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The argument in favour of eHealth standardization in ETSI

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About the authors

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Scott Cadzow has over the past 20 years become a recognized standards development expert, primarily for security standards, in a number of international standards development organizations including ETSI, ITU-T and ISO. In ETSI Scott is or has been the rapporteur for the TETRA security specifications, the suite of guidance documents for effective security standards development (covering Common Criteria, risk analysis, and security requirements engineering) in technical bodies MTS and TISPAN, and has acted as an expert to a number of Specialist Task Forces in RRS, TETRA, TISPAN, HF, MTS, eHEALTH and AT-D. He has served as chairman of the ETSI ITS Security group and as vice-chairman of each of ETSI Project TETRA WG6 (Security), TETRA Security and Fraud Prevention Group (SFPG), and of the ETSI Lawful Interception group. Scott has contributed to reports from ENISA on network resilience, supply chain integrity and on measures to counter internet bullying. More recently Scott has been involved in a number of projects under the FP7/CIP/H2020 umbrella looking at security and privacy aspects of smart cities. This has led Scott to take a wider view at the whole interoperability conundrum and to address the need to look more deeply at the problems we will face with the IoT and dynamic self-configuring equipment.

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Suno WOOD

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Suno is a business development consultant with a medical background. Her association with CMS, a Russian clinic, for 10 years resulted in the successful introduction of specialized telemedicine solutions to America. This has given her a clear understanding of the advantages and conflicts in the growing use of advanced medical technology. Suno has extensive experience of working with and representing technical experts. She acted as team leader for international technical experts and local mobile telecoms companies in the Ukraine to establish proposals for ‘e’ and ‘m’ banking systems. She managed the introduction of a computerized pilot scheme for company registration in 5 Russian regions. She advised the Russian and Ukrainian governments and liaised with British and European counterpart organizations in a series of projects over 10 years in the field of licensing, registration and access to information. She also facilitated new commercial projects, such as the construction of a large glass production facility in the Moscow Region. Suno Wood believes in the importance of ETSI's role in creating standards which both protect the public and enable the cost-effective use of advanced technology in medical applications. She particularly believes in the role of the ETSI eHealth project to advance European developments in telemedicine. It provides a valuable opportunity to address interoperability, confidentiality and security issues in today’s fragmented market for health services, with its ethical, social and financial challenges.

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Contents

Abstract

Medical technology has often been viewed as a niche market, paling into commercial insignificance when compared to 'life-style' devices, and complicated by issues surrounding medical device regulation and government procurement practices. This view has been reinforced in Europe by the uneven success of early eHealth systems which were dependent on the successful introduction of new digital communications and a new approach to medical services.

However in 2018 and into the future we ought to be able to put this behind us and open up the market for eHealth that can take advantage of the possibilities of speed and volume of data transfer to be offered by ubiquitous availability of high speed digital connectivity, to open the market for communications backed by a new political awareness of the need to expand. Medical devices and communications services are no longer a small 'niche.' Sensors will be at the heart of smart cities, agriculture and food and transport industries, and the things they sense will need to be shared. To facilitate this growth, we need robust technical standards, included in the design process at an early stage, which are supported by an understanding of the demands of modern medicine.

The intent of this paper is thus to highlight the role of standards in eHealth technology today and their ability to serve the global population in the management of health. The main body of this paper illustrates that the core competences of ETSI's membership are well matched to development of the eHealth digital infrastructure in extending and evolving the networks and systems already standardized with a view to supporting eHealth.

Defining the boundaries of eHealth

Today there are some 7.6 billion people on the planet and only 15 million doctors! If the global population continues to increase at the same rate as it has for the past 20 or 30 years there will only be a bigger gap between the number of health professionals and the wider population. The role of eHealth will in part allow us to use technology to allow the small set of health professionals to deliver effective care to an increasing proportion of the increasing population. This white paper posits the notion that by effective use of eHealth, and by global technical and procedural standards to enable effectiveness, that all people can find a path to access to healthcare.

It is clear that only technology used with appropriate controls can augment the availability of health professionals in developed and undeveloped nations alike. This linking of technology and professional activity offers a true significance to the term 'eHealth.' It offers the only way to meet the challenges of provision of health services as the health services continue to grow in complexity and cost.

What role should be played by eHealth technology generally and by technical standards in particular to serve the global population in managing health?

The challenge is to apply technology in novel ways and new complex combinations so as to improve global health in a cost effective and practical manner. One of the roles of ETSI in this domain is to enable a climate of innovation in eHealth, underpinned by standards that ensure interoperability, efficiency, security, privacy and safety.

The size of the global health market is often difficult to judge but a reasonable figure is 10% of global GDP (all estimates come from the OECD). Figures to compare this to telecommunications expenditure are similarly hard to find but estimates of 3% of GDP seem common, for transport a figure of less than 1% of GDP is indicative. This suggests that the global market for health is significantly bigger than other "big" industries. Direct comparisons are difficult to make as the nature of the spending is different with health spending covering drugs, health professionals and the buildings (e.g. hospitals) as well as technology. However the message is clear: The health, and potential eHealth market, is massive.

