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ΕΒΡΟΠΕΪΣΚΑ ΑΣΟΪΙΑΪΙΑ ΝΑ ΣΤΑΡΣΗΤΕ ΒΟΛΝΗΧΝΗ ΛΕΚΑΡΗ  
ASOCIATIA EUROPEANA A MEDICILOR DIN SPITALE**

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## European Code of Practice for Telehealth Services launched



The *European Code of Practice for Telehealth Services* was formally launched end October. The Code marks the culmination of extensive work by partners to the European Commission funded TeleSCoPE project and it fits well with some of the roadmaps that have been addressed in the European Commission's eHealth Action Plan 2012-2020 that was released last year.

The Code of Practice provides a benchmark standard against which telehealth service providers can be accredited. The service 'domains' in the Code are concerned with such matters as health coaching, medication adherence and activity monitoring as well as vital-signs monitoring and social alarms.

The Code structure gives close attention to key issues around, for instance, ethical principles and personal information management. The 55 clauses and five appendices offer a framework by which telehealth services are guided and supported.

Telehealth services throughout the EU are now being invited to consider becoming accredited to the Code. This may mean reviewing the way they currently operate and making some adjustments. New services will be able to be guided by the Code and its clauses.

By virtue of providing a benchmark standard, the Code also has the potential to satisfy the requirements of governments, public and regulatory bodies who are concerned for any services that contribute to meeting people's healthcare and support needs.

The Code also aims to help give ordinary people, users and carers confidence and trust in the services which they may use. Perhaps high among the potential risks when using or accessing telehealth services are those that relate to the safeguarding of personal information but there are also crucial considerations addressed in the Code that relate to service sustainability; the way that services are marketed and that technologies are procured; and the way in which communication takes place with users in both face to face and teleconsultations. Without these, and the other requirements within the Code, there is a risk of an unconstrained market where commercial objectives could over-ride those which are concerned with care and support.

The Code (here attached) can also be viewed and downloaded from [www.telehealthcode.eu](http://www.telehealthcode.eu). For more information or to see if and how your telehealth service can be accredited against this Code, contact [Malcolm Fisk](#).



EUROPEAN  
CODE OF PRACTICE FOR  
TELEHEALTH SERVICES  
2014

1

*A Quality Benchmark ...  
Changing the Shape  
of Telehealth*

Produced by the partners of the  
TeleSCoPE Project

Telehealth is the means by which technologies and related services concerned with health and well-being are accessed by people or provided for them, at a distance.

## Preamble

The successful development of telehealth services needs the trust of clinicians; health, social care and support practitioners; service users and carers. The call for such trust has been made by the European Commission, governments in member states, clinicians and both patient and service user representative organisations.

The European Code of Practice for Telehealth Services offers a basis for such trust. It provides a quality benchmark against which telehealth services (including telecare) can be assessed and accredited. Importantly the Code encourages telehealth service to adopt approaches by which more people are encouraged to take greater responsibility for their own health. In so doing, the Code addresses health in both its clinical and well-being senses; is positioned within a preventative and public health arena; and is important for service users and patients of all ages.

## Preambule

Een succesvolle ontwikkeling van telegzorg diensten vereist het vertrouwen van artsen, verpleegkundigen, zorgverleners, sociale dienstverleners, gebruikers/patiënten en mantelzorgers. De oproep tot een dergelijk vertrouwen werd reeds herhaaldelijk geformuleerd door de Europese Commissie, door beleidsmakers in de verschillende lidstaten, en door zorgverstrekkers en patiënten- en gebruikersverenigingen.

De Europese praktijkcode voor telegzorg diensten biedt een basis voor het tot stand brengen van dat vertrouwen. Het is een kwaliteitsmaatstaf waartegenover telegzorg diensten kunnen worden beoordeeld/geaudit en geaccrediteerd. Belangrijk hierbij is dat de code een benadering van telegzorg diensten aanmoedigt die mensen in staat stelt om meer verantwoordelijkheid te nemen voor hun eigen gezondheid. Hierbij richt de code zich zowel op gezondheid in klinische als in welzijnszin en is ze belangrijk voor gebruikers en patiënten van alle leeftijden

3

## Preambolo

Lo sviluppo virtuoso dei servizi di telemedicina ha bisogno della fiducia dello staff medico, del personale socio sanitario e paramedico, degli utenti e dei loro care giver. La necessità di tale fiducia è stata espressa dalla Commissione Europea, dai governi degli stati membri, dai medici e dalle associazioni di pazienti e utenti.

Il Codice Europeo di buona Pratica per i Servizi di Telemedicina offre una base su cui costruire tale fiducia. Esso fornisce un punto di riferimento per gli standard di qualità sui quali i servizi di telemedicina (inclusi quelli di telecare) possono misurarsi ed essere ispezionati/controllati e accreditati. Il Codice vuole incoraggiare i servizi a mantenere un approccio che promuova l'assunzione di maggiore responsabilità verso la propria salute da parte dei cittadini. In tal modo, il Codice si occupa di salute in maniera globale, sia dal punto di vista clinico, sia del benessere della persona, posizionandosi nell'ambito della salute preventiva e pubblica e occupando un ruolo importante presso tutti gli utenti dei servizi e i pazienti di tutte le età.

## Préambule

La réussite du développement des services de télésanté dépend de la confiance des cliniciens, du personnel de santé, médical et social, ainsi qu'administratif, des usagers de ces services et de leurs soignants. L'appel à cette confiance a été fait par la Commission Européenne, les gouvernements des Etats Membres, les cliniciens et les organisations représentant les utilisateurs de ces services et les patients.

Le Code Européen de la Pratique des Services de Télésanté constitue une base pour cette confiance. Il crée une référence de mesure et d'accréditation pour la qualité des services de télésanté. De plus, le Code encourage de nouvelles approches de la télésanté afin que toutes les personnes puissent être plus responsable de leur propre santé. Ce faisant, le Code aborde cette santé non seulement du point de vue clinique, mais aussi sur le plan du bien-être, ce qui est important pour les usagers des services et les patients de tout âge.

## Predgovor

Uspešen razvoj storitev zdravja na daljavo temelji na zaupanju v tovrstne storitve s strani zdravnikov in drugih delavcev v zdravstvu, oseb, ki se nemedicinsko ukvarjajo z zdravjem, socialnih delavcev, uporabnikov teh storitev in njihovih oskrbovalcev. K ustvarjanju takega zaupanja je Evropska komisija pozvala tako vlade držav članic, kot zdravstvene delavce, organizacije, predstavnike uporabnikov in uporabnike.

Evropski kodeks ravnanja za storitve zdravja na daljavo nudi podlago za takšno zaupanje. Zagotavlja kakovostno merilo, s katerim je mogoče te storitve vrednotiti/presojeti in certificirati. Pomembno je, da kodeks vzpodbuja uporabo storitev zdravja na daljavo, s katerimi bo lahko v prihodnosti vse več ljudi prevzelo večjo odgovornost za lastno zdravje. Kodeks naslavlja zdravje v kliničnem pomenu besede in zdravje kot dobro počutje, zato je pomemben tako za paciente vseh starosti kot za zdrave uporabnike tovrstnih storitev.

## Előszó

A teleegészség szolgáltatások sikeres fejlesztéséhez szükség van a klinikai szakorvosok, az egészségügyi-, szociális gondozói- és támogatószolgálati szakemberek, valamint a szolgáltatást igénybevevő ellátottak, illetve gondozóik bizalmára. Az Európai Bizottság, a tagállamok kormányai, orvosok, valamint a páciensek, ellátottak érdekvédelmi szervezetei is felhívták a figyelmet e bizalom szükségességére.

Az Teleegészség Szolgáltatások Egységes Európai Kódexe e bizalom létrehozásához kínál jó alapot. A Kódex egy olyan minőségi viszonyítási szintet definiál, aminek alapján a tele-egészség (beleértve a távgondozó) szolgáltatásokat át lehet világitani, auditálni és akkreditálni. Lényeges szempont, hogy a Kódex ösztönzi az emberek saját egészségük iránti felelősségtudatát, így az egészséget mind orvosi, mind közérzeti, életminőségi szempontból is középpontba állítja, a megelőzés és a gyógyellátás területén kínált szolgáltatásokat minősíti, ezért a Kódex fontos az ellátottak, illetve a betegek minden korosztálya számára.

## Предисловие

Успешното развитие на услугите в сферата на електронното здравеопазване се нуждае от доверието на всички заети и имащи допир с тази сфера – медицински персонал, доставчици на услуги, потребители. Необходимостта от изграждане на това доверие е многократно подчертавана от Европейската комисия, правителствата в държавите-членки, лекарите, както и от пациентските и потребителските организации.

Европейският Кодекс на добри практики в сферата на електронното здравеопазване предлага основа за това доверие. Той осигурява качествени критерии, спрямо които услугите в сферата на електронното здравеопазване могат да бъдат оценени и сертифицирани. Важно е да се отбележи, че Кодексът насърчава услугите в сферата на електронното здравеопазване, чрез които повече хора са в състояние да поемат по-голяма отговорност за собственото си здраве. Кодексът обръща внимание на клиничните аспекти на здравето, но и на физическото и психическото благополучие на гражданите и е важен за потребителите и пациенти от всички възрасти.

## Part A: Overview

### 1. Introduction

The European Code of Practice for Telehealth Services (the Code) provides a new and robust quality benchmark. It is for all countries of the EU. The Code fits closely with the direction set by the European Commission's eHealth Action Plan 2012-2020. It is open to all and copies are available for viewing on and downloading from the website at [www.telehealthcode.eu](http://www.telehealthcode.eu).

The process by which telehealth services can be assessed and accredited to the Code provides reassurance for

- telehealth service providers and their staff;
- users of telehealth services and their carers;
- organisations that procure or commission telehealth services; and
- governments and strategic agencies concerned for health and support service provision.

The Code operates in the arena of preventative and public health. It underpins telehealth services for people of *all* ages and it helps to promote both their clinical health and wider well-being. While its focus is on telehealth, the Code is relevant to and includes telecare, social/safety alarms and some aspects of telemedicine.

The Code is not prescriptive. Rather it offers a framework that enables and encourages telehealth service providers to plan and manage their services in inclusive and ethically appropriate ways.

The importance of the Code will increase because of demographic, political and economic factors. More people will be living with and managing long-term conditions. These and others will increasingly wish to access services that help them adopt and manage appropriate lifestyles. Therefore it is necessary that healthcare and support services should be accessible to a wide range of people – whether at home, in school or college, in the workplace or out and about in the wider community.

Because telehealth services are provided in different ways, people are being given new or additional choices. Users and carers are increasingly able to access services in ways that fit with their needs and lifestyles. This means that telehealth is equally relevant to a 26 year old managing her diabetes as it is to an 86 year old being supported with his dementia. Telehealth services can, furthermore, support people in relation to shorter term (e.g. during a period of pregnancy, recovery or rehabilitation) or longer term support needs.

