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Foreword

This Special Report (SR) 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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Executive summary

The present document is structured as follows:

- clause 4 provides an overview of the pandemic to date, identifies roles played by ICT, and offers a rationale for the role of ICT standardization;
- clause 5 reviews some of the specific ICT applications in reacting to the COVID-19 pandemic;
- clause 6 addresses known constraints for application of ICT in pandemic response;
- clause 7 reviews the role of ETSI as an ICT SDO in pandemic response;
- clause 8 is where the present document considers the specific role of ETSI TBs in pandemic responses; and
- in clause 9 the main points raised in the present document are reflected back in a conclusion and summary.

In addressing the activities of clauses 7 and 8, the present document identifies the role of ICT standardization in the management of health crisis and the role of standardized ICT in societal recovery from such crisis.

- NOTE 1: The stimulus for the present document is the impact of the 2019 SARS-CoV-2 pandemic on global society.
- NOTE 2: Whilst in the context of eHealth the present document does not address the epidemiology of COVID or any other epidemic unless the epidemiology has a direct impact on the effectiveness of applying ICT.

1 Scope

The present document is a detailed review of actions to be taken by ETSI, in partnership with other SDOs and industrial development groups, in driving ICT standards to support societal responses to health crisis. The present document considers the role played by ICT in response to the SARS-CoV-19 pandemic and identifies where there were successes, where there were failures, and where ICT and particularly standards in ICT, may play a role in future mitigations.

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 White paper no. 33, 1st edition. May, 2020: "The role of SDOs in developing standards for ICT to mitigate the impact of a pandemic", Scott Cadzow and Suno Wood.

NOTE: Available at

https://www.etsi.org/images/files/ETSIWhitePapers/etsi wp33 eHealth standard role pandemic.pdf.

[i.2] Listings of WHO's response to COVID-19.

NOTE: Available at https://www.who.int/news/item/29-06-2020-covidtimeline.

[i.3] ETSI White paper no. 29, 1st edition, September 2018: "The argument in favour of eHealth standardization in ETSI", Scott Cadzow and Suno Wood.

NOTE: Available at

https://www.etsi.org/images/files/ETSIWhitePapers/etsi wp29 ehealth standardization FINAL.pdf.

[i.4] World Health Organization pandemic list.

NOTE: Available at https://www.gov.uk/guidance/high-consequence-infectious-diseases-hcid#classification-of-hcids.

[i.5] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

[i.6] Regulation (EU) 2021/821 of the European Parliament and of the Council of 20 May 2021 setting up a Union regime for the control of exports, brokering, technical assistance, transit and transfer of dual use items.

[i.7] ETSI GR E4P 002: "Europe for Privacy-Preserving Pandemic Protection (E4P); Comparison of existing pandemic contact tracing systems".

[i.8] ETSI GS E4P 003: "Europe for Privacy-Preserving Pandemic Protection (E4P); High level requirements for pandemic contact tracing systems using mobile devices".

[i.9] ETSI GS E4P 006: "Europe for Privacy-Preserving Pandemic Protection (E4P); Device-Based Mechanisms for pandemic contact tracing systems".

[i.10] ETSI GS E4P 007: "Europe for Privacy-Preserving Pandemic Protection (E4P); Pandemic

proximity tracing systems: Interoperability Framework".

[i.11] ETSI GS E4P 008: "Europe for Privacy-Preserving Pandemic Protection (E4P); Back-End

mechanisms for pandemic contact tracing systems".

3 Definition of terms, symbols and abbreviations

3.1 Terms

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

digital exclusion: consequence of making access to ICT a requirement thus excluding one or more members of the population to fully participate in society

ICT assisted: ICT capabilities acting as an accelerant in carrying out the function

ICT enabled: ICT capabilities being essential in order to enable the function

3.2 Symbols

Void.

3.3 Abbreviations

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

3GPP 3G (mobile) Partnership Project ACT Asynchronous Contact Tracing

AI Artificial Intelligence

AIDS Acquired Immune Deficiency Syndrome

ATTM Access, Terminals, Transmission and Multiplexing

BAN Body Area Network BMI Body Mass Index

CDC Centers for Disease Control and Prevention

NOTE: See https://www.cdc.gov/.

COVID-19 Coronavirus Disease 2019
DCT Digital Contact Tracing
DLT Distributed Ledger Technology

E4P Europe for Privacy-Preserving Pandemic Protection

EC European Commission

ECDC European Centre for Disease Prevention and Control

EMA European Medicines Agency

EP ETSI Project

EPP ETSI Partnership Project

ERM Electromagnetic compatibility and Radio Matters

ESI Electronic Signatures and Infrastructure

EU European Union

EUROCITIES Network of European cities

NOTE: See https://eurocities.eu/.

GDPR General Data Protection Regulation

GR Group Report

GS Group Specification HF Human Factors

HIV Human Immunodeficiency Virus

ICT Information Communications Technology

ISG Industry Specification Group IT Information Technology

ITU International Telecommunication Union

oneM2M oneM2M Partnership Project
PDL Permissioned Distributed Ledger

PHEIC Public Health Emergency of International Concern

QoS Quality of Service QR Quick Response

NOTE: Deprecated in favour of QR code.

