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Status quo analysis on service models and regulatory framework

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ENSAFE

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Content

1. Introduction Status quo analysis on service models and regulatory framework

Work package 1 was all about the initial need assessment and status quo involving users and stakeholders. The initial case finding started with the identification of the archetypical end users of the project products in each pilot region. The end users were defined as elderly (aged 65+) with mild to moderate care needs, who are physically able to use a normal mobile phone and are able to independently manage their personal care. These end users were involved in a wide spread survey in the different regions during which almost 400 end users were included. These results were then validated in smaller focus group sessions with involved stakeholders which resulted in a good insight and need assessment of the end users to feed in the preparations for the prototype development and service solution. Subsequently, co-creation sessions were scheduled to support the definition of the product service concept and iterations.

Figure 1: Focus areas and involved stakeholders within the ENSAFE project

However, for the ENSAFE project to become successful other input needs to be taken into account during the development as well. Therefore a status quo analysis on the current service models and regulatory framework was carried out relying on input from the partner countries. The input gathered will feed into the draft business model including value proposition and business plan by detecting the feasibility for the integration of the developed product service systems into the operation of the health and/or social care institutions at the local pilot sites. Regulatory issues need to be collected since they have implications for the feasibility of service deployment and scalability.

After discussions with partners it was decided that this should be seen as a live document as Regulations and Status Quo is in constant flux across all European markets. Furthermore, the Ambient Assisted Living Program should be approached as they may have better knowledge and be able to support in this area. The partners suspect that while there may be local factors that will need to be considered (ie on a country to country basis) there may also be European Regulations that will need to be investigated as the ENSAFE “product” will be deployed across Europe.

2. Definition of health and ehealth

At the beginning of a project it is important to have make sure all partners are on the same page and talking the same language. Therefore definitions of health and eHealth were shared and approved.

According to the World Health organisation is the definition of Health “a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”. The definition has not been amended since 1948 (WHO, 2016).

There is considerable international interest in exploiting the potential of digital health care solutions, often referred to as eHealth—the use of information and communication technologies—to enhance the quality and safety of health care. Often accompanied by large costs, any large-scale expenditure on eHealth—such as electronic health records, picture archiving and communication systems, ePrescribing, associated computerized provider order entry systems, and computerized decision support systems—has tended to be justified on the grounds that these are efficient and cost-effective means for improving health care. In 2005, the World Health Assembly passed an eHealth resolution (WHA 58.28) that acknowledged, “eHealth is the cost-effective and secure use of information and communications technologies in support of health and health-related fields, including health-care services, health surveillance, health literature, and health education, knowledge and research,” and urged member states to develop and implement eHealth technologies. Since then, implementing eHealth technologies has become a main priority for many countries. For example, England has invested at least £12.8 billion in a National Programme for Information Technology for the National Health Service, and the Obama administration in the United States has committed to a US$38 billion eHealth investment in health care (Black et al. 2011).

But what is the definition of ehealth?
According to Eysenback in 2001 this word was barely in use before 1999, this term now seems to serve as a general "buzzword," used to characterize not only "Internet medicine", but also virtually everything related to computers and medicine. And it still is..

The term was apparently first used by industry leaders and marketing people rather than academics. However, as another member of the Editorial Board noted, "stamping a definition on something like e-health is somewhat like stamping a definition on 'the Internet': It is defined how it is used - the definition cannot be pinned down, as it is a dynamic environment, constantly moving." (Eysenbach, 2001)

e-health is an emerging field in the intersection of medical informatics, public health and business, referring to health services and information delivered or enhanced through the Internet and related technologies. In a broader sense, the term characterizes not only a technical development, but also a state-of-mind, a way of thinking, an attitude, and a commitment for networked, global thinking, to improve health care locally, regionally, and worldwide by using information and communication technology. (Eysenbach, 2001). Below the 10 E’s of eHealth are listed as defined by Eysenbach (2001).

