2016 International Code of Practice for Telehealth Services
including guidelines

An International Quality Benchmark: Changing the Shape of Telehealth

www.telehealth.global
Telehealth is the means by which technologies and related services concerned with health and well-being are accessed by people or provided for them irrespective of their location.

The International Code of Practice for Telehealth Services has been developed and is wholly owned by the Telehealth Quality Group, TQG (see www.telehealth.global). The predecessor European Code was developed within the European Commission funded TeleSCoPE project (EAHC 2009 11 11).

The Telehealth Quality Group is an EEIG (European Economic Interest Group) incorporated at Companies House in Cardiff, United Kingdom (Registration Number GE000306). The IP for the Code is held by the Telehealth Quality Group EEIG (TQG).
PREAMBLE

To be successful, telehealth services need the trust of clinicians; health, social care and support practitioners; service users and both formal and informal carers. The International Code of Practice for Telehealth Services provides a quality benchmark against which telehealth services (including telecare) can be assessed and certified. In so doing, it provides a basis for that trust.

It is important to note that the Code addresses health in both its clinical and well-being senses. It is positioned, therefore, largely within a preventive and public health arena; and is relevant to us all, regardless of our age or any care or support need. In taking a strategic position, furthermore, the Code is able to act as an ‘umbrella’ that can link to operational codes concerned with specific tasks undertaken by telehealth services (see below).

CONTENTS

A. Overview

1. About the Code 4
2. Defining Telehealth 4
3. The Purpose of the Code 4
4. Telehealth Domains 5
5. Assessments for and Certification to the Code 5
6. ISO Certification 5
7. Updating the Code 6
8. The Code and its Structure 6

B. The Code

Preliminary Notes 7
List of Clauses and Index 8
Code 10
Appendix 50
A. OVERVIEW

1. About the Code

The International Code of Practice for Telehealth Services (the Code) derives from the European Code developed with European Commission funding and launched in 2013. It has been taken forward as an International Code by the Telehealth Quality Group, TQG (see www.telehealth.global).


The Code incorporates the quality planning guidelines set out in ISO/TS 13131 (2014). This means that a telehealth service that is certified to the Code also satisfies the requirement of the ISO Technical Specification 13131.

Where telehealth services are certified to the Code, this gives reassurance to service providers and their staff; service users and their carers; organisations that procure or commission services; health insurers; and governments, health and support agencies with an interest in telehealth.

Further testimony to service quality can be provided for telehealth services that also operate in accordance with one or more ‘operational’ codes (for particular aspects of service provision such as video-consultations, social/safety/medical alarms and PERS). In this way the Code can be seen ‘strategic’ and acting as an umbrella that covers and can be supported by operational codes. The Code is relevant to people of all ages e.g. to a 26 year old managing her diabetes; a 46 year old challenged with his mental health; or an 86 year old supported with her dementia.

The importance of the Code will increase because of demographic, political and economic factors. More people are living with and managing long-term conditions. Others have shorter term needs (e.g. during a period of pregnancy and childbirth, recovery or rehabilitation). And we can expect more people to access and use telehealth services to help guide them in relation to their everyday health and fitness.

Finally it must be recognised that telehealth services frequently operate alongside or are integrated with traditional health, care, housing and other support services. These ‘other’ services may include personal assistance and counselling; provision of specific therapies and treatments; planning for hospital admissions and discharges; tenancy support; or be concerned with access to specialist assistive technologies (e.g. aids to vision or hearing) and community equipment. Many telehealth services may, therefore, play a part in care and support ‘packages’ and within ‘care pathways’ that are specific to certain (and sometimes multiple) health conditions.

2. Defining Telehealth

Telehealth is the means by which technologies and related services concerned with health and well-being are accessed by people or provided for them irrespective of their location. This means that telehealth services can operate locally (within relatively small communities) or internationally. The common feature is that the person accessing the service (sometimes referred to as the patient or client) is not physically in the same location as the person providing the service (e.g. a physician or responder).

3. The Purpose of the Code

The Code provides a quality benchmark for telehealth service providers; addresses the way that services, related procedures and practices are organised; and the way that risks are addressed. It also points to some of the skills, knowledge and competencies that are required by service staff. Service requirements that are addressed in the Code include the way in which communication takes place with users and carers. In addition the Code sets out requirements that will help to minimise the potential for people’s privacy or autonomy to be undermined.
4. Telehealth Domains

Domains for telehealth services include needs that range from pregnancy to palliative care. Services may focus on one or more of these domains and involve the use of a variety of technologies. The latter can include telephony devices, television and web-cams, video links and fixed or wireless telecommunication and computing devices (including smart phones and tablets) that may be provided directly by the services or by service users themselves. Services may also involve the use of environmental controllers and apps where these enable access to and/or the sharing of health, well-being or activity related information.

### Telehealth Service Domains

- Health and motivational coaching and advice
- Activity and lifestyle monitoring
- Safeguarding and monitoring in care settings
- Gait, seizure and falls prediction / management
- Point of care testing and diagnoses
- Vital signs monitoring
- Mobile Health technology systems (e.g. apps)
- Medication or therapy adherence
- Rehabilitation and (re)ablement
- Responses to adverse ‘events’ and incidents
- Tele-consultation and virtual presence

It is important to recognise, in addition, that some of the technologies used within telehealth services can provide people with access to a wider range of different kinds of (non-telehealth) services such as information, social networks, email, training opportunities, etc. Telehealth services may, therefore, be positioned to provide economic and social as well as health and well-being benefits for their users and carers.

5. Assessments for and Certification to the Code

Procedures whereby services can be certified to the Code are set out on the TQG website at www.telehealth.global. To become certified, telehealth services shall satisfy the requirements of each clause that applies to them. This includes all the clauses of ISO/TS 13131. Services may self-certify or be assessed for compliance by an independent organisation approved by the TQG.

DNV GL (Healthcare) is the first independent organisation to be approved by the TQG to undertake such assessments. A range of charges apply. The level of the charge depends on the size and complexity of the service.

Services that either self-certify or are certified through independent assessments to the Code:

- have an obligation to facilitate conformity checks or investigations of their service (these can be undertaken without prior notice); and
- accept the manner in which certification can be suspended, renewed or revoked.

Services that are certified:

- are included in listings on the TQG website; and
- have freedom to use a logo that indicates certification on their websites and their literature.

Certification in accordance with the requirements of the Code, as well as bearing testimony to service quality, gives services an advantage when competing with other providers.

6. ISO Certification

The Code incorporates ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services. It, therefore, offers a holistic framework that guides telehealth services in ways that respond sensitively to the range of people who can benefit; and provides a robust benchmark against which procedures around e.g. risk management can be assessed. It provides significant added value and ensures that all key areas that relate to telehealth service provision are addressed.
7. Updating of the Code

The Code is reviewed and updated on an annual basis. Other updates may, however, be made at any time during the year and it is the responsibility of services to check that they (and their staff) are operating according to the latest version of the Code.

8. The Code and its Structure

The Code has nine sections as shown in the figure below. The person who uses telehealth services is at the centre – this position symbolising their importance and their being able to:

- exercise choices about services and service options;
- give explicit consent to the way in which their personal (including health) information is gathered, stored and used;
- have their views and opinions heard and taken into account; and
- have their human rights and dignity protected.

International Code of Practice for Telehealth Services: Framework
B. THE CODE

Preliminary Notes

In general, the Code does not include clauses where the responsibilities of service providers are enshrined in the legislation or regulatory requirements of the countries in which they are based and/or operate. Certified telehealth services shall, however, comply with country-specific legislation or regulatory requirements as well as all applicable clauses in this Code.

The following notes apply:

1. Where there is any difference between the requirements of this Code and the legislation or regulatory requirements of the countries in which services are based or operate the most stringent of the requirements shall apply.
2. Where reference is made to documents, policies, information or declarations that are placed on the website of the telehealth service or lodged in the Discovery Zone of the TQG website (there are five of these); these shall be provided in the primary language or languages relevant to its areas of operation and its service users.
3. Where reference is made to the need to review documents, policies or strategies (etc.) this must be done at least every two years unless specifically stated otherwise.
4. No single clause is concerned with the explicit consent for service provision that is given by users or carers. The issue of such consent is, however, very important for various aspects of service provision and it is, therefore, a requirement in several clauses.
5. There are 54 clauses. No service can be certified without being compliant with 47 of these. They are colour coded dark green (in the left panel). Certified services shall comply with all the clauses that are applicable to them. Those clauses which apply only when the activity is undertaken as part of the service are colour coded light green.
6. The guidance provided in relation to each clause provides pointers to good practice. Some elements of such good practice may become requirements of the Code in the future.
7. The guidance requires every service to comply with all relevant technical standards of the countries in which services are based or operate. Such compliance is supported by, but not limited to, a number of specific clauses within the Code.
8. An attempt has been made in this Code to avoid the use of jargon such as ‘co-production’, ‘care bundles’ and the like. The need for the active involvement of users and carers together with the pursuit of goals that relate to service integration (as suggested by such terms) are, however, strongly endorsed.

