2014): *European Code of Practice for Telehealth Services, V5 Standard*, http://www.telehealthcode.eu/images/stories/telehea/pdf/TELESCOPE_2014_V5_STANDARD_CODE_FINAL.pdf. Accessed 23 August 2014.