



TECHNICAL REPORT

**eHEALTH;
Standardization use cases for eHealth**

Reference

DTR/EHEALTH-007

Keywords

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Foreword

This Technical Report (TR) has been produced by ETSI Project co-ordination of activities in the Health ICT domain (eHEALTH).

Modal verbs terminology

In the present document "**should**", "**should not**", "**may**", "**need not**", "**will**", "**will not**", "**can**" and "**cannot**" are to be interpreted as described in clause 3.2 of the [ETSI Drafting Rules](#) (Verbal forms for the expression of provisions).

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1 Scope

The present document presents a number of typical use cases in the eHealth domain and their analysis to identify gaps in standardization. The analysis covers aspects of link connectivity, network interconnectivity, semantic and syntactic interoperability, security (risks and provisions) and the existence of standards to meet each aspect. Furthermore the analysis identifies actors and their roles, for each of primary, secondary and tertiary involvement in the use case.

The use case examples have been drawn or informed by publications from industry, from completed FP7 and H2020 projects, from ETSI Technical Bodies, and from current eHealth and Health industry practices.

2 References

2.1 Normative references

Normative references are not applicable in the present document.

2.2 Informative references

References are either specific (identified by date of publication and/or edition number or version number) or non-specific. For specific references, only the cited version applies. For non-specific references, the latest version of the referenced document (including any amendments) applies.

NOTE: While any hyperlinks included in this clause were valid at the time of publication, ETSI cannot guarantee their long term validity.

The following referenced documents are not necessary for the application of the present document but they assist the user with regard to a particular subject area.

- [i.1] ETSI TR 118 501: "oneM2M Use Case collection".
- [i.2] EC Directive 2007/47/EC of the European Parliament and of the Council of 5 September 2007 amending Council Directive 90/385/EEC on the approximation of the laws of the Member States relating to active implantable medical devices, Council Directive 93/42/EEC concerning medical devices and Directive 98/8/EC concerning the placing of biocidal products on the market.
- [i.3] ETSI TR 102 764: "eHEALTH; Architecture; Analysis of user service models, technologies and applications supporting eHealth".
- [i.4] ETSI SR 002 564: "Applicability of existing ETSI and ETSI/3GPP deliverables to eHealth".
- [i.5] Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

NOTE: Available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0024>.

- [i.6] GDPR: "General Data Protection Regulation (GDPR) (EU) 2016/679".
- [i.7] Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union (NIS Directive).

NOTE: Available from <https://eur-lex.europa.eu/eli/dir/2016/1148/oj>.

- [i.8] Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cybersecurity) and on information and communications technology cybersecurity certification and repealing Regulation (EU) No 526/2013 (Cybersecurity Act).
- [i.9] ISO/IEC 7498-1:1994: "Information technology -- Open Systems Interconnection -- Basic Reference Model: The Basic Model".

- [i.10] IEC 60906-2: "IEC system of plugs and socket-outlets for household and similar purposes - Part 2: Plugs and socket-outlets 15 A 125 V a.c. and 20 A 125 V a.c.".
- [i.11] Directive 2005/36/EC of the European Parliament and of the Council of 7 September 2005 on the recognition of professional qualifications (Text with EEA relevance).

NOTE: Available at <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32005L0036>.

3 Definition of terms, symbols and abbreviations

3.1 Terms

For the purposes of the present document, the following terms apply:

asset: anything that has value to the organization, its business operations and its continuity

care services: all services and goods provided with the aim of preventing, alleviating, curing or healing human illness and physical and/or cognitive impairments

causation: indication that one event is the result of the occurrence of the other event

NOTE: I.e. there is a causal relationship between the two events.

clinical staff: professional caregivers, responsible to deliver care services to patients, including care specialists and care institution managers

correlation: statistical measure (expressed as a number) that describes the size and direction of a relationship between two or more variables

exergaming: combination of exercise and game

NOTE: I.e. using games as a means of exercising.

General Practitioner (GP): medical doctor qualified to practice medicine, responsible for medical treatment

nurse: professional caregiver responsible to deliver care services to patients, including giving medical and other attention

3.2 Symbols

Void.

3.3 Abbreviations

For the purposes of the present document, the following abbreviations apply:

AC	Alternating Current
ATM	Asynchronous Transfer Mode
BAN	Body Area Network
CIA	Confidentiality, integrity and availability
CIM	Context Information Management
DC	direct current
EC	European Commission
GDPR	General Data Protection Regulation
HRM	Heart Rate Monitor
ICT	Information and Communications Technology
IEC	International Electrotechnical Commission
IP	Internet Protocol
ISG	Industry Specification Group
ISM	Industrial Scientific Medical

MTBF	Mean Time Before Failure
MTTR	Meant Time To Repair
OSI	Open Systems Interconnection
SAREF	Smart Applications REference ontology
UNCAP	Ubiquitous iNteroperable Care for Ageing People

4 Introduction to eHealth use cases

4.1 Structure of use cases

Use cases are developed to examine problem statements that are a concise description of issues that need to be solved in the context of the use case. The purpose of the use case is to clearly describe:

- What the problem is.
- Who has that problem i.e. who will benefit when it is solved.
- What are the consequences of the problem.
- What a possible solution would be, this sets the expectations and the scope of the solution (is it a new process, an application, etc.).

In the context of standardization the problem is multifold but is primarily concerned with determination of interoperability. This may be at the application level where syntactic and semantic coherence is critical, or at any of the layers of the OSI stack (see ISO/IEC 7498-1 [i.9]). For communications interoperability the main concerns are to give assurance of connectivity, of routing (i.e. the ability of devices to connect in order to provide reliable transport of information from source to sink), and of mutuality of transfer rates (i.e. to ensure that data produced at a given rate can be consumed at the same rate).