The eHealth environment

Caring for patients, the diagnosis and treatment of illness by medical practitioners is a vital service and the challenge for technology is to understand and develop its position as an intrinsic and supportive part of the process. There is no element of competition here. eHealth serves the doctor/patient relationship. Without these end-users there is no need for our equipment or our services. However, this relationship has often been uneasy in the past and successful implementation of new technology has been marred by a sense of competition or mute aggression between its proponents and the medical community.

The situation is complicated by the dynamic nature of the medical world which copes with, amongst many other issues:

- The daily demands of its population from birth to death
- Disease and illness from environmental sources (pollution, tainted food and water sources)
- Local catastrophic events that may also be seen as accidents and emergencies at local or national level

- Global linkage in which linguistic, cultural, and political differences affect diagnostics, treatment and outcomes

Each situation offers opportunity for technical support. Unfortunately all events are complex and usually demand the use of equipment, software and services from different sources. So the interconnections of subsystems from different origins is a condition, *sine qua non*[1], for the realization of an effective eHealth infrastructure. This is turns means that there are many stakeholders involved and has made for difficulties in defining use cases for standards proposals.

However the sharing of information to treat health events is very similar to the need to share data for any other security event (e.g. distribution of malware, terrorist activity) in order to trigger a defence.

Evidence based healthcare

If we take the view that more knowledge of symptoms and environment leads to a more accurate diagnosis, this is one area in which eHealth is expected to take a vital role. Very simply, sensors can be used to record health data to present in support of diagnosis.

There is an adage, much favoured by engineers, that you cannot know what you cannot measure. To some extent this recalls what is increasingly becoming considered as the Rumsfeld[2] conundrum ``… there are known knowns … there are known unknowns … there are also unknown unknowns …'', and we have to assume that it is not possible to identify or measure everything, but we have to try as that knowledge is essential in effective diagnosis of a patient. Once we have data, the next stage in the problem is analysing that data. There are ICT techniques such as semantic labelling, Artificial Intelligence (AI) processing and similar that may be applied in eHealth to assist in health processing.

Evidence is essential in classification and response. For example, if we don't know the endemic level of a disease, illness or disorder then we cannot determine the severity of an outbreak. Thus, the various definitions given below are meaningless without accurate measurement to generate evidence:

- Sporadic: a disease that occurs infrequently and irregularly.
- Endemic: the baseline in a population within a geographic area.
- Hyperendemic: persistent, high levels of an endemic.
- Epidemic: an increase, often sudden, in the number of cases of a disease above the endemic level
- Outbreak: an epidemic but where the geographic area or population is more limited
- Cluster: an aggregation of outbreaks
- Pandemic: an epidemic that has spread over several countries or continents, usually affecting a large number of people.

[1] If this condition is not met there cannot be any such thing as an eHealth system

[2] "Reports that say that something hasn't happened are always interesting to me, because as we know, there are known knowns; there are things we know we know. We also know there are known unknowns; that is to say we know there are some things we do not know. But there are also unknown unknowns – the ones we don't know we don't know. And if one looks throughout the history of our country and other free countries, it is the latter category that tend to be the difficult ones." Attributed to Donald Rumsfeld on 12-February-2002.

It is worthwhile noting that in 2016, the Commission on a Global Health Risk Framework[3] for the Future estimated that pandemic disease events would cost the global economy over $6 trillion in the 21st century - over $60 billion per year, and went on to recommended spending $4.5 billion annually on global prevention and response capabilities to reduce the threat posed by pandemic events. A part of this global spend will be in the domain of eHealth and in particular in measurement, collation and use of "big data". However, any spending on prevention will not be effective if there are no base standards to exchange either raw or processed data, the latter in the form of knowledge, or to set a base-point for measurements.

In summary, it is clear that health is 'about people' and by logical extension, eHealth has also got to be 'about people.' See Figure 1 for a simplified concept relationship diagram to illustrate this. It demonstrates the difficulty inherent in the relationship of any person to a system and can be reduced to one core concept: Behaviour modifies health and health modifies behaviour. In alternative terms, running naked in the snow may lead you to catch a cold, and having a cold may make it less likely for you to go out and run naked in the snow.