For people with higher levels of need this means that telehealth services will often operate alongside or be integrated within other services. Such other services may include personal assistance; the provision of specific therapies and treatments; or the support provided through access to community equipment. Services that provide healthcare in other ways may look to telehealth as part of care and support 'packages'.

### 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, at a distance. This definition is included in Part C: Glossary of Terms. Telehealth, telecare and telemedicine are all aspects of eHealth. eHealth includes a wider range of devices and services, based on information and communication technologies, that are used to assist and enhance the prevention, diagnosis, treatment, monitoring, and management of people's health and lifestyles.



### 3. The Purpose of the Code

#### The Code

- addresses the way that telehealth services, related procedures and practices are organised;
- provides a framework for services within which there can be greater ease of access by users and carers;
- encourages the engagement of users and carers to assist in service planning and development;
- ensures consistency in service quality by providing a benchmark standard; and
- points to some of the skills, knowledge and competency requirements for service staff.

Service requirements that are addressed in the Code include the way in which communication takes place with users and carers. In addition, in a context where telehealth technologies can measure, gather, store and analyse increasing quantities of personal information, the Code sets out requirements that will help to minimise the potential for people's privacy or autonomy to be undermined.

### 4. Telehealth Domains

Some of the conditions or circumstances that can be assisted through telehealth are noted below. They range from pregnancy to palliative care. A number of 'domains' (i.e. areas of activity for telehealth services) are also set out. The needs arising from the conditions or circumstances listed can be met through telehealth service provision in a manner that accords with any one or more of the domains indicated.

Addressing these domains within telehealth services can involve the use of a variety of technologies - including interactive television and web-cams, video links, fixed or wireless telecommunication and computing devices (including smart phones and tablets). 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.

7

Some Conditions and Circumstances	Telehealth Service Domains
Sight or hearing loss Mobility and dexterity problems Mental health problems Chronic kidney, heart or lung conditions Neurological conditions Diabetes Frailty Dementia Pregnancy Learning disabilities Palliative care	Provision of health information Health and motivational coaching Activity, behavioural and lifestyle monitoring Gait, seizure and falls monitoring Point of care testing, and support for diagnoses/decision making Vital signs monitoring mHealth Prompting for medication or therapy adherence Rehabilitation and (re)ablement Responding to 'events' Tele-consultation

It is important to note that some of the technologies used also provide people with access to a wider range of different kinds of (non-telehealth) services - information, social networks, email, etc. There is, therefore, an important potential for

telehealth services to offer the means by which there can be social as well as health and well-being benefits for users and carers.

## 5. Accreditation to the Code

To become accredited to the Code, service providers must follow set procedures. These include registration with the responsible body and being subject to assessment by an approved organisation. A range of charges apply. Accreditation is conferred by the responsible body.

After service providers are registered with the responsible body, the following take place:

- on-site inspections by the assessing organisation, meetings with key service staff, etc.; and
- off-site examination by the assessing organisation of relevant materials, declarations and of documents posted on the service website.

Accredited services

- are included in listings on the website of the responsible body;
- have freedom to use a logo (indicating accreditation) on their websites, literature, etc.;
- have an obligation to facilitate spot checks and/or investigations of their service if these become necessary; and
- accept the manner in which accreditation can be suspended, renewed or revoked.

Accreditation in accordance with the requirements of the Code, as well as helping improve the quality of provision, gives telehealth services an advantage when competing with services that are not accredited.

## 6. ISO Certification

As well as becoming accredited to the Code, telehealth services may, in due course, also seek 'certification' to ISO 9001. Obtaining such 'certification' requires a specific range of documentation to be in place. This can be aligned with the requirements of the Code. A separate range of charges and procedures applies.

## 7. Partners to the TeleSCoPE Project

Twelve partner organisations from Belgium (2), Bulgaria (1), Hungary (2), Italy (2), Ireland (1), Slovenia (2) and the United Kingdom (2) were part of the TeleSCoPE project that developed this Code. These comprised four service user representative bodies, two academic institutions and six others (see Appendix AA).

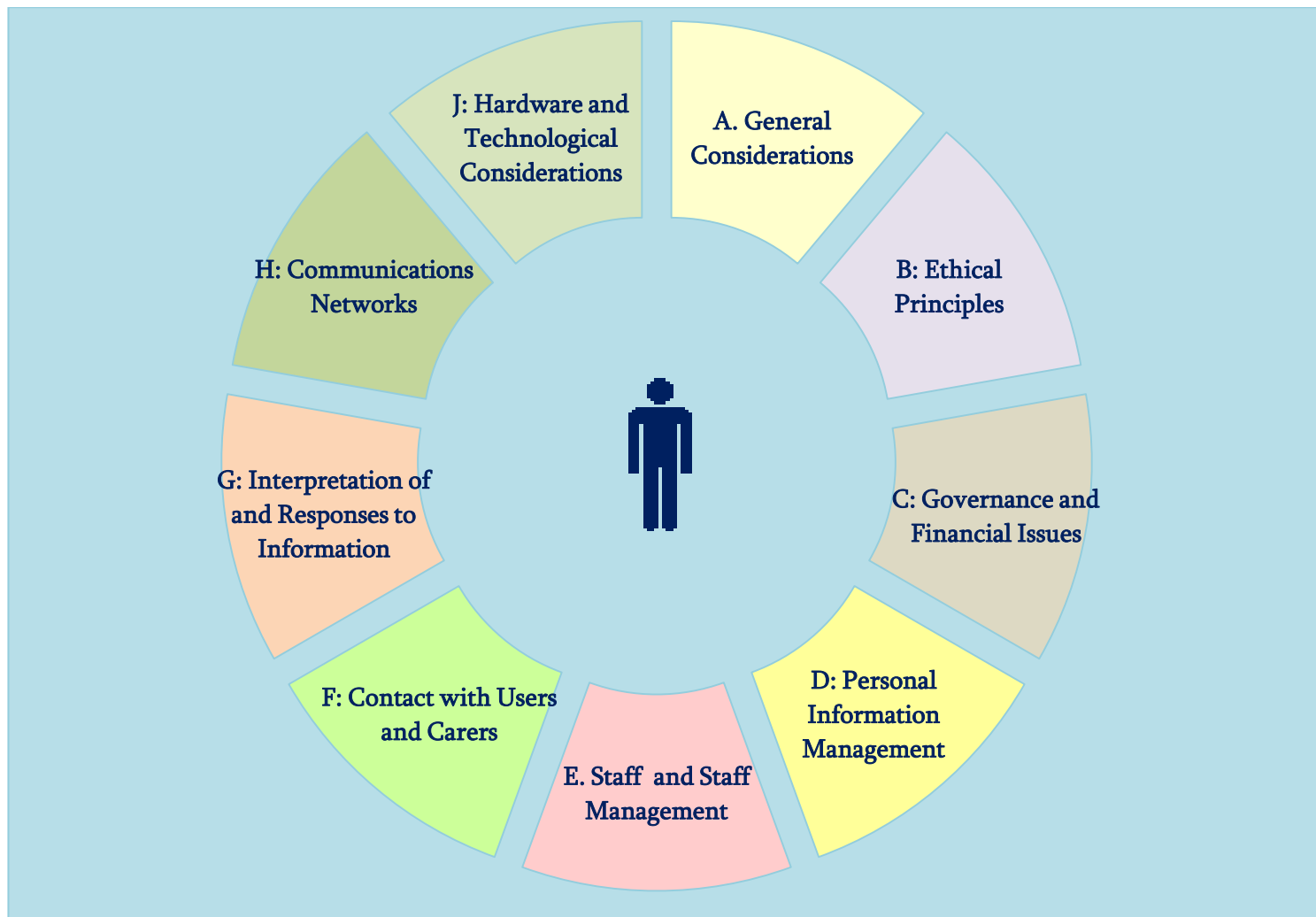
The TeleSCoPE project was completed at the end of September 2013. Most of the original partner organisations are involved in helping to take the Code forward.

## Part B: Code Content and Structure

The Code has nine sections shown in Fig 1 below. The person who accesses telehealth services is represented by the figure at the centre. Their central position symbolises the importance of service users within any telehealth service. It is recognised, therefore, that the nature of telehealth services should be such that people who access or use them will be 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, where appropriate, those of carers); and
- have their human rights and dignity protected.

**Fig 1: Framework of the European Code of Practice for Telehealth Services**



## Part C: Glossary of Key Terms

Only terms that are used in this document are listed in the glossary. Additional comment on some terms is offered below.

### **Currency**

Where the term 'current' is used, this means that the matter to which it relates must have been reviewed or reassessed and consequential amendments made, as appropriate, to procedures, protocols, etc. within the previous 12 months.

### **Staff**

The term 'staff' is used in a manner that does not distinguish between personnel working in different fields. The term therefore includes clinical, health, allied health, social care or other staff with different levels and types of expertise. Using the word, 'staff' in this way avoids what might otherwise be taken as an endorsement of some of the divisions between staff roles, whether or not they reflect certain specialisms or are supported by particular professional bodies. In addition it is recognised that volunteers can make a contribution to the work of telehealth services. They are included in the term 'staff'. Where engaged by services, therefore, it is necessary that the knowledge, skills and competencies of volunteers are seen as equally relevant to those of paid staff.

### **Users and Carers**

The dual term 'users and carers' is frequently used. This should not be taken to indicate that services should invariably involve carers when telehealth services are provided or accessed. The contrary is the case. Many users will not have carers. More than this, even when a user does have a carer, it is the user view that will normally take precedence. The exception relates to where the main beneficiary is a dependent child or a person who is significantly cognitively impaired or is otherwise unable to either give explicit consent or to engage in a dialogue regarding the service being accessed.

In some cases there may be intermediary organisations that are contracted with telehealth services by virtue of which users and carers have access to them. The nature of the contact between services and such users and carers is affected by such circumstances.