In any large and interdisciplinary problem space there are many stakeholders involved. For the purposes of use case modelling these stakeholders are identified as actors with one or many roles to play in each scenario that is represented. The use cases are structured in particular with the focus on interoperability in order to identify where standards are required to fulfil the use case. This is especially true when the solution aims to provide functionalities and processes in the medical context, which involve collection of medical and other personal data, and acting upon that data or even using it to provide treatment. Thus, it is of highest importance to identify as many stakeholders as possible that are in any way involved in the problem and who will be resultant stakeholders in the solution. This includes both primary stakeholders, who will be directly affected by the solution, as well as secondary stakeholders that will only feel the results indirectly. Stakeholders can be both individuals and organizations, and should in addition to the entities accepting care (the patients) and the entities providing care (care providers, nurses, physicians) also include the supporting entities and controlling entities. The latter two groups encompass the manufacturers, equipment vendors, solution providers, developers, distributors, payers; and regulators, agencies, committees, boards and unions.

For practical reasons the role of machines and the interconnection of machines in eHealth is particularly important.

The use cases in the present document complement the Machine-to-Machine use cases for eHealth found in ETSI TR 118 501 [i.1]. Further, the use cases in the present document extend the model presented in ETSI TR 102 764 [i.3] beyond the purely communications model in which for each use case consideration was given to identification of the originating and terminating parties for the eHealth **communication** as follows:

- Patient originated: Health Professional terminated (noting that the Health Professional could be equipment rather than a person).
- Health Professional originated: Patient terminated.
- Health Professional originated: Health Professional terminated.
- Patient to Health Professional dialogue.
- Health Authority to Citizen (Health Authority originated: Citizen terminated).

In addition the present document extends the view of eHealth intervention which may invoke each other:

- Telemedicine.
- Remote monitoring.
- Mobile monitoring.
- Therapy intervention.
- Emergency intervention.
- Wellness monitoring.

NOTE 1: Monitoring wellness activity is not considered a medical monitoring activity but may be used to supplement information presented to a health professional. Furthermore a wellness monitor is not expected to be classified as a medical device (see Annex B).

- Exergaming.

NOTE 2: Exergaming, the role of games in exercise, is not considered a medical intervention and as such the equipment involved and the results logged are not expected to be classified as medical devices (see Annex B) but the record of the activity may be made available to a health professional in support of a diagnosis or treatment session.

The present document refreshes the model used in classification of the communications requirements from [i.3] in expanding the use cases:

- Unidirectional.
- Acknowledged uni-directional.
- Symmetric bi-directional.
- Asymmetric bi-directional.

In eHealth it is anticipated that a significant proportion of the communication will be between actors where the actor is a machine, for example, between monitoring equipment, e.g. a BAN, and eHealth middleware; the Health professional will receive alarms and will when necessary or convenient access the information (where the distinction between necessary or convenient will be determined in part by the priority of the message and by the pre-processing of the message content).

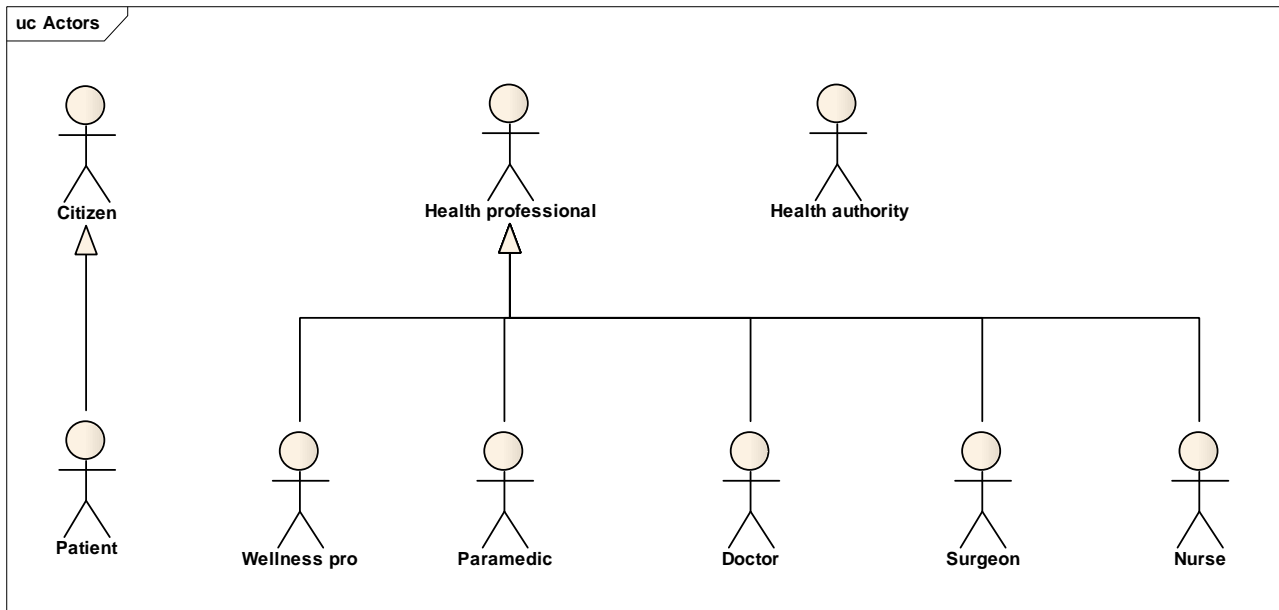
4.2 Actors and roles

In the eHealth context the obvious actors are those from the medical intervention group and thus Doctors, Nurses, Surgeons and the many specialisms are covered. However, eHealth is not simply about medical professionals and thus the stakeholders and the actors representing them should include standards bodies, operators, manufacturers, regulators and governments (national, regional and international) and of course medical sensors and intervention devices. In addition, as health and healthcare is a significant cost item there will be instances where medical insurance companies, administrators of medical facilities, research analysts and others will require access to health data.

The purpose of access to eHealth data and services is not simple to categorize. For example, in addition to diagnostic medicine and care, it is also necessary to identify effectiveness of treatments, of the how diseases spread and so forth. The consequence is that the set of actors in eHealth both by role and by name has to be mutable over the lifetime of the system.