RNA Ribonucleic Acid

SAREF Smart Applications REFerence ontology SARS Severe Acute Respiratory Syndrome

SARS-CoV-2 Severe Acute Respiratory Syndrome Coronavirus 2

SCT Synchronous Contact Tracing

SDMC Sustainable Digital Multiservice Communities

SDO Standard Developing Organization SmartBAN Smart Body Area Network SmartM2M Smart Machine-to-Machine

SPRP Strategic Preparedness and Response Plan

SR Special Report
TB Technical Body
TC Technical Committee
UK United Kingdom
US United States
UV UltraViolet
WG Working Group

WHO World Health Organization

4 Information Communications Technology (ICT) role

4.1 General considerations during the SARS-CoV-2 (2019) pandemic

The present document is compiled on the assertion that technology does not cause medical crisis, engender an epidemic, nor does it accelerate any epidemic to become a pandemic. Rather, as indicated in the title, "The role of ICT to enable health crisis management and recovery", the intent of the present document is to drive the use of ICT, and standardization of ICT, in such a way that any crisis, now or in the future, can be more effectively managed and thus the detrimental impact on society (in all its forms) minimized.

In Spring 2021 an extensive program of measures to ensure a safe reopening of society following recovery from the worst health impacts of the pandemic related to SARS-CoV-2 (2019), often referred to as simply COVID-19, was begun across much of the world. There is a strong political will to mitigate the impact of the virus, and to control the impact of its recurrence (by mutation), by continuing regulations for social distancing, mask wearing (shields), improved contact tracing of infected and at risk individuals, and by certification of people who are deemed to be of low risk or virus free.

NOTE 1: The term low risk or virus free is understood to refer to those individuals that have antibodies in their blood to the SARS-CoV2 virus and who have been classified as very unlikely to pass the virus to other people.

NOTE 2: It is widely understood that SARS-CoV-2 will become endemic or hyperendemic in due course.

NOTE 3: Eradication of coronaviruses is considered possible.

- NOTE 4: Early infection is mostly asymptomatic and studies have suggested that many asymptomatic carriers never move to a symptomatic phase.
- NOTE 5: Vaccinated individuals appear to look like asymptomatic individuals: infection and infectiousness is not excluded.

The nature of the SARS-CoV-2 pandemic has revealed some weaknesses in social and organizational systems, that have resulted in adding significant stress to health care systems, and the various mitigation strategies employed have called into question the relative role of citizen's legal rights and entitlements. The division of family and work groups, and the fear of being infected by strangers has led to mental, social and health problems, across all population groups. In this respect SARS-CoV-2 is quite different from many of the other actively monitored pandemics (see the list maintained by the WHO [i.4]) in both its means of distribution and its rate of mutation. It is also recognized that the resultant pathology from SARS-CoV-2 is very broad, meaning that whilst it primarily impacts the respiratory system (it is a Severe Acute Respiratory Syndrome), it also impacts the digestive system, the cardiovascular system and the nervous system. It is also recognized that anything impacting the respiratory system places stresses on other bodily systems. In short, medically, SARS-CoV-2 is very bad. Details of the medical and scientific diagnosis of SARS-CoV-2 are not addressed by the present document but are used to inform it and to identify where ICT can help. A short bibliography of useful sources on the medical and scientific sources and impacts of SARS-CoV-2 can be found in the Bibliography of the present document.

Whilst the focus of conventional health governance and reporting organizations such as the WHO, the European Centre for Disease Prevention and Control and the US-based CDC (Centers for Disease Control) are on health mitigations, the role of ICT as a tool in enabling health governance has been understated. In very simple terms ICT has played a positive role in mitigating the effects of the pandemic on both individuals and on society. A number of examples are offered to illustrate the role of ICT:

- it has facilitated contact tracing and transmission of test results for infected persons;
- it has facilitated home schooling;
- it has ensured business continuity by some use of home working;
- it has enabled the collection and handling of vast quantities of statistical health data to facilitate the work of Public Health Authorities;
- it has enabled agility in the logistics of supply and the distribution of medicines and hospital supplies;
- it has also enabled rethinking of last mile delivery systems to allow policies of lockdown to work whilst ensuring access to food and other retail outlets; and
- it has changed the role of cash and promoted the use of contactless payment schemes.

However, the very success of ICT has drawn attention to its polarizing effect. Those who could afford it have made good use. But poorer members of society, or those in communities without the necessary infrastructure, have had limited access and missed out on its benefits.

EXAMPLE:

In the UK, having shopping delivered to home requires online access to a supermarket that is in delivery range, and a bank account that allows for online payments. In addition, it is noted that to qualify for free delivery a minimum charge is often applied which for many is above the weekly budget. This is not discounting the need for adequate food storage space in the home.

Management of a pandemic requires cataloguing every instance of the condition and to map the likelihood of cross infection (i.e. passing the infection from one person to another through contact). In most novel pandemics, such as that of SARS-CoV-2 (2019), the level of understanding of rates and susceptibility to infection, evolves as the infection spreads. Identifying instances of infection, identifying sufficient demographic data to determine if there are demographic factors at play, who the infected individual may have been at risk of passing the infection to, and similar data, are all classed as personal data and gathering such data has to be done in such a way that it balances the rights of the individual with the need to protect society as a whole. Where data gathering is programmed into ICT devices and systems there is an obligation of care to address such privacy issues across the entire design. Re-purposing a device to achieve such goals, after its entry on the market, is a less than ideal scenario.

The need to respond quickly to a pandemic is well understood. When the nature of the condition is that it is highly contagious or infectious, and where the replication rate across populations is significant, with no readily available cure or mitigation, the approach to containment can be politically and socially significant. The simple answer is preparedness but that is often not achievable. Similarly, it is almost impossible to shut an entire population away from any contact with anyone in the hope or expectation that in due course the problem will go away of its own accord. In practical terms cures or mitigations have to be able to work alongside society.

