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5G and e-Health

1 Socio-economic drivers of e-Health in Horizon 2020

Although socio-economically the sector addressed by this white paper is the health sector, the detailed analysis will be provided for the e-Health and m-Health sub-areas as they are more directly relevant for the identification of requirements on the future infrastructures and the development of new business models and value chains as well as any related discussion pertaining to policy and regulation. Due to the lack of crisp definitions the white paper will also cover areas such as telematics, telemedicine, robotics, tele-health, which are frequently used synonymously. As e-health and m-health are currently the most popular terms and in many ways do cover the telecommunication aspects of other overlapping areas for the reason of simplicity we will refer to e-Health and m-Health in this paper. However, if needed, we will refer to the specific areas as mentioned above.

The e-Health sector is identified as a priority in the European Digital Agenda and subsequently in many national digital agendas for the following main reasons:

- The current average spending in the healthcare sector is around 10% of GDP in Europe.
- The rise in healthcare costs as percentage of GDP continues to outperform the average economic growth (GDP).
- Digitalization and virtualization of care have been considered a major driver towards the transition of healthcare from a hospital based, specialist driven system towards a distributed, patient centred care model with the point of care shifting to the periphery.

According to the World Health Organisation (WHO), e-health is the transfer of health resources and health care by electronic means. It encompasses three main areas:

- The delivery of health information, for health professionals and health consumers, through the Internet and telecommunications.
- Using the power of IT and e-commerce to improve public health services, e.g. through the education and training of health workers.
- The use of e-commerce and e-business practices in health systems management.

Furthermore, WHO and the EC in its green paper on mobile Health, define m-Health as the medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices[1].

The main socio-economic driver in the development of the Health sector is certainly related to the cost of delivery of health care. The cost factor is rooted in the changing demographics of the society in Europe, as well as in the improvement of the health coverage and quality.

In most European countries direct healthcare costs stand for more than 10% of the GDP with a strong annual increase. According to OECD data the annual average growth rate in health expenditure per capita in the period 2000-2009 was around 4%, while at the same time the corresponding average increase of the GDP was only 1.6%. These indicators suggest that the cost of delivery of healthcare is not sustainable and that measures have to be taken to mitigate this risk.

A number of indicators in the healthcare system, such as the number of hospital beds, the Average Length of Stay (ALS) in hospital, etc. suggest that a fundamental transformation of the sector is ongoing. Healthcare is being shifted from the 20th century centralized model to the 21st century totally scattered, or distributed model.

The Socio-Economic Impact of m-Health report produced by PwC in 2013[2] was the first to highlight the potential and significant benefits of mobile health development for Europe. Amongst the various conclusions, the report stated that mobile health could save 99 billion EUR in healthcare costs in the EU by 2017 if its adoption is encouraged.

1.1 Decentralisation trend

Deliver treatment or care outside hospitals

- in homes
- general practitioners' practices
- nursing homes
- day surgeries / clinics
- rehabilitation
- over networks (for example the Internet)
- rural areas

Attention is being shifted to the root causes

- lifestyle
- wellness

Increased attention to care for people with one or more chronic conditions

- Prevention: action to reduce or eliminate the onset, causes, complications or recurrence of diseases
- Compensation & Support: action to reduce physical or cognitive impairments

[1] WHO, Global Observatory for e-Health series http://www.who.int/goe/publications/en/ and EC green paper on mobile Health http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=5147

[2] PWC, "Socio-economic impact of m-Health - An assessment report for the European Union," September 2013

- Independent & Active Ageing: action to allow autonomous living, participation in social activities and remaining longer at work.

1.2 Current trends with social context

- Community services for patients and users allowing voluntary sharing of observations with peers
- Services for benchmarking and competitions in the scope of wellbeing/healthy lifestyle
- Personalised care
- Reducing the risk of accidents, like falls and burns
- Enabling informal carers and lesser qualified professionals to take on routine tasks of more qualified individuals to reduce the burden to social systems[3]
- Self-care
- Social/crowd care (including community and rating services)
- Patient-controlled information sharing/access
- Education and behavioural change communication

1.2.1 Global context

Most of the trends indicated above are global trends. A notable concrete impact is provided for Africa. Mobile health could save over 1 million lives in Sub-Saharan Africa over the next five years. Indeed, the average distance between a person and the nearest medical center in Africa is 5 miles and there are 20 times less health professionals per 100 000 population in Africa compared to Europe. Therefore, access to health services with traditional means is very complex.

Encouraging results have already been obtained on this front, such as[4]:

- Delivering prevention and awareness information via text messages to pregnant and young mothers in Mali has helped reduce perinatal and maternal mortality by 30%
- In Kenya, mobile health helped to improve antiretroviral mediation compliance by 11%

Driven by demographic predictions where it is forecasted that the old age dependency ratio will reach similar levels to Europe by 2040 China is paying significant attention to the maintenance of healthcare standards and is proactively seeking to implement strategies to virtualize care to curb the demand for face to face health services in hospitals. Outpatient numbers in urban Chinese hospitals can reach numbers as high as 15000 patients per day, which is clearly unsustainable. An estimated amount of 60 - 70 million people in China are suffering from COPD and Asthma whereby the prevalence is still increasing. According to WHO figures the prevalence of asthma is currently 5.9% of the adult population.[5] Chronic respiratory disease is one of the prime examples of diseases, which might be treated much better utilizing smart, ICT enabled pharmaceuticals in the future. The use of this innovative, 5G-supported technology will significantly reduce the numbers of outpatient appointments and improve individual health through long term, service assisted behavioural change. The same accounts for several high prevalence illnesses in Asia such as COPD, gastroesophageal reflux disease and

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[3] National Information Board (2014) Personalised Health and Care 2020, Using Data and Technology to Transform Outcomes for Patients and Citizens, HM Government

[4] MV. Kinney, JE. Lawn, KJ Kerber, "Science in Action - Saving the lives of Africa's mothers, newborns and children," ASADI, 2009

[5] http://www.who.int/gard/publications/chronic_respiratory_diseases.pdf

others. Furthermore, 5G enhanced e- and m-health technologies will reduce disparities between urban and rural healthcare through ubiquitous access to health care anywhere, anyhow and at any time.

From a health-economic perspective it needs to be highlighted that China will incur a much higher relative increase in their healthcare spending from now until 2020 than any European country or the US. While in Europe and the US healthcare spending will roughly double by 2020 in comparison to 2012 in China healthcare spending will climb by factor seven to 1000 billion USD.[6]

1.3 Roadmap

The ongoing fundamental transformation of the way of delivering healthcare that is induced by ICT is preventing concrete statements about the roadmap in the whole vertical sector. If at all, information is only available on narrow areas of the sector. The industry together with healthcare providers and standards organisations are currently focusing on the identification of the broad areas that are subject to a greater impact. Such areas include: (i) Wireless patient monitoring, (ii) Mobile system access, (iii) Medical devices, (iv) Smart Pharmaceuticals, (v) Robotics, (vi) Tele-healthcare, (vii) Ambient Assisted Living (viii), prevention, (ix) lifestyle and wellbeing.

Overall, the most frequently cited issues that are being addressed and must be resolved include: (i) greater emphasis on interoperability, (ii) increased coordination over e-Health standardisation, (iii) ensuring privacy, security and safety (iv) how to leverage on the fast evolving ICT and last but not least (v) Governance.