The set of actors described in the present document extends the model presented in [i.3] in order to address changes in the eHealth landscape. In particular the consideration of specialist forms of eHealth professional and of patients as citizens is extended to consider the role of machines in the eHealth environment.

NOTE: The list of eHealth actors is indicative and is not considered as complete.



NOTE: Each actor may be represented by a machine (i.e. a doctor does not need to be a human being).

Figure 1: Actors in use cases for eHealth analysis

In addition to the patient being a simple case of a citizen suggested in Figure 1 the patient may also be represented by 3rd parties that may include carers and wellness agents. In such cases the authority of the 3rd party to act on behalf of the patient may be represented as shown in Figure 2.

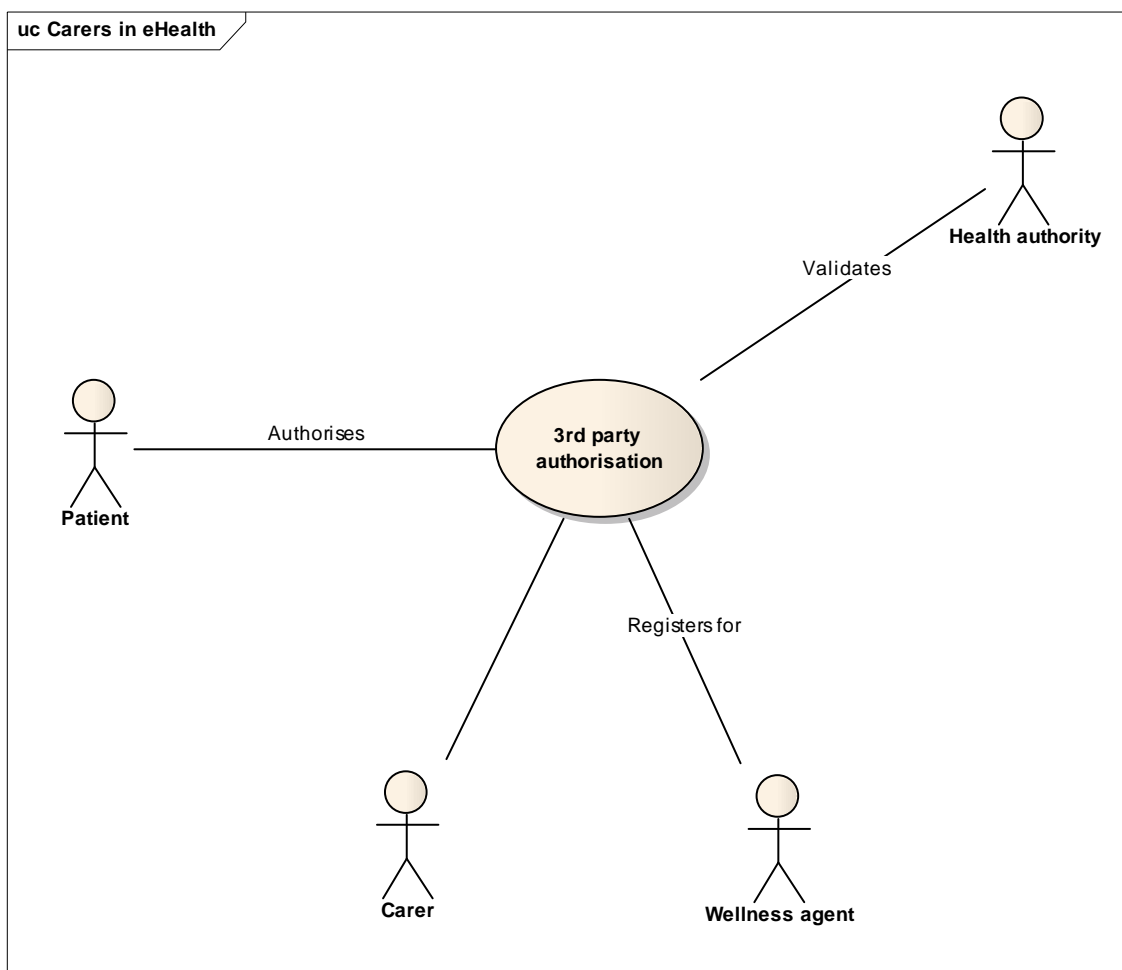


Figure 2: Example of carers and like actors being authorized by patient

4.3 Time and performance constraints

eHealth is a global phenomenon and will require that data is passed across borders without undue delay. Any constraints on processing speed, network transfer rate and data lifetime should be identified in the use case analysis.

For the purposes of analysis a border is not limited to a national (geographic or political) border but may also refer to the interface between equipment and between services. For some geographic domains specific constraints and obligations apply including those for eHealth data in Europe Directive 2011/24/EU [i.5] applies. For data that is not specifically eHealth data in the scope of 2011/24/EU [i.5] the wider provisions of the GDPR [i.6] and equivalent regulation would be expected to apply.

4.4 Forms of interoperability

4.4.1 Syntactic interoperability

Syntax derives from the Greek word meaning ordering and arrangement. The sentence structure of subject-verb-object is a simple example of syntax, and generally in formal language syntax is the set of rules that allows a well formed expression to be formed from a fundamental set of symbols. In computing science syntax refers to the normative structure of data. In order to achieve syntactic interoperability there has to be a shared understanding of the symbol set and of the ordering of symbols. In any language the dictionary of symbols is restricted, thus in general a verb should not be misconstrued as a noun for example (although there are particularly glaring examples of misuse that have become normal use, e.g. the use of "medal" as a verb wherein the conventional text "He won a medal" has now been abused as "He medalled"). In the context of eHealth standardization a formally defined message transfer syntax should be considered as the baseline for interoperability.