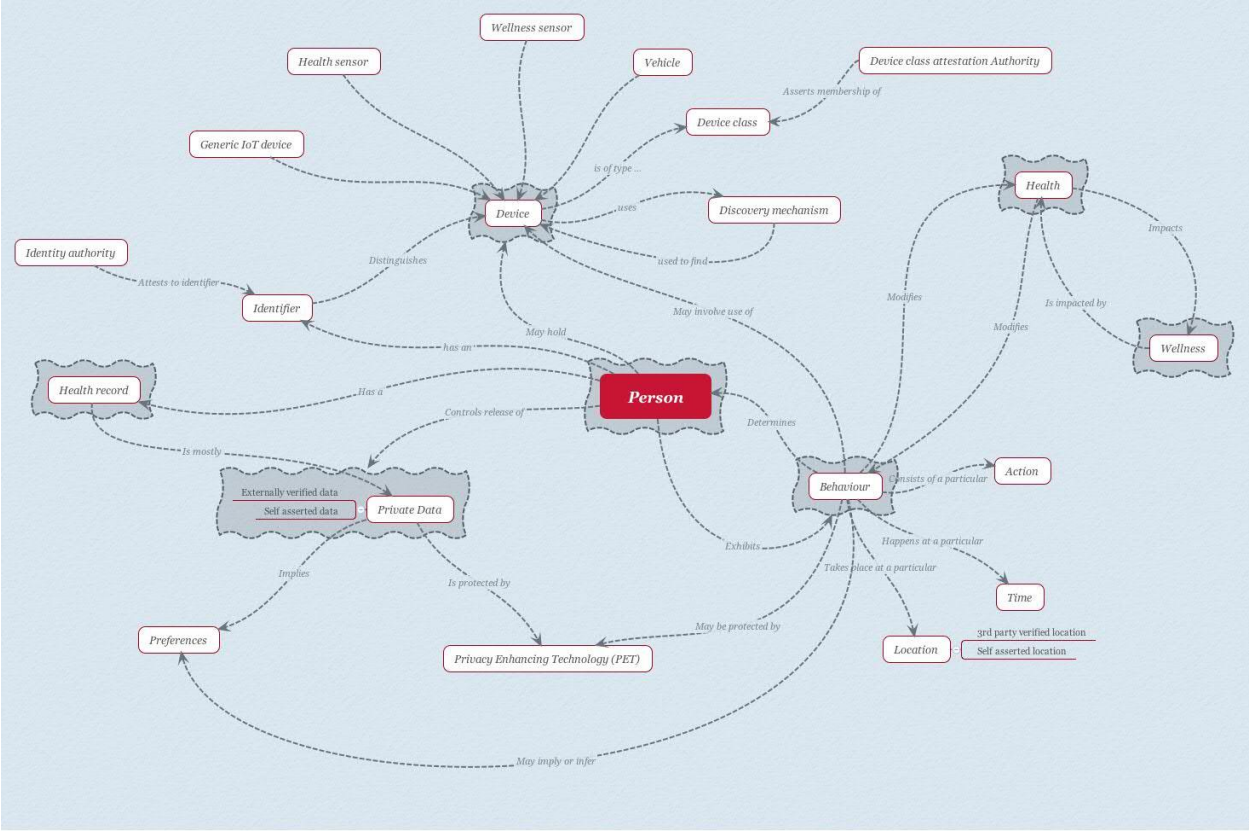

Figure 1: Concept relationship diagram for patient/person in health

So, the number of variables in the eHealth domain is constantly changing. Whilst this is addressed in the "behaviour" element there is a degree of complexity surrounding the "time" element which needs to be explored. A common conceit of health is that it is a cradle to grave issue but this ignores genetic

[3] Established by the US based National Academy of Medicine (https://nam.edu/about-the-nam/)

predisposition, it ignores the influence of the parents (particularly the mother whilst carrying the child to term), and it ignores the lessons we can learn after a death. The impact is that health has to be considered as a minimum as from cradle to grave but sometimes consideration must be given to events outside these limits.

eHealth and privacy

It is clear that health is a very private and personal concern and that is reflected in the records that surround it. When establishing a health record for an individual it is not known who will need to access it but even with this intrinsic uncertainty it is certain that it is privileged information. It is also clear that whilst a health record “belongs” to a patient as the subject of the record, it also “belongs” in part to the health professionals who treat that patient, who, as part of their duty of care under their medical ethics obligations, are obliged to maintain the confidentiality of that record, and only to share knowledge of the contents in the interests of the patient. However, in the real world there is a difficult distinction between what is private and what may reveal the identity of a particular individual. In some cases it may be justified for a health professional to access health records of patients without their knowledge or explicit consent. In the eHealth environment the privacy concerns can never be diluted and part of the activity that will need to be undertaken is to ensure that such issues as private by default are properly considered in eHealth work.

Defining Use Cases for eHealth

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, with a particular 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 a collection of medical and other personal data, and, acting upon that data, ultimately 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.

Whilst detailed examination of use cases inevitably leads to technical discussion that is out of scope of the present document, the main cases of communication that eHealth technologies have to consider are broadly as follows:

- Patient originated: Health Professional[4]terminated
- Health Professional originated: Patient terminated
- Health Professional originated: Health Professional terminated

There are some additional broad cases of communication for eHealth that add the Health Authority and the Citizen as actors for the purpose of wider notification of health incidents for example.

- Health Authority originated: Citizen terminated (one way communication)
- Health Professional originated: Health Authority terminated (noting that this is an essential element for control of notifiable disease)

In addition use cases have to consider eHealth intervention types:

- Telemedicine
- Telehealth
- Remote monitoring
- Mobile monitoring
- Therapy intervention

[4] The Health Professional could be equipment rather than a person

- Emergency intervention
- Wellness monitoring[5]
- Exergaming[6]

Finally use cases have to be considered with respect to the topology of the communications:

- Unidirectional
- Acknowledged uni-directional
- Symmetric bi-directional
- Asymmetric bi-directional
- Multicast (one to many)
- Broadcast (one to all)