The WHO in its second Global Survey on e-Health (2011), reports a “groundswell of activity” in the use of mobile health technologies. 83% of WHO’s Member States offer at least one type of m-Health service, and many countries having initiated four to six specific m-Health programmes. However no sufficient data are available to quantify the level of adoption of a particular technology, in order to help extrapolate the availability and introduction of future capabilities in an operational and sustained way.

A European survey on e-health in 2011 concluded that the adoption of e-health technologies in Europe is sluggish and behind expectations due to the lack of confidence and trust of stakeholders[7]. During further consultations Large Scale Demonstrators were considered a suitable path to further spread and acceptance of e-health technology[8].

However, over recent years there have been clear signs of a pickup of the speed of developments in the deployment and distribution of e-health technologies. Most recent indicators for change is the amendment of regulations in many countries which turns e-health consultations into eligible costs, which can be charged by health care providers to patients or their health insurers. Furthermore

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[6] Le Deu F, Parekh R, Zhang F, Zhou G (2012) Health care in China: Entering uncharted waters, McKinsey&Co, http://www.mckinsey.com/insights/health_systems_and_services/health_care_in_china_entering_uncharted_waters

[7] European Commission (2011) Report on the public consultation on e-Health action plan 2012-2020

[8] European Commission (2012) Communication from the Commission to the European Parliament, the council, the European Economic and Social Committee and the Committee of regions, e-Health Action Plan 2012-2020 - Innovative healthcare for the 21st century.

Germany has started a formal process to introduce a so called “e-Health Legislation” (Legislation for secure digital communication and applications in the health care domain) in Juli 2015 [9]

With regards to specific examples for the rapid progressive implementation of e-health solutions with significant future market potential over the next decade the pharmaceutical industry could be one of the key drivers. Over recent years concepts of more individual (pharmaceutical) and dynamic treatments have been developed globally. In the United States the most prominent approach has become well known under the term “Precision Medicine”[10]. Precision Medicine is aiming at the collection of a variety of personal data leading to an individual pharmaceutical approach towards rather than applying estimated dosages of pharmaceuticals derived from statistical analysis of large groups or populations. This will inevitably require the collection of a rapidly increasing amount of individual data on a day to day basis via sensors, embedded systems and cyber-physical systems quickly exhausting the available network capacities.

On the other hand there are serious efforts on the way to enable pharmaceuticals for the treatment of chronic diseases such as asthma, COPD and diabetes wirelessly in order to enable patients and their informal carers to self-manage the disease during stable phases, thereby reducing the amount of clinic visits and hospital admissions.

The topic has been discussed in the EU-China IoT advisory board (Beijing 2015) and has been included in the EU-China Joint White Paper on the Internet of Things[11]. There are concrete plans by pharmaceutical companies to release first products in 2020. These products have the potential to significantly increase the requirements for cheap connectivity of thousands more devices per geographical area. The sheer mass of these devices will also add stress on the existing network infrastructures.

Currently a study at Technical University Munich is on the way to establish a better understanding how smart pharmaceuticals, robotics, bar code technology, RFID, monitoring devices, artificial organs and other solutions will affect the digital footprint of a health care facility in an urban area. Furthermore a twinned Large Scale Project in Shanghai and Munich has just been agreed and will commence in 2016, once the local infrastructure will be established[12]

Due to the overall economic relevance of healthcare for European Countries and China a EU-China working group on e-health is currently under preparation.

In the area of telematic surgery and robotics there is a clear case for a significant reduction in end-to-end latency. Currently advanced robotic systems have a system immanent latency of around 180 ms. From scientific studies it is well known, that latencies beyond 200 ms affect the performance of surgeons and beyond 250 ms it is very difficult for surgeons to operate at all. However, due to the fact that only in relatively few surgical centres all specialties and sub-specialties are represented it can be expected that in the future experts will join operations performed by local teams virtually and will get involved remotely. Currently this is only possible in selected cases due to the experimental character and the lack of facilities in most hospitals. However, networks must not add further to the system

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[9] http://www.bmg.bund.de/themen/krankenversicherung/e-health-gesetz.html

[10] Collins FS, Varmus H, A New Initiative on Precision Medicine, New England Journal of Medicine 2015; 372: 793-795

[11] EU-China IoT Advisory Group (2015) EU-China Joint White Paper on the Internet of Things

[12] http://huawei.eu/press-release/huawei-builds-large-scale-5g-testbed-real-life-environment-munich

immanent latency and the end-to-end latency of future networks should be clearly beyond 30 ms [13]. Ideally the network should cater for mobile technology as wiring of hospitals is extremely expensive, disruptive and in the case of leased facilities sometimes almost impossible.

Another important future topic which has already been subject to extensive research under the European FI-STAR project, which has been part of the European FI-PPP Programme is the end to end management of the pharmaceutical value chain in order to cut hospital waste and reduce patient and health care provider risks by preventing counterfeiting[14].

2 How can 5G be a catalyst for e-/m-Health?

The main requirements in the sector can be categorized along the line of "cared for" and "cared by", although we acknowledge that the categorisation is greatly simplified. In the category of "cared for" we put the user/patient including its social context; in the category of "cared by" we put the health professionals and providers as well as the health insurance providers, etc.

2.1 Health / Insurance Provider Requirements

- Increase efficiency
    - Optimise healthcare decision making processes
    - Empower patients, informal carers and lesser qualified professionals
    - Empower patients, informal carers and lesser qualified professionals
    - Optimise sourcing (e.g. cloud, outsourcing)
    - Reduce wastage of pharmaceuticals due to accidental expiry
    - Track hospital assets
    - Enable safe, secure and state of the art tele-surgery
    - Interlink health – and social care
- Engage cared for in proactive healthcare and wellness
    - Behaviour change capabilities
- Ubiquitous Access
    - Anytime and from everywhere (online, off-line, mobile)
    - Certificates for smart device interaction
- Flexible sharing with different providers / sources
    - Service interoperability
    - Data portability
    - Data owner authentication and authorization
    - Selective data sharing
    - Non-repudiation
- Information accountability
    - Certification (legal, ethical, technological)
    - Monitoring
    - Governance

[13] http://www.handelsblatt.com/technik/hannovermesse/mobilfunk-5g-die-ferngesteuerte-welt/11615084.html

[14] http://www.fi-star.eu

    - Non repudiation
- Auditability
- Protect patients and stakeholders
    - Prevent and counteract on counterfeited drugs
    - Patient identification
    - Object identification

2.2 User / Data Owner Requirements

- Support ability to choose where and how to obtain health care services
- Control over own data
- Accessible anytime and from everywhere (online and off-line, mobile)
- Flexible sharing with different processors / sources
- Consent for data sharing
- Data portability
- Monitoring Access
- Social interactions
- Storage by a trusted organisation, offering data / access information accountability measures (considering the legislative boundaries for the information storage and retrieval as well as possible location dependent deployment constraints), including possibly entirely self-hosted either through individual, organisational or community-driven schemes

A trusted organisation is typically the national or regional entity that provides infrastructures for offering data storage and access services. At the EU level these services are called EU is called Personal Health Record (PHR) and Electronic Health Records (EHR). The ePSOS[15] infrastructure, developed with support of the EC Competitiveness and Innovation Programme (CIP), provides service and semantic interworking capabilities between national PHR/EHR. Thus, the new 5G network should facilitate the integration with the service layer and enable an effective network resource negotiation (i.e. QoS, latency, speed, reliability, etc…). For this reason, it is necessary to investigate how the existing infrastructure matches the new 5G network infrastructure in order to save the investment already made, and address future requirements.

2.3 Future Healthcare application areas of interest

Here below some possible scenarios where the new capabilities offered by the 5G network can improve the right execution of the use cases.