### **Sources Used**

The sources of the terms listed in this glossary are indicated. Where accompanied by an asterisk [\*] the original definition from that source has been amended. Overall the definitions have either been decided upon by partners in the TeleSCoPE project (taking account of definitions available elsewhere where appropriate) or they have been taken from the following sources:

- ATA (American Telemedicine Association)
- Eurocarers
- European Commission
- European Health Literacy Project
- Impact in Europe Project
- ISO (International Organization for Standardization)
- ISQua (International Society for Quality in Healthcare)
- NIFTE (National Initiative for Telehealth, Canada)
- United Nations

## Glossary of Key Terms A-C

Term	Definition	Source
<b>Abuse</b>	Abuse is the violation of an individual's human and civil rights. It can be manifest through neglect or through causing emotional, physical, sexual or financial harm.	TeleSCoPE
<b>Accreditation</b>	A process used by health care organisations to accurately assess their level of performance in relation to established standards.	ISQua [*]
<b>App</b> (Application)	Software used in devices such as mobile phones, TVs or tablet PCs (including that which can relate to personal health and well-being). Includes medical applications (medapps).	TeleSCoPE
<b>Assistive Technology</b>	Any item, piece of equipment, or product system that is used to increase, maintain or improve the functional capabilities of people with disabilities.	Impact in Europe project
<b>Benchmark</b>	An assessed level of service that enables comparisons to be made with similar provider organisations regarding e.g. quality, performance and user satisfaction.	TeleSCoPE
<b>Carer</b>	A person who provides unpaid care to someone with a chronic illness, disability or other long lasting health or care need, outside a professional or formal framework. Can include personal assistants.	Eurocarers
<b>Certification</b>	Formal recognition of compliance with set standards validated by external evaluation. A term used when there is compliance with ISO standards.	ISQua
<b>CE Mark</b>	The marking required for products that testifies to their having been assessed as meeting EU safety, health and environmental protection requirements before being placed on the market.	European Commission
<b>Commissioning</b>	Giving authority and/or instruction to an individual or agency to undertake specified tasks or duties.	TeleSCoPE
<b>Consent</b>	Voluntary permission given orally or in writing, in a context of understanding by the user/patient (or where appropriate their carers or an authorised third party), to the purpose, procedures, benefits, risks and rights relating to their use of a technology or service.	TeleSCoPE

## Glossary of Key Terms D-L

<b>Data Harvesting</b>	The remote gathering of personal or other data facilitated through communications networks.	TeleSCoPE
<b>Disability</b>	Disabilities result from long-term physical, mental, intellectual or sensory impairments, whether congenital or acquired, which, in interaction with various barriers, may hinder people in their full and effective participation in society on an equal basis with others.	United Nations [*]
<b>eHealth</b>	The range of devices and services (based on information and communication technologies) used to assist and enhance the prevention, diagnosis, treatment, monitoring and management of people's health and lifestyles.	European Commission [*]
<b>Empowerment</b>	A process through which people gain or are afforded greater control over decisions and actions affecting their lives.	TeleSCoPE
<b>Good Practice</b>	Practice that is informed, shared with others and operates according to principles associated with appropriate political, economic and social goals.	TeleSCoPE
<b>Governance</b>	The function of determining an organisation's direction, objectives, policy and practice frameworks in order to ensure effective service provision.	TeleSCoPE
<b>Health Coaching</b>	The use of techniques based on psychological evidence to help people change behaviours that are known to cause ill-health. Also known as motivational coaching. Health coaching may include the use of Cognitive Behavioural Therapy (CBT).	TeleSCoPE
<b>Health Data</b>	Any information, whether or not recorded electronically, pertaining to an individual and relating to his or her health and well-being.	TeleSCoPE
<b>Health Literacy</b>	People's knowledge, motivation and competence to access, understand, appraise and apply health information, make judgments and take decisions regarding their health and wellbeing.	European Health Literacy project [*]
<b>Interoperability</b>	The ability of two or more devices or systems to interact with one another and exchange information in order to achieve predictable results.	NIFTE [*]
<b>Intermediary Organisation</b>	An organisation (possibly a landlord or care provider) that purchases telehealth services on behalf of users and carers.	TeleSCoPE

## Glossary of Key Terms M-S

<b>Medical Device</b>	Any instrument, apparatus, appliance, software, material or other article used specifically for the investigation, diagnosis, prevention, monitoring, treatment or alleviation of disease, injury or handicap	European Commission [*]
<b>Medication Compliance</b>	Patient concordance with prescribed treatments and therapies decided upon by a doctor or another health professional.	TeleSCoPE
<b>mHealth</b>	The use of mobile devices to help in people's management of their health. Not to be confused with mobile health which is sometimes used to describe services provided using mobile 'units' (e.g. on a vehicle).	TeleSCoPE
<b>Personal Assistant</b>	A person, normally under the guidance of or employed by someone with a disability or illness, who assists them to live their life more fully and independently.	TeleSCoPE
<b>Personal Data</b>	Any information relating to an identifiable person whether it relates to his or her private, professional or public life. It includes health data.	European Commission
<b>Personal Plan</b>	A plan that contains information about a person's health and well-being and sets out agreed actions to facilitate health and/or lifestyle maintenance or improvement.	TeleSCoPE
<b>Privacy</b>	A state where users/patients can exercise their right to control access to them with regard to information about them (including images and data).	TeleSCoPE
<b>Protocol</b>	A set of rules that determines a course of action on receipt of information.	TeleSCoPE
<b>Safeguarding</b>	Processes and procedures whereby vulnerable adults and/or children are protected against different forms of abuse or power. These usually involve several different agencies.	TeleSCoPE
<b>Service Provider</b>	Formally constituted organisations, in the public, private or not-for-profit sectors, that provide services.	TeleSCoPE
<b>Service user</b>	See User.	TeleSCoPE
<b>Social Alarm</b>	A device located in the home which, when activated, communicates with a responder and can send information relevant to the user's well-being. Also known as safety alarms.	TeleSCoPE

## Glossary of Key Terms S-Z

<b>Standard</b>	Criterion used as a rule, guideline or definition by which materials, products, processes and services can be determined as fit for the purpose.	ISO [*]
<b>Staff</b>	Persons employed and paid at a commercial rate in specific roles and who perform tasks associated with service objectives. Qualified staff are those with the knowledge and competences to perform specific tasks – potentially recognised through registration, accreditation, certification or licensing. Note: The term staff, as used within this Code, includes volunteers.	TeleSCoPE/ NIFTE [*]
<b>Telecare</b>	The means by which technologies and related services, concerned with people's well-being and independent living, are provided for them at a distance.	TeleSCoPE
<b>Tele-consultation</b>	An encounter between a staff member and a users or carer that is normally mediated by video-communication technologies.	TeleSCoPE
<b>Telehealth</b>	The means by which technologies and related services concerned with people's health and well-being are accessed by them or provided for them at a distance. A telehealth service may be staffed or automatic.	TeleSCoPE
<b>User</b>	An individual who accesses and/or uses services.	TeleSCoPE
<b>Vital Signs</b>	Measures of health or activity that relate to a person's well-being. Includes but is not limited to heart and breathing rates, blood pressure and body temperature.	TeleSCoPE
<b>Volunteer</b>	A person who acts voluntarily and may receive expenses and further reimbursement at a nominal level only.	TeleSCoPE



## Part D: The Code

### **Preliminary Notes**

1. In general, this Code does not include clauses that relate to responsibilities of service providers where these are enshrined in the legislation or regulatory requirements of particular countries. Accredited (or certified) telehealth services must, however, comply with such (country-specific) legislation or regulatory requirements as well as all applicable clauses in this Code.
2. Where reference is made to documents, policies, information, declarations on the service website, etc. these shall be provided in the primary language or languages relevant to the area of operation of the telehealth service. If certification is sought for compliance with ISO standards, relevant documentation shall be provided in English.
3. There is no one clause that 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 in relation to various aspects of service provision and it is, therefore, a requirement in several clauses.
4. There are 55 clauses. No service can be accredited without being initially compliant with 48 of these (and 50 within 12 months of service commencement). All accredited services shall comply with all the clauses that apply to them.

### **The Code**

The clauses that make up the Code are set out in the ensuing pages. The nine sections are supported by six appendices. Further guidance in the form of new or amended appendices may be periodically issued.

15

- A. General Considerations
- B. Ethical Principles
- 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
- J. Hardware and Technological Considerations

**Appendix AA:** Acknowledgments, Code Authorship and the TeleSCoPE Partners

**Appendix IS:** Some Applicable ISO Standards

**Appendix PS:** Personal Safety of Telehealth Staff

**Appendix SK:** Skills, Knowledge and Training of Telehealth Staff

**Appendix SM:** Surveys – Some Methodological Issues

**Appendix UD:** Users and Carers with Disabilities

## List of Clauses and Index

		Page
<b>A. General Considerations</b>		<b>18</b>
A1	Compliance with the Code	18
A2	Availability of the Code	18
A3	Service Website and Internet Presence	19
A4	Compliance with Statutory Requirements	19
A5	Adjustments to Changes in Statutory Requirements	20
A6	Sustainability Policy	20
A7	Outcomes Focussed Appraisal	21
A8	Agreements with Users and Carers	21
A9	Integrity of Service Locations	22
A10	Insurances	22
<b>B. Ethical Principles</b>		<b>23</b>
B1	Mission Statement	23
B2	Conflicts of Interest	23
B3	Promotion and Marketing	24
B4	Providing Information for Users and Carers	25
B5	Taking Account of User and Carer Views	36
<b>C. Governance and Financial Issues</b>		<b>27</b>
C1	Governance Structure	27
C2	Business Continuity	27
C3	Risk Management Plan	28
C4	Maintaining Records	29
C5	Back Up Arrangements	30
<b>D. Personal Information Management</b>		<b>31</b>
D1	Protecting Personal Information	31
D2	Staff Access to Personal Information	32
D3	User and Carer Access to Personal Information	33
D4	Dealing with Personal Information after Service Cessation to the Individual and/or Carer	33
D5	Anonymisation and Further Usage of Personal Information	33
<b>E. Staff and Staff Management</b>		<b>34</b>
E1	Sufficiency of Staff for Service Provision	34
E2	Staff Recruitment Policies	34
E3	Providing for the Support and Well-being of Staff	35
E4	Safeguarding Staff when Travelling and Visiting	35
E5	Staff Training	36
E6	Whistle-blowing Policy	36

<b>F. Contact with Users and Carers</b>		<b>37</b>
F1	Agreements with Users and Carers	37
F2	In-person Visits	38
F3	Tele-consultation (via Video)	39
F4	Guidance and Training for Users and Carers	40
F5	Development of Personal Plans with Users and Carers	40
F6	Prompts to Users and Carers with regard to Service Needs	41
F7	Service Discontinuation to Individual Users and Carers by Provider	41
F8	Survey of User and Carer Views of and Satisfaction with the Service	42
F9	Complaints, Compliments and Suggestions	42
F10	User and Carer Fault Reporting	43
F11	User and Carer Changes to Network Supplier	43
F12	Provider Changes to Network Supplier	43
F13	Abuse	44
<b>G. Interpretation of and Responses to Information</b>		<b>45</b>
G1	Procedures and Protocols within Personal Plans	45
G2	Responding to Information gathered through Remote Monitoring	46
<b>H. Communications Networks</b>		<b>47</b>
H1	Agreements between Services and Telecommunications Providers	47
H2	Monitoring of the Communications Networks	47
<b>J. Hardware and Technological Considerations</b>		<b>48</b>
J1	Fitness of Technologies/Equipment and Related Software for the Purpose of the Service	48
J2	Database of Technologies/Equipment	49
J3	Equipment Recall, Removal and Disconnection Procedures	49
J4	Protection and Safe-keeping of Technologies/Equipment	49
J5	Installation, Programming and Demonstrating of Technologies/Equipment	50
J6	Maintenance, Servicing, Repair and Replacement of Technologies/Equipment	51
J7	Recovery, Recycling and Re-Use of Technologies/Equipment	52
<b>Appendices</b>		<b>53</b>
AA	Acknowledgments, Code Authorship and the TeleSCoPE Partners	53
IS	Some Relevant ISO Standards	54
PS	Personal Safety of Telehealth Staff	55
SK	Skills, Knowledge and Training of Telehealth Staff	56
SM	Surveys - Some Methodological Issues	57
UD	Users and Carers with Disabilities	59