4.4.2 Semantic interoperability

Syntax cannot convey meaning and this is where semantics is introduced. Semantics derives meaning from syntactically correct statements. Semantic understanding itself is dependent on both pragmatics and context. Thus a statement such as "Patient-X has a heart-rate of 150 bpm" may be syntactically correct but has no practical role without understanding the context. Thus a heart-rate of 150 bpm for a 50-year old male riding a bike at 15 km/h up a 10 % hill is probably not a health concern, but the same value when the same 50 year old male is at rest (and has been at rest for 60 minutes) is very likely a serious health concern. There are a number of ways of exchanging semantic information although the success is dependent on structuring data to optimize the availability of semantic content and the transfer of contextual knowledge (although the transfer of pragmatics is less clear).

There are a number of existing ontologies in eHealth but there does not appear to be a (single) global standard for the transfer of semantic data within a common syntax. There is therefore a challenge to resolve the means to transfer semantic knowledge with representation of both context and pragmatics.

ASSERTION: Semantic interoperability is essential to allow machine based eHealth intervention.

NOTE: The ETSI SmartM2M group is supporting standardization of the SAREF ontology and this may be considered as a starting point for an eHealth ontology (<http://ontology.tno.nl/saref/>).

4.4.3 Electrical and mechanical interoperability

Quite simply a device with a power connector using, for example, a Type- IEC 60906-2 [i.10] connection cannot accept power from anything other than a IEC 60906-2 [i.10]. Similarly, for example, a serial port complying to USB-Type-A will not be able to connect with a USB-Type-C lead. In addition to simple mechanical compatibility there is a requirement to ensure electrical interoperability covering amongst others the voltage level, amperage level, DC or AC, frequency if AC, variation levels and so forth.

4.4.4 Radio communication interoperability

In the eHealth environment devices have to be able to interconnect and if wireless communication is deployed then it is obvious that the communicating end-points use the same means to communicate. In the radio sense this means sharing knowledge of frequency band, modulation technique, symbol rate, power, and so forth. The current Industrial Scientific Medical (ISM) band allocations are in this respect not strongly protected and many non-ISM devices use the ISM bands ("A" bands are allocated to ISM applications, "B" bands may be used by ISM and non-ISM applications).

A consequence of the current management of the ISM bands is that knowledge of the frequency does not determine modulation waveform and vice versa.

4.4.5 Mutual understanding of vocabulary

Any term in eHealth has to be clearly and unambiguously understood. The requirements for syntactic and semantic interoperability described above apply. In addition the glossary of terms introduced in Annex D (Extended glossary of terms) of the present document also apply.

5 eHealth objectives and high level requirements

5.1 ICT centric requirements

In ETSI TR 102 764 [i.3] a statement was made of the objectives that an eHealth system should be designed to meet. Whilst the statements in [i.3] were primarily derived from analysis of the network requirements for eHealth the present document also addresses the data and user management aspects of an eHealth system. The objectives stated in [i.3] are reflected in the present document and updated in Table 1 to address changes in the technology and regulatory environment and to address the wider scope of the present document.

Table 1: Mapping of eHealth objectives and requirement class

Objective to meet	Resulting requirement class
A user should expect ubiquitous network connectivity.	Reliability and availability (network interoperability)
The user should reasonably know that eHealth equipment that requires to be connected through a network should be able to access the network.	Availability
The eHealth system should support the interworking of heterogeneous devices and networks.	Network interoperability
An eHealth device should be able to interact securely with the eHealth infrastructure.	Security: Availability
Information held within an eHealth device should be protected from unauthorized access, modification and destruction.	Security: Availability; Security: Integrity
Services provided within the eHealth infrastructure should be available only to authorized users of the eHealth system.	Security: Availability (authorization)
Information sent to or from a registered user of the eHealth system should be protected against unauthorized or malicious modification or manipulation during transmission.	Security: Integrity
Information sent to or from a registered user of the eHealth system should not be revealed to any unauthorized 3 rd party.	Security: Confidentiality, Security: Availability (Access control); Security: Confidentiality
An eHealth user should be able to communicate confidentially with other users within the eHealth network.	Security: Confidentiality, Privacy
Details relating to the identity of an eHealth user should not be revealed to any unauthorized 3 rd party within the eHealth network or in the wider ICT networks.	Security: Availability (Access Control), Security: Availability (Identity Management), Security: Confidentiality, Privacy
Access to the operation of services by authorized eHealth users should not be prevented by malicious activity within the eHealth network or in the wider ICT networks.	Availability
The eHealth system should be able to collect information relating to the context of any eHealth transaction.	See ISG CIM work
The eHealth system and the devices used to access it should allow any member of society to be able to use the system.	Availability

5.2 Person centric health eco-system

The objectives and requirements related to the eHealth system identified in clause 5.1 above are unfortunately incomplete and in part this is a consequence of lack of semantic and syntactic interoperability, and to an extent poor understanding of contexts of health measurement. A simplified concept relationship diagram is shown in Figure 3.

However, there are a large number of questions that have still to be posed and answered: Does trauma (say a broken bone) mean the person suffering the trauma is unhealthy? If a health professional is involved in treatment of trauma it will be recorded in the documentary health record. Multiple instances of repeated trauma may imply other health issues, however there may be only indirect causal links. Thus, whilst smoking may lead to a higher propensity to respiratory disease there is no evidence proven link that a smoker will end up with a respiratory disease.

The assertions in Figure 3 are quite strong: Behaviour modifies health and health modifies behaviour. Or in alternative terms running naked in the snow may lead a person to catch a cold, and having a cold may make it less likely for that same person to go out and run naked in the snow. However there is a strong requirement in medical diagnosis to not confuse correlation and causation.