The purpose of all of these use case scenarios is ultimately both successful diagnosis and successful treatment leading to a condition of good health for all. The more data that the health professional has available the more likely it is that diagnosis will be correct and the resulting treatment a success. One way to achieve this is to encourage the doctor patient dialogue to be longer, to be more wide ranging and to be open. It is also necessary to have some knowledge of the patient's history (genetic and environmental). There is therefore a certain degree of intimacy in the doctor patient relationship necessary to perform a rapid diagnosis. The reality however is that such intimate relationships are difficult to achieve with the current ratio of health professionals to the general population, thus diagnosis tends to occur over a very short period. The capability, the potential, of ICT standards-led eHealth, is that the doctor can extend the data gathering period to give him the data necessary for diagnosis and treatment. The result is that by using technology we can simplify the discussion of use cases in eHealth to a simple set of statements:

- A ***Diagnostic sensor*** delivers a ***Measurement*** taken at time ***t*** in ***Context*** relating to ***Patient*** to ***Health professional***
- A ***Patient*** exists in a particular ***Context***
- A ***Diagnostic sensor*** complies with the specification for ***Measurement*** published by ***Publisher***

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 Body Area Network, and eHealth middleware; the Health professional will receive alarms and will when necessary or convenient access the information. The focus for eHealth is on the patient and their interaction with a

[5] 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 and may not comply with acceptable standards of security and confidentiality

[6] Exercise through game playing with the distinction that this refers to video games where body movement or reactions are used within the game

health professional and thus making most effective use of time and technology to achieve a better interaction.

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 (these can be modelled as proxies for the patient and health professional). 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. As social and political support evolves for e-health, patients are demanding a greater role in decision making and easy access to their personal records and medical information. In return they are carrying increased legal, personal responsibility for their treatment.

The consequence of the longevity of people, that we want to both extend and improve in quality, is that the set of actors in eHealth both by role and by name has to be mutable over the lifetime of the system. This inevitably means that the eHealth/Health system has to encompass both uncertainty and mutability which leads to complexity. This complexity has to be resolved such that health records for example can remain secure over the life of a patient, and that new technologies can be introduced without compromizing the integrity of the system.

The presentation of linking telemedicine centres serving the patient, and the supporting ICT infrastructure offers an alternative way of looking at use cases in eHealth, as shown in Figure 2.

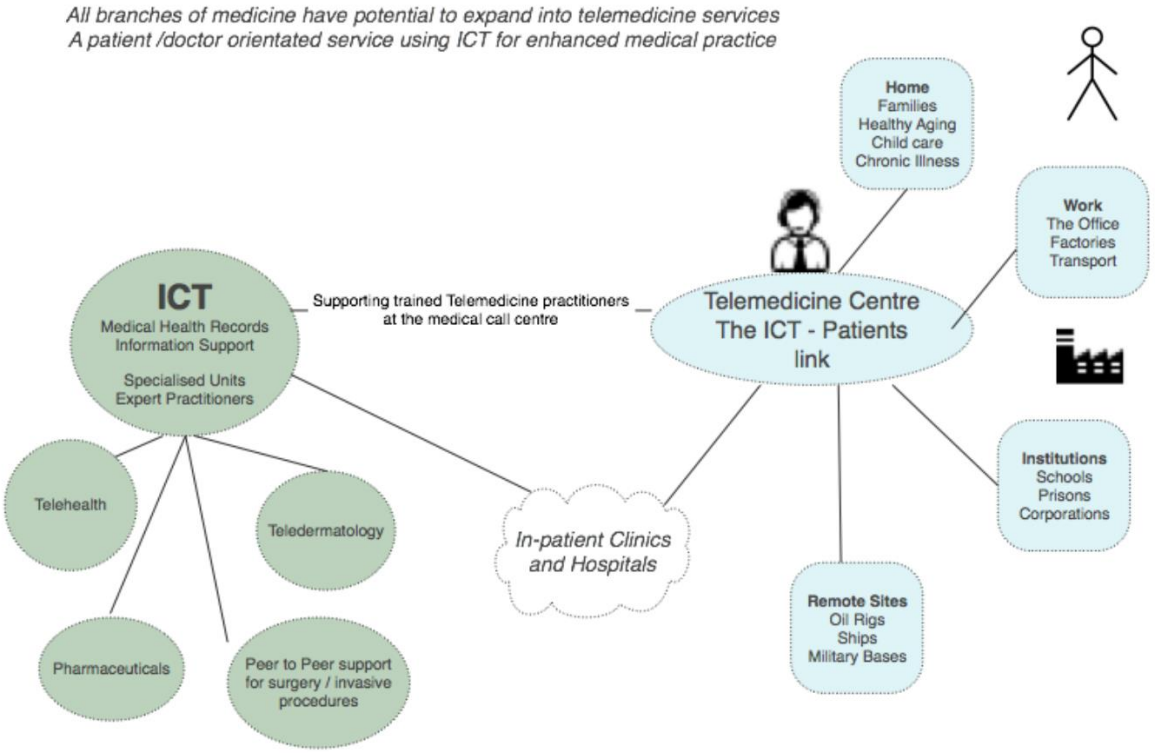

Figure 2: Linking telemedicine centres with ICT facilities

Expectations and scope for standardization in eHealth

The health environment is highly mutable and it has to be ensured that the standards that provide the interoperability backbone for eHealth are sufficiently flexible to meet both societal and business expectations that come from good health. A key to this is the interconnection fabric, the digital communications capabilities, that are addressed in the work done in networks standardization. These must be able to address the requirements for connection topology that will come from eHealth.