## A: GENERAL CONSIDERATIONS

Number	Clause	Notes for Assessment
A1	<p><b>Compliance with the Code</b></p> <p><b>Requirement:</b> Services shall be compliant with all relevant clauses that relate to the telehealth service they provide.</p> <p><b>Guidance:</b> <i>No telehealth functions undertaken by the service, its agents or sub-contractors shall be excluded from the requirement to comply. Judgements will be exercised where compliance with individual clauses is achieved in different ways, or satisfaction of key requirements is contributed to by related activities addressed in other clauses.</i> <i>The declaration (see across) shall be dated and renewed annually. It will apply only to those areas assessed.</i></p>	<p>Compliance <b>mandatory for all services.</b></p> <p>A clear declaration, specific to the telehealth service is required on the website.</p>
A2	<p><b>Availability of the Code</b></p> <p><b>Requirement:</b> Staff, users and carers (and any intermediary organisations) shall all be aware of this Code and where they can view and obtain copies.</p> <p><b>Guidance:</b> <i>Making the Code widely available helps to build trust in telehealth among the various stakeholders.</i></p>	<p>Compliance <b>mandatory for all services.</b></p>

<p><b>A3</b></p>	<p><b>Service Website and Internet Presence</b></p> <p><b>Requirement:</b></p> <p>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.</p> <p><b>Guidance:</b></p> <p><i>The European Commission provides guidelines on web content accessibility. Services shall take account of these. See <a href="http://ec.europa.eu/ipg/standards/accessibility/eu_policy/index_en.htm">http://ec.europa.eu/ipg/standards/accessibility/eu_policy/index_en.htm</a></i></p> <p><i>Services might also wish to maintain their ‘internet presence’ through social media portals. The same principles regarding accessibility shall apply in those contexts.</i></p>	<p>Compliance <b>mandatory for all services.</b></p>
<p><b>A4</b></p>	<p><b>Compliance with Statutory Requirements</b></p> <p><b>Requirement:</b></p> <p>Services shall be compliant with laws and regulatory requirements of the member state or states in which the service is provided.</p> <p><b>Guidance:</b></p> <p><i>The laws, regulatory and licensing requirements that shall be considered by services include those that follow from the relevant European Commission Directives such as</i></p> <ul style="list-style-type: none"> <li>○ <i>2011/24/EU on Patients Rights in Cross-Border Healthcare</i></li> <li>○ <i>2009/136/EC on Service User Rights</i></li> <li>○ <i>95/46/EC on Data Protection</i></li> <li>○ <i>98/79/EC on Medical Devices</i></li> </ul> <p><i>... and other Directives concerned with requirements, for example, around health and safety, employment law, reimbursement and the registration and competencies of employees. Not all will necessarily apply.</i></p> <p><i>The laws of individual member states take precedence over the requirements of this Code.</i></p> <p><i>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.</i></p> <p><i>The declaration (see across) shall be dated and renewed annually.</i></p>	<p>Compliance <b>mandatory for all services.</b></p> <p>A clear declaration of compliance with laws and regulatory requirements is required on the website.</p>

<p><b>A5</b></p>	<p><b>Adjustments to Changes in Statutory Requirements</b></p> <p><b>Requirement:</b> Services shall be prepared for and act in order to meet, in a timely fashion, any relevant legislative changes that arise.</p> <p><b>Guidance:</b> <i>Many such changes are heralded by work within the European Commission that lead to the issuing of new Directives.</i></p>	<p>Compliance <b>mandatory for all services.</b></p>
<p><b>A6</b></p>	<p><b>Sustainability Policy</b></p> <p><b>Requirement:</b> Services shall have a current sustainability policy.</p> <p><b>Guidance:</b> <i>A sustainability policy will show, in service configuration and provision, how the economic, social and environmental context is taken account of. It shall demonstrate an understanding of needs and markets specific to the service being provided and how this understanding impacts on planned changes to development of the service.</i> <i>In relation to environmental issues, consideration might be given in a sustainability policy to the way that telehealth can reduce travel for staff, service users and carers.</i> <i>Services shall be guided by the principles set out in ISO 14001 and 27001 (see Appendix IS).</i> <i>The sustainability policy shall be dated.</i></p>	<p>Compliance <b>mandatory for all services.</b></p>

A7	<p><b>Outcomes Focused Appraisal</b></p> <p><b>Requirement:</b> Services shall undertake an annual outcomes focused appraisal of their service.</p> <p><b>Guidance:</b> <i>The outcomes focused appraisal shall examine the extent to which the service has succeeded in its mission and the related objectives. It shall give attention to the manner in which specific health benefits have or have not accrued to service users and carers - including those benefits that relate to personal well-being, health maintenance, health literacy, (re)habilitation and (re)engagement in family, community, education or work activities.</i></p> <p><i>It is recognised that where intermediary organisations are involved that exploration of such outcomes, to the desired extent, may not be possible.</i></p> <p><i>The appraisal shall provide pointers to potential changes in the manner of service provision..</i></p> <p><i>The outcomes focused appraisal shall be dated and renewed at least annually.</i></p>	Compliance <b>mandatory for all services</b> after they have been operational for 12 months.
A8	<p><b>Agreements with Users and Carers</b></p> <p><b>Requirement:</b> Services shall have agreements with users (and carers, where appropriate).</p> <p><b>Guidance:</b> <i>The agreements (which may be formal contracts and which may be given effect through intermediary organisations) 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; 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 when withdrawing from the service.</i></p> <p><i>Early termination of agreements that is initiated by users or carers shall be able to take place without any charge or penalty when this arises as a result 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.</i></p>	Compliance <b>mandatory for all services.</b>

<p><b>A9</b></p>	<p><b>Integrity of Service Locations</b></p> <p><b>Requirement:</b> Services shall take preventive and responsive measures to ensure the integrity of the location or locations from which their service operates.</p> <p><b>Guidance:</b> <i>Measures such as motion activated or security lighting, controlled access and CCTV (closed circuit TV); and arrangements for incidental repairs relating to e.g. locks and glazing shall be considered.</i> <i>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.</i> <i>Further security measures shall be taken in respect of e.g. personal data where servers used (for data storage, etc.) are located at remote locations that are not under the control of the telehealth service. See D1.</i> <i>Services shall be guided by the principles set out in ISO 27001 and 27002 (see Appendix IS).</i> <i>European Commission Directive 95/46/EC on Data Protection pertains.</i></p>	<p>Compliance <b>mandatory for all services.</b></p>
<p><b>A10</b></p>	<p><b>Insurances</b></p> <p><b>Requirement:</b> Services shall carry current insurances for buildings and equipment, public and product liability, professional indemnity, employer's liability and medical negligence.</p> <p><b>Guidance:</b> <i>Insurances shall be at levels commensurate with the nature of the service provided and the risks that pertain. The declaration (see across) shall be dated and renewed annually.</i></p>	<p>Compliance <b>mandatory for all services.</b></p> <p>A clear declaration regarding insurances is required on the website.</p>



## B: ETHICAL PRINCIPLES

Number	Clause	Notes for Assessment
B1	<p><b>Mission Statement</b></p> <p><b>Requirement:</b> Services shall have a current mission statement that gives attention to ethical principles.</p> <p><b>Guidance:</b> <i>Services shall have a mission statement that sets a clear direction for the service with regard to its objectives and modus operandi and which is in accordance with the ethical principles that apply to service provision in the healthcare field.</i> <i>The mission statement shall be dated and renewed annually.</i></p>	<p>Compliance <b>mandatory for all services.</b></p> <p>The service's mission statement must be posted on the website.</p>
B2	<p><b>Conflicts of Interest</b></p> <p><b>Requirement:</b> 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 of the telehealth service.</p> <p><b>Guidance:</b> <i>The declaration of and openness regarding conflicts of interest links with the ethical foundations that underpin telehealth services. Conflicts of interest might include shareholdings or official positions held in companies that are closely associated with the telehealth service or with which the service has significant dealings. These conflicts or potential conflicts shall be disclosed and included in a current and publically available register of interests.</i> <i>Service shall be aware of the potential for conflicts of interest for intermediary organisations and also seek to ensure that these are avoided or managed.</i> <i>The register and information therein shall be dated and renewed at least annually.</i></p>	<p>Compliance <b>mandatory for all services.</b></p> <p>The names of directors and senior management staff must be posted on the website.</p>

<p><b>B3</b></p>	<p><b>Promotion and Marketing</b></p> <p><b>Requirement:</b>                  Services shall not promote or market their wares by preying on fear, omitting important or giving misleading or unsubstantiated information.</p> <p><b>Guidance:</b>  <i>The vulnerability of some users and carers is such that they will be at higher risk in relation to their health and well-being. Neither the extent of that risk, nor the anticipated benefits of telehealth, shall be exaggerated.</i>  <i>Misleading and/or unsubstantiated information might relate to e.g. claims regarding the medical credentials of the service and/or its staff, or claims regarding service outcomes that are poorly evidenced.</i>  <i>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) as victims or sufferers.</i></p>	<p>Compliance <b>mandatory for all services.</b></p>
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B4	<p><b>Providing Information for Users and Carers</b></p> <p><b>Requirement:</b> Services shall make information about the service available to users and carers whereby they may exercise informed choices regarding their acceptance (or not) of the service and service options.</p> <p><b>Guidance:</b> <i>Informed choice means that users and carers must receive information that is</i></p> <ul style="list-style-type: none"> <li>★ <i>timely;</i></li> <li>★ <i>clear; and</i></li> <li>★ <i>comprehensive.</i></li> </ul> <p><i>Through such information users and carers need to be clearly aware of</i></p> <ul style="list-style-type: none"> <li>★ <i>service options;</i></li> <li>★ <i>the manner of service operation;</i></li> <li>★ <i>arrangements for termination of or withdrawal from the service;</i></li> <li>★ <i>all applicable charges and costs – including those that apply when devices are supplied by users and carers themselves; and</i></li> <li>★ <i>where there is the potential for tax relief when technology/equipment is purchased.</i></li> </ul> <p><i>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.</i></p> <p><i>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 (see Appendix UD).</i></p>	Compliance <b>mandatory for all services.</b>
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<p><b>B5</b></p>	<p><b>Taking Account of User and Carer Views</b></p> <p><b>Requirement:</b>                  Services shall, in all aspects of their operation, give due consideration to the views, opinions and choices of their service users and carers.</p> <p><b>Guidance:</b>  <i>The views of the user shall take precedence over those of carers except for children without competence or for adults where there is substantial dependency arising e.g. out of cognitive impairment or mental illness. Service may wish to demonstrate their willingness to take account of user and carer views through e.g. their involvement in overall service planning.</i></p> <p><i>It is recognised that, where intermediary organisations are involved that obtaining the views of users and carers to the desired extent may not be possible.</i></p>	<p>Compliance <b>mandatory for all services.</b></p>
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## C: GOVERNANCE AND FINANCIAL ISSUES