The clauses that make up the Code are set out in the ensuing pages within sections as follows:

A. General Considerations
B. Ethical Perspective
C. Governance and Financial Issues
D. Personal Information Management
E. Staff and Staff Management
F. Contact with Users and Carers
G. Interpretation of and Responses to Information
H. Communications Networks
I. Hardware and Technological Considerations
<table>
<thead>
<tr>
<th>Clause</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>Compliance with the Code</td>
<td>10</td>
</tr>
<tr>
<td>A2</td>
<td>Availability of the Code</td>
<td>10</td>
</tr>
<tr>
<td>A3</td>
<td>Service Website and Internet Presence</td>
<td>11</td>
</tr>
<tr>
<td>A4</td>
<td>Compliance with Statutory Requirements</td>
<td>12</td>
</tr>
<tr>
<td>A5</td>
<td>Sustainability Strategy</td>
<td>13</td>
</tr>
<tr>
<td>A6</td>
<td>Outcomes Focussed Appraisal</td>
<td>14</td>
</tr>
<tr>
<td>A7</td>
<td>Service Performance</td>
<td>15</td>
</tr>
<tr>
<td>A8</td>
<td>Suitability and Security of Service Locations</td>
<td>16</td>
</tr>
<tr>
<td>A9</td>
<td>Insurances</td>
<td>16</td>
</tr>
<tr>
<td>B1</td>
<td>Mission Statement</td>
<td>17</td>
</tr>
<tr>
<td>B2</td>
<td>Quality Plan</td>
<td>17</td>
</tr>
<tr>
<td>B3</td>
<td>Conflicts of Interest</td>
<td>18</td>
</tr>
<tr>
<td>B4</td>
<td>Promotion and Marketing</td>
<td>19</td>
</tr>
<tr>
<td>B5</td>
<td>Providing Information for Users and Carers</td>
<td>20</td>
</tr>
<tr>
<td>B6</td>
<td>Taking Account of User and Carer Views</td>
<td>21</td>
</tr>
<tr>
<td>B7</td>
<td>Taking Account of Staff Views</td>
<td>21</td>
</tr>
<tr>
<td>C1</td>
<td>Governance Structure</td>
<td>22</td>
</tr>
<tr>
<td>C2</td>
<td>Business Continuity</td>
<td>23</td>
</tr>
<tr>
<td>C3</td>
<td>Risk Management</td>
<td>24</td>
</tr>
<tr>
<td>C4</td>
<td>Maintaining Records</td>
<td>25</td>
</tr>
<tr>
<td>C5</td>
<td>Back Up IT Arrangements</td>
<td>26</td>
</tr>
<tr>
<td>D1</td>
<td>Protecting Personal Information</td>
<td>27</td>
</tr>
<tr>
<td>D2</td>
<td>Staff Access to Personal Information</td>
<td>28</td>
</tr>
<tr>
<td>D3</td>
<td>User and Carer Access to Personal Information</td>
<td>29</td>
</tr>
<tr>
<td>D4</td>
<td>Further Usage of Personal Information</td>
<td>29</td>
</tr>
<tr>
<td>D5</td>
<td>Dealing with Personal Information after Service Cessation</td>
<td>30</td>
</tr>
<tr>
<td>E1</td>
<td>Sufficiency of Staff for Service Provision</td>
<td>31</td>
</tr>
<tr>
<td>E2</td>
<td>Staff Recruitment and Leaving Policies</td>
<td>32</td>
</tr>
<tr>
<td>E3</td>
<td>Providing for the Support and Well-being of Staff</td>
<td>33</td>
</tr>
<tr>
<td>E4</td>
<td>Safeguarding Staff when Travelling and Visiting</td>
<td>33</td>
</tr>
<tr>
<td>E5</td>
<td>Staff Training and Development</td>
<td>34</td>
</tr>
<tr>
<td>E6</td>
<td>Whistle-blowing Policy</td>
<td>34</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td></td>
</tr>
<tr>
<td>F. Contact with Users and Carers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>F1</td>
<td>Agreements with Users and Carers</td>
<td></td>
</tr>
<tr>
<td>F2</td>
<td>In-person Visits</td>
<td></td>
</tr>
<tr>
<td>F3</td>
<td>Tele-consultations</td>
<td></td>
</tr>
<tr>
<td>F4</td>
<td>Guidance and Training for Users and Carers</td>
<td></td>
</tr>
<tr>
<td>F5</td>
<td>Development of Personal Service Plans and Healthcare Plans with Users and Carers</td>
<td></td>
</tr>
<tr>
<td>F6</td>
<td>Prompts to Users and Carers with regard to Service Needs</td>
<td></td>
</tr>
<tr>
<td>F7</td>
<td>Service Discontinuation to Individual Users and Carers by Provider</td>
<td></td>
</tr>
<tr>
<td>F8</td>
<td>Complaints and Suggestions</td>
<td></td>
</tr>
<tr>
<td>F9</td>
<td>User and Carer Fault Reporting</td>
<td></td>
</tr>
<tr>
<td>F10</td>
<td>User and Carer Changes to Network Supplier</td>
<td></td>
</tr>
<tr>
<td>F11</td>
<td>Abuse</td>
<td></td>
</tr>
<tr>
<td>G. Interpretation of and Responses to Information</td>
<td></td>
<td></td>
</tr>
<tr>
<td>G1</td>
<td>Responding to Information Gathered through Remote Monitoring</td>
<td></td>
</tr>
<tr>
<td>G2</td>
<td>Handover After an Event or Change of Circumstances</td>
<td></td>
</tr>
<tr>
<td>H. Communications Networks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>H1</td>
<td>Agreements between Services and Telecommunications Providers</td>
<td></td>
</tr>
<tr>
<td>H2</td>
<td>Monitoring of the Communications Networks</td>
<td></td>
</tr>
<tr>
<td>I. Hardware and Technological Considerations</td>
<td></td>
<td></td>
</tr>
<tr>
<td>I1</td>
<td>Fitness of Technologies/Equipment and Related Software</td>
<td></td>
</tr>
<tr>
<td>I2</td>
<td>Database of Technologies/Equipment</td>
<td></td>
</tr>
<tr>
<td>I3</td>
<td>Equipment Recall, Removal and Disconnection Procedures</td>
<td></td>
</tr>
<tr>
<td>I4</td>
<td>Protection and Safe-keeping of Technologies/Equipment</td>
<td></td>
</tr>
<tr>
<td>I5</td>
<td>Installation, Programming and Demonstrating of Technologies/Equipment</td>
<td></td>
</tr>
<tr>
<td>I6</td>
<td>Maintenance, Servicing, Repair and Replacement of Technologies/Equipment</td>
<td></td>
</tr>
<tr>
<td>I7</td>
<td>Recovery, Recycling and Re-Use of Technologies/Equipment</td>
<td></td>
</tr>
<tr>
<td>Appendix</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Some Relevant ISO Standards</td>
<td></td>
</tr>
</tbody>
</table>
## A: GENERAL CONSIDERATIONS

<table>
<thead>
<tr>
<th>Number</th>
<th>Clause</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A1</strong></td>
<td>Compliance with the Code</td>
</tr>
<tr>
<td><strong>Requirement:</strong></td>
<td>Services shall be compliant with all clauses that relate to the telehealth service they provide.</td>
</tr>
<tr>
<td><strong>Applicability:</strong></td>
<td>Applicable to all services.</td>
</tr>
<tr>
<td><strong>Guidance:</strong></td>
<td>No telehealth functions that are undertaken by the service, its agents or sub-contractors shall be excluded from the requirement to comply. A clear declaration regarding compliance, specific to the telehealth service, shall be placed on the website or in the Discovery Zone of the TQG website. The declaration shall be dated and reviewed annually. It shall be clear where that compliance applies only to specific services. If a service provides some telehealth functions which are not compliant with the code, the website shall make it clear which functions are not covered so that there is no confusion.</td>
</tr>
<tr>
<td><strong>ISO/TS 13131:</strong></td>
<td>This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.</td>
</tr>
<tr>
<td><strong>A2</strong></td>
<td>Availability of the Code</td>
</tr>
<tr>
<td><strong>Requirement:</strong></td>
<td>Staff, users and carers (and any intermediary organisations) shall all be aware of this Code and as to where they can view and obtain copies.</td>
</tr>
<tr>
<td><strong>Applicability:</strong></td>
<td>Applicable to all services.</td>
</tr>
<tr>
<td><strong>Guidance:</strong></td>
<td>Making the Code fully available to staff and others helps to ensure the efficacy of service provision and to build trust in telehealth.</td>
</tr>
<tr>
<td><strong>ISO/TS 13131:</strong></td>
<td>This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.</td>
</tr>
</tbody>
</table>
### Service Website and Internet Presence

**Requirement:**

Services shall maintain a current website, or a readily accessible area within the website of the organisation of which they are part, that is specific to the telehealth service.