Any ICT solution to a pandemic cannot be simply developed on demand. Although many of the pre-requisites for deployment may be readily or quickly available there is always going to be some lag between stating the requirement and having the tools to fulfil it. In developing societal responses that rely upon ICT there is a need to be aware of the risk of digital exclusion. Digital exclusion and its impacts will need to be examined when developing any future ICT function in response to the pandemic.

The question that the ICT development and standards community need to ask now is: can ICT do more?

4.2 ICT role in societal resilience and recovery

There are many criteria currently under discussion for the safe relaxation of lockdown regulations. ICT will have a role in this. However, what is the ICT that is required? What is essential and what is simply desirable?

- EXAMPLE 1: Keeping the population entertained using ICT is a highly desirable goal as it may stave off isolation and stress, mental and physical ill-health. So online exercise tools, or online broadcasters, all have a role to play, albeit at significant financial cost in both infrastructure and to the end user.
- EXAMPLE 2: ICT assisted testing, contact tracing and recording of illness status may be a required effort and burden necessary to allow safe mixing of the population.

If it is required to have been vaccinated prior to travel can ICT support the delivery of proof of vaccination? The mechanical aspects of creating a signed attestation are well known, and many smartphones have been accredited as viable holders for such attestations. However, to be fully workable there is a governance and recognition framework to be developed alongside the mechanical parts. This may also require staff training, new policies and even new legal frameworks. ICT is not a microcosm and has to work alongside the societies it serves, thus whilst ICT is important it is neither more nor less important than the many other parts of societal recovery from COVID-19.

The remainder of the present document examines the future role of ICT in developing, and being a part of, pandemic mitigation systems. In particular the present document considers the role of standards for ICT as one of the societal enablers for recovery and management of the post pandemic age.

5 Existing ICT tools used in mitigation of COVID-19

5.1 Tools for protection of individuals and/or community

5.1.1 Testing

It is accepted that testing for COVID-19 infection and infectiousness is an epidemiological function with a basis in biochemistry. The test tools are often highly automated, the logistics supply chain is similarly highly automated. The automation of supply chains and the role of ICT in enabling such automation is not specific to any response to a pandemic.

As with conventional ICT tests there are 3 results: Pass; Fail; Inconclusive. The same broad classification exists in COVID-19 tests. The present document does not make any judgement on the type and conduct of tests but, rather, looks to identify the role that ICT has played and continues to play in the test programme. However, a short summary of the form of tests is outlined below (these are not complete lists).

- Direct testing of the individual using samples of bodily fluids:
 - Molecular Test
 - Antigen Test

- Antibody Test
- Indirect testing of the presence of SARS-CoV-2 virus traces in geo-locations: wastewater testing; cleaning water testing; air quality testing.

Unfortunately, many tests are either inconclusive or imprecise. In part this is a direct result of the specific nature of SARS-CoV-2 (2019): A relatively long gestation period where tests may not be able to detect the presence of the virus; a period of asymptomatic infection where regular testing will exhibit an increasing likelihood of detection of the virus; Full symptomatic infection with extremely high probability of detection.

It is further recognized that antibodies developed from one set of mutations may be ineffective against a future mutation.

To accurately identify specific mutations of a coronavirus is a non-trivial extension of testing for the presence of a coronavirus, by means of genetic sequencing of the virus. Testing involves significant effort, both human and financial, and would therefore in many cases be seen as unreasonable to impose blanket testing of a population, rather than to target the most at risk demographics.

In simple terms individuals are in a number of states:

- Infected, and able to transfer the virus both symphonically and asymptomatically
- Uninfected
- Post infected and with active anti-bodies

The role of ICT tools in the test domain have been mostly restricted to the means by which records are maintained and by which health records can be shared.

EXAMPLE: A number of ICT "Apps" exist on smartphones to record test results and to allow results to be shared with selected parties. This includes using onscreen QR codes that contain the test result or a link to it.

ICT enables in depth recording, in a privacy preserving manner, of the tests of an individual, including not only the test result but also which type of test was done, how the test was done (self-test, supervised self-test or done by medical staff), when the test was done etc. Accumulating all this information could lead to a much more reliable judgment of the infectiousness of a given person. Additionally, it will avoid unnecessary tests caused by missing information flows, e.g. one test in the morning for school, another one in the afternoon for the music school, and maybe a third in the evening for shopping - just because the information exchange does not work well in a purely paper-based system. Removing such hurdles will increase the overall usability and thus strength the acceptance among the population.

5.1.2 Track and Trace

On the basis that testing everyone at regular and frequent intervals is both logistically and economically a significant effort (and which may be infeasible), it is good practice to test, to track the rate of infection, and to trace those at risk of infection for further testing. With knowledge of the way that SARS-CoV-2 (2019) spreads (aerosol distribution) traditional contact tracing interviews as have been in common use, e.g. used for tracking HIV/AIDS, are not able to detect the frequent lower infection risk cases peculiar to SARS-CoV-2 (2019) and may be considered as no longer fit for purpose. It would be more effective to test based on other diagnostic metrics to either seek to confirm a diagnosis, or to positively exclude a diagnosis. There has been significant effort across industry in using the short range radio capabilities to allow devices to record when they have been in the presence of another radio (specifically for Bluetooth® enabled smartphones). This form of proximity detection and recording has been widely adopted and used in the wider context of track and trace. Unfortunately track and trace is still a game of identifying quickly, isolating or offering treatment quickly, and to a large extent that requires human intervention. What ICT offers is a substantial advantage in complementing the traditional contact tracing and in identifying where to use the human resources.