Table 1: The 10 e's in "e-health" (Eysenbach, 2001)

Efficiency	One of the promises of e-health is to increase efficiency in health care, thereby decreasing costs. One possible way of decreasing costs would be by avoiding duplicative or unnecessary diagnostic or therapeutic interventions, through enhanced communication possibilities between health care establishments, and through patient involvement.
Enhancing quality of care	Enhancing quality of care - increasing efficiency involves not only reducing costs, but at the same time improving quality. E-health may enhance the quality of health care for example by allowing comparisons between different providers, involving consumers as additional power for quality assurance, and directing patient streams to the best quality providers.
Evidence based	Evidence based - e-health interventions should be evidence-based in a sense that their effectiveness and efficiency should not be assumed but proven by rigorous scientific evaluation. Much work still has to be done in this area.
Empowerment of consumers and patients	Empowerment of consumers and patients - by making the knowledge bases of medicine and personal electronic records accessible to consumers over the Internet, e-health opens new avenues for patient-centered medicine, and enables evidence-based patient choice.
Encouragement of a new relationship	Encouragement of a new relationship between the patient and health professional, towards a true partnership, where decisions are made in a shared manner.
Education of physicians & consumers	Education of physicians through online sources (continuing medical education) and consumers (health education, tailored preventive information for consumers)
Enabling information exchange and communication	Enabling information exchange and communication in a standardized way between health care establishments. computers and networks, cannot use computers effectively. As a result, these patient populations (which would actually benefit the most from health information) are those who are the least
Extending the scope of health care	Extending the scope of health care beyond its conventional boundaries. This is meant in both a geographical sense as well as in a conceptual sense. e-health enables consumers to easily obtain health services online from global providers. These services can range from simple advice to more complex interventions or products such a pharmaceuticals.
Ethics	Ethics - e-health involves new forms of patient-physician interaction and poses new challenges and threats to ethical issues such as online professional practice, informed consent, privacy and equity issues.
Equity	Equity - to make health care more equitable is one of the promises of e-health, but at the same time there is a considerable threat that e-health may deepen the gap between the "haves" and "have-nots". People, who do not have the money, skills, and access to likely to benefit from advances in information technology, unless political measures ensure equitable access for all. The digital divide currently runs between rural vs. urban populations, rich vs. poor, young vs. old, male vs. female people, and between neglected/rare vs. common diseases.
Easy-to-use **Entertaining** **Exciting**	In addition to these 10 essential e's, e-health should also be • easy-to-use, • entertaining (no-one will use something that is boring!) and • exciting - and it should definitely exist!

3. ENSAFE Vision

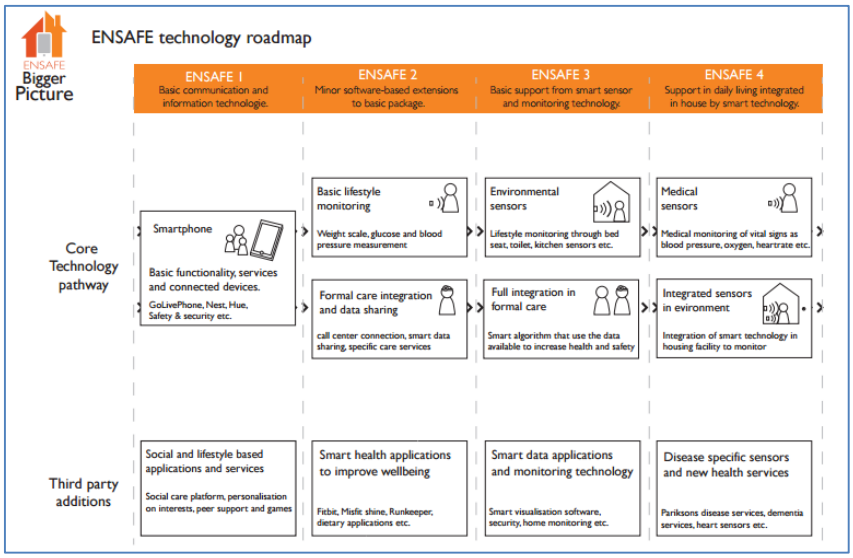
The ambition of the ENSAFE project is to develop a dynamic platform based solution that caters for the entire continuum of care. Due to the flexible and custom nature of the ENSAFE solution it is able support people in different ways and address a wide variety of needs. In the pilot as part of this project we will evaluate a few of these specific cases to showcase the potential of the solution.