**Applicability:**

Applicable to all services.

**Guidance:**

Proper consideration shall be given to website accessibility with this being reflected in the content and format.

The names of directors and senior management staff shall also be posted on the website with it being made clear which individuals or organisations have a controlling interest in the service.

Services might also wish to maintain their 'internet presence' through social media portals. The same principles regarding accessibility shall apply in those contexts.

**ISO/TS 13131:**

This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
Compliance with Statutory Requirements

Requirement:
Services shall be compliant with laws and regulatory requirements for all the countries or regions in which the service is provided or is incorporated. Services shall be prepared for and act in order to meet, in a timely fashion, any relevant legislative changes that arise.

Applicability:
Applicable to all services. An exemption may be applied where telehealth services are provided for people who travel internationally for business or recreation purposes.

Guidance:
The laws, regulatory and licensing requirements that shall be considered by services include those that relate to health and safety, employment law, data protection, reimbursement; the registration and competencies of employees; and, where used, specific medical device regulatory frameworks.
The laws, regulatory and licensing requirement of countries, states, provinces or regions shall take precedence over the requirements of this Code; excepting where the requirements of this Code are more stringent.
This clause does not apply to the homes or other locations of users and carers over which services have no control - except with regard to installations, specific use, etc. of any technologies/equipment provided.
Services shall be guided by the principles set out in ISO 27001, 27002, 27799 and 13485 and, where services operate within the European Union, the European Commission Directives 2011/24/EU, 2009/136/EC and 95/46/EC.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
A5  

**Sustainability Strategy**

**Requirement:**
Services shall have a current sustainability strategy.

**Applicability:**
Applicable to all services.

**Guidance:**
The importance of service sustainability cannot easily be overstated in view of the characteristics and needs of many users and carers.

A sustainability strategy will show, in service configuration and provision, how the economic/financial, social and environmental context is taken into account. It shall demonstrate an understanding of needs and markets specific to the service being provided and how this understanding impacts on planned changes to or the development of the service. It shall offer sufficient information, drawn from a business or financial plan, to show the sustainability of service funding.

In relation to environmental issues, consideration might be given in a sustainability strategy to the way that telehealth can reduce travel for staff, service users and carers.

Services shall be guided by the principles set out in ISO 14001, 26000 and 27001.

The sustainability policy shall be dated and reviewed at least annually.

**ISO/TS 13131:**

This clause together with C3, C5, H1 and H2 covers Clauses 6.5, 6.6, 7.1, 7.2, 7.3, 10.6 and 13.1 to 13.7 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
A6  Outcomes Focused Appraisal

**Requirement:**

Services shall undertake an annual outcome focused appraisal of their service as it relates to the health and well-being of service users and carers – and to the relevant national or regional health and social care economies.

**Applicability:**

Applicable to all services.

**Guidance:**

The outcomes focused appraisal shall examine, in an impartial manner, the extent to which the service has succeeded in its mission and related objectives. It shall provide pointers to potential changes in service provision having given attention, amongst other things to:

- the health benefits that have or have not accrued to service users and carers;
- how the service has acted upon the complaints, compliments and suggestions received; and
- feedback from any surveys of users and carers.

It is recognised that, where intermediary organisations are involved, exploration of such outcomes to the desired extent, may not be possible.

In new services the outcomes focused appraisal shall put baselines in place and offer a framework against which future measurement of progress can be made.

The outcomes focused appraisal shall be dated and reviewed at least annually. It shall feed into the Quality Plan and carry the personal endorsement of a senior staff member.

**ISO/TS 13131:**

This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
## Service Performance

**Requirement:**

Services shall record their performance in relation to a set of relevant measures.

**Applicability:**

Applicable to all services.

**Guidance:**

Services shall determine the relevant measures of performance. These will in some cases include operational data. In any case a set of relevant measures should be determined so that there is a framework against which future measurement of performance can be made.

Operational measures might usefully include the time taken, number or frequency with regard to:
- provision, calibration, testing, installation or removal of devices and related technologies;
- examining data and/or responding to needs indicated through enquiries or device activation;
- verifying and updating user details, service choices and consents;
- dealing with complaints, compliments and suggestions.

It is highly desirable that services honestly and openly display a range of such measures on their website or in other publicly available material.

A clear **declaration** regarding compliance, specific to the telehealth service, shall be placed on the website or in the Discovery Zone of the TQG website. The declaration shall be dated and reviewed annually.

**ISO/TS 13131:**

This clause together with A5, B2, C2, C3, C5, F1, H1 and H2 covers Clauses 5.3, 8.1 to 8.4 and 13.6 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
### A8 Suitability and Security of Service Locations

**Requirement:**
Services shall take preventive and responsive measures to ensure the suitability, physical and e-security of the location or locations from which their service operates and the channels through which information flows.

**Applicability:**
Applicable to all services.

**Guidance:**
For physical locations there shall be

a) adequate facilities (in terms of physical space, comfort and privacy); and

b) offer a high level of security (including such measures as motion activated or security lighting, controlled access and CCTV (closed circuit TV)).

For communications channels procedures shall be in place that check, at least daily, their integrity and effective operation.

Where breaches of security take place these shall be reported to the appropriate authorities and the provisions of the service regarding such security shall be reviewed.


**ISO/TS 13131:**
This requirement covers Clauses 12.1 and 12.2 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

### A9 Insurances

**Requirement:**
Services shall carry current insurances including, for example, buildings and equipment, public and product liability, professional indemnity, employer’s liability and, where appropriate, clinical negligence and relevant health (including key person) insurances.

**Applicability:**
Applicable to all services.

**Guidance:**
Insurances shall be at levels commensurate with the nature of the service provided and the risks that pertain to staff, service users and carers. A clear declaration regarding insurances shall be placed on the website or in the Discovery Zone of the TQG website. The declaration shall be dated and reviewed annually.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
## B: ETHICAL PERSPECTIVES

<table>
<thead>
<tr>
<th>Number</th>
<th>Clause</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### B1 Mission Statement

**Requirement:**
Services shall have a current mission statement that gives attention to ethical principles.

**Applicability:**
Applicable to all services.

**Guidance:**
The mission statement shall set a clear direction for the service with regard to its objectives and modus operandi and which is in accordance with the ethical principles for service provision in the healthcare fields that apply. The service’s mission statement shall be posted on the website or in the Discovery Zone of the TQG website. It shall be dated and reviewed annually.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

### B2 Quality Plan

**Requirement:**
Services shall have a quality plan that defines the purpose of the services it offers, how these purposes are achieved and how service progress in relation to those purposes are reviewed. It shall address for each quality objective, the procedure by which risks are mitigated in relation to the same.

**Applicability:**
Applicable to all services.

**Guidance:**
The quality plan contributes to service objectives associated with transparency, accountability, safety and effectiveness. It shall make clear who is responsible for its implementation, monitoring and review; and shall clearly reference the service’s resources and their usage / management. It shall show how it ensures that the quality and quantity of data collected or shared is sufficient for effective service operation.

The quality plan shall be included in the portfolio (or manual) of key policy and practice documents. It shall be dated and reviewed annually.