NOTE: A balance between expedience and excellence is often difficult to achieve. In the domain of proximity detection for contact tracing apps the use of pre-existing Bluetooth capabilities, idealized for short range connectivity and with a pairing protocol enabling recognition of the presence of another device, could be viewed as a convenient solution, but technically was a high risk choice, as Bluetooth implementations on smartphones were not designed for such as purpose.

In support of Track and Trace efforts, ETSI, in collaboration with health authorities and major smartphone manufacturers, in the guise of the emergency forming of the Industry Specification Group (ISG) E4P, "Europe for Privacy-Preserving Pandemic Protection (E4P)" developed and published 5 deliverables (GS and GR):

- ETSI GR E4P 002 [i.7]: "Europe for Privacy-Preserving Pandemic Protection (E4P); Comparison of existing pandemic contact tracing systems".
- ETSI GS E4P 003 [i.8]: "Europe for Privacy-Preserving Pandemic Protection (E4P); High level requirements for pandemic contact tracing systems using mobile devices".
- ETSI GS E4P 006 [i.9]: "Europe for Privacy-Preserving Pandemic Protection (E4P); Device-Based Mechanisms for pandemic contact tracing systems".
- ETSI GS E4P 007 [i.10]: "Europe for Privacy-Preserving Pandemic Protection (E4P); Pandemic proximity tracing systems: Interoperability Framework".
- ETSI GS E4P 008 [i.11]: "Europe for Privacy-Preserving Pandemic Protection (E4P); Back-End mechanisms for pandemic contact tracing systems".

It is interesting to note the timetable of ETSI's response in forming ISG E4P and to identify lessons to learn. Before doing that it is essential to recognize both the likelihood and impact of an epidemic: The likelihood of an epidemic/pandemic is such that it can be described as inevitable: it will happen; in assessing the impact of an epidemic/pandemic it is clear from the definition that it will impact many countries at once, and a significant proportion of the population, resulting in considerable risk of overload of healthcare resources. Building into risk assessment is the degree of novelty of the epidemic/pandemic, which for SARS-CoV-2 was significant, to the point that there was no readily available treatment, this characteristic increases the evaluation of the impact as until such time as a cure or other mitigation can be applied, all normal activity has to be suspended or is severely impacted. Using conventional risk assessment metrics that classify risk as the product of likelihood and impact it is reasonable to state that the risk of an epidemic/pandemic is extremely high as both likelihood and impact are high. In ETSI's culture where ICT and security are concerned any risk classified as high is normally addressed with urgency. It should be a concern therefore that ETSI, and other SDOs, were not addressing this form of risk in any significant way prior to the declaration of the pandemic. Figure 5.2 consider the timetable of events in this instance.



PHEIC Public Health Emergency of International Concern SPRP Strategic Preparedness and Response Plan

Figure 5.1: Initial WHO timetable of responses in identifying the pandemic (summarized from [i.3])

Extending from the initial timetable of the WHO Figure 5.2 identifies some of the events from ETSI in addition to the medical response.



Figure 5.2: Additional milestones in COVID-19 response

There was, as seen above, a significant time between the first cases, and declaration of first a PHEIC, and later of a pandemic (3 to 4 months). In addition to those cited in the figures, many other events have taken place in private industry, in government responses at national and regional level, and in health services globally. Whilst many of the major players in the ICT industry were invited to the WHO convened ICT roundtable in February 2020, it can be reasonably suggested that the major SDOs were not on that guest list.

In addition to proximity tracking many other ICT based initiatives and tools have been used, the most visible being use of QR-codes and QR-scanning from most smartphone COVID-Tracking Apps for registration to events or venues. Some governments and some organizations have attempted to make such apps compulsory but have been denied as it excludes a large proportion of the public (digital exclusion) and data for a positive contact and the resulting advice given has not always been consistent with the risk identified by the medical science.

EXAMPLE 1: Being in proximity raises the risk of infection but does not guarantee that the affected person is infected, this can only be verified by a test. Isolation without proof of infection may be counterproductive if it removes essential workers from their activity, or it may increase anxiety without due cause.

EXAMPLE 2: In a location where an infected person has been registered there is a need to test others who have registered to the same location in order to either confirm transmission of the infection or to reassure individuals that they are not at increased risk.

There is a role for standards and reports such as those published by ETSI (as ISG E4P) to assist in track and trace, but does not alter the infectiousness of COVID-19 nor does proximity detection, or location registration. The role is to complement traditional test, track and trace, and assist in making most effective use of resources, i.e. the track and trace personnel and the medical resources to enable test and therapy, therefore the integration with existing and dedicated health system functions is essential.

5.1.3 Vaccination

Whereas testing is the main tool to detect the rate and depth of spread of COVID-19, vaccinations target the development of at least partial immunity, reducing the symptom load, and reducing the percentage of cases that develop into life threatening levels of seriousness, or which require use of scarce hospital and medical resources.

Large scale management of the vaccination programme is ICT assisted. Much of the data in the vaccination programme is sensitive personal data, and the programme management is both politically and societally sensitive.

Vaccination is a science led discipline, and almost by definition in the 21st Century, science is substantially ICT assisted, and may at times be classified as ICT enabled (i.e. impossible without ICT resources). ICT in the form of AI, Imaging, Data analysis, and hypothesis simulation, have been able to substantially accelerate the development of vaccines. In addition where vaccines have adopted new RNA based approaches the globally shared genome sequencing project, with its consistent data taxonomy, has allowed global data and resource sharing. This has been further enabled by developments in the modelling of vaccines, and of therapies in general, that have been accelerated by the need to come to terms with the pandemic.

