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The role of SDOs in developing standards for ICT to mitigate the impact of a pandemic

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Scott Cadzow has over the past 25 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 a large number of technical bodies and has acted as an expert to a number of Specialist Task Forces. 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. In the wider EU standards and technical R&D environment Scott has contributed to reports from both JRC and ENISA and has been involved in a number of projects under the FP7/CIP/H2020 umbrella looking at the societal, security and privacy aspects of smart cities.

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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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Foreword – the context of this report

COVID-19 (Corona Virus Disease 2019) is a particularly aggressive form of coronavirus discovered in 2019 that has rapidly spread across the human population of the planet, becoming classified by the World Health Organisation as a Public Health Emergency of International Concern on 30 January 2020 (in short it was recognised as a pandemic in late January 2020 only 1 month after its official recognition). The virulence of COVID-19 is 2 to 2½ times more than that of seasonal flu and its mortality rate is significantly higher, with a hospitalisation rate an order of magnitude higher again. This is not a mild pandemic, it is a serious, often lethal, health condition, the impact of which is seriously detrimental to social and economic life across the world.

This short paper acts to identify a "call to arms" to Standards Development Organisations (SDOs) and their constituent members to ensure that when the next pandemic arrives we can rely on greater harmonization of the supply chain. As an SDO in the ICT domain ETSI is obviously a key party in the chain, but it is obvious that ETSI cannot solve the global supply chain necessary to the protection of the health of the global population by itself. Rather ETSI is one of many hundreds of partners who must come together to identify and carry out their responsibilities in defining appropriate ICT solutions.

ICT today, has its foundations in data. ICT has passed many of the hurdles of a developing technology of achieving reliability and interoperability, and has now moved to become largely utilitarian. In much the same way that society has learnt to expect electricity on demand, and clean water on demand, ICT capabilities are now expected to be available on demand. Driving this utility to social good at this time is what this White Paper is all about.

Pandemics are rare but even rarer is a health crisis that affects *every* citizen of our modern, interconnected world leading to global, economic crisis. Far reaching political decisions are being made and changed daily. These are supported by data supplied by communications systems and advanced medical technology. But this has not been enough. It is vital that we learn lessons from the experiences of today so that we can better tackle the pandemic of tomorrow. There will be one, it is simply a question of time, and how we will respond.

Much of the document that follows highlight the point that whilst very little of ICT is eHealth specific, all of eHealth depends on ICT. If a network cannot meet the requirements of an eHealth request for security, latency, delay, reliability 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 and designed with the eHealth domain in mind. In short ICT standards should be designed with the assumption that they will be applied in a health environment and as part of a global ICT solution to evolving health issues.



Section I

Standards for a post COVID-19 world

As a standards body with a societal role ETSI has to ask what it, and its partner SDOs, can do to help. A few simple steps are identified in this white paper that are worth taking immediately:

1. An Ethical code and standpoint – the standards that ETSI produce shall follow a general principle of "doing no harm". Additionally the standards that ETSI produce shall encourage a safe, private, and secure society by the use of effective ICT standards.
2. ETSI shall lead by example to ensure that all standards including those from its partner SDOs are freely and widely available to ensure that standards can never be cited as a barrier to development of solutions.
3. ETSI and its partner SDOs should work to resolve any uncertainty regarding legislation that applies to the use of ICT in a medical or health care environment, in order to ensure that when ICT standards are designed with the assumption that they will be applied in a health environment, that they can be deployed in such environments.
4. ETSI and its partner SDOs have to actively engage with the health domain (and vice versa).

A great range of figures are available relating to the severity of the COVID-19 pandemic and even if few are ratified, all are frightening. As of the end of April 2020 there were over 3.2 million reported cases and a mortality rate of between 7% and 19%. Particularly shocking has been the revelation that more than half of patients receiving intensive care do not recover. Even more disturbing is the fact that the virus has struck poorer and ethnic communities twice as harshly as white, middle class families.

The flow of data has been central to public health decisions and generally, countries and health providers have acted transparently in its provision. But the lack of standardization in this data flow (e.g. format, provenance) has made comparisons difficult. There is no 'like for like' in accounting for the spread of the disease or for its victims. All however would agree that the use of ICT has been key to creating effective treatment schedules and also to maintaining 'lock-down' measures.