**ISO/TS 13131:**
This requirement, together with other clauses covers Clauses 6.1 to 6.8, 8.1, 8.4, 14.6 and 14.7 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
## B3 Conflicts of Interest

**Requirement:**
Services shall ensure that all directors, staff (including volunteers), agents and sub-contractors are transparent about and avoid or manage conflicts or potential conflicts of interest that relate to their activities, involvement and/or shareholdings, in or outside the telehealth service.

**Applicability:**
Applicable to all services.

**Guidance:**
Conflicts of interest might include shareholdings or official positions held or previously held by the individual him/herself or other connected persons (including close family members) in bodies with which the telehealth service has significant dealings.

Such directors, staff (including volunteers), agents and sub-contractors or other connected persons shall not, in any case, acquire benefits from the telehealth service of such a magnitude that might impair his/her independence in the performance of his/her duties.

Service shall be aware of the potential for conflicts of interest for sub-contractors and intermediary organisations and seek to ensure that these are similarly avoided or managed.

These conflicts or potential conflicts shall be included in an up to date register of interests held by the service.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
### B4 Promotion and Marketing

**Requirement:**
Services shall not promote or market their wares by preying on fear, omitting important or giving misleading or unsubstantiated information.

**Applicability:**
Applicable to all services.

**Guidance:**
Some service users will be at higher risk than others in relation to their health and well-being. Neither the extent of that risk, nor the anticipated benefits of telehealth, shall be exaggerated. Misleading and/or unsubstantiated information might relate to e.g. claims regarding the medical credentials of the service and/or its staff or the technologies used; or claims regarding service outcomes that are poorly evidenced.

Preying on fear includes the portrayal (in text, voice or images) of users or potential users (or those with whom it is intended that they might identify) in a way that is likely to create disproportionate worry or anxiety.

Good practice with regard to promotion and marketing might reference robust, validated and openly available research and/or evaluations that specifically relate to elements of the service.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
B5 Providing Information for Users and Carers

Requirement:
Services shall make information about the service available to users and carers so they can exercise informed choices and give explicit consent regarding their acceptance (or not) of the service and service options.

Applicability:
Applicable to all services.

Guidance:
Informed choice means that users and carers shall receive information (whether in speech, written or printed, in video, DVD or in apps) that is timely, clear and comprehensive. Through such information users and carers need to be clearly aware of service options; the risks and benefits pertaining to service operation; rights and responsibilities; arrangements for termination of or withdrawal from the service; and all applicable charges and costs (for different service options including those that apply when devices are supplied by users and carers themselves).

The information made available or provided shall normally be directly to users and carers but it is recognised that the contact may be indirect where intermediary organisations are involved.

Enabling the making of informed choices means that, in communicating information, proper attention is given by services to the needs of users and carers with e.g. hearing loss, sight loss, physical or cognitive impairments.

Exceptionally, but only when authorised in law or applicable regulatory frameworks, the need for explicit consent may be overridden.

ISO/TS 13131:
B6 Taking Account of User and Carer Views

Requirement:
Services shall, in all aspects of their operation, give due consideration to the views, opinions and choices of their service users and carers.

Applicability:
Applicable to all services.

Guidance:
The views of the main beneficiary shall take precedence over the views of carers except where the former are children without competence or adults with substantial dependency arising e.g. out of cognitive impairment or mental illness. Services may wish to demonstrate their willingness to take account of user and carer views through facilitating their involvement in overall service planning; making use of feedback (on-line or in other ways) in relation to service provision; or making follow-up calls after user or carer interaction with the service.

It is recognised that, where intermediary organisations are involved, obtaining the views of users and carers to the desired extent may not be possible.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

B7 Taking Account of Staff Views

Requirement:
Services shall give due consideration to the views, opinions and choices of their staff and consult with them wherever appropriate about relevant service plans or changes that impact on workflow, workloads, required skills and training.

Applicability:
Applicable to all services.

Guidance:
The views of the staff are important to the effective operation of telehealth services and need to be taken into account. In some cases those views may be gathered through staff representatives.

It is recognised that, where intermediary organisations are involved, obtaining the views of staff would not be appropriate.

ISO/TS 13131:
This clause covers Clause 9.3 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
## C: GOVERNANCE AND FINANCIAL ISSUES

<table>
<thead>
<tr>
<th>Number</th>
<th>Clause</th>
</tr>
</thead>
<tbody>
<tr>
<td>C1</td>
<td>Governance Structure</td>
</tr>
</tbody>
</table>

### C1 Governance Structure

**Requirement:**

Services shall have a clear governance structure (i.e. ensuring effective decision-making) that encourages good customer care.

**Applicability:**

Applicable to all services.

**Guidance:**

The governance structure shall be evidenced in the way that decisions are made, responsibilities assigned, accountability ensured, reporting processes practiced, and the way that staff are managed.

The structure shall, where appropriate, include provision for clinical governance by which the needs of users with particular needs as ‘patients’ are taken into account.

The extent to which services satisfy the requirement of this clause takes account of other clauses elsewhere within the Code.

A clear declaration regarding the governance framework shall be placed on the website or in the Discovery Zone of the TQG website. It shall be dated and reviewed annually.

Services shall be guided by the principles set out in ISO 9001 and 22301.

**ISO/TS 13131:**

This clause covers Clauses 10.1 and 10.2 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
### C2 Business Continuity

**Requirement:**
Services shall have a business continuity plan.

**Applicability:**
Applicable to all services.

**Guidance:**
Services shall have a current plan that supports service dependability and determines the way in which major disruption to the service will be dealt with or closure achieved - whilst, at the same time, providing safeguards for users and carers, and including safeguards for personal data.

Considerations around major disruption might include (among other things) network failures, extreme weather, employee illness, loss of a key sub-contractor or service insolvency.

If there are planned changes to the network supplier, careful consideration shall be given to ensure that any disruption to the service is minimised – with service users, carers and others informed.

The business continuity plan shall dated and be tested, at an appropriate level, at least annually.

**ISO/TS 13131:**
This clause covers Clauses 8.1, 8.3, 10.4, 10.6 and 13.3 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
<table>
<thead>
<tr>
<th>C3</th>
<th>Risk Management</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Requirement:</strong></td>
<td>Services shall have a current risk management system that takes account of the outcomes of risk assessments and seeks to reduce the likelihood and impact of any adverse incidents for all elements of service provision.</td>
</tr>
<tr>
<td><strong>Applicability:</strong></td>
<td>Applicable to all services.</td>
</tr>
<tr>
<td><strong>Guidance:</strong></td>
<td>This system and related documents shall identify and follow a clear risk assessment process by which these are assessed and prioritised. It shall cover risks that relate to buildings, the communications infrastructure, contamination of equipment/technologies and other matters relating to service provision. Specific and close attention shall be given to risks to staff including those that attach to in-person (home) visits where these are undertaken; and to the risks to users and carers relating to service provision and usage. The system and related documents shall (except for new services) set out, in summary, how adverse events or risks evident within or arising during the prior year have been dealt with or countered. Key information relating to the same shall be included within the Quality Plan. Services shall be guided by the principles set out in ISO 27005.</td>
</tr>
<tr>
<td>ISO/TS 13131:</td>
<td>This clause together with C5, H1 and H2 covers Clauses 6.5, 6.6, 7.1, 7.2, 7.3, 10.6 and 13.1 to 13.7 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.</td>
</tr>
</tbody>
</table>
C4 Maintaining Records

Requirement:
Services shall maintain comprehensive and up to date records in relation to the service.

Applicability:
Applicable to all services.

Guidance:
Records shall document actions pertaining to service operation and service users noting the modes of such actions (extending from electronic communications to written information and involving data, images, video and voice information). They shall include matters such as
★ personal (health and related) information regarding service users and carers;
★ in-person (home) visits and tele-consultations;
★ other interactions with service users and carers;
★ interactions or consultations with health, social care and other professionals;
★ care and support packages; and
★ detail of consents given and related service protocols.
These records shall be held for the period of service (to or for a user) plus a minimum further two years or in accordance with country, state, province or region specific legislative or regulatory requirements.
Records shall also document information on
★ staff (including volunteers) engaged; and the
★ qualifications, training and competencies of staff.
These records shall be held for the period of staff engagement/employment plus a minimum further two years or in accordance with country, state, province or region specific legislative or regulatory requirements.
Services shall be guided by the principles set out in ISO 9001, 22301 and 27001.