Number	Clause	Notes for Assessment
C1	<p><b>Governance Structure</b></p> <p><b>Requirement:</b> Services shall have a governance structure that ensures effective financial, staff and data (including clinical data) management; and encourages good customer care.</p> <p><b>Guidance:</b> <i>This structure shall be evidenced in the way that decisions are made, responsibilities assigned, and the way that staff are managed. These shall be pertinent to the core activities of the service.</i> <i>The structure shall, wherever appropriate, include provision for clinical governance by which the needs of users with particular needs as 'patients' are taken into account. The declaration (see across) shall be dated and renewed annually.</i> <i>Services shall be guided by the principles set out in ISO 9001 and 22301 (see Appendix IS).</i></p>	<p>Compliance <b>mandatory for all services.</b></p> <p>A clear declaration regarding the governance framework is required on the website.</p>
C2	<p><b>Business Continuity</b></p> <p><b>Requirement:</b> Services shall have a business continuity plan.</p> <p><b>Guidance:</b> <i>Providing for business continuity requires that services shall have a current plan that takes account of the way in which major disruption to the service can be dealt with or closure of the service achieved - whilst, at the same time, providing safeguards for users and carers. The latter shall include attention to the safeguards placed on personal data.</i> <i>The business continuity plan shall dated and be tested, at an appropriate level, at least annually.</i> <i>Services shall be guided by the principles set out in ISO 22301 and 27002 (see Appendix IS).</i></p>	<p>Compliance <b>mandatory for all services.</b></p>

<p><b>C3</b></p>	<p><b>Risk Management Plan</b></p> <p><b>Requirement:</b>                  Services shall have a current risk management plan that takes account of the outcomes of risk assessments for all elements of service provision.</p> <p><b>Guidance:</b>  <i>This shall cover the 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 the risks to staff including those risks that attach to in-person (home) visits where these are undertaken; and to the risks to users and carers as they relate to service provision and usage.</i></p> <p><i>The plan shall set out, in summary, how adverse events or risks evident within or arising during the prior year have been dealt with or countered.</i></p> <p><i>Services shall be guided by the principles set out in ISO 27005 (see Appendix IS).</i></p>	<p>Compliance  <b>mandatory for all                  services.</b></p>
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C4	<p><b>Maintaining Records</b></p> <p><b>Requirement:</b> Services shall maintain comprehensive and contemporaneous records in relation to the service.</p> <p><b>Guidance:</b> <i>Records shall document actions pertaining to service operation (including data, images, video and voice information) and include matters such as</i></p> <ul style="list-style-type: none"> <li>★ <i>personal information regarding service users and carers;</i></li> <li>★ <i>in-person (home) visits and tele-consultations;</i></li> <li>★ <i>care and support packages; and</i></li> <li>★ <i>detail of consents given and related service protocols.</i></li> </ul> <p><i>These records shall be held for the period of service (to or for a user) plus a further six years or in accordance with country specific legislative or regulatory requirements.</i></p> <p><i>Records shall also document information on</i></p> <ul style="list-style-type: none"> <li>★ <i>staff (including volunteers) engaged; and the</i></li> <li>★ <i>qualifications, training and competencies of staff.</i></li> </ul> <p><i>These records shall be held for the period of staff engagement/employment plus a further six years or in accordance with country specific legislative or regulatory requirements.</i></p> <p><i>Services shall be guided by the principles set out in ISO 9001, 22301 and 27001 (see Appendix IS).</i></p>	Compliance <b>mandatory for all services.</b>
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<p><b>C5</b></p>	<p><b>Back Up Arrangements</b></p> <p><b>Requirement:</b>                  Services shall maintain procedures for real time or, at a minimum, hourly transfer of information relating to service operation and the personal data of users and carers, to a secure environment. An exception applies (see below).</p> <p><b>Guidance:</b>  <i>The back up procedures adopted by a telehealth service shall relate to all its core functions. They represent one of the means by which personal information regarding service users and carers is safeguarded and, crucially, helps to ensure the efficacy and integrity of service provision.</i>  <i>Less frequent (but no less than daily) back up arrangements are permissible for services with no more than 100 users.</i>  <i>Services shall be guided by the principles set out in ISO 27005 (see Appendix IS).</i></p>	<p>Compliance  <b>mandatory for all                  services.</b></p>
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## D: PERSONAL INFORMATION MANAGEMENT

Number	Clause	Notes for – Assessment
D1	<p><b>Protecting Personal Information</b></p> <p><b>Requirement:</b> Services shall maintain current policies and procedures for the management and protection of personal information.</p> <p><b>Guidance:</b> <i>These shall ensure that they operate in a manner that is fully in accordance with country 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.</i></p> <p><i>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.</i></p> <p><i>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.</i></p> <p><i>Services shall be guided by the principles set out in ISO 27001 (see Appendix IS).</i></p> <p><i>The policies and procedures for the management and protection of personal information shall be dated and renewed annually.</i></p>	<p>Compliance <b>mandatory for all services.</b></p> <p>The policies and procedures for the management and protection of personal information must be posted on the website.</p>

D2	<p><b>Staff Access to Personal Information</b></p> <p><b>Requirement:</b> Services shall ensure that only authorised staff are able to input, amend or access personal information regarding users and carers and their service usage.</p> <p><b>Guidance:</b> <i>Inputting of information shall only be undertaken by authorised service staff. An exception applies for users and carers when uploading 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 shall be maintained of where, when, by whom and for what purpose access, inputting, addition, correction or alteration to personal information was made.</i> <i>Authorised staff may include those from partner agencies or intermediary organisations where there are relevant contractual arrangements in place and, exceptionally, other authorised persons.</i> <i>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.</i> <i>Services shall be guided by the principles set out in ISO 27001 (see Appendix IS).</i></p>	Compliance <b>mandatory for all services.</b>
D3	<p><b>User and Carer Access to Personal Information</b></p> <p><b>Requirement:</b> Services shall make provision for users and carers to access their personal information.</p> <p><b>Guidance:</b> <i>Full access to personal information 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 (see D2). Their right to request corrections and, in certain circumstances, to object to the processing of their personal data must be recognised.</i> <i>This right of access extends to users and carers where their service access arises through a contracted arrangement with an intermediary organisation.</i> <i>Services shall be guided by the principles set out in ISO 27001 (see Appendix IS).</i> <i>European Commission Directive 95/46/EC on Data Protection pertains.</i></p>	Compliance <b>mandatory for all services.</b>

<p><b>D4</b></p>	<p><b>Dealing with Personal Information after Service Cessation to the Individual and/or Carer.</b></p> <p><b>Requirement:</b> Services shall, after service cessation, keep the personal information of users and carers securely pending its transfer, deletion and/or anonymisation.</p> <p><b>Guidance:</b> <i>After service cessation, full access to personal information must be available to users and carers and authorised others for a minimum period of six years or in accordance with country 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).</i> <i>Services shall be guided by the principles set out in ISO 27001 (see Appendix IS).</i></p>	<p>Compliance <b>mandatory for all services.</b></p>
<p><b>D5</b></p>	<p><b>Anonymisation and Further Usage of Personal Information</b></p> <p><b>Requirement:</b> Services shall, subject to any regulatory requirements that are in place, be able to share anonymised personal information with relevant agencies where there is a clear wider public or clinical health benefit.</p> <p><b>Guidance:</b> <i>Where the sharing of anonymised personal information takes place, the procedure selected shall ensure that all reasonable steps are taken to remove the possibility that individuals will be able to be identified from the information in question. Such anonymisation will have had the prior explicit and informed consent of users and carers or of their heirs or legal representatives.</i> <i>A clear wider public or clinical health benefit would relate to the use of such anonymised data in research undertaken (or clearly endorsed) by appropriate public sector bodies, universities and independent research institutes.</i> <i>Where services undertake not to share anonymised personal information the website declaration shall state this. The declaration (see across) shall be dated and renewed annually.</i> <i>Services shall be guided by the principles set out in ISO 27001 (see Appendix IS).</i> <i>European Commission Directive 95/46/EC on Data Protection pertains.</i></p>	<p>Compliance <b>mandatory when undertaken as part of the service.</b></p> <p>A clear declaration regarding the sharing of personal information is required on the website.</p>

## E: STAFF AND STAFF MANAGEMENT

Number	Clause	Notes for Assessment
E1	<p><b>Sufficiency of Staff for Service Provision</b></p> <p><b>Requirement:</b> Services shall engage a sufficient range and number of staff commensurate with effective and sustained operation of the service.</p> <p><b>Guidance:</b> <i>This requires services to demonstrate how they determine and monitor, on an ongoing basis, the 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); and how they plan for service growth or development.</i></p>	Compliance mandatory for all services.
E2	<p><b>Staff Recruitment Policies</b></p> <p><b>Requirement:</b> Services shall have recruitment policies that are relevant to the nature of their service.</p> <p><b>Guidance:</b> <i>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. See Appendices SK.</i></p> <p><i>Staff who have contact with users and carers shall be issued with appropriate identification documents. These documents shall be recovered when the member of staff leaves.</i></p>	Compliance mandatory for all services.

<p><b>E3</b></p>	<p><b>Providing for the Support and Well-being of Staff</b></p> <p><b>Requirement:</b> Services shall make provision for the support, well-being, comfort and security of their staff.</p> <p><b>Guidance:</b> <i>This requires that consideration is given to the way in which staff are managed and their performance reviewed against the requirements of the service. It also requires consideration of their places of work (including those of staff who work from home) and the travel undertaken in the course of their work. See also E4.</i></p>	<p>Compliance <b>mandatory for all services.</b></p>
<p><b>E4</b></p>	<p><b>Safeguarding Staff when Travelling and Visiting</b></p> <p><b>Requirement:</b> Services shall have procedures and practices that help to safeguard staff when travelling and visiting in the course of their work.</p> <p><b>Guidance:</b> <i>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, therefore, agreed practices. See Appendix PS.</i></p>	<p>Compliance <b>mandatory for all services.</b></p>

<p><b>E5</b></p>	<p><b>Staff Training</b></p> <p><b>Requirement:</b> Services shall provide staff with (or support them in accessing) training.</p> <p><b>Guidance:</b> <i>Training shall ensure that staff (including volunteers) acquire, maintain and develop relevant knowledge, skills and competencies. Services shall recognise the importance of such training for the personal development of their staff.</i> <i>The content of the training shall address, where applicable, appropriate communications methods that take account of the needs of users and carers who have communication difficulties (e.g. who may be deaf or hard of hearing). See Appendix UD.</i> <i>Increasing numbers of courses are becoming available that relate to strategic and operational aspects of telehealth services. These can complement 'in-house' training and may enable the attainment of recognised qualifications. See Appendix SK.</i></p>	<p>Compliance <b>mandatory for all services.</b></p>
<p><b>E6</b></p>	<p><b>Whistle-blowing Policy</b></p> <p><b>Requirement:</b> Services shall have a whistle-blowing policy by which staff are able to report any concerns.</p> <p><b>Guidance:</b> <i>This policy shall ensure that all staff are fully aware of their responsibility to, and the avenues by which, they can report (in confidence and without prejudice to themselves) if elements of the service may have fallen or be at risk of falling below the required standards.</i> <i>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 accreditation body 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 be made to protect, where appropriate, the anonymity of the informant.</i></p>	<p>Compliance <b>mandatory for all services.</b></p>

## F: CONTACT WITH USERS AND CARERS

Number	Clause	Notes for Assessment
F1	<p><b>Agreements with Users and Carers</b></p> <p><b>Requirement:</b></p> <p>Services shall have an agreement with users and carers regarding the manner of service provision (including the supply of technologies/equipment), selected payment option(s), arrangements for gathering personal information and response protocols.</p> <p><b>Guidance:</b></p> <p><i>Agreements shall provide detail of all the consents obtained and protocols agreed. These may be within the context of personal plans and will normally be referenced in applicable formal contracts. Information regarding payment will not apply where services are provided free of charge.</i></p> <p><i>Where re-cycled technologies/equipment are provided, users and carers shall be clearly informed of this. See J7.</i></p> <p><i>Agreements may include, where appropriate, encouragement for users and carers to test their telehealth equipment on a periodic basis. Service provision shall not depend on such action being undertaken by them.</i></p> <p><i>It is recognised that some agreements may be given effect through intermediary organisations.</i></p> <p><i>Services shall be guided by the principles set out in ISO 9001 (see Appendix IS).</i></p>	Compliance mandatory for all services.