2.3.1 Assets and interventions management in Hospitals

a) Assets tracking and management

Hospitals have to manage their assets as they are limited goods and can potentially be scattered over the entire hospital. On the other hand hospital needs to prevent their high value assets, for example wheelchairs, ECG (electrocardiogram) monitors, infusion pumps, etc. from being removed from the hospital. This does not always happen with bad intention but wheelchairs and other equipment might be taken by mistake by ambulance crews when patients are being discharged or transferred to other hospitals etc.

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[15] http://www.epsos.eu/

- Tagging and tracking of equipment and consumables in the operating theatre. Hereby it is important to manage a massive amount of objects for accountability, patient safety and governance / quality control.
- Real time tracking of value asset and geo-fencing. The hospital should be able to prevent the unauthorised removal of their value items
- End-to-end monitoring and management of pharmaceuticals along the value and supply chain. Prevention of counterfeiting and protection of patients from harmful drugs. Detection of «forgotten» pharmaceuticals and consumables, which are coming closer to their expiry date. Automated ordering systems.

b) Intervention planning and follow up

In the transplant scenario, the surgery planning requires the smart management of waiting lists to set the right priority of the items in the surgery list and setup the scheduling. For critical surgeries, a lot of information has to be available for the correct scheduling:

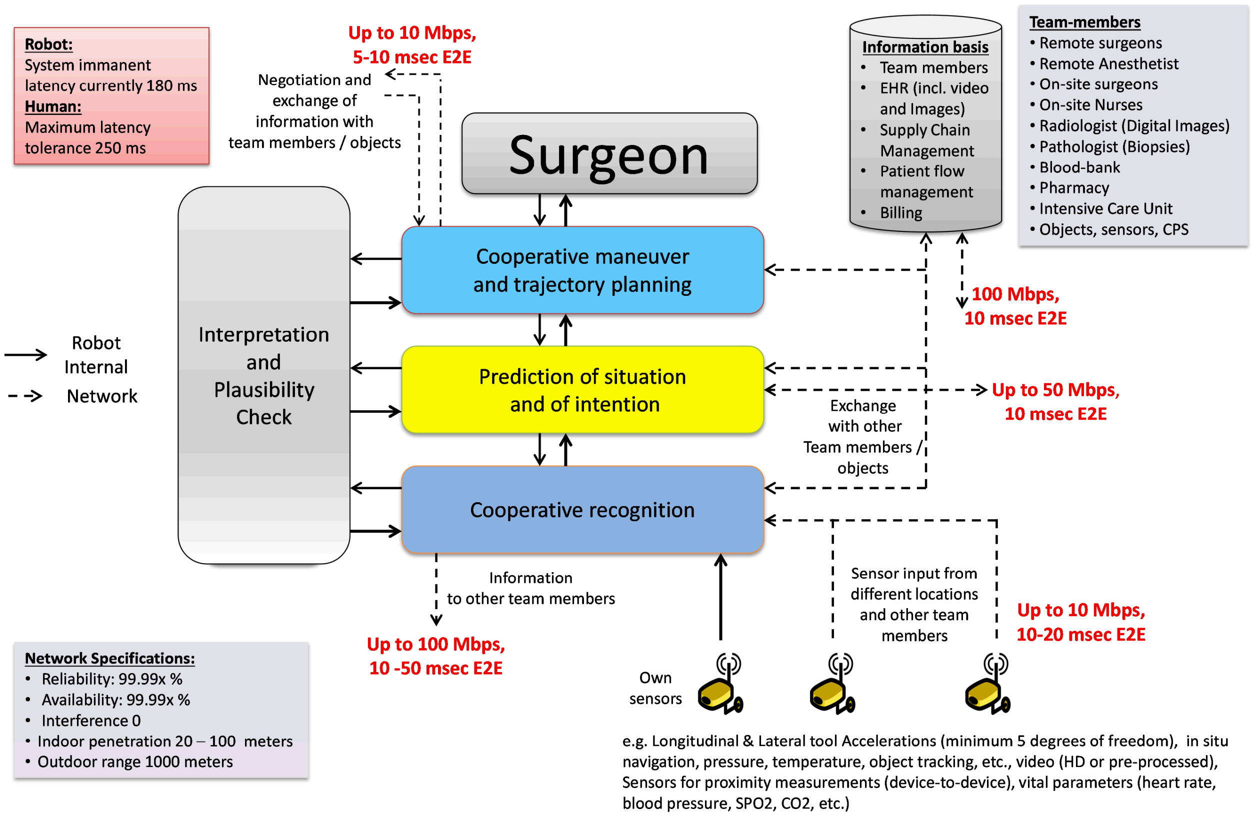
- Data from registry on organ donation and transplantation. Service integration with the registry on organ donation and transplantation could be suitable for planning transplantation according to priority and organ availability.
- Data on readiness of the theatre, availability of the right clinical staff (in the scrubbed area), etc.
- Data from the clinical history of the patient or, in case of follow up, clinical report and clinical images done during hospitalization (maybe in different healthcare facilities).
- Data related to vital signs and critical clinical parameters could be monitored for a rescheduling of the surgery list and the efficient follow up. In this critical context it is important to have available data of the patient updated in real time. It can be performed by means of continuous monitoring of the patient. This goal requires the availability of clinical staff for the management and monitoring of data and personal medical devices connected to a central infrastructure by means a secure and reliable network when the patient is located at home.

2.3.2 Robotics

a) Remote surgery

- Reduction of latency to enable remotely assisted surgery. Specialists are not available in many hospitals and could join a local surgeon remotely to perform certain procedures which require expert skills.
- Entering the operating theatre is time consuming and costly for surgeons. In the future surgeons would not have to be in theatre all the time but could operate robots from their offices via mobile connection.
- Senior surgeons would be able to assist junior surgeons remotely provided the end-to-end latency was well below 200 ms. The system immanent latency of a modern operating robot is already around 180 ms (DaVinci System).
- First experiences of remote surgery have shown that the first need is to have a better feeling of remote movements for surgeons to have a sensation closer to reality like the resistance of different organs (related to haptics improvement). Latency of 200 ms end-to-end would be enough for this use case.

In a robotics assisted tele-surgery scenario, the requirements for cooperative action coordination are immense, and include the guaranteed and reliable availability of information from back-end databases and real time data streams from a large variety of sources. Such a robotics assisted tele-surgery scenario is depicted in the next figure.



b) Cloud Service Robotics for Assisted Living

- Increasing storage capabilities; exploiting the capabilities of mobile robots to have a greater exchange of information with the environment and users.
- Offloading computation-intensive tasks to the cloud (i.e. natural language, object recognition, cognitive capabilities, etc.)
- Accessing and sharing a vast amount of data, knowledge, capabilities and acquired information.
- Management of fleet of robots over the Cloud with real time control.
- Reducing the cost of a single robot.

2.3.3 Remote monitoring of health or wellness data

a) Ageing well

The demographic profile of Europe is changing in a momentous way, with the familiar population 'pyramid' giving way to a new shape tapered at both ends. Before too long, its new form - many older people supported by dwindling numbers of young – will pose a real challenge to society. Ageing, and the illnesses that accompany later life, will demand resources to an extent that many existing social structures – and assumptions – will be tested to breaking point.