ISO/TS 13131:
This clause covers Clauses 10.7 and 14.5 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
C5 Back Up IT Arrangements

Requirement:
Services shall maintain procedures for real time or, at a minimum, daily transfer of information relating to service operation and the personal data of users and carers, to a secure environment.

Applicability:
Applicable to all services.

Guidance:
The back-up procedures shall relate to all core functions of the service. These shall enable the minimisation of any disruption following an ‘event’ and the continued operation (or prompt recommencement of operation) at a satisfactory level (i.e. with on-going monitoring of or for service users). The procedures shall take account of the potential for disruption that can arise due to IT failure or a hacking incident, problems with the telecommunications network or staff shortages. In any event the procedures must ensure that personal information regarding service users and carers (and access to it) is safeguarded.

Services shall be guided by the principles set out in ISO 27005.

ISO/TS 13131:
This clause together with C3, H1 and H2 covers Clauses 6.5, 6.6, 7.1, 7.2, 7.3, 10.6 and 13.1 to 13.7 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
### D: PERSONAL INFORMATION MANAGEMENT

<table>
<thead>
<tr>
<th>Number</th>
<th>Clause</th>
</tr>
</thead>
<tbody>
<tr>
<td>D1</td>
<td>Protecting Personal Information</td>
</tr>
</tbody>
</table>

**Requirement:**

Services shall maintain current policies and procedures for the management and protection of personal information.

**Applicability:**

Applicable to all services.

**Guidance:**

These policies and procedures shall ensure that services operate in a manner that is fully in accordance with country, state, province or region specific legislative or regulatory requirements. The policies and procedures shall give attention to the transfer of personal information over publicly accessible networks and the manner in which such information is accessed - whether via fixed or portable devices. Specific procedures for the protection of personal information might include the use of password protection and time out facilities.

Policies and procedures shall ensure that the manner of storage, management and sharing of personal information normally carries the explicit and informed consent of users and carers. It follows that such consent shall be renewed prior to any proposed change in arrangements for the transfer or storage of personal information.

In this context, services shall demonstrate an understanding that such personal information is owned by the users and carers themselves. It is, therefore, entrusted by users and carers to the service for the contracted period and can only be retained by a service provider in certain circumstances that will normally require their consent.

Exceptionally, but only when authorised by law, the need for explicit consent may be overridden. Policies relating to the management and protection of personal information shall be posted on the website or in the Discovery Zone of the TQG website. They shall be dated and reviewed annually. Services shall be guided by the principles set out in ISO 27001.

**ISO/TS 13131:**

### D2 Staff Access to Personal Information

**Requirement:**
Services shall ensure that only authorised staff can input, amend or access personal information regarding users and carers and their service usage.

**Applicability:**
Applicable to all services.

**Guidance:**
- Inputting of information shall only be undertaken by authorised service staff. An exception applies for users and carers when they upload information e.g. regarding measures of their vital-signs.
- Alteration of personal information shall only be undertaken for the correction of errors or the making of clarifications. A clear record (i.e. providing an audit trail) shall be maintained of where, when, by whom and for what purpose access, inputting, addition, correction or alteration to personal information was made.
- Authorised staff may include those from partner agencies, sub-contractors or intermediary organisations where there are relevant contractual arrangements in place and, exceptionally, other authorised persons.
- The accessing and use of personal data or any wider data harvesting in the context of service provision shall only be undertaken with the explicit consent of users and carers.
- Exceptionally, but only when authorised by law, the need for explicit consent may be overridden.
- Services shall be guided by the principles set out in ISO 27001.

**ISO/TS 13131:**
### D3 User and Carer Access to Personal Information

**Requirement:**
Services shall make provision for users and carers to access their personal information.

**Applicability:**
Applicable to all services.

**Guidance:**
Full access to personal information (including audit trails relating to access to and usage of the same) shall be available to users and carers, but they shall not be able to alter or add to such information except in respect of updating their circumstances or service choices; and when uploading information e.g. regarding measures of their vital signs. Their right to request corrections and, in certain circumstances, to object to the processing of their personal data shall be recognised. It follows that services shall respond favourably to reasonable user and carer requests on such matters (including amendments to and corrections of their personal information).

This right of access extends to users and carers where the service is provided through a contracted arrangement with an intermediary organisation.


**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

### D4 Further Usage of Personal Information

**Requirement:**
Services shall ensure that users and carers are aware of whether, how and in what circumstances their personal information is shared with other bodies (and whether any opt outs apply).

**Applicability:**
Applicable when undertaken as part of the service.

**Guidance:**
Sharing may or may not be subject to anonymization. In the case of the former, the procedure selected shall ensure that all reasonable steps are taken to remove the possibility that individuals can be identified from the information in question.


**ISO/TS:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
**D5 Dealing with Personal Information after Service Cessation**

**Requirement:**
Services shall, after service cessation, keep the personal information of users and carers securely pending its transfer, deletion and/or anonymisation.

**Applicability:**
Applicable to all services.

**Guidance:**
After service cessation, full access to personal information shall be available to users and carers and authorised others for a minimum period of six years or in accordance with country, state, province or region specific legislative or regulatory requirements. Users and carers shall retain the right for such data to be released, transferred (e.g. to an alternative service) or erased by the service when formally requested to do so by them (or by their heirs or legal representatives). Copies of such data can only be retained by a service provider in certain circumstances that will normally require the consent of users and carers.

Services shall be guided by the principles set out in ISO 27001.

**ISO/TS 13131:**
This clause together with D1 covers Clauses 14.1, 14.2 and 14.4 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
E: STAFF AND STAFF MANAGEMENT

<table>
<thead>
<tr>
<th>Number</th>
<th>Clause</th>
</tr>
</thead>
<tbody>
<tr>
<td>E1</td>
<td></td>
</tr>
</tbody>
</table>

**Sufficiency of Staff for Service Provision**

**Requirement:**
Services shall engage a sufficient range and number of staff with skills and knowledge that are commensurate with safe, effective and sustained operation of the service.

**Applicability:**
Applicable to all services.

**Guidance:**
Services shall be able to demonstrate how they determine and monitor, on an ongoing basis, the appropriate number of staff (and their skills and knowledge) in relation to each aspect of the service; how they respond where there are deficiencies (including dealing with high ‘call’ volumes and/or emergency situations that may threaten business continuity); the extent to which staff roles and functions are supported by or, in part, replaced through automated elements of the service; and how they plan for their staff resource in the context of service maintenance, growth or development.

**ISO/TS 13131:**
This clause together with E5 covers Clauses 9.1, 9.2 and 14.6 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
**E2 Staff Recruitment and Leaving Policies**

**Requirement:**
Services shall have staff recruitment and leaving policies that are relevant to the nature of their service.

**Applicability:**
Applicable to all services.

**Guidance:**
The recruitment policies (or policy) shall seek to ensure that staff (including volunteers) are of good character and demonstrate informed, empathetic and non-judgemental approaches in their dealings with users and carers. Services shall normally, in any case, employ staff with the relevant health, social care and/or related expertise or have ready access to such expertise during the contracted hours of service provision.

Staff who have contact with users and carers shall be issued with appropriate identification documents, badges and, where appropriate, uniforms. When a member of staff leaves, these documents and all other information relating to the service that is held by him/her shall be recovered; and passwords, etc. that permit access to databases, non-public parts of any websites, etc. immediately removed.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
E3 Providing for the Support and Well-being of Staff

Requirement:
Services shall make provision for the support, well-being, comfort and security of their staff.

Applicability:
Applicable to all services.

Guidance:
In seeking to ensure the well-being and comfort of staff, services shall give consideration to the way in which staff are managed and their performance reviewed against the requirements; and also to their places of work and the travel undertaken in the course of their work.

For staff who may undertake work from home they shall have sole and secure access to technologies, equipment or software used for the service; and there shall be reasonable precautions taken by staff to preclude access to or viewing by any other person; and to avoid damage by children, pets, etc.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

E4 Safeguarding Staff when Travelling and Visiting

Requirement:
Services shall have procedures and practices that help to safeguard staff when travelling and visiting in the course of their work.

Applicability:
Applicable to all services.

Guidance:
Travel may be to/from in-person (home) visits to users and carers or for other work related reasons (including training). The procedures and practices shall ensure that staff are clear about their shared responsibility with the telehealth service provider for their personal safety and follow these.