F2	<p><b>In-person Visits</b></p> <p><b>Requirement:</b> Services shall have policies, where included as part of the contracted service, for in-person (home) visits to users and carers.</p> <p><b>Guidance:</b> <i>In-person (home) visits shall only be undertaken by authorised staff and must follow clear procedures. These shall include</i></p> <ul style="list-style-type: none"> <li>★ <i>agreement with users and carers or other relevant persons for the visits and/or due advance notice being given;</i></li> <li>★ <i>a record being made of the visit, its purpose and its outcome; and</i></li> <li>★ <i>any special considerations regarding e.g. access to property.</i></li> </ul> <p><i>The above also applies to visits made for the purpose of delivery, installation, removal, replacement, etc. of technologies/equipment.</i></p> <p><i>Exceptions (in respect of procedures for planned in-person visits) apply when responses are made by services to known or suspected urgent or necessitous circumstances. Nevertheless, clear endeavours must be made to contact users and carers or other relevant persons (e.g. key-holders, relatives) when such situations arise.</i></p> <p><i>Authorised staff (including volunteers) must carry identification, including a photo, to be proffered to (potential) users and carers on arrival (see E2). Staff must, where not explicit (or in the case of any doubt), make it clear the reason for their visit.</i></p> <p><i>Where planned visits are delayed notification shall be made to users and carers and/or other relevant persons of the same.</i></p>	Compliance mandatory when undertaken as part of the service.
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F3	<p><b>Tele-consultation (via Video)</b></p> <p><b>Requirement:</b> Services shall have policies, where included as part of the contracted service, for tele-consultations (via video) to users and carers.</p> <p><b>Guidance:</b> <i>Tele-consultations shall only be undertaken by authorised staff and must follow clear procedures. These shall include</i></p> <ul style="list-style-type: none"> <li>★ <i>agreement with users and carers or other relevant persons for the visits and/or due advance notice being given;</i></li> <li>★ <i>a record being made of the visit, its purpose and its outcome;</i></li> <li>★ <i>how interaction with users and carers can, where necessary, be afforded the necessary level of privacy e.g. taking account of the potential presence of others; and</i></li> <li>★ <i>any special considerations (e.g. the manner in which introductions are made).</i></li> </ul> <p><i>Authorised staff undertaking such tele-consultations shall clearly identify themselves on-line at the beginning of the encounter. They 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 and at the location of the user/carer). There is, therefore, the need for some prior contact and/or an audible and/or visual signal to be given to the user and/or carer.</i></p> <p><i>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 audio links have been closed.</i></p> <p><i>Where tele-consultations initiated by services are delayed notification shall be made to users and carers and/or other relevant persons of the same.</i></p>	Compliance mandatory when undertaken as part of the service.
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F4	<p><b>Guidance and Training for Users and Carers</b></p> <p><b>Requirement:</b> Services shall provide guidance and, where appropriate, training to service users and carers.</p> <p><b>Guidance:</b> <i>Guidance and (where necessary) training shall be provided in order to enhance the understanding of users and carers (and relevant others if appropriate) of the service and the technologies/equipment concerned. A simple document to confirm receipt of training shall be signed by users and carers.</i></p> <p><i>Where appropriate, guidance or training shall be given before and at the point of service commencement. It must be recognised that advice and training may be required subsequently or periodically for some service users and carers. Services shall endeavour to meet such requirements (including through any intermediary organisation).</i></p>	Compliance mandatory for all services.
F5	<p><b>Development of Personal Plans with Users and Carers</b></p> <p><b>Requirement:</b> Services shall ensure that only authorised persons engage with users and carers to develop, agree and review personal plans.</p> <p><b>Guidance:</b> <i>Personal 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.</i></p> <p><i>Personal plans shall be reviewed with users and carers at least annually. See also G1.</i></p>	Compliance mandatory when undertaken as part of the service.

<p><b>F6</b></p>	<p><b>Prompts to Users and Carers with regard to Service Needs</b></p> <p><b>Requirement:</b></p> <p>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 at least annually, to reconsider their service needs.</p> <p><b>Guidance:</b></p> <p><i>Prompting can enable (re)consideration 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. It may also indicate where users or carers could benefit from complementary or different services. Users and carers shall be 'signposted' in relation to the range of such other service options.</i></p> <p><i>It is recognised that, where intermediary organisations are involved, that such prompting and signposting may require to be given effect by those organisations.</i></p> <p><i>Services shall be guided by the principles set out in ISO 9001 (see Appendix IS).</i></p>	<p>Compliance <b>mandatory for all services.</b></p>
<p><b>F7</b></p>	<p><b>Service Discontinuation to Individual Users and Carers by Provider</b></p> <p><b>Requirement:</b></p> <p>Services shall only discontinue provision to individual users and carers where there are clear contractual breaches and/or abuse, by users and/or carers, of the service.</p> <p><b>Guidance:</b></p> <p><i>Discontinuation shall take place only after making reasonable efforts to seek appropriate remedies. Where there may be any increased risk to the users and/or carers arising from the discontinuation, services shall inform (and, where appropriate, engage in a dialogue with) relevant health, social care or other agencies (including intermediary organisations). The exception applies in the event of service closure where other provisions apply (see C2).</i></p> <p><i>Circumstances that constitute abuse of the service may include its repeated and ongoing 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; are not commensurate with the purpose of the service; and/or are clearly outside the protocols agreed with the user and/or carer.</i></p>	<p>Compliance <b>mandatory for all services.</b></p>

<p><b>F8</b></p>	<p><b>Survey of User and Carer Views of and Satisfaction with the Service</b></p> <p><b>Requirement:</b> Services shall carry out and report openly regarding the outcome of an annual survey of the views and level of satisfaction or dissatisfaction of users and carers.</p> <p><b>Guidance:</b> <i>A number of methodological considerations apply (see Appendix SM).</i> <i>It is recognised that, where intermediary organisations are involved, that the undertaking of such surveys to the desired extent may not be possible.</i> <i>Services shall be guided by the principles set out in ISO 9001 (see Appendix IS).</i> <i>The information posted (see across) shall be dated and renewed at least annually.</i></p>	<p>Compliance <b>mandatory for all services</b> after they have been operational for 12 months.</p> <p>Key outcomes for user and carer satisfaction are required to be posted on the website.</p>
<p><b>F9</b></p>	<p><b>Complaints, Compliments and Suggestions</b></p> <p><b>Requirement:</b> Services shall keep a log of complaints, compliments and suggestions made to them.</p> <p><b>Guidance:</b> <i>This log shall include all complaints, compliments and suggestions where these are made in writing (or other text). Services shall produce an annual report that demonstrates, where appropriate, how they have acted upon the complaints, compliments and suggestions received - together with the feedback from surveys of users and carers (see F8). Such a report may be incorporated within the Outcomes Focused Appraisal (see A7).</i> <i>Services shall be guided by the principles set out in ISO 9001 (see Appendix IS).</i></p>	<p>Compliance <b>mandatory for all services.</b></p>

<p><b>F10</b></p>	<p><b>User and Carer Fault Reporting</b></p> <p><b>Requirement:</b> Services shall provide service users and carers with an easy means of reporting faults or failures of the technologies/equipment.</p> <p><b>Guidance:</b> <i>There shall be a facility for users and carers to report faults via the web-site and (during the contracted service hours) via telephone. Faults reported in this and other ways shall be dealt with promptly (and responded to at least daily).</i> <i>The information posted to guide service users and carers (see across) shall be dated and renewed at least annually.</i> <i>Services shall be guided by the principles set out in ISO 9001 (see Appendix IS).</i></p>	<p>Compliance <b>mandatory for all services.</b></p> <p>Clear information is required to be posted on the website.</p>
<p><b>F11</b></p>	<p><b>User and Carer Changes to Network Supplier</b></p> <p><b>Requirement:</b> Services shall, in their contract agreements and supporting documents, make users and carers (and any intermediary organisations) aware 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.</p> <p><b>Guidance:</b> <i>Reporting on any intended change is important in view of the potential affect on service provision. A clause to this effect shall normally be required within service contracts with users and carers or intermediary organisations.</i></p>	<p>Compliance <b>mandatory for all services.</b></p>
<p><b>F12</b></p>	<p><b>Provider Changes to Network Supplier</b></p> <p><b>Requirement:</b> Services shall make users and carers (and any intermediary organisations) aware of any intention to make changes in the network supplier used for service provision.</p> <p><b>Guidance:</b> <i>Changes to the network supplier used by the service may affect service provision. No change shall be made without careful consideration of any potential impact on users and carers (including those for whom services are given effect through intermediary organisations); and ensuring that their position is safeguarded.</i> <i>Where changes are made, notice shall be given to users and carers (and any intermediary organisations) at least three calendar months in advance.</i></p>	<p>Compliance <b>mandatory for all services.</b></p>

<p><b>F13</b></p>	<p><b>Abuse</b></p> <p><b>Requirement:</b> Services shall have a policy relating to abuse/potential abuse of users and/or carers.</p> <p><b>Guidance:</b> <i>Staff (including volunteers) shall be 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 with users or carers of the service.</i> <i>Such procedures shall include, where appropriate, making contact with or working in collaboration with relevant health, social care or law enforcement agencies.</i></p>	<p>Compliance <b>mandatory for all services.</b></p>
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## G: INTERPRETATION OF AND RESPONSES TO INFORMATION