As the vaccination programmes develop and testing of efficacy, and therefore modelling of the long term vaccination programme, can be undertaken, it is the ICT enabling of data transfer and the interoperability of that data through syntactic and semantic standardization that will be key to ongoing attempts to be ahead of the curve against the mutations of the pandemic itself. Understanding, based on data, of efficacy against current and future mutations will be key and the ICT community has tools to support this activity.

5.2 Existing tools for movement and opening of society

One of the more controversial issues related to the data gathering around the pandemic has been privacy. In recent years the societal pressure to live private lives within a connected world has become more and more significant, and to a criminal mindset has offered a significant resource to plunder for gain. There are significant issues regarding the use of health data in opening society that have to be overcome, including those of discrimination and of privacy violation.

In the context of regulatory tools such as GDPR the need to balance public and private interests is addressed and will be considered in more detail later in the present document.

6 Issues and constraints for ICT tools development

6.1 Technical impact

In general health professionals' only interest is in the welfare of the patient and the driver for their work is not the tools but the ability of tools to improve the welfare of the patient. In common with this view ICT is not the purpose in health but one of many tools to be used by health professionals in management of patient welfare. In the particular case of a pandemic the argument can be made that the welfare of society as a whole is at risk, thus the role of ICT in eHealth and the context of the present document is also to be seen as a tool that assists health professionals to manage societal welfare.

This clause considers a number of constraints that apply to the application of technology in health.

It remains to be developed how ICT could impact societal benefits and measures versus health targets, versus policy targets, versus cultural changes and demographic issues. Enormous amounts of data exist and are available on the demographic and cultural mix of a geographical area:

- Use of ICT to give authoritative knowledge of these things?
- The Use of data mining, data sharing and AI to process data quickly.

6.2 Co-morbidities and other medical issues

The human body is a complex set of interacting systems. A fault in one system is rarely completely isolated and impacts many other systems. Whilst SARS-CoV-2 is labelled as a respiratory system disease it is clear, when considering the human body as a series of connected and dependent systems, that a fault or weakness in any one can be exaggerated by a fault or weakness in another. There is, unfortunately, a very emotive attachment to some of the co-morbidities that are addressed in Annex B, and as such their treatment has to be considered within that emotional framework.

6.3 Ethics and ethical issues

Ethics is a complex topic of study which is unlikely to produce clear and simple answers to a question such as: Is this the right thing to do? The ethical standpoint of an individual often reflects that of the society they are a member of, but there are often quite significant differences between societies, and groups within society, that will identify what is "right" for one group will be "wrong" (in the sense of "not right") for another.

It is probably reasonable to require that ICT tools are neutral - they will not cause harm. However it is at the same time probably unreasonable to define what is harmful from the application of ICT tools. Many examples can be cited regarding technology that is good for one purpose but harmful when re-purposed (this is the basis of dual use regulation that places export controls on things such as cryptographic algorithms, see [i.6]). Ethical use of any technology is ultimately not a technology only concern (using a knife to prepare a meal is quite different from using the same knife to harm a fellow human, though it is not the knife that determines its use).

It has to be considered, however, that ICT tools do have effects that can endanger the health of an individual, directly or indirectly. Examples in this context are:

- Missed cases of potential infection transfer
- Errors in planning models leading to making insufficient resources available, or resources unnecessarily assigned to other activities

In support of ethics the preservation of privacy, and protection of data by application of security tools, are key elements in ICT development. In addition prediction and simulation of the effect of decisions using ICT may become critical. In the guise of identifying least bad paths when all options are bad there will be substantial roles for ICT in the form of AI, of big-data analysis, of data gathering, and to disseminate decisions. In this context, particularly of AI, risks exist in data poisoning, in data bias (including algorithmic bias), and in wrong or misleading interpretation.

The key contribution in development of ICT is adoption of the credos regarding "secure by default" and "privacy by design". It is acknowledged that with respect to privacy these approaches are endorsed by Article 25 of the GDPR [i.5] where it applies.

6.4 Legal Issues - The public use of private data

Allowing, or requiring, personal data to be used to modify the risk profile of wider society is a difficult challenge under both the legal and ethical frameworks of societies. No illness is purely personal, and sharing knowledge of being ill is a high risk strategy as it may result in negative consequences. The nature of SARS-CoV-2 is that it is a reportable disease, it is potentially fatal, it is also asymptomatic in many instances. There is a social and moral (ethical) responsibility to minimize risk to the wider population and this means making "public" use of private data.

In the course of 2020 and in the first half of 2021 a lot of the response to the pandemic was driven by data, and data used to assist in correlating the scientific findings. Such data usage, even if data was incomplete on not always of sufficient quality, has allowed health authorities to try to prioritize vulnerable patients to advise them to shield, and patient histories have been used to prioritize those most in need of early vaccination. In the EU, there are provisions in GDPR that allow national or public safety to take precedence over individual consent, and to date these have been invoked with care. In the world of DCT the release of contact data has been mainly developed with privacy as the primary driver requiring explicit consent to release data to health authorities. In the context of restoring societal activity and travel post-pandemic, it is crucial that ethical, operational, technical considerations in design applications fulfil the Privacy by Design principle, to provide interoperable, effective, safe and secure technology solutions.

7 ETSI and the Role of Standards in ICT for Health

7.1 Overview of ETSI's role

The eHealth white paper [i.2] made the statement that "Very little of ICT is eHealth specific, all of eHealth depends on ICT" which underpins the role of ETSI examined in the present document.