Interoperability - the key to a solution where more than one stakeholder is involved

When a patient presents with a problem, the diagnostic tools and methods, the means to describe the outcome of the diagnosis, the resulting treatment and so on, have to be sharable both inside and outside of the wider health system. This core requirement arises from acceptance that more than one health professional will be involved. If this is true they need to discuss the patient, they need to do that in confidence, and they need to be accountable for their actions which need to be recorded. Some diseases are “notifiable” and, again, to meet the requirement records have to be kept and shared. When travelling, a person may enter a country with an endemic health issue (e.g. malaria) and require immunization or medication before, during and following the visit. Sharing knowledge of the local environment and any endemic health issues requires that the reporting and receiving entities share understanding.

Shared understanding and the sharing of data necessary to achieve it is the essence of interoperability. No matter where it starts, eHealth cannot progress without interoperability and a secure digital platform as its foundation.

In terms of roles and expectations for standardization the primary expectation is that the standards lead to interoperability. For a system as complex as health this is not simply a choice of radio frequency for wireless devices in a health clinic, or just of the health records used to account for the chargeable time of a health professional, but requires interoperability across the knowledge stack. The intent is that data that is required to make decisions can flow from the sensors through to the decision-making apparatus at the heart of health provision.

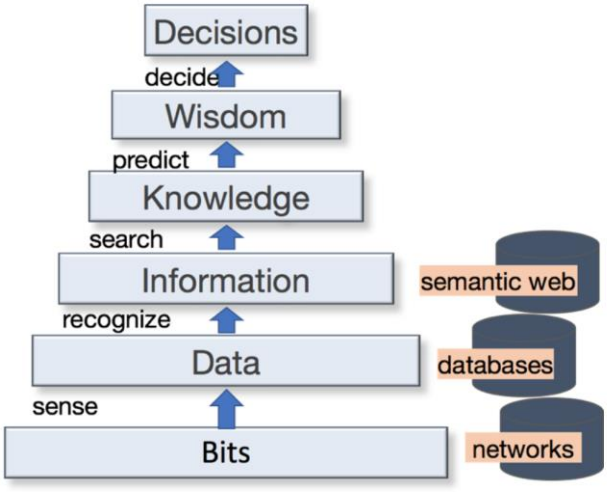

Figure 3: Hierarchical relationship from data to wisdom

An important aspect of standardization in this knowledge stack is to recognize and examine the standardization of the health records that will form a significant part of the conduct of diagnostic and preventative medicine. Simply, healthcare 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 on patients' rights in cross-border healthcare. Whilst is it 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 advises against it. Furthermore, if such a centralized supranational server was to exist the political leverage afforded to the hosting country would reasonably be considered a significant source of risk to the operation of such a resource and thus advise against such a design.

In the realistic assumption that health records will be stored in multiple locations, and be of variable size and sensitivity, this again feeds back to the core requirement for interoperability at each of the semantic, syntactic and base dictionary levels.

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.

A health record has a number of purposes:

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

A health record will also be used in a 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.

Supply chain in eHealth

It is well documented that ingesting some things will kill you. It is also well documented that some poisons accumulate in the body. If we assume that what goes into the body is part of the supply chain and what comes out of the body can be used as part of a feedback loop then it is reasonable position to take to consider how supply chains impact global health and to then work on how the eHealth supply chain works.

Eating "safe" food, drinking "safe" water, these maxims may be enforceable by controlling the supply chain of food and water such that consumers (potential patients) may be prevented from ingesting unsafe food and water. We can assert that supply chain integrity is directly related to assurances of public health.

Some consideration should be given to exhaust analysis in active health monitoring. This is obviously akin to the feedback loops in Internal Combustion Engine controls where the state of health of the engine can, in part, be assessed by analysis of the exhaust gasses (measuring the completeness of combustion and using this information to modify the input). In other words we need to determine the controls, in the sense of feedback and feedforward mechanisms, in eHealth.

A maxim which has long been held to be important to the best principles of staying healthy, that of healthy body, healthy mind, now is finding new significance in the 'connected' world where fitness devices are being actively promoted and where patients are expected to help themselves by conducting a healthy life-style.

In ETSI a number of groups are looking at aspects of supply chain integrity and whilst this is often attributed to security it does impact all groups in standardization.

Design for all – coping with an ageing population

Very simply put, the percentage of the population that is classified as elderly is increasing. For example, in Germany in the period from 1970 to 2014 the percentage of the population classified as elderly rose from 13.18% to 21.45% whilst at the same time the percentage of the population in work went from 63.65% to 61.48%, but more crucially there has been a decline from a peak of 70.18% in 1986/7. This is fairly consistent with the overall trend in the OECD nations where the working proportion of the population supporting the non-working proportion is steadily reaching the point where for every 3 working persons there are 2 others being supported. It is also a little bit unclear as the definitions of the OECD data identify an elderly person as being over 65, and a young person as being under 15 with the working population being those in the middle. In practice the bulk of countries in Western Europe are moving these limits such that state-retirement age is moving upwards, and the expectation of involvement in formal education is such that active involvement in the work force is likely to be much beyond the age of 15. It is also significant that even if 60% or so of the population is of working age, not all of these will be willing or able to work. The hard reality of this is that as societies mature (taking a very broad assumption that western Europe is a mature model) the funding of healthcare is going to be increasingly difficult if only 40% of the population is paying taxes or insurance premiums to fund it. Once again technology may help in bridging the gap between expectation and realization.