As stated in the foreword, as all of eHealth depends on ICT, it should naturally follow that all ICT standards should be designed with the assumption that they will be applied in a health environment.

It is clear that there are already many ICT products, services and standards already being deployed that are assisting COVID-19 responses. A summary of current and anticipated work in ETSI is given in section 2 of this paper.



Standards in ICT as an enabler for responding to a pandemic

This paper avers that good data can lead to good information, that can lead to accurate diagnosis, effective therapeutic intervention, and accurate tracking of recovery.

There are many stages in the management of a pandemic and there will be a lot of argument regarding those stages. For our purposes and to study the role that ICT can take we consider the following stages only:



The core conceit of ICT in health (eHealth) is that this cycle is made possible by 2 things:

1. Data; and,
2. Interoperability

Data for a pandemic has to be able to cross borders. It has to be gathered at relatively low cost and be of sufficient quality. For the global population we cannot rely simply on human health professionals to do the tests. This suggests that SDOs prioritise development in the standards domain that enable medical and health data to be gathered, analysed, and acted on.

There are of course many legislative hooks for pandemic planning:

- Regulation (EC) No 851/2004, which established the European Centre for Disease Prevention and Control. The Centre's mission includes **identifying**, assessing and **communicating** current and emerging threats to human health from communicable diseases.
- Article 12 of Decision No 1082/2013/EU on serious **cross-border** threats to health, which provides that the European Commission may recognise a public health emergency situation in relation to influenza epidemics with pandemic potential. This recognition enables the use of Article 2 of Regulation (EC) No 507/2006 on the conditional marketing authorisation for medicinal products for human use, which allows for the accelerated marketing of certain medicinal products in the case of urgent need, by means, of a conditional marketing authorisation and of the temporary option of granting a variation to the terms of a marketing authorisation for a human influenza vaccine, even where certain non-clinical or clinical **data** are missing'.
- Regulation (EU) No 282/2014 on the establishment of a third Programme for the Union's action in the field of health (2014-2020), which states that, in order to minimise the public health consequences of **cross-border** threats to health as set out in the aforementioned Decision (No 1082), 'the Programme should support coordinated public health measures at Union level to address different aspects of cross-border health threats, building on preparedness and response planning, robust and reliable **risk assessment** and a strong risk and crisis management framework'.



All of these regulations or decisions allow for the use of state of the art ICT technologies in gathering data for analytic purposes. However it is quite difficult to find explicit enabling directives to ensure that the ICT community is engaged with the regulation. In some cases, for the world of clinical medicine, technologists often stumble at the first hurdle, as access often requires to be a practicing medical professional. Such hurdles need to be removed and barriers to entry of both SDOs and the ICT community they represent extinguished. This, at a stroke, will allow more intellectual effort to be expended on solving the long term structural barriers to developing a connected eHealth world. This will have a huge impact and provide immediate benefit to everyone. It has the potential to increase the coverage of good health care across society. **It is simply the right thing to do.**

One easily observed issue is that many ICT capabilities are not designed as medical enablers. With rare exceptions, such as smart enabled pacemakers and defibrillators, ICT capabilities do not work directly on the body. It may be argued that a pacemaker is addressing a symptom and not a root cause – it corrects arrhythmias. If a signal generated at A is expected to reach point B but doesn't get there it is possible to bypass the routing problem and to directly stimulate the signal at point B. This doesn't fix the signal transmission problem. In the human heart though it does fix the issue in that it allows the heart to keep beating. It is a crude solution to the problem and adds as many problems as it solves. In computing parlance it is a hack – expedient in that it works, but is also inelegant and brutal – it is somewhat like replacing a frequently tripping fuse with a metal bar as a bypass – it will deliver electricity to where it is needed but the safeguards have gone, and the root problem has not been fixed.