The risks associated with lone working and/or of travel in insecure areas shall be taken account of and suitable precautionary or ‘alert’ procedures put in place where warranted. The latter may include precluding unaccompanied entry to certain areas or properties and/or the usage/operation of (lone) worker monitoring procedures.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
### E5 Staff Training and Development

**Requirement:**

Services shall provide staff with (or support them in accessing) training and opportunities for personal development.

**Applicability:**

Applicable to all services.

**Guidance:**

Training shall ensure that staff (including volunteers) acquire, maintain and develop relevant knowledge, skills and competencies. The content of the training shall address, where applicable, appropriate communications methods that e.g. take account of the needs of users and carers who have communication difficulties because of cognitive, physical or sensory impairments (including those who may be deaf or hard of hearing).

**ISO/TS 13131:**

This clause together with E1 covers Clause 9.2 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

### E6 Whistle-blowing Policy

**Requirement:**

Services shall have a whistle-blowing policy by which staff can report any concerns.

**Applicability:**

Applicable to all services.

**Guidance:**

This policy shall ensure that all staff (including volunteers) are fully aware of their responsibility to, and the avenues by which, they can (in confidence and without prejudice to themselves) report if elements of the service may have fallen or be at risk of falling below the required standards. It follows that contracts for staff shall contain a suitable ‘whistle-blower’ clause and that procedures for reporting their concerns shall be set out. Reporting that may be construed as ‘whistle-blowing’ shall, in normal circumstances, be to a more senior (or a designated) staff member. But an alternative option, e.g. reporting to the certification body (i.e. the TQG or its agents) or the main national body responsible for quality of health and/or social care services, shall also be clearly pointed to. In either circumstance any concerns reported by staff shall be properly documented and held securely. Provision shall, in addition, be made to protect, where appropriate, the anonymity of the informant.

**ISO/TS 13131:**

This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
F: CONTACT WITH USERS AND CARERS

<table>
<thead>
<tr>
<th>Number</th>
<th>Clause</th>
</tr>
</thead>
<tbody>
<tr>
<td>F1</td>
<td></td>
</tr>
</tbody>
</table>

**Agreements with Users and Carers**

**Requirement:**
Services shall have an agreement with users and carers regarding the manner of service provision (including supply of technologies/equipment), selected payment option(s) where they apply, arrangements for gathering personal information, response protocols, and procedures for service discontinuation.

**Applicability:**
Applicable to all services.

**Guidance:**
Agreements shall clearly set out details of the service (including the technologies/equipment supplied/used and any applicable costs) and the rights and obligations of the parties concerned. They shall include attention to processes that relate to informed and normally explicit consent; protocols for handling personal information; the following of clinical guidelines and protocols where applicable, charges for different service options (including when users/carers supply their own devices); and the process by which (and any penalties for) users and carers can withdraw from the service.

Agreements shall enable early termination, without any charge or penalty, where this is initiated by users or carers because of a significant change in health/medical need; or in the availability of (formal or informal) carer support; or because of the necessity to move to a specialised care institution; or end of life. Such agreements may be within the context of personal service plans and will normally be referenced in applicable formal contracts.

Where appropriate, agreements may include encouragement for users and carers to periodically test their telehealth equipment. Service provision shall not, however, depend on such action being undertaken.

Where re-cycled technologies/equipment are provided, users and carers shall be clearly informed of this.

It is recognised that some agreements may be given effect through sub-contractors and/or intermediary organisations.

Services shall be guided by the principles set out in ISO 9001.

**ISO/TS 13131:**
This clause covers Clauses 8.1, 8.2, 10.5 and 11.1 to 11.4 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
<table>
<thead>
<tr>
<th>Requirement:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Services shall have policies, where included as part of the contracted service, for in-person (home) visits by authorised staff (including volunteers) to users and carers.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Applicability:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Applicable when undertaken as part of the service.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Guidance:</th>
</tr>
</thead>
<tbody>
<tr>
<td>In-person (home) visits shall only be undertaken by authorised staff and shall follow clear procedures. These shall include</td>
</tr>
<tr>
<td>★ agreement with users and carers or other relevant persons for the visits and/or due advance notice being given;</td>
</tr>
<tr>
<td>★ a record being made of the visit, its purpose and its outcome; and</td>
</tr>
<tr>
<td>★ any special considerations regarding e.g. access to property.</td>
</tr>
</tbody>
</table>

As well as relating to those aspects of the service concerned with health and well-being, the above applies to visits made for the purpose of delivery, installation, removal, replacement, etc. of technologies/equipment.

Specific procedures for in-person visits shall apply when responses are made by services to known or suspected urgent or necessitous circumstances. These shall include the manner in which clear endeavours are made to contact users and carers or other relevant persons (e.g. key-holders, relatives); and the means by which the identity of all persons involved is readily verified.

Authorised staff (including volunteers) making in-person (home) visits shall carry identification, including a photo, to be proffered to (potential) users and carers (and other persons) on arrival. Staff shall, where not explicit or in the case of any doubt, make it clear to users and carers the reason for their visit.

Where planned visits are delayed, notification shall be made to users and carers and/or other relevant persons of the same.

<table>
<thead>
<tr>
<th>ISO/TS 13131:</th>
</tr>
</thead>
<tbody>
<tr>
<td>This clause covers Clause 14.3 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.</td>
</tr>
</tbody>
</table>
Tele-consultations

Requirement:
Services shall have policies, where included as part of the contracted service, for tele-consultations with users and carers (via telephone, video-links, Skype, etc.).

Applicability:
Applicable when undertaken as part of the service.

Guidance:
Tele-consultations shall only be undertaken by authorised staff and shall follow clear procedures. These shall include
- agreement with users and carers or other relevant persons for the visits and/or due advance notice being given;
- a record being made of the visit, its purpose and its outcome;
- how interaction with users and carers is, where necessary, afforded the necessary level of privacy e.g. taking account of the potential presence of others;
- advance audible and/or visual signals given to the user and/or carer;
- the adequacy for the consultation of the location (accommodation) in terms of space, comfort and privacy..

Authorised staff undertaking such tele-consultations shall clearly identify themselves on-line at the beginning of the encounter. There shall be the means in place by which the identity of all persons involved is readily verified. Authorised staff shall, where not explicit, make it clear the reason for their ‘visit’. No opening of video or audio channels shall take place until the ‘call’ has been accepted by the user or carer (or an authorised member of staff on their behalf who is at the location of the user/carer).

Provision shall be made for tele-consultations to be initiated by users and/or carers as well as by the service provider. Provision shall also be made for users and/or carers to easily terminate tele-consultations. It shall, in either case, be clear to them when video and/or audio links have been closed.

It shall be borne in mind that inherent within tele-consultations is the transmission of personal information. Therefore services shall make it clear to users and carers when tele-consultations operate via non-encrypted public networks and systems.

Where tele-consultations initiated by services are delayed, notification shall be made to users and carers and/or other relevant persons of the same.

ISO/TS 13131:
This clause covers Clauses 12.2, 12.3 and 14.3 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
F4  Guidance and Training for Users and Carers

Requirement:
Services shall provide guidance and, where appropriate, training to service users and carers.

Applicability:
Applicable to all services.

Guidance:
Guidance and (where appropriate) training shall be provided in order to enhance the understanding of users and carers (and relevant others if necessary) of the service and the technologies/equipment concerned. This with a view to ensuring a sufficient level of competency in relation to their use of the service provided. It shall be recognised that guidance and training may be required periodically for some service users and carers. Services shall endeavour to meet such requirements (including through any sub-contractors and/or intermediary organisation).

Modern media could, in part, be used (e.g. via You Tube clips) for both guidance and training but with consideration requiring to be given to the extent to which users and carers can access the same.

ISO/TS 13131:
This clause covers Clause 11.7 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

F5  Development of Personal Service Plans or Healthcare Plans with Users and Carers

Requirement:
Services shall ensure that only authorised persons engage with users and carers to develop, agree and review personal service or healthcare plans.

Applicability:
Applicable when undertaken as part of the service.

Guidance:
Personal service plans or healthcare plans, where they are used, shall take proper account of the needs, views and choices of users and carers. In some cases (where there are particular circumstances) such plans will necessarily be developed in collaboration with specialist staff, some of whom may be employed by partner (or other) agencies. Where appropriate they shall follow clinical guidelines and protocols that are determined by recognised professional bodies.

Personal service or healthcare plans shall be reviewed with users and carers as necessary (e.g. because of a change of circumstances) and at least annually.