Within the ETSI standards environment eHealth will be expected to leverage the expertise in groups including the Human Factors group (HF) and others who have developed standards that support the design for all concept and who would be expected to take a lead in expanding the concept for any specific aspects applicable to eHealth.

Ethics and ethical concerns of eHealth

A simple question asked of eHealth networks "Can the Hippocratic oath be applied to machines (i.e. how to assure that devices ***do no harm***?". Whilst it is accepted that health professionals sign up to agree to some code of ethics and have a number of penalties that can be applied if they fail to act ethically there is as of this writing no similar code when a health professional is represented by a machine. This may

require that eHealth machines act together as Ethical Turing Machines, but as of this writing such a thing is not known to exist.

In order to reach ethical eHealth we need to have a definition of ethical behaviour, and a common view is that ethics address how an organization ensures that all its decisions, actions and stakeholder interactions conform to the organization's moral and professional principles. The organization in eHealth is unfortunately unclear but as a system it may be necessary to view ethics across the entire supply chain.

Ethics involves practical reasoning. In practice this requires the system knowing what is, on balance, right. However we also need to recognize that ethical frameworks have review and management structures, and penalties if the ethical codes are violated. Simply put a person acting unethically will lose their job.

The move in the long term to semi-autonomous or fully-autonomous machine driven eHealth will require that ethics is addressed. This is not going to be a simple task.

The Way Forward

Whilst the "Elephant in the room" of who pays for healthcare cannot really be avoided, the ethical viewpoint that everyone requires and expects to have access to healthcare is assumed to be universal. As society in all its dimensions can be considered as a benefactor, this paper assumes that ways will be found to fund eHealth and consequently a healthy world population.

The strategic objective for ETSI's involvement in eHealth standardization can be written as:

To create a standards based market for the health and wellbeing of the global population.

Achieving such a goal will take many years and involve many thousands of stakeholders. Many of the stakeholders will be unaware of their role as stakeholders and many of them may not become actively involved for some years. Some stakeholders will be passive, others will be active. Active stakeholders may be such across the entirety of the project, some will be involved for only a short period. In order to achieve the strategic goal it is also clear that an SDO such as ETSI cannot be the only standards contributor, rather a number of SDOs will have to come together and agree their role in achieving the strategic goal. Within ETSI there is already one group with the remit to do such work and this is EP eHEALTH. However, by itself EP eHEALTH can do very little other than guide and encourage. Every ETSI Technical Body, and every associated SDO on the global stage has to undertake its role too. It has to be recognized that for every person on the planet, health is a lifetime concern, and this means that for every government on the planet with a role to ensure the health and safety of its citizens, that these governments too have a role in the standards development strategy. Within the global standards community, and the global governments in general, the commitment of time, manpower and financial resources to eHealth standardization is essential. As indicated above there are standards required to be developed within an eHealth strategy for all ICT technologies, there are also gaps in technology and capability that will need to be closed. It is essential to work together to build eHealth.

Buying into the strategic plan will be made more straightforward if benefits can be shown to be realistic and viable. In order to achieve this, periodically it will be essential to demonstrate proofs of concept and to sponsor research. Such proofs and research are illustrated in the drafts of the plans illustrated below that extrapolate from the conventional standards development concept of the ISDN era. The core concept of a 3-stage development plan is still valid:

- Stage 1: Gathering objectives and requirements, laying out the technical strategy
- Stage 2: Identifying the core architecture that is necessary in an abstract way to achieve the objectives and to satisfy the requirements.
- Stage 3: The nitty-gritty of what an implementation has to do. This is the only part of the process in which mandates are made, and recommendations given. This is also the only part that is formally tested although there should be a clear link from every mandate to an objective and requirement stated in stage 1.

The conventional model of standards development is shown in Figure 4.