Number	Clause	Notes for Assessment
G1	<p><b>Procedures and Protocols within Personal Plans</b></p> <p><b>Requirement:</b></p> <p>Where there are personal plans in place or required, services shall follow procedures and protocols agreed with and configured for the specific benefit of individual users and carers.</p> <p><b>Guidance:</b></p> <p><i>Procedures and protocols shall have been determined, where necessary with the guidance of a clinician or other authorised health or social care practitioner, and shall ensure that</i></p> <ul style="list-style-type: none"> <li>★ <i>actions are taken and documented on the collection or receipt of information or in the event of other contact (however initiated) with a service user or carer;</i></li> <li>★ <i>the service recognises its particular responsibility for user and carer health and wellbeing after receipt of information that points to any adverse change or threat; and that</i></li> <li>★ <i>the responsibility of the telehealth service continues until transferred to responsible others or any adverse change in or specific threat to health and well-being has been countered. See also F5.</i></li> </ul> <p><i>Services shall be guided by the principles set out in ISO 9001 (see Appendix IS).</i></p>	<p>Compliance mandatory when undertaken as part of the service.</p>

G2	<p><b>Responding to Information gathered through Remote Monitoring</b></p> <p><b>Requirement:</b></p> <p>Services whose staff are involved in 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.</p> <p><b>Guidance:</b></p> <p><i>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 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) 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.</i></p> <p><i>The action shall take place regardless of whether the change in circumstances is identified automatically or by staff when e.g. viewing or reviewing data. The action and its outcome shall be documented.</i></p> <p><i>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 or the advisory information provided to them).</i></p>	Compliance mandatory when undertaken as part of the service.
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## H: COMMUNICATIONS NETWORKS

Number	Clause	Notes for Assessment
H1	<p><b>Agreements between Services and Telecommunications Providers</b></p> <p><b>Requirement:</b> Services shall maintain current agreements with relevant telecommunications providers, companies or their agents by which their use of the communications networks used is safeguarded.</p> <p><b>Guidance:</b> <i>Agreements shall make clear the networks used and specify any guarantees (or the absence of any guarantees) regarding the integrity of the communications links.</i> <i>The declaration (see across) shall be dated and renewed at least annually.</i> <i>Services shall be guided by the principles set out in ISO 22301 and 27001 (see Appendix IS).</i></p>	<p>Compliance <b>mandatory for all services.</b></p> <p>A clear declaration regarding such agreements is required on the website.</p>
H2	<p><b>Monitoring of the Communications Networks</b></p> <p><b>Requirement:</b> Services shall monitor the communications networks used to ensure that they are operational and that faults are speedily identified and remedied.</p> <p><b>Guidance:</b> <i>Reliability of the communications networks shall be a factor considered by services when selecting the provider. The outcomes of such monitoring shall be recorded.</i> <i>The monitoring shall aim to ensure that the integrity of communications networks is maintained in accordance with guarantees given (see H1).</i> <i>Technologies/equipment may be available that can automatically monitor communications networks.</i> <i>Services shall be guided by the principles set out in ISO 27001 (see Appendix IS).</i></p>	<p>Compliance <b>mandatory for all services.</b></p>

## J: HARDWARE &amp; TECHNOLOGICAL CONSIDERATIONS

Number	Clause	Notes for Assessment
J1	<p><b>Fitness of Technologies/Equipment and Related Software for the Purpose of the Service</b></p> <p><b>Requirement:</b> Services shall operate using technologies/equipment (including operational software and, where applicable, apps) that are 'fit for purpose' and conform to relevant European regulatory standards. Exceptions apply (see below).</p> <p><b>Guidance:</b> <i>Medical devices that are used shall be marked with their class which, in the context of telehealth, will normally be 1 or 2a. Some medical and other technologies/equipment and software will carry a CE Mark that testifies to their safety.</i></p> <p><i>Fitness for purpose includes consideration of</i></p> <ul style="list-style-type: none"> <li>★ <i>the acceptability and usability of the technologies/equipment to users and carers who may have physical (including dexterity) and sensory impairments (see Appendix UD);</i></li> <li>★ <i>the reliability of the technologies/equipment (and e.g. their electro-magnetic compatibility with other devices); ;</i></li> <li>★ <i>the interoperability of the technologies/equipment;</i></li> <li>★ <i>the interoperability of health and personal information (e.g. where linking to electronic and/or personal health records); and</i></li> <li>★ <i>their conformity with appropriate technical standards.</i></li> </ul> <p><i>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 sourced/owned by users and carers may be utilised.</i></p> <p><i>The declaration (see across) shall be dated and renewed annually.</i></p> <p><i>Services shall be guided by the principles set out in ISO 27001 (see Appendix IS).</i></p>	<p>Compliance <b>mandatory for all services.</b></p> <p>A clear declaration regarding the fitness for purpose of the technologies/equipment used is required on the website.</p>

<p><b>J2</b></p>	<p><b>Database of Technologies/Equipment</b></p> <p><b>Requirement:</b> Services shall maintain a contemporaneous database of technologies/equipment that is stored or supplied to users and carers.</p> <p><b>Guidance:</b> <i>Services shall be able to track the history and location of the technologies/equipment used. This shall also include a record of faults and repairs to the devices in question. At least annual stock audits shall be undertaken to assist in this.</i> <i>Services shall be guided by the principles set out in ISO 22301 and 27001 (see Appendix IS).</i></p>	<p>Compliance <b>mandatory for all services.</b></p>
<p><b>J3</b></p>	<p><b>Equipment Recall, Removal and Disconnection Procedures</b></p> <p><b>Requirement:</b> Services shall have procedures for the recall, removal and/or disconnection of faulty or contaminated equipment from users and carers.</p> <p><b>Guidance:</b> <i>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.</i> <i>It is recognised that for some services such procedures may be given effect through intermediary organisations.</i> <i>Services shall be guided by the principles set out in ISO 27002 (see Appendix IS).</i></p>	<p>Compliance <b>mandatory for all services.</b></p>
<p><b>J4</b></p>	<p><b>Protection and Safe-keeping of Technologies/Equipment</b></p> <p><b>Requirement:</b> Services shall make provision for the protection, safe operation and storage of technologies/equipment; and of the related physical and communications infrastructure.</p> <p><b>Guidance:</b> <i>Provision shall either be undertaken directly by services or via arrangements with sub-contractors.</i> <i>Services shall be guided by the principles set out in ISO 27001 (see Appendix IS).</i></p>	<p>Compliance <b>mandatory for all services.</b></p>

J5	<p><b>Installation, Programming and Demonstrating of Technologies/Equipment</b></p> <p><b>Requirement:</b></p> <p>Services shall ensure that the installation, programming, calibration, initial testing and demonstrating of technologies/equipment are undertaken in accordance with the manufacturer's or supplier's guidance.</p> <p><b>Guidance:</b></p> <p><i>Installation and related work shall only be undertaken by people who have the required skills, knowledge and expertise. It follows that services shall at least annually (and promptly for any new staff member or contractor) check on the skills, knowledge and expertise of staff or contractors undertaking such tasks. Exceptions apply where the installer (who may be a user or carer) has the clear capability for the same and is not exposed to risk in so doing.</i></p> <p><i>In planning for installations, etc. 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.</i></p> <p><i>Where technologies/equipment are sourced or owned directly 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. See J1.</i></p> <p><i>Services shall be guided by the principles set out in ISO 27001 (see Appendix IS).</i></p>	Compliance mandatory for all services.
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J6	<p><b>Maintenance, Servicing, Repair and Replacement of Technologies/Equipment</b></p> <p><b>Requirement:</b></p> <p>Services shall have robust procedures in place to enable maintenance, servicing, repair or replacement of technologies/equipment.</p> <p><b>Guidance:</b></p> <p><i>Maintenance, servicing, repair or replacement shall be undertaken within contracted timescales, in accordance with manufacturer's or supplier's guidance and only by people who have current and required skills, knowledge and expertise. Such expertise shall be periodically checked by reference to the certificates or other documentation that demonstrates the same. See also J5.</i></p> <p><i>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.</i></p> <p><i>Maintenance shall include, wherever appropriate, cleansing and decontamination, (re)calibration, battery replacement (or re-charging) and functional checks.</i></p> <p><i>Separate quality assurance checks may be necessary for devices that measure vital signs or are used for testing at the point of care.</i></p> <p><i>Services shall be guided by the principles set out in ISO 27001 (see Appendix IS).</i></p>	Compliance mandatory for all services.
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J7	<p><b>Recovery, Recycling and Re-Use of Technologies/Equipment</b></p> <p><b>Requirement:</b> 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).</p> <p><b>Guidance:</b> <i>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.</i> <i>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 shall take account of the need to minimise the risk to staff who undertake such tasks or transport technologies/equipment as well as for any new user or carer.</i> <i>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.</i> <i>Services shall be guided by the principles set out in ISO 14001 and 27001 (see Appendix IS).</i> <i>For recycling the EC Directive 2002/96/EC on Waste Electrical and Electronic Equipment applies.</i></p>	Compliance mandatory for all services.
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## Appendix AA:

Acknowledgments, Code Authorship and the TeleSCoPE Partners

The partners within the TeleSCoPE project were as follows. The authorship of the Code is shared by representatives of the partner organisations as indicated.

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<b>Trevor Single</b>	Telecare Services Association (United Kingdom)

Eleonora Kovacs represented GE Hungary until early 2012. GE Hungary withdrew from the partnership as a result of organisational changes. InHAM and NSIOS are not retaining direct involvement in Code development, etc. post September 2013.

The work of the partners should be fully recognised - both in their writing of this Code and in the research and consultations that were a necessary precondition to the writing.

The input, support and guidance of many other people have been greatly appreciated. Such inputs, from all parts of European Union and beyond, took place both within and outside a range of specific consultation exercises, visioning events and the validation exercises. Responsibility for the contents of the Code, however, rest with the authors.

## Appendix IS:

### Some Relevant ISO Standards

The International Organization for Standardization (ISO) standards that are mentioned within the Code have been adopted within all member states of the European Union. Services are required to be guided by the principles set out in the standards but do not need to be fully compliant with them.

They are as follows. A further ISO standard (ISO 13131 concerned with 'Quality Criteria for Services and Systems for Telehealth') has not been adopted within all member states and is not, therefore, offered as a reference point in this Code. Each summary description is drawn from the ISO website ([www.iso.org](http://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 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 and ISO 27005**

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.

Telehealth services seeking accreditation to the Code are required to be guided by the principles within the above ISOs. Services may, furthermore, seek certification of their conformity with the ISOs alongside accreditation to the Code.



## Appendix PS:

### Personal Safety of Telehealth Staff

Telehealth services providers have a duty of care to their staff (including volunteers). There are a number of common sense precautions that can be taken to help ensure their safety. Such precautions have particular importance for those who travel and/or undertake in-person (home) visits in the course of their work.

Services should, therefore, develop procedures and practices by which staff

- dress appropriately;
- carry identification (badge or card);
- make sure that others know their itinerary and the addresses of the homes or locations being visited;
- do not enter a dwelling or enclosed space where he/she has doubts about safety;
- opt to sit close to an exit door when within homes or buildings;
- know where there are local sources of help;
- carry an alarm device;
- carry mobile phones, switched on and charged; and
- leave any dwelling (or other location) where he/she feels at risk.