The role of ICT, for example, in the field of Digital Contact Tracing (DCT) is fundamental. So, beginning in 2020, Synchronous Contact Tracing (SCT) and Asynchronous Contact Tracing (ACT) approaches were developed, by teams working actively throughout the pandemic. However, this represented only a part of the impacted wider landscape where scenarios could be drawn from such areas as remote office working, online meetings, AI support, enterprise assistance, online education as well as smart healthcare. For all these areas in ICT standardization, healthcare may not be a key activity, nevertheless, smart healthcare is the main focus of the present document.

In looking at the response of the WHO in calling for a roundtable of ICT groups it can be asked what do the SDOs need to do to ensure that they are included in such guest lists? Reliance on the industry players to pool resources with the SDOs is not sufficient, although many (if not all) are active across the standardization community. There is a perception however of standards being **de jure**, rather than is normally the case of being voluntary and **de facto**. In having the SDOs at the centre of the pandemic response the risk of being seen too far to the **de jure** end of the scale and to risk standards being used as regulatory tools will need to be managed carefully.

NOTE: It is recognized that ITU is often consulted by the WHO but as both lie within a wider UN framework it could be argued that this serves as is internal recognition of a peer group rather than wholesale recognition of the ICT standards community.

Whilst bodies such as the WHO offer medical views of efficacy and suitability of vaccines and tests these may be viewed as data points in an ICT environment and should be able to be externally verified. This allows the expertise of groups such as WHO, ECDC, EMA, CDC and others, to prepare the data points for use in the ICT domain. The ICT domain, and the wider building of trust networks, that allow users to trust data can then make progress without having to be seen as stepping into the expert domains of others.

7.2 Meeting the challenge of the Pandemic

Examining the role of ICT Standards for the safe reopening of society following the pandemic crisis, began with ETSI launching specific activities for digital contact tracing, both in its synchronous and asynchronous versions. A new ETSI ISG (ISG E4P) was formed to enable members and non-members to pool their knowledge and proposals. These and other activities, including the establishment of an eHealth Hub coordination (by EP eHEALTH) between different TB/ISG have demonstrated a quick reaction by ETSI and a readiness to develop new activities as required. This revealed what was needed in the terms of standardization and also demonstrated the ETSI capacity and maturity to organize and coordinate the relevant resources available from within the ETSI membership.

7.3 Interoperability

There are several reasons why ICT standardization has been developed. However, its most basic, enabling characteristic is providing for interoperability, traditionally between different implementations of systems and networks. Moreover, it can be said that interoperability is what standardization is about. Related standardization issues, like privacy, security and safety are consequences arising from the need for interoperability in order to protect users and networks.

7.4 Complexity

The concrete particularities of the required interoperability capabilities of the different domains/verticals, namely for the present Special Report in the case of eHealth, are of extreme complexity. Not only the Health systems by themselves with their "internal" required interoperability. As well as its relations with other Verticals in particular with Smart Cities. The required international interoperability between Health systems, commencing with the different European countries, where the structure of the Health Systems is very different. This differs from case to case with different regulations and traditions, and may present problems of extreme complexity which need to be dealt with.

8 Specific ETSI TB roles and actions

8.0 Foreword

NOTE: Some of the text in this clause has been copied and expanded from the 2020 eHEALTH White Paper [i.1].

8.1 Structure of TBs in pandemic management and response

All ETSI TBs have a role to play in the wider societal response, recovery and management, of any pandemic. However some TBs will have a leading role, others a more supporting role following on from the strategic direction established by those in the primary group, with a third group capturing many lower layer details for devices and services as well as driving a longer vision.



Figure 8.1: Snapshot of ETSI TBs from the ETSI Portal

In short, every TB identified in ETSI Portal has a role to play in pandemic management and response. The remainder of this clause identifies roles to be played by some of these TBs.

8.2 Primary bodies

8.2.1 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; validation by testing and usability. The contribution of EP eHEALTH will be informed by previous work on the eHEALTH White Papers [i.1], [i.3], and on active work items addressing "eHEALTH Use Cases" and "eHEALTH Data recording requirements for eHealth".

The essential role of EP eHEALTH (or any successor) is to act as a focal point for both internal coordination and for external relationships.

8.2.2 TC CYBER

It has been stated a number of times that eHealth has to be secure, and the data and processes used have to be trusted. 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.

8.2.3 TC ESI

Many of the talked about "passports" (vaccination, antibody) can only be validated and trusted within a globally recognized trust framework. The role of ESI, alongside that of CYBER, is to give that trust network of the necessary attestations for a cautious reopening of society.

8.2.4 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.

In our societies and economies, the overwhelming role assumed by IT Applications, Data and AI, increases the role of interoperability of networks and systems. Until the present phase interoperability was mainly thought to be an issue of Connectivity of the network layers. Nowadays, semantic interoperability, is the ability to exchange data with shared meaning including inferred unambiguity, has become a preeminent part of the ICT interoperability requirements.

8.2.5 EPP oneM2M

In the last decade, oneM2M has been defined as a general-purpose standard to provide interoperability and scalability of IoT solutions across different domains. oneM2M promotes a global standard in contrast to National/Regional variants or proprietary approaches, bringing together all components in the IoT stack. Its architecture defines a common software middleware layer, labelled the common service layer, between devices and communications networks and IoT applications. This common service layer encompasses a set of common tools that all IoT systems depend upon.

Security, semantics, remote device management are three examples of functions comprised by this toolkit. oneM2M provides standardized links between connected devices, gateways, different types of communications networks and cloud infrastructure and supports interworking even with non-oneM2M entities. It also means that different applications of vertical industries can interoperate with one another.

oneM2M maturity is well established with an interoperability testing program (7 interoperability test events have been performed since 2015) and a certification program (launched 2017). Thus, oneM2M is ready for application to eHealth and is already being used in the ACT standard with the first version completed by the end of 2020.