In particular the following aspects of life can benefit from mobile and fixed-line easy to use services:

- Tele-care and telemedicine: open up new opportunities for providing medical care to the home, including ways of monitoring well-being and improving the medical information available to healthcare providers.
- Personal health systems: these include wearable and portable systems for monitoring, diagnosis and therapy, and supporting treatment plans for individuals with chronic disease. They are complemented by tele-monitoring and tableware.

b) Life style and prevention

The prevention task should be addressed to save investments and to improve the effective of the treatments. Prevention, wellness and lifestyle are three topics strictly connected. The healthcare system has to be able to collect data from different fonts and make available to the citizen and clinical professionals. The effective prevention needs a personalization of the clinical profile. The personalized medicine is possible if genetic data, personal clinical history data, and data form monitoring activity, i.e. coming from wearable devices to take biologic signal, are available. These three categories of data can provide a complete personalized information framework to promote lifestyle and schedule screening programs. The availability of the data, especially from the wearable device or from the medical devices and the network is a precondition to develop pervasive services (also in residential environment) for data management and data provisioning. The availability of this data would support individuals' understanding of wellbeing and trends such as community well-being, including collaborative sense-making.

c) Follow up after acute events and assisted living in chronic scenarios

Often, after an acute episode there is the need to start managing the upset of chronic conditions in the patient. Putting the patient at the centre of this process would mean patients but also carers and families more empowered and educated: they can play a greater role in managing their own care. The type and amount of resources (organizational, IT services, data availability, and monitoring activity) that the system has to make available can vary depending of the intensity of care needed. Identifying the correct needs is crucial to have an efficient and effective usage of the IT infrastructure. The aim is to ensure that health and social care providers will process information to coordinate their activities in a seamless way in order to guarantee more effective and higher quality of care for citizens. As previously reported, the trend is to decrease inappropriate and unplanned hospital admission and consequently optimised the hospital resources (i.e. bed and structures for hospitalization downsizing) improving the treatments at home. Better chronic disease management translates into better quality of live and life expectancy for the patient that then translates into lower health care cost. To perform in efficient way this process of care one of the key point is the possibility by the service to negotiate in a standard way the network resources such as bit rate, QoS and network availability (in rural context as well as in urban context with high density of users).

2.3.4 Smarter medication

a) Beyond Monitoring: applying medication to the patient on a remote basis

The role of e-health and wearable devices can be exploited beyond the remote health monitoring and reporting to making decision on behalf doctors and performing the decision on the patients. In cases where a quick action is needed, such approach can have a dramatic effect on the probability and length of recovery in patients. For example, brain stroke is one of the rising health issues in the Europe and while it might cause significant disabilities to the patient, immediate medication can dramatically increase chances of recovery. The decision for medication could be made not only based on monitoring from the patient's body but also communicating various high risk factors (e.g. air pollution, temperature, etc.), with the city-wide monitoring devices.

It could leverage on advances in mobile diagnostics like:

- Sensor scanning, data analysis, data recording
- Small- and Big data analysis for Public Health (for example Epidemics / Pandemics)

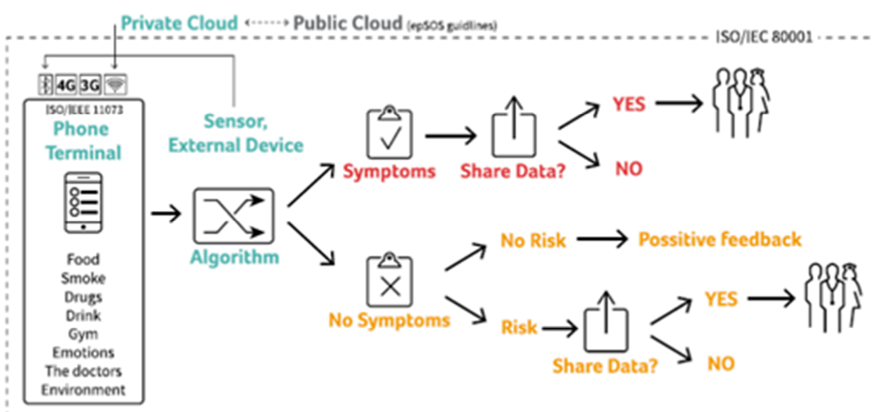
b) Smart Pharmaceuticals

New pharmaceuticals embedding connected devices could be used for the treatment of Asthma, Diabetes and Multiple Sclerosis, and the management of chronic diseases and pains in general. This would require however:

- Connection of thousand times more devices per geographical area
- Small data strings send to private clouds for further processing by health care provider, pharmaceutical companies and end-users after authorization by data owner
- Cyber-Physical Systems to be used in Personalised or Precision Medicine approaches as part of Health 4.0 strategy.
- Data to provide interface with smart algorithms on user's phones to support virtualization of care process

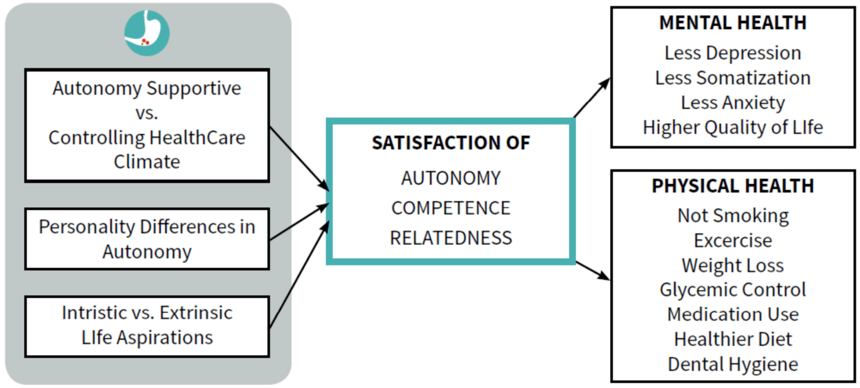
c) Algorithm supported theory-based health behaviour change

Behaviour change can be achieved in a hyper-connected community whereby the data keyed in by patients or captured by their smart phones from external devises (sensors, step counters, etc.) linked via Bluetooth are processed with the help of personal predictive algorithms. The personal predictive algorithm can be based on mathematical models such as Fuzzy Logic or Bayesian Logic. Information on the patients' environments, behaviour, emotional state and corresponding symptoms and vital signs such as blood pressure and heart rate can be sent from the connected devices via 5G data link to the healthcare provider in real-time to prevent severe episodes. The devices can also be connected to social network to allow the patient to interact with their health eco system at anytime, anywhere, anyhow in order to selectively share personal data safely and securely via the associated knowledge management system. The instant exchange of information will provide formal and informal carers with more information in real time and will help them to advise the patient more appropriately.



5G technologies will enable new ways of delivering personalised healthcare and more effective and efficient therapeutic approaches. Human computer interface and behaviour change theories such as the Self-Determination Theory[16] can be integrated in the design and development of m-Health applications. With the gathering of real-time psychological, physiological and symptomatic patient data and inputs from healthcare professionals, patients can achieve a greater degree of autonomy, competence and relatedness in self-managing their health and disease.

[16] Ryan, R. M., Patrick, H., Deci, E. L., & Williams, G. C. (2008). Facilitating health behaviour change and its maintenance: Interventions based on self-determination theory. The European Health Psychologist, vol.10: pp.2-5



Source: Self-Determination Theory, Ryan 2008

- AUTONOMY: Rather than a controlling health care climate, m-Health applications can enhance autonomy by giving the patient the choice to use the application any time, any place. Personalised predictive algorithm will allow for inter- and intra- individual differences with regards to lifestyle elements such as activity, stress and anxiety. The personal predictive algorithm will help patients to be more autonomous from clinical services and time schedules of healthcare professionals and formal carers.
- COMPETENCE: Offering specific information on diet and behavioural factors such as drinking, smoking and exercise can help to increase patients' knowledge about health and disease and address disease specific competence levels.
- RELATEDNESS: Patients can build and grow their own health eco-system with an interactive social network. They can selectively share and exchange their personal information with third parties safety and securely.