ISO/TS 13131:
This clause together with F8 covers Clauses 10.3, 11.6 and 11.8 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
### F6 Prompts to Users and Carers with regard to Service Needs

**Requirement:**
Services shall ensure that service users and carers (including those who pay privately for the service or receive the service free of charge) are prompted, where appropriate, at least annually, to reconsider their service needs.

**Applicability:**
Applicable when undertaken as part of the service.

**Guidance:**
Prompting in relation to service needs shall enable review with users and carers of service protocols, consents for the same and the merits (in light of any changing needs or preferences) of service options for users and carers. Where appropriate amendments would be made to any personal service plans or healthcare plans and consideration given where users or carers might benefit from complementary or different services.

It is recognised that, where intermediary organisations are involved, such prompting may require to be given effect by those organisations.

Services shall be guided by the principles set out in ISO 9001.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

### F7 Service Discontinuation to Individual Users and Carers by Provider

**Requirement:**
Services shall be able to discontinue service provision to individual users and carers only where they are clearly in breach of their contractual obligations and/or are abusing the service.

**Applicability:**
Applicable to all services.

**Guidance:**
Such discontinuation shall not take place without careful consideration being given wherever there may be a consequential increased risk to users or carers. Where appropriate, services shall inform in advance and with reasonable notice (and, where necessary engage in a dialogue with) relevant health, social care or other agencies (including intermediary organisations). An exception applies in the event of service closure where other provisions apply.

Circumstances that constitute abuse of the service may include its repeated and ongoing and inappropriate non-use or use in ways that are outside those which have been agreed; which do not relate to the health or well-being of the user and/or carer; and/or are not commensurate with the purpose of the service.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
F8 Complaints and Suggestions

**Requirement:**
Services shall keep a record of complaints and suggestions made to them.

**Applicability:**
Applicable to all services.

**Guidance:**
This shall include and date all complaints and suggestions where these are made in writing (or other text). Services shall incorporate in their Outcomes Focused Appraisal how they have acted upon the complaints and suggestions received - together with the feedback from any surveys of users and carers.

Services shall be guided by the principles set out in ISO 9001.

ISO/TS 13131:
This clause together with F5 covers Clause 11.8 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

F9 User and Carer Fault Reporting

**Requirement:**
Services shall provide service users and carers with an easy means of reporting faults or failures of the technologies/equipment.

**Applicability:**
Applicable to all services.

**Guidance:**
There shall be a facility for users and carers to report faults via the service web-site and/or via telephone. Faults reported in this and other ways shall be dealt with promptly.

Clear information shall be posted on the website or in the Discovery Zone of the TQG website. This shall be dated and reviewed annually.

Services should recognise that good practice in relation to such matters may include the use of telehealth technologies and communications systems that incorporate the ability to self-test and/or some level of redundancy whereby alternative communication routes may be used.

Services shall be guided by the principles set out in ISO 9001.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
F10 User and Carer Changes to Network Supplier

Requirement:
Services shall, in their contract agreements and supporting documents, make users and carers (and any sub-contractors and/or intermediary organisations) aware of the requirement to inform them of any intention (or desire) to make changes in their network supplier where this could affect access to or provision of the service.

Applicability:
Applicable to all services.

Guidance:
Reporting on any intended change by users and carers is important in view of the potential affect on service provision. A clause to this effect shall normally be included within service contracts with users and carers or intermediary organisations.
Services should recognise that good practice in relation to this matter includes periodic prompting or reminders to users and carers.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

F11 Abuse

Requirement:
Services, where there is contact with service users in their homes (whether face to face or through tele-consultations), shall have a policy relating to identification and the manner of dealing with abuse/potential abuse of users and/or carers.

Applicability:
Applicable to all services.

Guidance:
Training for staff (including volunteers) shall ensure that they are aware of the potential for users and carers to be the victims of abuse. Procedures shall be in place for dealing with actual or suspected abuse by any person who has contact (whether face to face or through tele-consultations) with users or carers of the service; or between users and carers.
Such procedures shall include, where appropriate, making contact with or working in collaboration with relevant health, social care or law enforcement agencies.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
### G: INTERPRETATION OF AND RESPONSES TO INFORMATION

<table>
<thead>
<tr>
<th>Number</th>
<th>Clause</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>G1</strong></td>
<td><strong>Responding to Information Gathered through Remote Monitoring</strong></td>
</tr>
</tbody>
</table>

**Requirement:**
Services that provide remote monitoring shall ensure that timely action is taken where there is a known or indicated change in health, well-being and/or personal circumstances of users or carers.

**Applicability:**
Applicable when undertaken as part of the service

**Guidance:**
Timely action may be immediate (e.g. in the event of falls, seizures or other necessitous circumstances) and requires to be taken regardless of whether there is a personal service plan in place. It will normally require that contact is made with the user and/or carer; and may result in an in-person (home) or tele-consultation visit being made by a staff member. There may also be a need to review (sometimes with urgency) the way in which service operation responds to such changes or events. The action and its outcome shall be documented.

Some services will, in supporting users to self-manage, give automated information, advice or prompts to them that respond to changes in their health, well-being and/or personal circumstances. The limitations of such automated information shall be absolutely clear to users and carers and set out in contract documents and/or the advisory information provided to them.

**ISO/TS 13131:**
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
G2  Handover After an Event or Change of Circumstances

Requirement:
Services shall follow procedures and protocols agreed with and configured for the specific benefit of individual users and carers relating to events or changes of circumstances.

Applicability:
Applicable when undertaken as part of the service.

Guidance:
Procedures and protocols shall have been determined (where necessary with the guidance of a clinician or other authorised health or social care practitioner or in accordance with the requirements of a service procurer or commissioner) and shall ensure that after actions have been taken that relate to the remit of the service (responding e.g. to an event or change of circumstances) that responsibility for user and carer health and wellbeing is satisfactorily handed over - unless it is already absolutely clear that any adverse change in or specific threat to health and well-being has been fully countered. This includes procedures and protocols that relate to the needs of users and carers at the end of a period of reablement (or rehabilitation).

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
H: COMMUNICATIONS NETWORKS

<table>
<thead>
<tr>
<th>Number</th>
<th>Clause</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>H1</strong></td>
<td>Agreements between Services and Telecommunications Providers</td>
</tr>
<tr>
<td><strong>Requirement:</strong></td>
<td>Services shall maintain current agreements with relevant telecommunications providers, companies or their agents by which their use of the communications networks used is safeguarded.</td>
</tr>
<tr>
<td><strong>Applicability:</strong></td>
<td>Applicable to all services.</td>
</tr>
<tr>
<td><strong>Guidance:</strong></td>
<td>Agreements shall make clear the networks used and specify any guarantees (or the absence of any guarantees) regarding the integrity of the communications links. Services shall be guided by the principles set out in ISO 22301 and 27001.</td>
</tr>
<tr>
<td><strong>ISO/TS 13131:</strong></td>
<td>This clause together with A5, C3, C5 and H2 covers Clauses 6.5, 6.6, 7.1, 7.2, 7.3, 10.6 and 13.1 to 13.7 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.</td>
</tr>
</tbody>
</table>

| **H2** | Monitoring of the Communications Networks |
| **Requirement:** | Services shall monitor the communications networks used to ensure that they are operational and that faults are speedily identified and remedied. |
| **Applicability:** | Applicable to all services. |
| **Guidance:** | Reliability of the communications networks shall be a factor considered by services when selecting the network provider. The outcomes of such monitoring shall be recorded. The monitoring shall aim to ensure that the integrity of communications networks is maintained in accordance with guarantees given. Services shall be guided by the principles set out in ISO 27001. |
| **ISO/TS 13131:** | This clause together with C3, C5 and H1 covers Clauses 6.5, 6.6, 7.1, 7.2, 7.3, 10.6 and 13.1 to 13.7 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services. |
I: HARDWARE & TECHNOLOGICAL CONSIDERATIONS

<table>
<thead>
<tr>
<th>Number</th>
<th>Clause</th>
</tr>
</thead>
<tbody>
<tr>
<td>I1</td>
<td>Fitness of Technologies/Equipment and Related Software</td>
</tr>
</tbody>
</table>

**Requirement:**
Services shall operate using technologies/equipment (including operational software and, where applicable, apps) that are ‘fit for purpose’ and conform to relevant standards. Exceptions apply (see below).