Once a contagion is labelled as a pandemic it may already be too late. It has already spread across borders and impacted significant numbers of people. However, the pre-requisite to make a declaration of a pandemic is identification of the contagion or virus, and to assess its impact. This requires tests and logistically this is a major problem. How much testing is reasonable? How do you capitalise on positive tests to maximize the value of the data from testing? Is there an effective test that can give results and which allows quarantine action to occur before there is a risk of new contagion (the tested party passing on the virus to somebody whilst the result of the test is unknown)?

Example of ICT application - Contact tracing

There are good ICT techniques and technologies that can help to build a picture of how a contagion spreads, and with data on the risk of infection, assist in determining who has been infected and who is at risk. This idea has become termed "contact tracing" and works on the principle that if "Alice" is tested and found positive, and she has interacted with "Bob", then perform a test on "Bob", whilst isolating "Alice". ICT enabled contact tracing is a tool that deviates from asking "Alice" directly about her movements and contacts, but builds a picture of proximal contacts "Alice" has had over a finite time period.

There are a number of approaches to achieving ICT enabled contact tracing, with trade-offs in privacy and data gathering speed. A primary point that has to be considered is that contact tracing is **not** a diagnostic tool – it is a tool that may assist in making decisions of who to test. A bad design may lead to good understanding of proximity but with significant risk of both false-positive and false-negative assertions, a good design may augment the contact tracing for a true-positive test. Thus contact tracing has to fit into a wider data and test system.