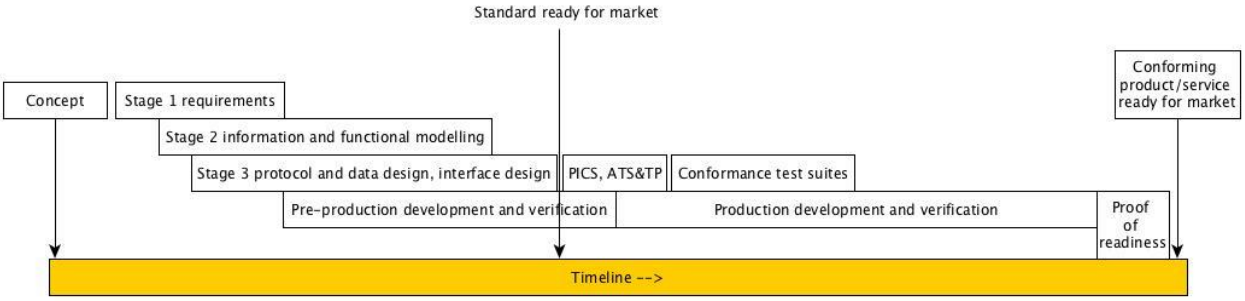

Figure 4: Conventional standards development lifecycle

The base model is extended as shown in Figure 5 with a pair of views: Proof of Concept (PoC), often used to prove that the core technology will actually work; and a Reference Implementation which may involve a mathematical model or source code. The PoC is a consequence that a lot of the technology and services that will make up eHealth will be novel and it is inevitable that they will need to be proven as concepts prior to standardization. In some instances it will be necessary to develop reference implementations (actual implementations of a standardized technology or service) in order to manage the market where safety and security have to be managed in a particular way.

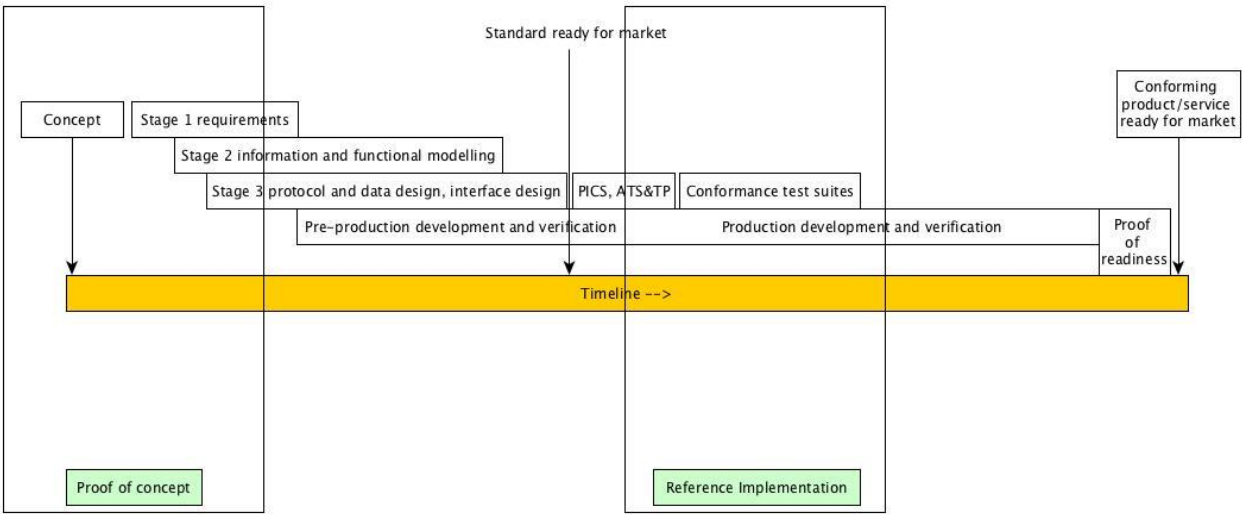

Figure 5: Extending the standards development lifecycle with proof of concept and reference implementation

eHealth cannot be delivered without the interaction of health professionals. For example, the semantic data model for one form of health specialization (e.g. oncology) may not be transferable or interoperable with other health specializations (e.g. paediatrics). However, in a data transmission system there may be no distinction (it is just bits on a wire) but there may need to be. Understanding of the role and benefit of ICT (eHealth) to health requires that health professionals can access and contribute to the development, and ultimately be recipients of the benefits for their patients.

The role of ETSI's Technical Bodies in eHealth standardization

Introduction

The purpose of standards is to enable interoperability and through that to open markets. ETSI has a very wide exposure to the elements of technical provision in eHealth from radio, through networks and services.

Historically ETSI has tended to focus on the Communications in ICT standardization, and to some extent even specialized in telecommunications. However, it is increasingly difficult to address any aspect of ICT in isolation. Thus, ETSI's role addresses a number of aspects of communication technology and brings them together in an ICT framework.

In simple terms taking the use case model from earlier it is clear that ETSI is in a position to tackle most of the highlighted terms.

- A ***Diagnostic sensor*** delivers a ***Measurement*** taken at time ***t*** in ***Context*** relating to ***Patient*** to ***Health professional***
- A ***Patient*** exists in a particular ***Context***
- A ***Diagnostic sensor*** complies with the specification for ***Measurement*** published by ***Publisher***

The role of delivering measurements from the sensor is clearly a communications role, a natural role for ETSI to address. Defining what a sensor is and what its measurement metric is, is already being defined in ETSI's various Technical Bodies but in particular TC smartM2M, oneM2M and TC CYBER with their activity in semantic interoperability. ETSI has huge experience in the means to achieve assurance of standards compliance. eHealth can leverage this with the conformance test support and interoperability test support offered by ETSI's Centre for Testing and Interoperability.

Networks and systems

There are a number of bodies in ETSI that address networks and systems. eHealth is not specific to any of them, but the general constraints of eHealth will need to be met by all of them. This means that items such as data confidentiality, locality of information processing, visibility of the nature of information processing, latency and delay in information processing and many other aspects have to be considered in the design of networks and systems of networks.