8.2.6 ISG PDL

Electronic Health requires data to be immutable against unauthorized modification and entry. Records entered and logged, data being quickly retrievable. These are intrinsic capabilities of Distributed Ledger/Block-chain technology, where a DLT token once place of the data record in un-tamper proof, and access and modification strictly logged. Clearly the Governance to adding a DLT token needs to be authorized and secure.

The opportunity of PDL in eHealth is more complex and more exciting. It defines multiple ledgers for various forms of actor with a number of roles where not all data has to be known to all parties but where ledgers on occasion intersect.

Ledgers may exist for a surgeon that will intersect with multiple patients over time, and may intersect with other assets where a ledger is also kept (Op-theatre staff say, or cleaning records for surgical tools, or records of which oxygen supplier and which batch was used by the anaesthetist, and so on).

There is a need that records are immutable, as one thing to be avoided is medical fraud. There is also a need that data is anonymized data for research. PDL on its own is not the solution. However, PDL tokens linked to database records show many of the capabilities that will match the eHealth requirement. This will be explored more in the development of the work on eHealth of health medical data records. These tokens can be used to record its creation, any modifications (and what was the reason for modification), its availability to be read used and modified and timeliness. From the technical view Health record are another highly private record that is open to incorrect use and incorrect information content. Each Health file can be composed of sub-records with a separate Distributed Block-chain Token. So the sub-record cannot be visible without a shared token, it may be corrected by the Owner and controller independently of the other parts of the File.

- EXAMPLE 1: Airline staff when the user is travelling do not need access to scans and medical operation details.
- EXAMPLE 2: Pharmacy assistants only need access to prescribed medicines, timely information, They need to be sure these cannot be copied falsified, the last and next issue, etc.

In the future, it becomes clear that non-medical professionals need limited rapid and available access to correct timely and appropriate data, e.g.: airline staff need ensured access to immunizations and anti-viral test results. Where Health professionals wherever the individual travels can access the complete records. Smart contracts and Distributed Block-chain Tokens ensure the entry maintenance and visibility of such data without it falling into unauthorized uses visibility.

Distributed Block-chain Tokens by their nature allow distributed parts of the token that preserves the data use. Access is only available when the "token" is presented to the database. A report detailing Offline Distributed Block-chain token use is ongoing, a specification detailing a solution of a Smart Contract for one or a number of Distributed Block-chain token(s) is starting.

8.2.7 SmartBAN

TC SmartBAN has primarily responsibility for the development and maintenance of ETSI deliverables to support the development and implementation of Smart Body Area Network technologies (Wireless BAN, Personal BAN, Personal Networks etc.) in health, wellness, leisure, sport and other relevant domains. The technical domains addressed include physical layer, network layer, security, QoS, and also provision of generic applications and services for standardization in the area of Body Network Area technologies.

TC SmartBAN continues activities that are in the Health ICT domain in close co-operation with relevant standards activities within and outside ETSI. The activities of TC SmartBAN relevant to eHealth include:

- standardization activities in all relevant areas to and preparation of ETSI deliverables for the wireless Body Area Network for personal welfare;
- close liaison with TB eHEALTH;
- close liaison with ETSI TC ERM, TC M2M, 3GPP and other relevant ETSI TBs;
- participation in co-ordination of Health ICT related requirements in order to produce a consistent set of ETSI
 deliverables and to undertake measures to efficiently continue and stimulate further Health ICT related work
 within ETSI.

8.3 Secondary bodies

8.3.1 EPP 3GPP

Responsible for 2G/3G/4G and 5G standardization where both mobile networks and connected devices are key to all actors in the health domain. In looking at the backbone of connectivity anywhere the role of 3GPP cannot be underestimated, and through 3GPP there is a core link to the development of Consumer Mobile Devices that are characterized in smartphones where the combination of connectivity and computing power with a user accessible interface come together.

8.3.2 TC ATTM WG SDMC

As had been evidenced in the practical application of contact tracing there is a significant role to be played in the role of city management in coordinating resources.

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".

8.3.3 TC HF and USER group

A core assertion is that eHealth is person-centric and revolves around supporting the doctor-patient relationship. The expertise in each of ETSI 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.

8.4 Tertiary bodies

It can be summarized somewhat trivially that all other TBs in ETSI have a role in eHealth. It is not considered as essential for the purposes of the present document to address each TB individually.

9 Conclusions and summary

As identified in clause 8 all of ETSI TBs have a role to play in the wider societal response, recovery and management, of any pandemic. The conclusion of the present document is that much has been done, but also that much has not been done in bringing ICT to bear in developing a societal response to the pandemic. It has been suggested that preparedness is key to success, but it is recognized that SDOs are not often seen as having a role in this area. To quote: "In looking at the response of the WHO in calling for a roundtable of ICT groups it can be asked what do the SDOs need to do to ensure that they are included in such guest lists?" It is a core recommendation therefore of the present document that ETSI develops a strategy that overcomes this lack of visibility of SDOs at such high level strategic sessions.

It is noted throughout the present document that the current pandemic (COVID-19) is not caused by ICT and that ICT is not a contributory factor in its spread or in the efficacy of any mitigations. However it is noted that ICT is critical in allowing society to function during a time of immense social and societal discord. It is this area that is seen as the domain where standards, led by ETSI across all of its TBs, can be most effective by allowing and promoting the role of ICT in the functioning of society. Therefore the characterization of ETSI as a responsible body for enabling societal function, and through that for the management and recovery of societies from things like the current pandemic, is pivotal and at the core of the present document.