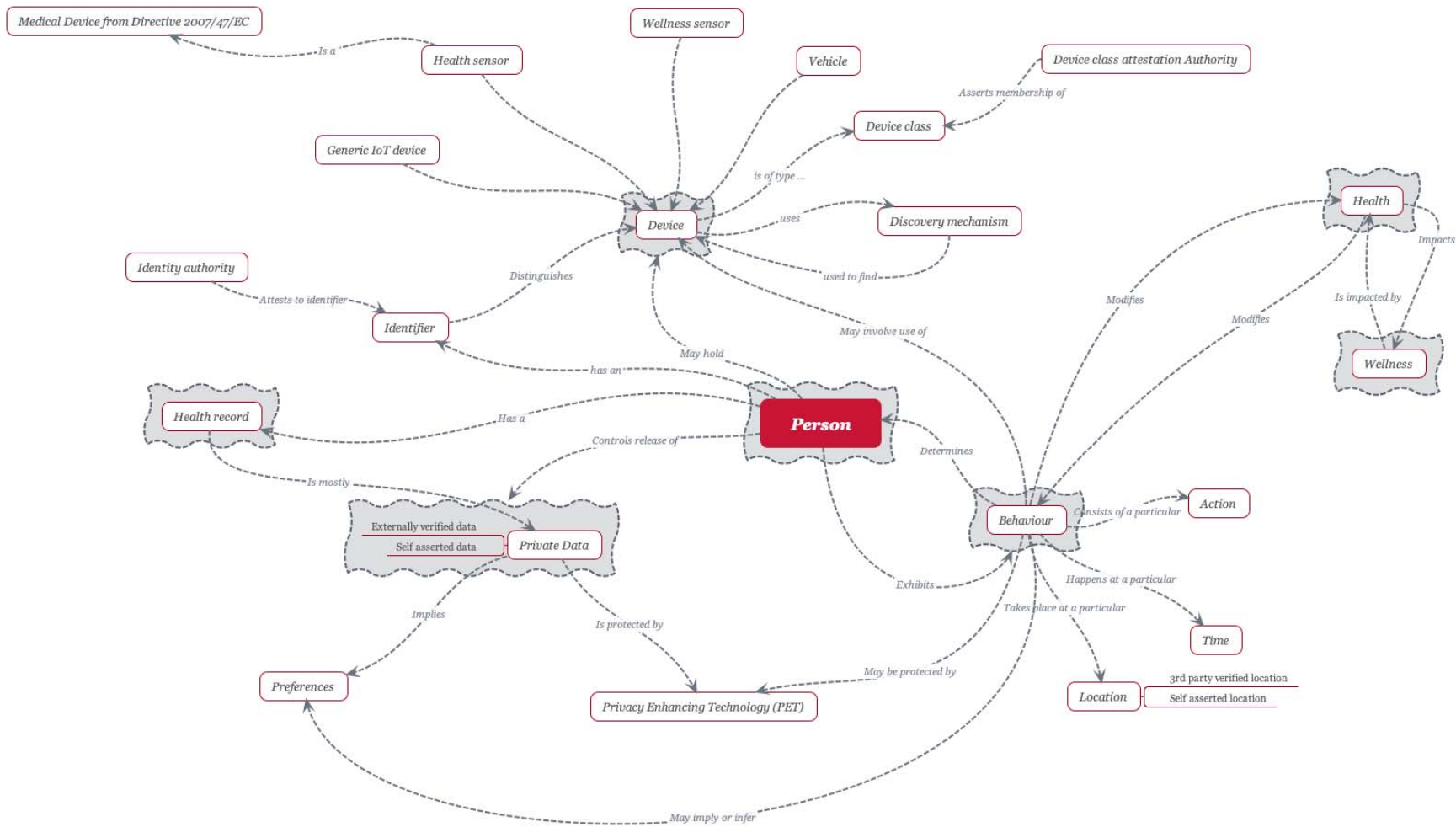


Figure 3: Concept relationship diagram for patient/person in health

It is also essential for a wider health environment to be able to ask other questions for each of physical and cognitive health, and for societal health. Understanding the relationships may lead to particular health policies (e.g. the role of immunisation on a population).

6 Diagnostic eHealth use cases

6.1 Overview

The following actors are considered:

- Patient.
- Diagnostic sensor.
- Health professional (may be a machine (software or hardware or any combination thereof)).
- Context.
- Measurement metric standard.

The following statement is used to illustrate the use case:

- A <<Diagnostic sensor>> delivers a <<Measurement>> taken at <<time t>> in <<Context>> relating to <<Patient>> to <<Health professional>>.

There are additional statements to be made that apply to this use case:

- A <<Patient>> exists in a particular <<Context>>.
- A <<Diagnostic sensor>> complies with the specification for <<Measurement>> published by <<Publisher>>.

6.2 Data transfer

As identified in [i.3] data transfer requirements may be identified in an abstract form using a set of attributes that the data transfer scheme has to meet and which are presented and updated in Table 2.

Table 2: Data transfer attribute modelling (updated from ETSI TR 102 764 [i.3])

Attribute	Definition	Possible attributions
Ubiquity	A telecommunications or network service is considered as ubiquitous when it is, or seems to be, omnipresent within the scope of its deployment.	Yes No
Mobility	Mobility within a telecommunications network is used to refer to the ability of a device to change its physical point of attachment to the network without losing its logical connectivity. The obvious example is cellular radio where moving from one cell, the physical point of attachment, to another causes no interruption to the user service (the logical connection).	Infrastructure managed (e.g. cellular networking); End point managed (e.g. Local Area Wireless Networking); No mobility supported
Security	The security capabilities are selected from the CIA paradigm to counter risk to the system from a number of forms of cyber attack. The common model is to consider security in broad terms as determination of the triplet {threat, security-dimension, countermeasure} such that a triple such as {interception, confidentiality, encryption} is formed. The threat in this case being interception which risks the confidentiality of communication, and to which the recommended countermeasure is encryption.	Entity authentication; Infrastructure authentication; Cryptographic integrity generation and validation; Confidentiality provision (link encryption, end to end encryption); Service authorization; Key management
Connection capability	In telecommunications there are two distinct modes of operation, circuit mode and packet mode. A circuit mode call is often considered as traditional telephony where a simple definition may be that for the period of the communication there is a continuous electrical connection between the end points where the order of entry of data is preserved on exit. In practical terms there is not in fact an actual continuous electrical connection. Packet mode connections treat each packet as discrete and therefore it is possible that each packet takes a different route and thus may arrive out of order. The dominant mode in modern telecommunications is packet mode. The operational mode is distinct from the technology used to implement it, therefore traditional circuit mode services (e.g. voice calls) can be delivered using packet transmission capabilities (e.g. ATM, IP).	Packet mode - symmetric Packet mode - asymmetric Circuit mode - symmetric Circuit mode - asymmetric
Connection (address) topology	The topology of a connection is used to describe much of the physical connection of calls and covers three distinct cases. In each case a communications session may require a topology for each direction of connection.	Unicast (point to point); Multicast (point to multipoint); Broadcast (point to all points)
Content type	Whilst in a digital age all content can essentially be represented as a series of binary encoded information there are other characteristics that may be used to assist the ICT platform in carrying the content by syntactic and semantic labelling of content.	Data Video Audio (including speech) Image, deferred audio, deferred video, etc.
Grade of Service (GoS)	GoS refers to the ability to access and establish services and includes the time required to establish sessions, system reliability (assessment of mean time before failure (MTBF) and meant time to repair (MTTR) for example) and recovery and system resilience (i.e. how it degrades).	Service establishment time System reliability System MTBF System MTTR
Quality of Service (QoS)	QoS refers to the maintenance of the session once established and covers aspects such as throughput, error recovery/detection.	latency jitter end-to-end delay