**Applicability:**
Applicable to all services.

**Guidance:**
Fitness for purpose includes consideration of

- the acceptability and usability of the technologies/equipment to users and carers who may have physical (including dexterity) and sensory impairments;
- the reliability of the technologies/equipment (and e.g. their electro-magnetic compatibility with other devices);
- the interoperability of the technologies/equipment;
- the interoperability of health and personal information (e.g. where linking to electronic and/or personal health records); and
- their conformity with appropriate technical standards.

Medical devices, where included, shall be marked with their classification which, in the context of telehealth, will testify to their satisfying regulatory and licensing requirements of the relevant countries, states, provinces or regions. Some medical and other technologies/equipment and software will carry a CE (pertaining to the European Union) and/or an FCC (Federal Communications Commission, United States) mark that testifies to their safety.

Where technologies/equipment are sourced or owned directly by users and carers (or any intermediary organisations), these will normally need to satisfy the same requirements. But subject to the integrity of communications systems or service operation not being compromised and personal information remaining protected, other devices may be linked. A clear declaration regarding the fitness for purpose of the technologies/equipment used shall be placed on the website or in the Discovery Zone of the TQG website. The declaration shall be dated and reviewed annually.

Services shall be guided by the principles set out in ISO 27001.

**ISO/TS 13131:**
This clause together with I2, I3 and I6 covers Clauses 13.4 and 13.5 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
### I2 Database of Technologies/Equipment

**Requirement:**
Services shall maintain a contemporaneous database of technologies/equipment that is stored or supplied to users and carers.

**Applicability:**
Applicable to all services.

**Guidance:**
Services shall be able to track the history and location of the technologies/equipment used. This shall also include, where supplied by the service, a record of faults and repairs to the devices in question. At least annual stock audits shall be undertaken to assist in this.

Services shall be guided by the principles set out in ISO 22301 and 27001.

**ISO/TS 13131:**
This clause together with I1, I3 and I6 covers Clauses 13.4 and 13.5 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

### I3 Equipment Recall, Removal and Disconnection Procedures

**Requirement:**
Services shall have procedures for the recall, removal and/or disconnection of faulty or contaminated equipment from users and carers.

**Applicability:**
Applicable to all services.

**Guidance:**
These procedures shall include, where appropriate, necessary actions in respect of technologies/equipment supplied by users and carers themselves. They shall ensure, wherever appropriate, timely replacement to ensure that users and carers are safeguarded.

It is recognised that for some services such procedures may be given effect through intermediary organisations.

Services shall be guided by the principles set out in ISO 27002.

**ISO/TS 13131:**
This clause together with I1, I2 and I6 covers Clauses 13.4 and 13.5 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
I4 Protection and Safe-keeping of Technologies/Equipment

Requirement:
Services shall make provision for the protection, safe-keeping and storage of technologies/equipment.

Applicability:
Applicable to all services.

Guidance:
The requirement for the protection and safekeeping of technologies/equipment shall be satisfied either directly by services or via arrangements with sub-contractors. It is recognised that such protection and safekeeping will, in some cases, be undertaken by intermediary organisations. Responsibility for protection and safe-keeping of technologies/equipment that are supplied to users and carers will normally reside with them.

Services shall be guided by the principles set out in ISO 27001.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.

I5 Installation, Programming and Demonstrating of Technologies/Equipment

Requirement:
Services shall ensure that the installation, programming, calibration, initial testing and demonstrating of technologies/equipment, are undertaken in accordance with manufacturer’s or supplier’s guidance.

Applicability:
Applicable to all services.

Guidance:
Installation and related work shall only be undertaken by people who have the required skills, knowledge and expertise. It follows that services shall make reasonable checks on the quality and effectiveness of the work to complete the tasks in question. In planning for installations or establishing the suitability of particular technologies/equipment, consideration shall be given to the effect on communications links that may arise because of the configuration of buildings or the manner of their construction; and to Internet speeds.

Where technologies/equipment are sourced, owned directly and installed by users and carers, these remain their responsibility but services need to be satisfied that installation, programming and calibration is undertaken in a way that satisfies the same requirements.

Services shall be guided by the principles set out in ISO 27001.

ISO/TS 13131:
This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
16 Maintenance, Servicing, Repair and Replacement of Technologies/Equipment

Requirement:
Services shall have robust procedures in place to enable maintenance, servicing, repair or replacement of technologies/equipment where supplied by the service.

Applicability:
Applicable to all services.

Guidance:
Maintenance, servicing, repair or replacement shall be undertaken within contracted timescales, in accordance with manufacturer’s or supplier’s guidance only by people who have required skills, knowledge and expertise.

Determining the maximum timescales for repairs and maintenance (within e.g. any contracted arrangement) will have involved consideration, by services, of the risks to users and carers. Required action may, for some services, be given effect through intermediary organisations.

Maintenance shall include, wherever appropriate, cleansing and decontamination, (re)calibration, battery replacement (or re-charging) and functional checks.

Separate quality assurance checks may be necessary for devices that measure vital signs or are used for testing at the point of care.

Services shall be guided by the principles set out in ISO 27001.

ISO/TS 13131:
This clause together with I1, I2 and I3 covers Clauses 13.4 and 13.5 of the ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
## Recovery, Recycling and Re-Use of Technologies/Equipment

**Requirement:**

Services shall have robust procedures in place for any technologies/equipment that is removed, recovered, returned, re-cycled or re-used (e.g. after service cessation for a prior user).

**Applicability:**

Applicable to all services.

**Guidance:**

Procedures shall include attention to cleaning, disinfecting and decontamination, re-calibration, functional checks, battery replacement and full erasure of any personal data stored on the technologies/equipment concerned.

No equipment shall be re-used where there is significant wear and tear; including where casings are broken or cracked. There shall be no missing pieces. The process of cleaning, disinfecting and decontamination, as well as safeguarding users and carers, shall take account of the need to minimise the risk to staff who undertake such tasks or transport the technologies/equipment in question.

Erasure of data held by any device shall only be undertaken after any requirement for submission to a health record has been satisfied. The process of erasure shall be double checked and the process recorded.

Where equipment is re-issued this shall be properly documented and made known in writing to users and carers.

For recycling, the regulatory and licensing requirements of the relevant countries, states, provinces or regions shall be satisfied.

Services shall be guided by the principles set out in ISO 14001 and 27001.

**ISO/TS 13131:**

This requirement adds to and complements those set out in ISO/TS 13131 Health Informatics - Quality Planning Guidelines for Telehealth Services.
Appendix:

Some Relevant ISO Standards

Where mentioned in specific clauses of the Code, services shall give attention to and be guided by the International Organization for Standardization (ISO) standards mentioned. Services do not, however, need to be fully compliant with them with the exception of ISO/TS 13131. The summary descriptions below, excepting for ISO/TS 13131, are drawn from the ISO website (www.iso.org).

ISO 9001

ISO 9001 sets out the criteria for a quality management system. It is based on a number of quality management principles including a strong customer focus, the motivation and implication of top management, the process approach and continual improvement. The standard helps ensure that customers get consistent, good quality products and services, which in turn brings many business benefits.

ISO/TS 13131

ISO/TS 13131 provides ‘generally applicable’ quality planning guidelines for telehealth services – with telehealth being recognised as ‘the use of information technologies to deliver healthcare and transmit health information over both long and short distances.’ It strongly emphasises issues around risk management.

ISO 13485

ISO 13485 specifies requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer requirements and regulatory requirements applicable to medical devices and related services.

ISO 14001

ISO 14001 specifies requirements for the development and implementation of an environmental management system. It relates to significant environmental matters over which organisations may have control or influence.

ISO 22301

ISO 22301 specifies requirements to plan, establish, implement, operate, monitor, review, maintain and continually improve a documented management system to protect against, reduce the likelihood of occurrence, prepare for, respond to, and recover from disruptive incidents when they arise.

ISO 27001

ISO 27001 specifies the requirements for establishing, implementing, operating, monitoring, reviewing, maintaining and improving an information security management system within the context of an organisation’s overall business risks.

ISO 27002, ISO 27005 and ISO 27799

ISO/IEC 27002 and 27005 provide guidelines for information security risk management. They support the general concepts specified in ISO/IEC 27001 and are designed to assist the satisfactory implementation of information security based on a risk management approach. ISO 27799 links to ISO/IEC 27002 and supports the interpretation and implementation in health informatics, whether words and numbers, sound recordings, drawings, video or medical images; and the means of their storage or transmission.

End