Within ENSAFE smart services are enabled by a perceptive layer, based on an heterogeneous set of sensing devices, including: smartphones, wearable sensors, home environmental sensors and clinical monitoring devices. Data coming from such devices will be gathered, fused and analyzed to infer useful information about the users' daily lives and health status. Outcome of such data processing will in turn enable feedback strategies toward the user itself (supporting awareness and motivation in pursuing healthy behaviors) as well as toward caregivers and healthcare services (supporting continuous monitoring, prevention and early diagnosis strategies). The goal in ENSAFE is to design and develop a platform and services that should be possible to implement in all countries and as well be able to commercialize in a broader market with business models that make it possible for partners and (third party) suppliers to make the step towards business in the care sector.

The ultimate goal of the whole data gathering and storage process is to enable the subsequent data analysis phase, during which the ENSAFE engine should be able to extract meaningful information about user's daily life habits and provide useful feedback to encourage healthy behaviours. In order to perform such a task, heterogeneous data fusion is necessary: merging the information provided by the smart home, the mobile phone and the clinical sensors together creates a richer description of what the routines of the user may look like. Also, combining information from multiple users may lead to much accurate and useful system feedback

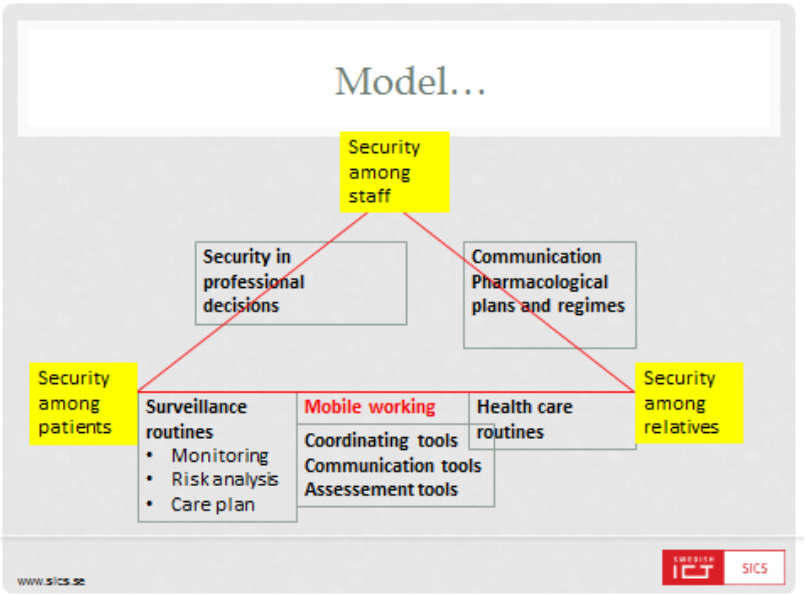
As a first step to support this vision we made a technology road map which takes the Smartphone (GoLivePhone) as a starting point to add custom hardware and service to as a flexible growing model. The figure is divided in five stages that correlate technology advancement with user needs. These are defined as: (1) Basic technology (Smartphone), and no healthcare needs, (2) Basic technology with extended service and minor healthcare needs, (3) Medically extended sensor platform and medium/high healthcare needs, and finally (4) intensive healthcare need in care home environment. These phases will be taken into account when further developing the business and service models in WP4.