6.3 Integrity and confidentiality

An observer of the system should not be able to determine the identity of the Patient or the Health Professional, nor make any assertion of the nature of the patient's health issue from observation of the content of the communication from the diagnostic sensor.

Any manipulation of the content of health data in the supply chain between the diagnostic sensor and the health professional should be visible to an observer.

6.4 Authenticity

The system should be able to unambiguously identify and verify the identity and function of the diagnostic sensor. The identifier and function should be able to identify the classification of the diagnostic equipment and the form of measurement it is delivering. Where a diagnostic measurement has to conform to a specific metric the system should retain a record of the calibration actions.

7 Clinical intervention use cases

7.1 Overview

The presentation of use cases is similar to that used for diagnostic eHealth. The following actors are considered:

- Patient.
- Diagnostic sensor.
- Medical actuator.
- Health professional (may be a machine (software or hardware or any combination thereof)).
- Context.
- Measurement metric standard.

The following statement is used to illustrate the use case:

- A <<medical actuator>> delivers a <<stimulus>> at <<time t>> in <<Context>> relating to <<Patient>>.

There are additional statements to be made that apply to this use case:

- A <<Patient>> exists in a particular <<Context>>.
- A <<medical actuator>> complies with the specification for reaction to a <<Stimulus>> published by <<Publisher>>.
- A <<Diagnostic actuator>> acts only under command of a recognized health authority.
- A recognized health authority may be represented by suitably approved ICT equipment.

In general clinical intervention should follow a prescribed diagnostic and treatment strategy. Thus it is suggested that delivery of drugs or other clinical/medical treatment should be traceable to specific recommendations from the diagnostic analysis.

The following are forms of clinical intervention that may be augmented by eHealth technologies:

- Non-surgical intervention
 - Drug monitoring and dose control
 - In this use case the context refers to the set of diagnostic measurements that indicate that a stimulus is required, e.g. the measure of blood-sugar in the blood indicating a requirement for an injection of insulin to the blood.
 - Physical well-being control

- Surgical intervention
 - ICT assisted surgery
 - In this use case the sensors and actuators required to perform surgery have to operate in real-time (or as close to as is practical), but decisions are made by a human operator. This conforms closely to the state of play today in which surgical procedures are made safe using eHealth technologies.
 - ICT enabled surgery
 - This extends the prior use case to address those parts of surgical intervention that may only be enabled by eHealth equipment. This conforms to many of the advanced keyhole and micro-surgeries that are enabled by eHealth technologies where unassisted and unenabled surgery would be impossible.
 - Mechanical and ICT performed surgery
 - This addresses the case where surgery is performed without direct human involvement.

7.2 Ethical concerns

The provision of eHealth, wherein ICT devices act wholly or partly as agents of human health professionals, would be expected to ensure that the responsible party follows the general ethical frameworks that health professionals are expected to comply with, and to give assurance that devices "do no harm".

The use cases for clinical intervention need to at the very least ensure that there is an evidence trail to verify the provenance and validity of any healthcare action.

8 Electronic Health records

8.1 Overview

Diagnostic and preventative medicine requires access to a valid and accurate record of patient health over as long a period as possible. Thus whilst it may be argued that health devices (heart rate monitors, blood pressure monitors and so forth) are critical, they are only critical if the readings they take are recorded, and as is suggested in the use case statement, identify with some accuracy the context of the reading.

Health records are required to cross international borders as has been explicitly stated in Directive 2011/24/EU [i.5] on patients' rights in cross-border healthcare. Whilst it is possible to conceive of a centralized supranational datastore maintained by a single data server, the security and reliability concerns of a single point of failure advise against it. Furthermore if such a centralized supranational server was to exist the political leverage afforded to the hosting country would be reasonably considered a significant source of risk to the operation of such a resource and thus advise against such a design.

8.2 Structure of a health record

A health record is a composite document and one of the difficulties surrounding the definition of a health record is in establishment of the boundary. In the domain of diagnostic medicine information is required to establish context. For example, many illnesses in their early stages have shared symptoms and to accurately attribute symptom to cause may mean the difference between survival and not.

A health record has no fixed start time and end time. Whilst for an individual a health record exists from birth, there are aspects of the individual's health that are directly linked to the parents (e.g. genetics) and to the period in the womb that need to be linked to the individual's record. Associated to the individual's record are also records of the health professionals, of the locations at which medical interventions occur (e.g. hospital, clinic), and of the medications prescribed, and so on.

8.3 What is the purpose of the records in eHealth?

A health record has a number of purposes, including but not restricted to the following:

- To log health status.
- To log health assessments.
- To log clinical interventions.
- To record recovery path.

A health record will also be used in review of the job performed by healthcare professionals and in specialist reviews such as reviews by Ethics boards, by transplant boards, by housing and social care agencies, by law courts and sentencing review boards and many more.