In short ETSI can take the lead in not just promoting the statement that "Very little of ICT is eHealth specific, all of eHealth depends on ICT" but extending that to developing all of ETSI's output such that all of ETSI's output is societally relevant (already done) and eHealth relevant for enabling Health crisis management and recovery.

In specific areas such as proximity detection there is an urgent need to further investigate the requirements of sensitivity of the entire system to improve effectiveness. This should be driven by the epidemiology of particular illnesses and steps should be taken by the ICT domains to be able to introduce requirements from such non-ICT domains into analysis. This is consistent with recognizing that fighting disease is a multi-faceted and extremely large scale (global scale) problem. In addressing both COVID-19 recovery and preparing for the next, and inevitable pandemic, all actors need to work together across borders, institutions, companies and pre-held beliefs to make this successful. ETSI has an opportunity through its unique composition and organization to be at the lead of this next stage of development.

Annex A:

Technology adoption for eHealth ICT preparedness

A.1 Bluetooth®

There are many areas where Bluetooth technology can improve healthcare operations. These include, but are not limited to, the following:

- Tracking of expensive of urgent-use equipment within hospitals.
- Geo-fencing to ensure, for example, that dementia sufferers do not "wander off" outside of care homes by using Bluetooth wearables and submitting alerts to care staff if the geo-fence is crossed.
- Detecting and alerting assisted living staff to residents who have fallen or have become incapacitated.
- Detecting patients in hospitals lying in corridors/bathrooms/remote stairways for a protracted period of time.
- Replacing limited Pager systems with an internal Bluetooth MESH messaging system that provide not only need, but patient context, to those being 'paged' for specialist consultation.
- Automatic population of Check-in/Check-out Venue Diary visits individuals have made which may be, with their permission, shared with contact tracing teams.

It is proposed that ETSI works in collaboration with other SDOs in further development of such technologies.

Annex B:

Impact of existing morbidities on COVID-19

B.1 Overview of major body systems

To simplify the understanding of the impact of particular morbidities on the human body when infected with COVID-19 the following list gives a very simple overview of the recognized systems in the body. All of the systems are always present and are interconnected and inter-dependent as outlined below:

Cardiovascular system

- Contains the heart and blood vessels. Blood is also the carrier of oxygen, and nutrients to all other systems, and acts as the carrier for the removal of waste.

Digestive system

This system resembles a long tube with attached organs. Ingested food is broken down into constituent nutrient molecules that are then absorbed into the bloodstream. Indigestible remains are then egested.

Endocrine system

Coordinates the metabolic activity of body cells by interacting with the nervous system. Endocrine
glands produce hormones (chemical messengers) released into the blood and transported to target sites
around the body.

Excretory system

- Made up of the kidneys, the bladder, and channels for moving liquid waste around.

• Immune system

- The immune system is a protection mechanism composed of specialized cells, cell products, tissues, organs and processes within an organism that protect against pathogens.

• Integumentary system

The skin. This system wraps the body in a protective covering with a number of functions such as UV protection and temperature regulation.

Musculoskeletal system

The skeleton provides an articulated framework on which the human body is arranged. It is to allow free movement in conjunction with the skeletal muscles. They control movement, posture and are held together by connective tissue.

Respiratory system

Our bodies are made up of countless cells all requiring oxygen to carry out the important process of
respiration. In this process cells use oxygen gas and produce carbon dioxide gas - a waste product that
has to be removed from the body. The process of breathing allows these gases to be exchanged between
the blood and lungs.

• Reproductive system

- The human body has a system of organs that work together for the purpose of reproduction. The biological purpose of this process is the continuation of life.

• Nervous system

The nervous system is made up of a network of specialized cells, tissues and organs that coordinate and regulate the responses of the body to internal and external stimuli.

In very simple terms, every system needs blood (cardiovascular system), oxygen (respiratory system), sensors to report state (nervous system), protection and management (immune and endocrine systems), waste management (cardiovascular, digestive and excretory systems), and a body to exist in (integumentary and the musculoskeletal systems).

B.2 Impacts of specific morbidities

B.2.1 Age

Although age of itself is not a morbidity (commonly defined as a condition arising from a disease or medical condition) advancing age has been the most evident factor in vulnerability to COVID-19. In simple terms as the body ages each system degrades and the response to stimulus takes longer, and on occasion has no impact.

In feeding data to the health system accurate reporting of age is vital in determination of the impact of age on spread and on the efficacy of treatments. Where data has been processed with a view to establishing priority, for example, in access to vaccination, improper reporting of age has to be ruled out.

However not all old people succumb and health living/age-friendly regimes have been shown to help. ICT has provided useful tools for monitoring and control of medicines/exercise routines and communications for this group (e.g. by promotion of exergaming).

B.2.2 Obesity

Obesity has been identified as a key factor in patient deaths from COVID-19.

Many bodies in the domain of Public Health (e.g. Public Health England) have estimated that having a Body Mass Index (BMI) of 35 to 40 could increase a person's chances of dying from COVID-19 by 40 %, while a BMI greater than 40 could increase the risk by 90 %. It is however recognized by many that BMI is a poor indicator of obesity in certain individuals and that other measures such as body fat ratio (leanness ratio), or the waist-height ratio, may give a more accurate measure for an individual. Notwithstanding the generality of BMI it is a good general indicator of relative risk.

It is recognized that whilst obesity is a significant factor in COVID-19 risk there is a similar risk at the other end of the BMI scale, i.e. being clinically underweight (BMI less than 18,5) is not conducive to good COVID-19 outlooks.

Annex C: Bibliography

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