3 Technical requirements for 5G

3.1 Technical requirements and KPIs for healthcare use cases

In this section, we will detail the requirements for 5G related to each family of use cases identified in section 2.3.

The following definitions are used to provide precise application-specific requirements associated with each use case:

- Latency (ms): Maximum tolerable end-to-end latency from the time a data packet is generated at the source application to the time it is received by the destination application.
- Reliability (10-x): Maximum tolerable packet loss rate at the application layer (i.e., after HARQ, ARQ, etc.). A packet is considered lost if it is not received by the destination application within the maximum tolerable end-to-end latency for that application. For example, 10-5 means the application tolerates at most 1 in 100,000 packets not being successfully received with in the maximum tolerable latency. This is sometimes expressed as a percentage (e.g., 99.999%) elsewhere.
- Mobility (km/h): Relative speed below which the application should achieve the specified reliability.
- Positioning accuracy (cm): Maximum positioning error tolerated by the application.

a) Assets and interventions management in Hospitals

The first requirement for this family of use cases is the scalability of connectivity in terms of number of connected devices. Indeed, it requires following thousands of objects in each hospital.

The second requirement is a more precise positioning accuracy. Indeed, in order to find objects rapidly in a very big hospital, we need a precision around 1 meter in indoor conditions.

The third requirement is the support for multi-Radio Access Technologies with seamless handover. Indeed, the access technologies may vary in the different areas of the hospital and outside of the hospital (tracking of assets in ambulances or other hospitals) but the service should ensure a good continuity.

The fourth requirement concerns mobile assets. For example, medical helicopters must be connected and services must be available at mission flight (includes the requirement for service availability at typical flight altitudes). It translates into a requirement to have a mobility > 300 km/h.

b) Robotics

The first requirement for this family of use cases is the reliability of transmit/received data. The connectivity should be available even in case of natural disaster. Indeed, the continuity of a remote surgery intervention must be preserved in all cases in order to avoid losing lives.

The second requirement for this family of use cases is a low latency in the order of 30 ms to cope with the system immanent latency of operating robots.

c) Remote monitoring of health or wellness data

The first requirement for this family of use case is to improve coverage. Since classical healthcare delivery in densely populated areas has a much higher penetration than in rural areas, the healthcare service delivery in rural areas via the future network is of particular importance for the sector. There is also a need for a very good indoor coverage. Indeed, doctors should not lose the data connection with the patient because he is in his basement.

The second requirement is to improve energy consumption and battery life at device level. The ultimate goal is to be able to deliver connected devices (wearable/implants) that are self-sustainable from an energy point of view for the full duration of a medical treatment, which can be weeks, months or even years. The target at the horizon 2020 is to avoid any charge/battery replacement for at least 10 years.

Beyond that, a wearable/implant must be able to work on several service configurations to deliver a patient experience in function of the disease evolution and of the treatment improvements. The service upgrade/downgrade can't imply the wearable/implant obsolescence. As a result, 5G infrastructures should support the possibility to run virtual devices to complement the processing power and storage embedded in wearables/implants.

Furthermore, this family of use cases impose a requirement related to mobility at high speeds (> 300 km/h). Indeed, related devices, such as sensors, wearable/implant must be connected and available in situation of high-speed trains.

d) Smarter medication

This family of use cases require a better coverage and mobility, as well as a better energy efficiency for connected artefacts, in the same order of magnitude as for remote monitoring.

Beyond that, there is a strong requirement for increasing the number of connected objects per covered area. Indeed, smart pharmaceuticals could mean tens of drugs connected simultaneously inside each individual.

All healthcare use cases require a strong security due to their vital nature. 5G needs to provide a strong and reliable authentication system. Sensors must also be authenticated by the network and associated to the patient identity. Indeed, patients want to be sure that there is no identity theft and no private data distributed to unauthorized parties. In addition, doctors want to be sure of the data quality to avoid biased diagnostics and subsequent liability consequences. It strongly calls for a security technology like SIM or embedded SIM as explained in a recent report from GSMA[17].

CAPEX / OPEX are issues for health and should be integrated in the KPIs for 5G network. Healthcare costs are increasing faster than the GDP so costs are closely monitored by governments. For example, the UK has created an institute to calculate what is worth or not worth to invest in for the healthcare sector. Significant added value must be proven in order to justify additional expenditures for new capabilities.

The cost structures in the sector are under constant scrutiny and examination by the public and the responsible regulators. Everything going beyond current level of price on connectivity services will trigger the intervention of the regulator because the health market is a strongly regulated market. Budget holders are reluctant to introduce changes and new capabilities unless there is a substantial value proposition offered.

Thus cost is of tremendous importance for the healthcare sector. As a result, healthcare use cases have an enormous pressure for low investment costs and very low operating and recurring costs. The regulators play a very important role with respect to costs structures in the sector and may greatly influence the uptake of 5G network infrastructure based solutions grounded on pricing models.

Concerning investment costs in infrastructures (CAPEX) there is a high impact of the decision processes in the sector for the timely deployment of new solutions or the introduction of improved solutions for existing healthcare services. The extension of coverage of healthcare services is typically an important issue. Beyond infrastructure costs the e-Health budgets are facing an increased demand for new medical devices and pharmaceuticals that consequently must be produced and made available at low cost. Hence also connectivity solutions embedded in such devices must meet very stringent cost targets.

Concerning recurring and operating costs (OPEX) the deployment of new devices and capabilities increase the pressure on the available budgets as well. Hence deployed devices and new services that will be introduced must meet extremely low recurring costs, including but not limited to connectivity costs (e.g. connectivity for simple medical connected devices…), the cost to service them (e.g. battery replacement…), or the energy and maintenance costs of the whole infrastructure.

3.2 Overview of 5G

5G is the next generation of mobile communication technology. It is expected to be defined by the end of this decade and to be widely deployed in the early years of the next decade. There are a great many researchers studying 5G and its component technologies – in funded EU projects, in national programs, in individual companies and in research institutions.

[17] https://gsmaintelligence.com/research/2015/03/understanding-sim-evolution/499/

Many bodies have developed visions of 5G, including NGMN Alliance (5G White Paper[18], February 2015), ITU-R (Recommendation ITU-R IMT Vision, July 2015) and 5G PPP Infrastructure Association (5G Vision[19], February 2015). Together, they describe the primary aspects of 5G:

- Increased performance of mobile technology in terms of more throughput, lower latency, ultra-high reliability, higher connectivity density, and higher mobility.
- Support for the convergence of vertical applications onto a single common wireless network. This is enabled by a flexible usage and configuration of network functions to enable use cases with very diverse requirements by means of network slices. 5G should become the first radio communication system designed to smoothly integrate Human Type Communications (HTC) with Machine Type Communications (MTC), thus becoming an enabler for the Internet of Things (IoT).
- A new flexible radio interface or radio interfaces as enabler for the items above, for deployment both in current mobile bands and new spectrum that could go as high as up to the millimetre wave range.