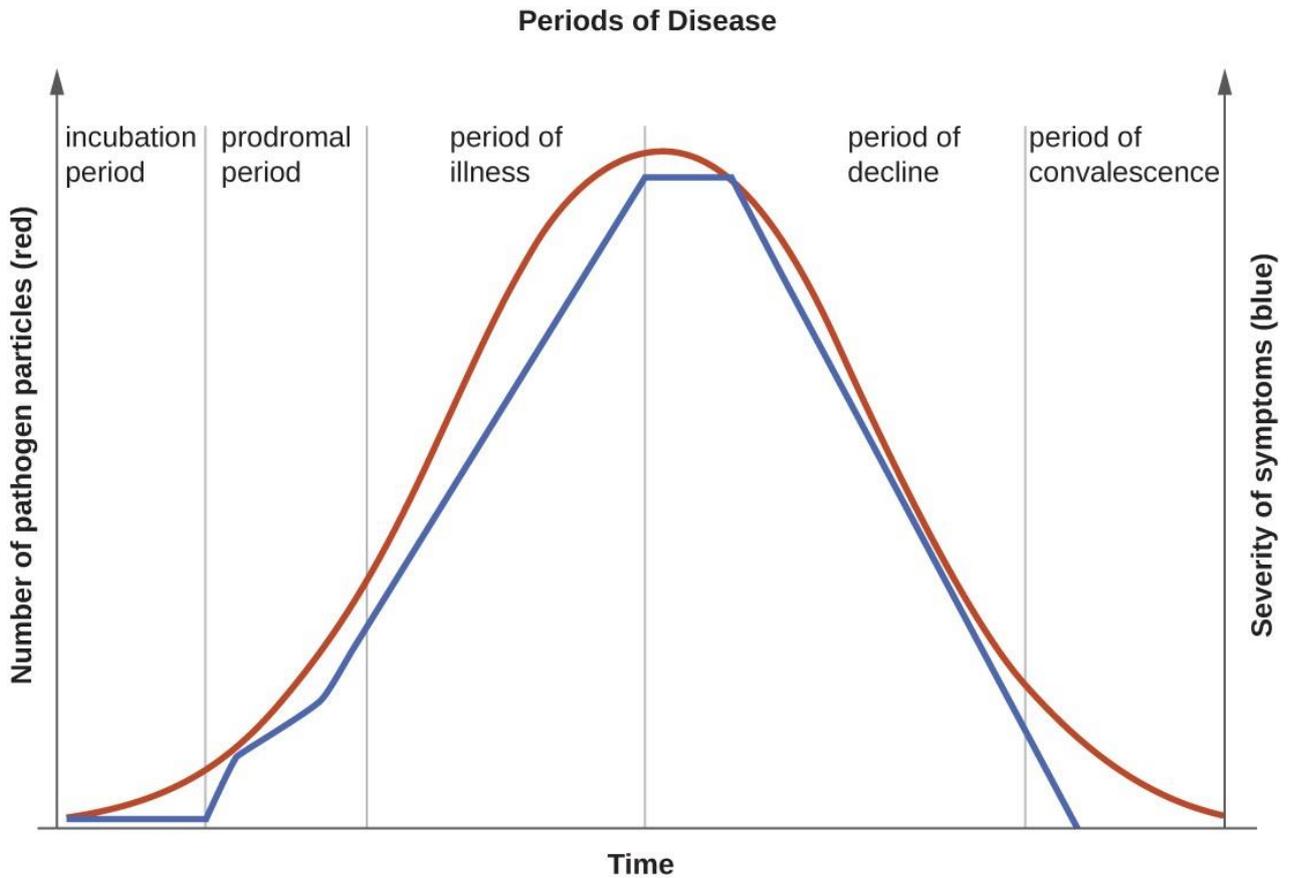


Smartphone technologies can be used to determine if another phone is close, and as the phone is a proxy for a person, then detection of nearby phones is akin to "tagging" a person as being close to you. It is clear that we can use technology to assist in contact tracing. However just because a technology can do something it is not always clear if it should. Is it ethical? What should be done with such technology once the risk of contagion has been eradicated?

For highly virulent cases the most recommended procedure to minimise transmission is to quarantine and treat those who are infected. Globally a number of strategies for lockdown have been used to mixed effect. The key point being to quarantine all possible carriers as early as possible and ideally for a period significantly longer than the sum of the periods of a disease (incubation → prodromal → illness → decline → convalescence). Those who reach the final stage (decline and convalescence) should have antibodies that offer a significant degree of immunity, thus they are very much less likely to pass on an active virus. If contact tracing is applied, in theory the number of people in quarantine at any time is less, as it only quarantines those with the virus or at risk through contact with an infected person.

Unfortunately, COVID-19 is a mutant and mutable virus so immunity to one mutation does not guarantee immunity from a future mutation (in this regard it is similar to other coronaviruses). There are a great many scientific papers on that very topic and this paper is not attempting to say what is the best strategy, rather it is attempting to identify the role of ICT in any strategy, present and future.

Ethical, secure, privacy preserving contact tracing has obvious benefits. As a solution it requires many of the things that ICT is good at and furthermore where standards are hugely beneficial. This starts with the goal of standards to achieve interoperability and shared understanding. The data models, the data transfer, the data analytics, all of these can be standardised. One clear advantage is that they can also build upon existing standards.



There are a number of ICT domains that have a role to play in building a framework of data, and communications that can help to mitigate, not just a pandemic, but any health issue. In practice eHealth is not specific to any of them – in other words we do not build a separate provision just because it is a health issue but we ensure that ICT technologies and systems support evolving health requirements. 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.



Section II

ETSI groups involved in standardization issues for pandemic crisis response

The ETSI Secretariat and the authors have identified ETSI groups that may be directly impacted by the concerns raised in the core of this white paper. The technical officer for EP eHEALTH, Patrick Guillemin has liaised with them to build this listing of the opportunity open to a number of ETSI Technical Bodies to address the requirements of the wider medical and healthcare community and to transpose those requirements into standards for ICT.

It is strongly asserted that ICT in eHealth crosses all of the layers of the conventional OSI model from physical layer through to application, and moreover across both physical and virtualised implementations. It is hoped that by engaging the experts in these ETSI TBs that the vision of eHealth ubiquity wherein all technical specifications for the communications infrastructure will, by default, be eHealth ready and can be met.

The ETSI Secretariat has identified current ETSI groups that are involved in “developing standards for ICT to mitigate the impact of a pandemic”. These groups include: a new ISG E4P, EP eHEALTH, EPP 3GPP, TC ATTM WG SDMC, TC CYBER, SC EMTEL, TC ERM (TG UWB, TG11, TG28 and TG30), TC HF and USER group, TC ITS, TC SmartBAN, TC SCP, TC SmartM2M, and EPP oneM2M.

new ISG E4P

The ISG E4P aims to develop a framework and the consistent set of specifications for proximity tracing systems. The work will facilitate the development of backward compatible and interoperable proximity tracing applications to be used to combat pandemics by helping to break viral transmission chains.