8.4 Access and Access Control

The concept of a health record as a composite document implies it may require different levels of access for each component of the document. Access control on anything that is not in the public domain should be based on a general principle of "need to know" or "least privilege". The problem in eHealth is that the details of who needs to know cannot be pre-determined so access control policies need to be flexible without harming the intent of minimizing exposure.

8.5 Cross border

The EU on behalf of all 28 member states has agreements that allow for the processing of data that is subject to GDPR [i.6] outside the borders of the EU-28. There is free movement of data internally to the EU-28 (e.g. any of the EU-28 states is allowed to store and process data in any of the other EU-28 states). eHealth data is subject to the provisions of the GDPR and should be processed in such a way that it maintains compliance at all times. This is in addition to the provisions stated in Directive 2011/24/EU [i.5].

8.6 Security design considerations for health records

A health record has to have the following properties:

- the record is a collection of events or transactions related to a patient;
- the eHealth record is the collective term for the entire set of transactions;
- every transaction in the record has to have proof of the source;
- every transaction once entered into the record has to be considered as immutable and provably so.

The nature of a health record is that it is composed of many elements. The addition of an element can be considered to be discrete, and to be a timed event. If the health record is modelled as a distributed database of records then it may be possible to use a blockchain approach to provide confidentiality protection of the growing record, or more conventional Merkle trees to protect the integrity of the growing record.

NOTE 1: A blockchain is a distributed database that maintains a continuously-growing list of records called blocks secured from tampering and revision. Each block contains a timestamp and a link to a previous block, in a Merkle tree structure.

NOTE 2: A hash tree or Merkle tree is a tree in which every non-leaf node is labelled with the hash of the labels or values (in case of leaves) of its child nodes. Hash trees allow efficient and secure verification of the contents of large data structures. Hash trees are a generalization of hash lists and hash chains.

Demonstrating that a leaf node is a part of the given hash tree requires processing an amount of data proportional to the logarithm of the number of nodes of the tree; this contrasts with hash lists, where the amount of processing required is proportional to the number of nodes in the list.

9 Autonomic eHealth

The ultimate expression of eHealth is life-time health care without human intervention where the combination of sensors, diagnostic algorithms, and intervention actuators, give assurance of long term health.

Annex A: Project UNCAP

A.1 Introduction

Ubiquitous iNteroperable Care for Ageing People (UNCAP) is a complex project looking into the role of technology in assisting the care of a very significant proportion of the global population. The percentage of the global population that is older than 65 years of age is growing, with many of the advanced industrial societies of the west already exceeding 20 % older than 65. If the general trend of industrial societies continues there will soon be significantly more than 1 billion individuals falling into this older people grouping. The matching trend is of a decreasing number of health professionals and over time it is reasonable to expect that there will be increasing need to provide medical care for the aging population by healthcare professionals increasingly distanced from the day-to-day experience of aging and the ailments that age confers.

To quote from the UNCAP press release:

"The ageing population is set to challenge health and care systems. Current care models are proving to be inappropriate and unsustainable. This situation is clearly calling for new care & assistance paradigms.

*UNCAP will address such a fast-evolving scenario through the development of an infrastructure designed to **help ageing people** (including those with **mild cognitive impairments**) live independently and with dignity.*

In particular, UNCAP will leverage on an interoperable ecosystem of biosensors and indoor & outdoor localisation solutions to deliver an infrastructure capable to continuously monitor and assist users in a non-invasive way.

*Furthermore, UNCAP will allow accurate monitoring of user's state (physical & cognitive), and also creating a range of brand new services designed to stimulate **healthier lifestyle** and more **active ageing process**. To this extent, the ultimate goal of UNCAP is to extend the duration of high-quality life of ageing, frail, and cognitive impaired citizens by helping them achieve higher **autonomy, independence, and dignity.**"*

A.2 Use cases

A.2.0 Note about Use cases in UNCAP

NOTE: The uses cases in the UNCAP project have been developed as experimental scenarios, hence for example the "fall detection" use case has been examined to determine viability of various detection technologies.

A.2.1 Fall detection

A consequence of aging is, unfortunately, a greater likelihood to fall. Whilst the set of age related impairments that lead to this greater likelihood are of themselves not addressed in this use case the consequence of a fall often become more severe as one ages. Recognizing a fall as quickly as possible and making possible medical or nursing assistance as quickly as possible is the primary goal in this use case.

There are a number of ways that a fall can be detected:

- pressure sensors on the floor with processing of sensor data to distinguish a fall from walking or running, or even from sitting or laying down;
- visual recognition of a fall. In this case the motion of a person falling is quite distinct from other behaviours such as sitting or lying and a suitably equipped visual processing system should be able to identify a fall;
- body worn accelerometers may be used to detect a fall as there is distinct dynamic related to falling as opposed to normal sit down or lie down behaviour.

Monitoring a patient to determine he has fallen may be intrusive or subject to false alarms. There are a number of privacy issues too if the monitoring is pervasive. Thus the intent is to gather understanding of the viability of a number of non-intrusive fall detection systems, that preserve privacy and dignity as much as possible.

A.2.2 Medication reminder

Many mild cognitive disorders are characterized by mild memory loss (forgetfulness). Whilst the idea of technology to remind a person to take their medication is not complex of itself the aim in the experimental phase of the use case is to identify means that are relatively non-intrusive and that record the dosage taken - so more than a simple reminder that could be done by a simple alarm system - and reset for the next dose.

A.2.3 Exergaming

The purpose of exergaming is to provide a form of light-to-moderate physical activity for adults. To give medical feedback, particularly on the impact on cognitive performance, assessment of the physiological wellbeing as well as the psychological wellbeing has to be made. It has been suggested, and some evidence does exist, that exergames can improve mental, improve measures of physical performance, e.g. the narrow walk time test and self-reported balance confidence. In the UNCAP project data will be gathered to allow quantification of the results of supervised exergaming.