It should be noted that smart cards are now able to be made at reasonable cost and can offer functionality that includes personal identification, details of their competences and (beneficial in some contexts) the means of access to buildings. Card readers may, in addition, help to track the movement of staff.

With regard to travel, provision should be made for staff to use, where appropriate, taxis or hired vehicles and, when the need arises, be provided with overnight accommodation.

When staff are using their own vehicles these must be road-worthy, taxed and insured. A badge or similar identification that displays the name of the telehealth service might be considered appropriate.

Regular contact should be maintained by staff with the service so that their progress and the completion of any 'round' of visits can be monitored; and any concerns relating to security can be discussed.

In some contexts it will be appropriate for staff to work with others. This can mean their undertaking home visits in pairs.

Automated lone working monitoring services are available and could be seen as appropriate for some staff of telehealth services. Some such services link to visiting schedules that can be used by service providers to track the movement of their staff. Special training might be appropriate in some instances.

Any incidents or threats made to the interviewer should be reported to the staff member's supervisor or service manager. Counselling and support may, in some instances, be necessary.

## Appendix SK:

### Skills, Knowledge and Training of Telehealth Staff

The quality of telehealth services is, in large part, reflected in the quality of staff (including volunteers). But ‘quality’ cannot be just assessed in relation to people’s general competencies. Rather it must take into account their aptitude for the work undertaken. Part of this aptitude needs to be considered in relation to the ethical principles in this Code. Staff will need to understand the reasons for such ethical principles being in place and demonstrate their accordance with these when fulfilling their roles within the telehealth service.

For many staff there will already be adequate skills and knowledge – these, together, determining their competence. But for others there may be a need for learning and training that is specific to the world of telehealth. Some such learning will be gained ‘on the job’. Other elements are likely to depend on training that is accessed externally. The content may relate to specific service areas (such as needs assessment, management of personal data or equipment options); or the wider context of telehealth (e.g. drawing on the international experience of telehealth initiatives and their impact on health reforms). Such training can be sourced from private or third sector bodies and from institutes of higher education.

But the novelty of telehealth means that there is only a limited range of courses that are available. Those courses that are provided by suppliers and manufacturers are important from the point of view of staff learning about technology and equipment options, issues concerned with installation, calibration, etc., but it may not be advisable to use these as the sole source of training when wider telehealth issues are considered. Other courses, provided by suitably knowledgeable private or third sector bodies can be used as appropriate. And there is a growing range of relevant courses at degree and post-graduate level within some EU universities.

#### **Required Skills and Knowledge**

Areas of skills and knowledge that are considered of particular usefulness to staff within telehealth services are as follows. The relevance of some, however, will be dependent on the particular tasks/roles undertaken.

- demonstrating appropriate levels of digital literacy;
- demonstrating effective inter-personal skills;
- having an understanding of the ethical context of telehealth services;
- having awareness of the potential of telehealth technologies to empower users and carers;
- having an appreciation of the importance of confidentiality (e.g. in relation to personal data);
- having an appreciation of the importance of obtaining explicit consent regarding different aspects of service provision (including for people with limited cognitive ability);
- having an understanding the positioning of telehealth services vis à vis other health and support services;
- appreciating the issues affecting installation, calibration and the linking of telehealth technologies/equipment onto communications networks;
- appreciating the risks around service provision that relate to contamination and/or infection; and
- having an ability to interpret information and make guided judgements regarding potential actions.

## Appendix SM:

### Surveys: Some Methodological Issues

As well as giving an indication of the level of satisfaction among service users and carers, surveys may elicit useful suggestions or ideas about service changes or improvements. But before undertaking surveys it is necessary to consider some methodological issues.

Most important among the methodological issues is the challenge, regardless of the survey method or methods chosen, of obtaining information that will give a good and broadly representative indication of people's views (for different facets of the services provided). The methodological challenge is heightened for services that support people who are frail or who have disabilities. Appendix UD is, therefore, also relevant.

#### **Sample Size**

The matter of numbers is important. Larger services may be positioned to manage substantial surveys, within which outcomes can be regarded as statistically significant. For some groups of respondents, therefore, such large services may have information from survey findings that show the proportion of people who are (e.g.) satisfied or very satisfied with their overall service or particular aspects of it. They may also be able to break down survey responses by age, gender, disability, etc. in order to help them with the more detailed aspects of service planning and development.

Smaller or medium sized services, however (perhaps with less than 500 users), will look to obtain firmly indicative information which (though not statistically significant) will, by reference to other sources (and, perhaps the experience of similar services elsewhere), provide them with a good basis for service planning and development.

In either case what is necessary is that telehealth services should make their best endeavours to engage with an appropriate range in order to obtain meaningful information. The services will need to be clear how they identify that 'appropriate range' of users and carers and the extent to which the survey responses can be considered broadly representative. The number in that range of users and carers, for small services, will not be less than 20.

#### **Personal Interviews and Focus Groups**

Two approaches are suggested here – personal interviews and focus groups. A precondition of confidentiality (regarding the views of users and carers) goes with both approaches. Alternatives for consideration are on-line or postal surveys.

In pursuing either personal interviews or focus groups there is the need for interviewers or facilitators (moderators) not to 'lead' people towards certain responses to any questions posed. The question 'how satisfied are you about ...?' should not, for instance, be asked without also indicating the potential not to be satisfied – through, perhaps, the question 'how satisfied or dissatisfied are you about ...?' and so on.

In focus groups it is for the participants to 'make the running' based on little more than a topic list provided or open questions asked by the facilitator (moderator). Hence in order to stimulate a discussion (in a focus group) about the telehealth service in question, a starting point might be (aside from introductions and an outline of the purpose of the discussion) to find out how long people have been using the service. This is an easy 'ice-breaker' for such fora. This kind of starting point could usefully be followed by a question such as 'how do you normally use the service?' and 'how often do you talk with service staff, etc.' perhaps then exploring the positives and negatives in their experience. There is always the option then (something to be considered for personal interviews and/or focus groups) to probe people's responses by

asking ‘can you give me an example?’ or ‘can you explain a little more?’ The key point here is that (neutral) probing is fine. Prompting (which might lead to particular answers) is, however, definitely not appropriate. The proformas (questionnaires) in surveys and the topic lists (for focus groups) need to reflect this.

Personal interviews should not need to last longer than 40 minutes. Focus groups might, by contrast, go on for 90 minutes – depending on the interest that is generated. The outcomes of one approach may, of course, suggest the usefulness of follow up surveys or focus groups to further explore issues that arise.

### **Special Considerations**

Overall (and in either methodological context), in seeking the views of people who are frail, etc. some special considerations are necessary. In the interests of inclusion, therefore, endeavours should be made by telehealth services to surmount some of the barriers to obtaining user and carer views (see Appendix UD for some guidance).

In any case, for all users and carers it will be necessary in the initial approaches made by telehealth services to be sensitive to what, on their part, might be a wariness about any survey, and to offer encouragement to them (and, if appropriate, incentives) for their participation. They should be properly thanked for their participation and provided with some summary feedback from the survey work (including the posting of information on the website).

## Appendix UD:

### Users and Carers with Disabilities

Good practice requires an appropriate level of engagement with users and carers. The fact that there are high numbers of users and carers who have disabilities presents a challenge to telehealth services. Such disabilities may relate to the consequences of physical, intellectual, sensory or developmental impairments.

With such matters in mind services should, when planning the manner of service provision and the technologies they make available, give consideration to the principles of universal design. These principles require that technologies/equipment are designed in such ways as to be useful to and usable by people with diverse abilities; can accommodate their preferences; and offer tolerance for user error. Wherever people have difficulty with 'ordinary' methods of communication (speech and writing) alternative methods of communication should be explored. Some of these are noted below.

The accommodation of the preferences of users and carers means that services should give proper consideration to their views. It follows that services should make their best endeavours to overcome any barriers to engagement with users and carers. Given the nature of some disabilities such engagement should, where appropriate, be undertaken with the support/guidance of or by persons who have specialist expertise.

#### **Overall**

In all aspects of the service provision the use of plain language and simple sentences is recommended. This should be combined with preparedness on the part of staff, for in-person (home) visits or tele-consultations, to repeat (and, where appropriate, rephrase) things in order to aid understanding. The following paragraphs give further guidance to services in respect of some of the challenges.

#### **People with Sight Loss**

Communication with people with sight loss is helped through large print or audio versions of information. Some users and carers would benefit from material written in Braille. When information is provided electronically (e.g. via email) accessible formats should be used (such as Word, rtf and epub). The use of pdf formats is appropriate only when accessibility guidelines are also provided.

For in-person (home) visits or tele-consultations, staff should be face to face and focused on the service user (or a carer) who may have sight loss). The visibility of visiting staff can be assisted through good lighting that is positioned in a way that avoids glare. During in-person visits for people with substantial sight loss (or who are blind) it is important for staff to inform the user and/or carer where they are and about his/her entry and exit. Furniture, etc. should be left in place. Staff should speak to the users and carers on both arrival and departure.

#### **People with Hearing Loss**

For in-person visits or tele-consultations with people with hearing loss, communication can be helped by hearing aids – with users and carers having them switched on and properly adjusted. It is best for staff to be face to face and focused on the service user - this being especially important where users and carers are able to lip-read. Good lighting can help. The

wearing of lipstick by the interviewer and the absence of a beard can be helpful for those users and carers who lip read. Different forms of sign language may be a good means of communication for some.

### **People with Sight and Hearing Loss**

The nature of communication with people who have both sight and hearing loss (deafblind) will vary depending on the extent and nature of their impairments. Different methods of communication can be used including e.g. tactile sign language or finger-spelling (where, in both cases, the 'reader' feels and follows the movement of the signer's hands) or tracking (where there is residual vision but the 'reader' is guided by holding the forearm or wrist of the signer).

### **People who have Cognitive Impairments**

Meaningful communication with people with mild to moderate cognitive impairments (potentially arising from e.g. learning disabilities, autism, acquired brain injury or a dementia) is usually possible. The essential need is for material produced about services and service options to be clear and easy to read - using simple language and illustrations. Reassurance, in any case, should be routinely provided by staff to users and carers when explaining about services or responding to queries. It must be noted, in addition, that there is a particular imperative for users with cognitive impairments that their views (and consents given) are reviewed at regular intervals.

For in-person visits or tele-consultations it may be necessary to arrange these through carers. When discussing things with a service user with dementia or a learning disability it is fine for staff to repeat things in different ways and, subject to it being clear that the user has an adequate degree of understanding, to accept and clearly record any decisions made by them about the nature of the care and support agreed with them.

For users with conditions such as brain injury or autism a more consistent approach may sometimes be required. As with other users where there is a cognitive impairment, subject to it being clear that the user has an adequate degree of understanding, staff can accept and clearly record any decisions made about the nature of the care and support agreed with them.

### **People with Physical Disabilities**

The principles of universal design have been noted above. Accordance with such principles can ensure that services are accessible and usable by a wide range of people with different physical disabilities. Other assistive technologies are, in addition, available that can respond to individual needs and may, therefore, help a wider range of users and carers.

**End.**