ISG E4P will produce technical documents to define “Requirements for Pandemic Tracing Systems”, the “Proximity Detection”, and the “Proximity Tracing System”. The work will consider recommendations on Data Protection and Information Security, in compliance with GDPR and EC regulation, and the definition of the requisite APIs.



EP eHEALTH

As the coordinating body for ETSI's wider response and management of standards for eHealth EP eHEALTH is expected to form the 'horizontal' nucleus for the co-ordination of ETSI's activities in the Health ICT domain. This is producing a 'Hub for Health!' as the group seeks ways to work in close co-operation with all relevant TCs, EPs and SCs within ETSI, 3GPP, and others. Vital aspects to be considered by EP eHealth are: security of systems and data, quality of services, interoperability and validation by testing, usability. The contribution of EP eHEALTH will be informed by previous work on the 1st EP eHEALTH White Paper "The argument in favour of eHealth standardization in ETSI (September 2018)", the present white paper, and on active work items addressing "eHEALTH Use Cases" and "eHEALTH Data recording requirements for eHealth".

EPP 3GPP

Responsible for 2G/3G/4G and 5G standardisation where both mobile networks and connected devices are key to all actors in the health domain.

TC ATM WG SDMC

Working on Smart Cities and Communities eHealth requirements (and Use Cases) in cooperation with EP eHEALTH. The expertise offered in the context of this white paper will be based on prior contributions to the EUROCITIES reaction to the Covid-19 emergency, the Eurocities "View on Smart City and Smart Infrastructure role in eHealth views", and the publication "Data people cities - EUROCITIES citizen data principles in action"

TC CYBER

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 recognise the legal frameworks for sharing of personal data and of such regulation as the GDPR and its equivalents in non-EU domains.



TC HF and USER group

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.

TC SmartM2M

TC SmartM2M has been the lead TB in the development and promotion of the EC supported SAREF (Smart Applications REFERENCE) ontology. Further work to extend SAREF to support the wider eHealth suite of existing ontologies would be expected, building on work already active in eHEALTH and Ageing Well, Wearables and for enabling IoT Semantic Interoperability alongside work with the oneM2M partnership project on Semantic Discovery and Query in oneM2M.

EPP oneM2M

As noted for SmartM2M.

Others

Other TBs will play a significant part in ensuring that devices, radio spectrum, smart-cards, transport, body area networks and body mounted sensors, and many other areas together support the ITC for eHealth, eHealth enabled ICT paradigm at the root of this White Paper:

- TC ITS
- TC SmartBAN,
- TC SCP
- SC EMTEL,
- TC ERM (TG UWB, TG11, TG28 and TG30)

Closing remarks

The specific nature of any pandemic will be unknown in advance – the specific pathology will be, almost by definition, novel. However, the human immunological response to any infectious disease is the same. This further suggests that common aspects of using ICT technologies as a backbone utility for allowing accurate data to be used to break the back of the pandemic is always going to be a common factor irrespective of the specific nature of the pandemic.

Thus whilst very little of ICT is eHealth specific, all of eHealth depends on ICT.

Let us not forget that if the challenges to eHealth in Europe are usually related to personal privacy and security, for many other regions of the world, simple, affordable connectivity is often in short supply.



However, if a network cannot meet the requirements of eHealth for security, reliability, latency, delay and throughput it should not be used to transport critical eHealth information. The immediate challenge is to get those requirements articulated, in such a manner that the promise of ICT utility can be realized. This will lead to a long term vision of eHealth ubiquity wherein all technical specifications for the communications infrastructure will be, by default, eHealth ready. In short, ICT standards should be designed with the assumption that they will be applied in a health environment.

The next phase for assuring SDOs commit to ICT standardization in support of preparing to counter a pandemic is detailed planning of the coordination and harmonization plan. The commitment to doing the right thing is the pre-requisite of effective planning. Thus this White Paper is the call to do the right thing and serve as that pre-requisite.



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