The current Key Performance Indicators for the 5G infrastructure for the fully connected society, as discussed and highlighted in the 5G Vision whitepaper developed by the 5G PPP Infrastructure Association[19] are sufficient to satisfy most of the technical requirements in the healthcare sector:

- 1,000 X in number of connected devices reaching a density ≥ 1M terminals/km2
- 1/10 X in energy consumption compared to 2010
- 1/5 X in end-to-end latency reaching 5 ms for e.g. tactile Internet and radio link latency reaching a target ≤1 ms for e.g. Vehicle to Vehicle communication
- 99.999% aggregate service reliability for safety-critical services
- Mobility support at speed ≥ 500km/h for ground transportation
- Accuracy of outdoor terminal location ≤ 1 meter
- Support for shared infrastructure, multi-tenancy and multi-Radio Access Technologies with seamless handover

However, the strong coverage extension requirement (especially indoor) for remote monitoring and the reliability even in the case of natural disasters for remote surgery are not addressed explicitly and should be considered in the future work streams on 5G design and standardization.

4 Capabilities which are not yet supported by existing technologies

A crucial aspect for addressing various of the aforementioned requirements, such as latency, availability, providing services at (high) speed, and others, is that of supporting **flexible content and service function placement** that would evolve the current CDN model towards a model where server surrogates could be placed within the vicinity of end users, sensors, devices and the computing resources that make sense of data. Although cloud computing has seen entry into mobile-centric health deployment, e.g., through mobile offloading solutions or through the introduction of cloud-based fitness data storages (e.g., Apple

[18] https://www.ngmn.org/uploads/media/NGMN_5G_White_Paper_V1_0.pdf

[19] 5G Infrastructure Association. (February 2015). *The 5G Infrastructure Public Private Partnership: The Next Generation of Communication Networks and Services.* https://5g-ppp.eu/wp-content/uploads/2015/02/5G-Vision-Brochure-v1.pdf

HealthKit, Google Fit, Microsoft Health Vault), solutions in this space are still heavily reliant on centralized data centres and are therefore often counter strict latency or availability requirements.

While advances in Network Function Virtualization (NFV) and Software-defined Networking (SDN) have increased the ability to flexible allocate computing resources within the network, NFV-based flexible function placement is still in its infancy. One limitation is that of *Virtual Machine (VM) granularity*, where network functions (NF) are treated at the level of heavyweight VMs, making a flexible and fast deployment (e.g., for overload situations in vehicular congestion scenarios) difficult. Another problem is that of *routing inflexibility*, where current CDN redirections (even in the possible presence of lightweight VM techniques) lead to inefficient routing from clients to possible surrogates due to the necessary DNS manipulations that come with such surrogate injections. This is particularly important when network or service functions are to be provided at the level of surrogates, i.e., authorized mirrors of provider resources (e.g., storage or processing resources), where the aforementioned redirections are particularly problematic. **Routing simplification** is difficult to achieve without re-thinking the overall routing approach within the radio access network as well as re-thinking the insertion of surrogates without the need for DNS manipulation. Novel propositions in this space include information-centric networking (ICN), which provides the ability of demand-driven path computation at runtime, combined with a simple forwarding of information along up-to-date and demand-optimized paths. Although ICN has not seen entry into 3GPP and other activities, the advances of SDN and the ability of some ICN approaches to appear as SDN-driven routing improvements could accelerate the adoption of such approaches in the future.

4.1 Embedded SIMs

In a report[20], the GSMA reports that alternative SIM solutions have recently been deployed in some M2M devices and tablets compared to the traditional SIM card approach (a removable SIM card issued by one operator).

This report describes a soft SIM as a collection of software applications and data that perform all of the functionality of a SIM card but does not reside in any kind of secure data storage. Instead, it would be stored in the memory and processor of the communications device itself (i.e. there would be no SIM hardware layer).This report clearly states that the physical hardware element adds an indispensable layer of security. As a result, a soft SIM solution is not recommended for healthcare applications due to their stringent requirements on security and data privacy.

However, the report identifies embedded SIM cards that are fixed in the device and cannot be removed. The benefits of an embedded SIM approach are the potential ability to immediately and directly connect a medical device to the network and dramatically simplify management and deployment of connected medical devices in large numbers without user/patient interaction other than switching on a device.

4.2 End-to-end control

Today an end-to-end service typically spans several networking technologies with different ways of controlling communication in each technology segment. E.g., a wireless medical device connects via Bluetooth to a smartphone, which connects via WiFi to a residential router, which in turn connects via LTE to the wide area network, which terminates at a data centre possibly via yet another networking technology. The result is that a service provider has not the capability to control network performance

[20] https://gsmaintelligence.com/research/2015/03/understanding-sim-evolution/499/

and functionality across the chain of networking technologies. In life and mission critical applications this lack of end-to-end service quality control and assurance is a roadblock for massive uptake of such applications.

4.3 Variety of technology options

Today there exist a wide variety of wireless network technologies, ranging from short-range point-to-point communication, over wireless sensor networks, cellular networks, wireless networks of the IEEE 802-family of networks, etc. In many cases each of the technologies specifies a number of profiles that are aimed to meet certain requirements. This situation makes it extremely difficult for developers to make the best choice of technologies to implement in a wireless medical device. The plethora of choices (technologies and profiles) has a profound impact on the developers of middle-boxes (gateways …) aimed to support several of these wireless technologies. The result is that ensuring and certifying proper functioning of the devices (e.g. interoperability among each other) is an extremely costly undertaking and is a roadblock for massive deployment of properly functioning and certified devices for medical applications.

4.4 Ease of use, Quality of Experience

According to studies on the ambiguity of Quality of Service and Quality of Experience requirements for e-Health services by Ullah, M., et al[21], the most important determinants that influence the implementation of e-Health services are User Acceptance 37%, and Technology deployment factors 29%. Other factors such as Policy and Legislation, Financing factors or Competitive Advantage score lower.

Hence “ease of use” is a factor that promotes or inhibits the implementation of e-health systems. Clinicians are deterred from or resistant to using new systems that added complexity to their workflow, or required additional effort or time. In the case of an e-Health system supporting physician-patient interaction, an effective clinical decision support system must minimise the effort required by clinicians to receive and act on system recommendations. This requirement is extended to include ease of use for patients and their family members and other service users, or even health professionals besides clinicians, such as nurses.