Figure 2: ENSAFE Technology roadmap



4. National and international main regulation frameworks in Sweden

In Sweden there are different responsibilities in health care. The municipalities are responsible for social care and social assistance. The county councils/regions are responsible for health and medical care and dental care. The health care system is tax-financed and decentralised (95%) where the 21 county councils finance almost all health care and provide most of the services. Each county decides on patient fees and mechanisms for paying providers. The state establish principles/guidelines, distribute responsibilities, supervises and allocates government grants. There are structural changes in Swedish health care with a movement from inpatient care to outpatient care and hospital care to home care. There is a focus on prevention of re-admission and priority areas are defined for optimal treatment of multiple diseases frail elderly (identification of frail persons at risk, planning and proactive approach to patient needs, follow up of patient condition, information and communication between patients, family members and staff). Service scenarios are developed like remotely security service and mobile working tools which need to fit the model below.



To which regulations medical devices and software with medical purpose should apply has been summarized by Medical Information Systems – guidance for qualification and classification of standalone software with a medical purpose: https://lakemedelsverket.se/upload/eng-mpa-se/vagledningar_eng/medical-information-system-guideline.pdf.

5. National and international main regulation frameworks in the UK

The UK has 2 main considerations when considering the route to market and regulation, The TSA and ORCHA.

The Organisation for the Review of Care and Health Applications (ORCHA: http://www.orcha.co.uk/) is building an evidence based framework to analyse the Quality of Health/Care Apps for the UK (and later will become international). Therefore, we approached them to give an overview of the necessary regulations that need be adhered to and in the future, further investigation will be needed to ensure ENSAFE scores highly according to their quality criteria. This will ensure that people searching for Apps see ENSAFE as close to the top of the list as possible. Please see overviews below.

Quality and safety

- The Medical Devices Directive (CE mark for medical devices): Council Directive 93/42/EEC.
- CE marking is regulated by the Medicines and Healthcare Regulatory Authority (MHRA) in the UKRelevant links
- PAS 277:2015: Health and wellness apps – Quality criteria across the life cycle – Code of practice.
- ISO13485
- ISO9000
- BS ISO/IEC 90003,
- ISO 9001:2000
- BS EN ISO 14971

information security, data protection, data and information sharing.

- ISO/IEC 27001 - Information security management Data protection Act
- DD ISO TS 25237, Health informatics – Pseudonymization
- GREAT BRITAIN. The Data Protection Act 1998. London: The Stationery Office.
- GREAT BRITAIN. The Consumer Protection Act 1987. London: The Stationery Office.
- SNOMED Clinical terms. Available from: http://ihtsdo.org/snomed-ct/
- HEALTH & SOCIAL CARE INFORMATION CENTRE. UK Terminology Centre (UKTC). Available from: http://systems.hscic.gov.uk/data/uktc.
- HEALTH & SOCIAL CARE INFORMATION CENTRE. HSCIC interoperability toolkit (ITK). Available from: http://systems.hscic.gov.uk/interop/background/itk/faqs
- National Information Board Interoperability guidance http://www.isb.nhs.uk/about/publications/interoperability.pdf

User experience

- The most useful guidance is that provided by Google Play and the Apple Store guidelines.
- BS EN 62366:2008, Medical devices – Application of usability engineering to medical devices
- Web content accessibility guidelines http://www.w3.org/WAI/intro/wcag

The Telecare Services Association (TSA) has recently rebranded to Telecare Voice (https://www.tsa-voice.org.uk/). This is the industry body for Technology Enabled Care (TEC), representing the largest industry specific network in Europe and bringing together a growing membership of organisations across local government, health and the private sector.

They organise the annual International Technology Enabled Care Conference and drives quality throughout the sector through its internationally recognised Integrated Code of Practice.

TSA is a not-for-profit membership based organisation, with a current membership of over 350 organisations across the UK and overseas. It is estimated that TSA's members currently help over 1.7 million people to remain in their own homes (rather than hospitals, care homes and other institutional settings) – supported by their families, friends and carers in familiar surroundings.