A.3 Healthy living

There is no good, well accepted, definition of a healthy lifestyle but good health probably requires both inclusion and avoidance in a reasonable balance. So in terms of diet is it reasonable to suggest that the diet is "balanced" between proteins, carbohydrates, fats and the rest. Similarly, it is commonly stated that being physically active is part of keeping healthy. The question that needs to be asked is "is the situation changing in a positive way?" In this respect the activity trackers (see Annex B) are of themselves not health devices as they do not track health status.

What is healthy? What is the starting datum point for assessing health? Is the lifestyle of the patient harming his health?

Annex B: Fitness versus formal medical devices

A medical device is one that is classified as such and marked, in the EU, by an appropriate CE mark. Very simply a Medical Device (from Directive 2007/47/EC [i.2]) means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception.

In addition to be considered as a medical device the object does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted by such means.

In contrast any other device, such as a fitness oriented Heart Rate Monitor (HRM), can only be used for indicative information and has to be specifically excluded from use in any form of diagnosis, monitoring, treatment or alleviation.

Annex C: Privacy considerations

Privacy in health care is a difficult topic and has close relationship to ethics and to dignity. Whilst ethics covers the questions of "is this the right thing to do?", "will this action lead to harm?", and dignity is a wider view of respect, the issue of privacy is more nuanced. There are many definitions of privacy but those from human rights regulation suggest that privacy is the "*right of the individual to have his identity, agency and action protected from any unwanted scrutiny and interference*". In healthcare it is often necessary for a lot of information to be gathered about lifestyle and actions to make a correct diagnosis and thus a correct treatment strategy. In a face-to-face conversation in closed room where there is a bond of trust between patient and doctor the patient may be more willing to disclose information that may otherwise be considered private.

NOTE: Privacy reinforces the individual's right to decisional autonomy and self-determination which are fundamental rights accorded to individuals within Europe.

The privacy concerns regarding eHealth are as a consequence of the loss of the closed room and the potential loss of the bond of trust established in a face-to-face conversation. The trust relationships established in pre-eHealth healthcare will not exist in the eHealth world in the same way.

Protecting patient privacy in eHealth is not as simple as simply encrypting files and file transfers. Privacy is rooted in both context and trust. Privacy protection has also to be considered alongside ethics, and alongside dignity. The former relates to being able to do the right thing as the right time, the latter relates to treatment of patients with respect and honour such that they maintain their dignity.

The core architecture of privacy protection has 3 elements as recognized in the GDPR [i.6]:

- 1) Data subject.
- 2) Data processor.
- 3) Data controller.

The data subject in eHealth is widely understood to be the patient but may also be a health practitioner.

Annex D: Extended glossary of terms

D.1 Introduction

Terms in common use in the Health domain often fail the requirements to be easily defined in an ETSI deliverable. The ETSI editing rules give the clear requirement that the form of a definition should be such that it can replace the term in context. Any additional information can only be given only in the form of examples or notes. This rather stringent rule makes a term, say health, difficult to simply define. When that same term is then extended by a modifier, such as eHealth, or mHealth, or telehealth, it becomes increasingly difficult to define with any degree of conciseness and still retain its accuracy. The purpose of this extended glossary is therefore to give a wider view of the meanings attributed to common terms in eHealth and to assist the reader in addressing the semantic, and syntactic meaning of a term.

D.2 Definitions and descriptions of eHealth domain

D.2.1 eHealth

The term "eHealth" is widely used by many individuals, academic institutions, professional bodies, and funding organizations in spite of there being no clear definition or understanding of its meaning. It can be considered as a generic term for the application of electronic Information and Communications Technology (ICT) across the whole range of functions that affect health. However this breadth of meaning is both a strength and a weakness. Saying eHealth will suggest to the recipient something about health and ICT but will not be able to specifically identify which health issue and which form of ICT.

Confusion surrounds the term and its presentation with multiple variants variously capitalized (e.g. eHEALTH, E-Health, e-Health) and hyphenated or not (e.g. eHealth, e-Health). Within ETSI the format eHEALTH referring to the ETSI Project has been preferred.

D.2.2 mHEALTH

Generic term for the application of mobile communications technology to the provision of health care services.

NOTE: Insofar as mHEALTH and eHEALTH have merged the primary difference in meaning is with the role of the terminal device connection to the network. It may be considered that mHEALTH is a subset of generic eHEALTH for connectivity of the end-points making use of cellular network technology. The existence of wireless (radio) technology to connect a sensor to a hub or processor does not imply mHEALTH.

D.2.3 Telemedicine

Integrated ICT environment designed to provide healthcare services by use of a remote internet connection between the patient and a medical practitioner, offering patients express diagnostics and advice outside medical facilities and conventional clinic hours.

D.2.4 Telecare

Remote healthcare involving patient monitoring.

D.2.5 tele-health

Tele-health includes surveillance, health promotion and public health functions. It is broader in definition than tele-medicine as it includes computer-assisted telecommunications to support management, surveillance, literature and access to medical knowledge.

D.3 Definitions and descriptions of eHealth actors and services

D.3.1 Telematics for health

Telematics for health is a WHO composite term for both tele-medicine and tele-health, or any health-related activities carried out over distance by means of information communication technologies.

D.3.2 Health Care Professional

The definition of health care professional is a superset of that of Health Care Provider (given below) in that there is an assumption of a governing body for and that the individual is paid for providing care.

D.3.3 Health Care Provider

A doctor of medicine, a nurse responsible for general care, a dental practitioner, a midwife or a pharmacist within the meaning of Directive 2005/36/EC [i.11], or another professional exercising activities in the healthcare sector which are restricted to a regulated profession as defined in Article 3(1)(a) of Directive 2005/36/EC [i.11], or a person considered to be a health professional according to the legislation of the Member State of treatment.

EU: Article 3f) of Directive 2011/24/EU [i.5] on the application of patients' rights in cross-border healthcare.

Annex E: Bibliography

ETSI TS 103 264 (V2.1.1) (03-2017): "SmartM2M; Smart Appliances; Reference Ontology and oneM2M Mapping".

History

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