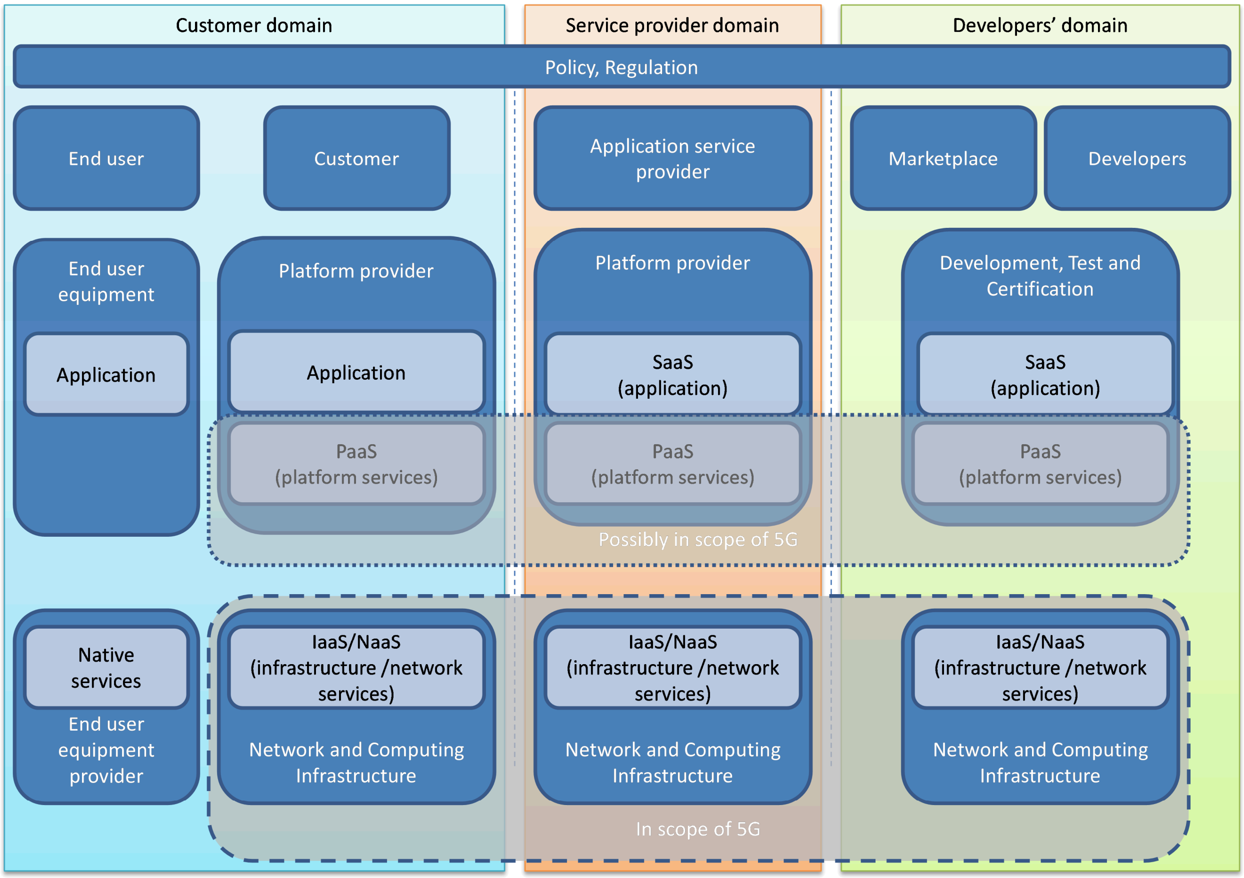
5 Business and policy aspects

5.1 Transformation of business models

Future business models and value chains should be flexible and adaptable to allow each stakeholder group to focus on its core competencies, such as delivery of care, sector application development, platform, infrastructure or network service provisioning. Identified interfaces must be specified, between all potential business roles that could be performed by stakeholders within the same of different administrative domains.

[21] Ullah, M.; Fiedler, M.; Wac, K., "On the ambiguity of Quality of Service and Quality of Experience requirements for eHealth services," doi: 10.1109/ISMICT.2012.6203030

The potential for supporting ecosystem development with flexible business models and value chains is illustrated in the following figure. In this figure the areas in scope or potentially in scope of the 5G network is depicted.



The business modelling concepts provide the means to model services in a multi stakeholder environment that offers future 5G infrastructures services. The business modelling concepts specify a common framework for all stakeholders in a service ecosystems and services market.

A business model which is constructed using the business modelling concepts of this framework uses the business roles and business relationships identified and described herein. Although the concepts derive from an e-Health biased services market, the concepts are generic enough, so that they can be used more broadly in the 5G infrastructure services context.

The instantiation of the abstract business model for a particular service enables:

- the identification of the business roles needed to provide a particular service,
- the association of the business roles with the involved stakeholders,
- the identification of the business relationships between the business roles and the business administrative domains owned by the stakeholders involved, and
- the specification of the reference points implementing the business relationships

The used concepts are defined as follows:

- Business administrative domain: A business administrative domain is defined by the requirements of one or more business roles and is governed by a single business objective. Business administrative domains interact with each other through reference points, which are the implementations of the business relationships between business administrative domains. The concept of business administrative domain is based on ownership. Ownership implies the universal privilege of managing the assets inside the domain.

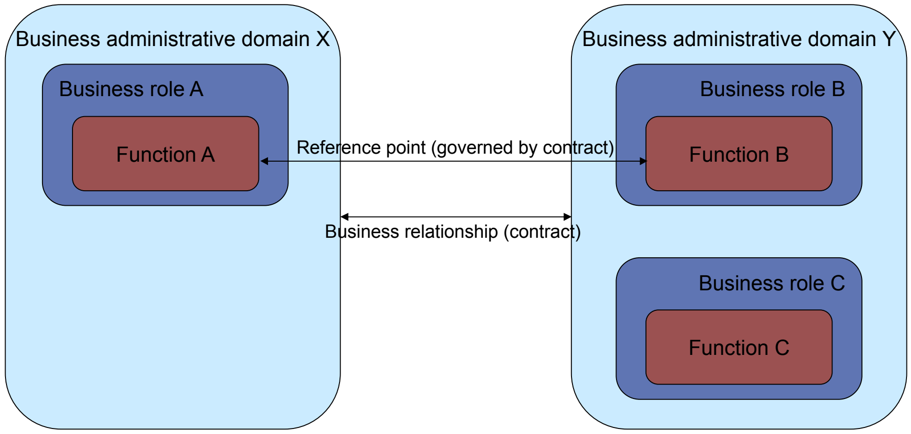
- Business role: The expected function performed by a stakeholder in a 5G infrastructure services enabled business environment. The business roles are identified by analysing the current and expected future business needs in the e-Health sector based on 5G infrastructure services. The definition of the business roles are driven by the following types of business separations:
  - Technical: areas of different development speed of technology are placed in different business roles.
  - Economic: business roles which are considered consumers and producers of services in the market are assigned to different business roles.
  - Regulatory: due to regulatory constraints certain separations of business roles are induced.

  All business roles play the role of user and provider towards specific other business roles. Whether a provider or user role is played is determined by the contract governing the interaction between the business roles. Business roles can be combined in business administrative domains to suit the needs of the stakeholder for its particular business.

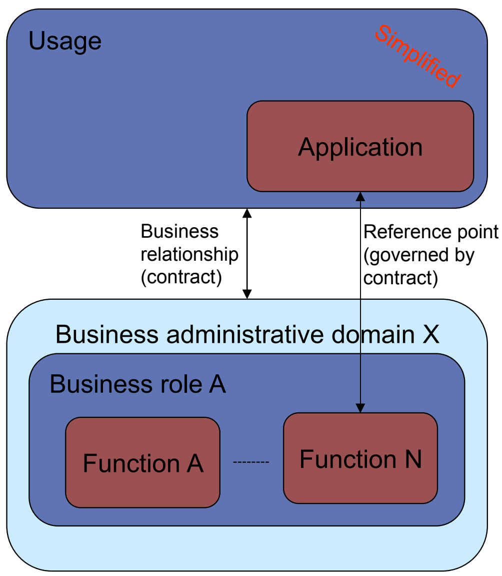
- Business relationship: An association between two business roles. A business relationship expresses the interaction requirements between two business roles. The manifestation of a business relationship between two business administrative domains is the reference point.
- Contract: A contract is the context defining constrains for one or more reference points to operate under. A contract provides the basis for the contexts defined in the supported specifications. Within the constraints specified in the contract, the contexts in the supported specifications can be modified by negotiation. However, the contract can never be modified as a result of the negotiations within the supported specifications, since a single specification only provides a partial view of the interactions between the business administrative domains and might violate the policies negotiated for other related specifications.
- Reference Point: The manifestation of a business relationship in the 5G infrastructure services enabled system. The reference point consists of several inter-related specifications governed by a contract. The specifications will typically cover aspects of information modelling and access interfaces (APIs).
- Stakeholder: A party that holds a business interest or concern in the 5G infrastructure services enabled business. A stakeholder owns one or more business administrative domains.