Whilst as stated little of this is eHealth specific there is a specific dependency: If a network cannot meet the requirements of an eHealth request for security, latency, delay and throughput it will not be allowed to transport the eHealth information. If eHealth is to be ubiquitous then all technical specifications for the communications infrastructure have to be eHealth ready.

Radio link technologies

Radio is critical in eHealth. Radio links have to be able to support the interconnection of health sensors and to achieve those links with a degree of assuredness managed by the eHealth application. This, like the requirements on networks, is not eHealth specific but may be used by the application to filter some radio technologies from selection for certain services.

Human factors and user requirements

The core assertion throughout this white paper has been that eHealth is person-centric and revolves around supporting the doctor-patient relationship. The expertise in each of ETSI's USER and HF groups is in formulating standards for how to develop the means by which human actors interact with systems. It is expected that USER and HF will act to define standards and guidelines on the means by which users interact with the eHealth system.

Security and privacy protection

It has been stated a number of times that eHealth has to be secure. The consequence of this is that what secure means has to be defined. This requires that groups such as ETSI's technical committee for Cybersecurity define standards for system integrity, system confidentiality, for identification of actors and their authentication and authorization across very large distributed systems with a largely undefined lifetime (certainly longer than the lifetime of a single cryptographic algorithm or key). Furthermore, the security model developed has to be applicable to all the components of an eHealth system that may transit many technology and administrative domains.

In ETSI and other SDOs there has been significant work in developing guiding principles for privacy protection in systems. The further application of such principles in the eHealth environment is a matter of urgency to establish a "private by default" as well as a "secure by default" and primarily a "safe by default" platform. In undertaking such work due care will have to be paid by the standards groups to recognize the legal frameworks for sharing of personal data and of such regulation as the GDPR and its equivalents in non-EU domains.

The future vision

In the preceding discussion the case has been made for involvement of the SDOs, mainly those from ETSI, and for the development of technical standards. However, it is clear that other strategic decisions need to be made: What is the role of regulation? What is the role of finance? What is the level of responsibility of each stakeholder?

eHealth is not simply a technical topic and demands open discussion. Whilst ETSI is a competent technical SDO it has no significant track record in the kind of societal change management that eHealth represents. A classical path mapping progress over time to the end goal can be given (see Figure 6). However to get to this we need to start somewhere. This paper is one starting point but the real starting point is when the stakeholders across ETSI, regulators, health professionals and others agree to sit down to plot the actual graph.

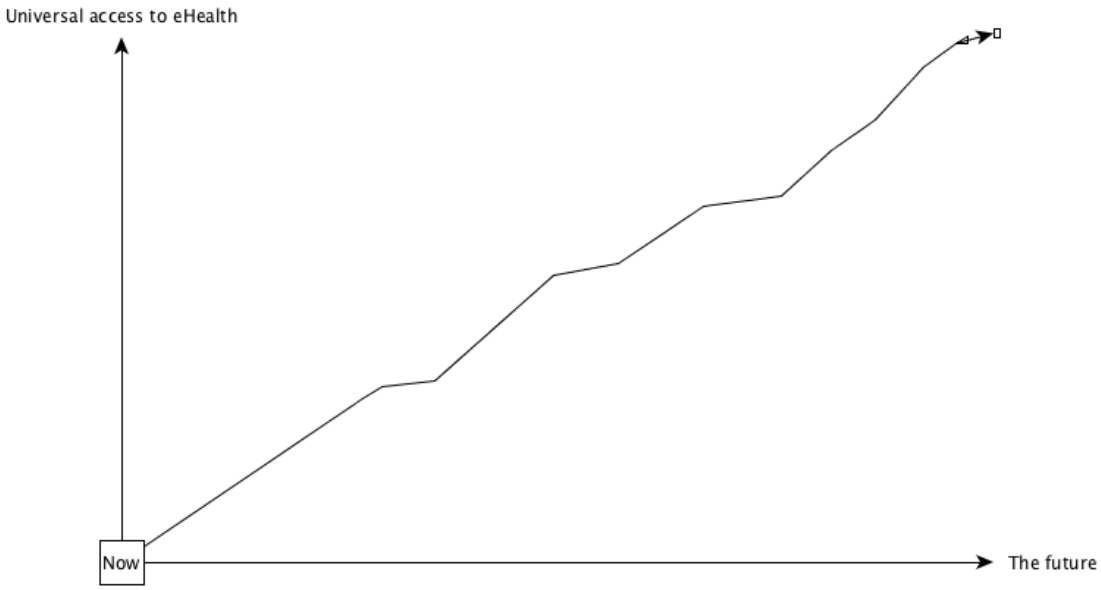

Figure 6: Getting to our goal

It would be nice to believe that the stakeholders agree to support the vision of eHealth as outlined in this paper, that stakeholders work both independently and co-operatively to deliver the necessary standards. The authors of this paper hope to see this real vision being embraced and will continue to support it across the long haul to achieve the end goal. However realistically we have to recognize that the end point will be pushing further ahead daily.

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