The basis of an open 5G infrastructure services enabled system is the set of assets that are used to instantiate and configure a service platform, and includes the information, networking and computing resources owned by business administrative domains and separated by reference points. In order to specify the policies and interactions between business administrative domains one needs to specify the visibility and rights on each type of asset in the domain with regard to related domains. These rights and visibility are included in a contract. The contract is established between business administrative domains and can be negotiated.

In the context of 5G infrastructure technologies and services, each function could be offered by a single business, implying that the functional modularisation of the 5G infrastructure service architecture is defined by business models. A single business role may offer several functions. These concepts are illustrated in the example figure below.



Following the modelling of the 5G infrastructure service level, which is the domain of the service providers and telecommunication operators, the same concepts can be used to model the use of the 5G infrastructure by the applications of the verticals. An application will typically be provided by an application provider which in turn uses the 5G infrastructure via its reference points (interfaces) that are governed as well by a contract between the application domain and the infrastructure domain as illustrated by the figure below.



5.2 Regulation, Policy, Standardisation

The considerations in standardisation and regulation must cover:

- Medical device technologies, including sensors
- Communications technologies
- Network Infrastructure, including access
- Software Technologies

5.2.1 Regulation

Regulation is an important challenge for the full deployment of m-Health solutions in Europe

- New m-Health devices are often covered by two regulatory frameworks

- Radio Equipment and Telecommunications Terminal Equipment (RTTE)
- EU Medical Devices Directives (MDD)
- Questions regarding the application and coordination between these different regulations
- Extended regulation for medical software
  - Medical software or medical device software are undefined terms to date
  - Software is considered an integral part of a product/device in the context of the EU Medical Device Directive
  - In the context of "softwaretized" networks with concepts like SDN (Software Defined Networks) and NFV (Network Function Virtualization), any 5G network applying these concepts and used for e-Health may also be considered integral part of the product/service (see also 5.2.2 Liability below).
- Data protection legal framework including practices and processes for:
  - Conditions and agreements to share private information
  - Obtaining consent from user/patient

5.2.2 Liability

Liability issues are introduced, since the network is inherent part of the service/product

- Traditionally product liability is limited to "products" in the form of tangible personal property
- The correct functioning of an IoT device includes the functioning network and service (in the cloud infrastructure)
- Smart (connected) devices will have a far reaching impact on manufacturers, service companies, insurers and consumers
- The product or service may become defective
  - Network or service failure (even temporal)
  - Discovered security vulnerabilities (in the device software, the "softwaretized" network, or the service in the cloud infrastructure)

5.2.3 Standardisation

- Many e-Health related standardisation bodies and initiatives at information, process and application level (IHE, Continua, …)
  - Increased attention to the semantic information interoperability / data nomenclature
- ETSI and ITU-T on networking aspects
  - ETSI M2M TC
  - ITU-T FG M2M (focuses explicitly on e-health)
- Specific requirements for standardisation have been identified
  - Security for personal health information
  - Privacy protection
  - e-health device profile support
  - Time synchronization and time stamping
  - Audit trail support

5.2.4 Spectrum

- ISM bands reserved for medical devices
  - ISM stands for Industrial, Scientific, Medical
  - Not intended use by Bluetooth, NFC, Wi-Fi, WSNs and in the future LTE-U
- Specific licensing of spectrum for medical use might be an innovation killer

- Manage interference
    - certify correct functioning
    - certify fair spectrum use

6 What is needed in terms of research and innovation?

Derived from the use-cases in chapter 2 and the requirements in chapter 3, the following technical areas can be foreseen of particular interest in terms of research and innovation for e-health:

- Massive machine-type communication (MTC) is a vital part of the overall 5G vision. Research efforts are required to further improve the MTC capacity in terms of density of connected objects per area and in terms of coverage. This capacity to extend coverage especially indoor and in rural areas is key for e-health applications.
- Improvement on latency, which can unlock use cases currently not supported by existing mobile communication technologies. More importantly than latency reduction, latency needs to be guaranteed, meaning that 99.999% of the packets needs to fulfil an upper latency bound limit of e.g. 30 ms in order to be usable for remote surgery.
- Reliability boost, which can match the existing wired solutions but also supersede them by e.g. using the inherent flexibility of 5G to improve the reliability of mobile communication substantially (e.g. automatic re-routing when there is a failure on a particular link). Massive MIMO techniques can also be used to improve the connectivity reliability.
- Energy consumption optimization is also very important for healthcare applications. In order to reach an autonomy of more than 15 years for wearables or implants, we need to revisit all communication layers from the air interface, where advanced MIMO and beamforming techniques could help to focus the energy usage where it matters, to the control layer in order to avoid unneccesary transmissions.
- Adequate security mechanisms are also needed to take into account the limited capabilities of constrained sensors, as well as the additional vulnerabilities if part of the security functions are offloaded to the cloud. Some important research objectives in this field are as follows:
    - Identity management: Networks should uniquely identify and authenticate health devices/wearables and control their remote access with a timely update of certificates.
    - Privacy protection: Personal information may be disclosed, but only with the individual’s knowledge and consent.
    - Data and message encryption and protection: Data and messages exchanged should be secured and checked for consistency.
    - Update of security mechanisms: The security mechanisms and algorithms should be developed such that they can be updated to adapt to new hackers threats.
- Research is also needed to build seamless multi Radio Access Technologies connectivity solutions. We can cite in particular the following topics:
    - o Flow based coordination schemes for multi-RAT communication.
    - o Procedures for multi-RAT interworking that allow embedding existing communication solutions (including short-range technologies) comprising multi-RAT mode selection.
    - o Optimized routing protocols for multi-RAT and multi-interface communications.
- Last but not least, 5G will embed advanced automation towards autonomics and cognitive management features which will improve operators efficiency and decrease basic connectivity prices for healthcare applications. Furthermore, ultra-low cost network options will be developed for low ARPU services or low density areas where it is hard to invest today. Lower

cost technologies at all levels of networks (access, backhaul, core, IT, energy) will be explored by relaxing target objectives on availability, peak rate, and latency.

Furthermore innovation in this sector towards massive deployment of new and upgrades m-Health and e-Health services based on 5G network infrastructure services requires attention on the following areas:

- Inter-disciplinary and evidence based trials and pilots of m-Health to support implementation and deployment. In particular in the area of "apps" that are being developed by various stakeholders there are not standards or best practices that support an assessment of whether an app is useful for purpose or even safe to use. Currently there is little evidence on the effectiveness of m-Health apps and as a consequence little experience on how to best evaluate such apps. The current trends suggest that there exists a great potential in promoting health education, lifestyle and even support clinical settings. However the currently fragmented landscape must be accompanied by clear frameworks of regulation and control to ensure quality design, appropriate recommendations on the use and application on issues as privacy and confidentiality or safety data.
- Pathways toward partnership between entrepreneurial technology developers and innovative healthcare systems to drive healthcare transformation. Entrepreneurship and Innovation are important processes for economic growth and for competitiveness that apply also in the e-Health sector albeit it is strictly regulated. In this context the development of human capital and fostering entrepreneurial spirit are essential elements to match technology innovation with societal and business challenges.
- Identification of innovative trial methodologies for use in the m-health sector. Following the centralised model of care delivery to date, most methodologies to assess the effectiveness of a treatment or programme are also centralised. However due to its inherently decentralised nature, m-Health requires new methodologies for trials' and pilots' evaluation, that consider and best leverage the distributed and decentralised service model.

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