TSA works across health, housing and social care through a wide range of public services (NHS, local authorities, Fire and Rescue Services), housing associations, leading industry suppliers, independent and voluntary sector organisations. TSA welcomes all organisations who have a professional or commercial interest in the provision of technology assisted services, including telecare, telehealth and mHealth. TSA promotes and supports the technology enabled care industry, highlighting the benefits of TEC for commissioners across health and social care, service users, their family and carers.

TSA Integrated Telecare and Telehealth Code of Practice Matrix

	PROCESS MODULES								
	ACCREDITED SERVICES								
	Service Blueprint	Referral	Assessment		Service Set Up		Monitoring	Response	Re-Evaluation
STANDARDS MODULES	Service Blueprint	Referral/Risk Stratification	User Profiling	Telecare/ Telehealth Plan	Service Tailoring	Installation	Monitoring	Response	Re-Evaluation
Safeguarding	✓	✓	✓	✓	✓	✓	✓	✓	✓
Organisational and Clinical Governance	✓	✓	✓	✓	✓	✓	✓	✓	✓
Staff & Training	✓	✓	✓	✓	✓	✓	✓	✓	✓
Information Governance	✓	✓	✓	✓	✓	✓	✓	✓	✓
Partnership Working	✓	✓	✓	✓	✓	✓	✓	✓	✓
User Communication	✓	✓	✓	✓	✓	✓	✓	✓	✓
Managing Access/ Working in the Home			✓			✓	✓	✓	✓
Technology Management						✓	✓	✓	
Business Continuity	✓					✓	✓	✓	
Development of SC							✓		
Legislation inc Health & Safety	✓	✓	✓	✓	✓	✓	✓	✓	✓
Key Performance Indicators	✓	✓	✓			✓	✓	✓	✓

✓ Telehealth only ✓ Telecare & Telehealth SC = Service Centre

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Innovation and Health Connected

BS EN 50134 – 7

If you are an equipment supplier:

Medical Devices Directive 93/42/EEC
ISO 13485
ISO 14971
ISO/IEC 27001

Social alarm:	EN50134-1 (system requirements), EN50134-2 (trigger device), EN50134-3 (local unit and controller)
EMC:	EN55022, EN55024, EN50130-4, EN301489-1, EN301489-3
Safety:	EN 60950
Radio:	ETSI EN300 220-2 Category 1
CE:	Compliant
Radio frequency:	869.2125MHz, compliant with European Social Alarm frequency band

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6. National and international main regulation frameworks in the Netherlands

- Gedragscode Elektronische Gegevensuitwisseling in de Zorg
- NEN 7510 - Informatiebeveiliging in de zorg
- NEN 7512 - Vertrouwensbasis voor gegevensuitwisseling
- NEN 7513 - Vastleggen van acties in elektronische patiëntendossiers
- NEN 8028 - Kwaliteitseisen telemedicine
- NHG-richtlijnen over informatie-uitwisseling
- Richtlijn Overdracht van medicatiegegevens in de keten
- ISO 27001/27002 (standaard voor inrichting processen rond informatiebeveiliging)
- NEN 7510 (gebaseerd op implementatie ISO 27002)
- NEN 7512 en NEN 7513
- Nictiz-norm voor Goed Beheerd Zorgsysteem
- For apps: To become a medical tool apps/services should have a CE marking approved by EU and IGZ (NL).

7. National and international main regulation frameworks in Italy

About Privacy in Healthcare

- D.LGS. 196/03, Codice in Materia di Protezione dei Dati Personali
  L. 145/2001, Ratifica ed esecuzione della Convenzione del Consiglio d'Europa per la protezione dei diritti dell'uomo e della dignità dell'essere umano riguardo all'applicazione della biologia e della medicina
  L. 833/1978, istitutiva del Servizio Sanitario Nazionale

About Quality/Accreditation/Certification in HealthCare

- Quality System ISO 9001:2000
  International Quality Indicator Project (IQIP)
  The Joint Commission Standards
  European Foundation for Quality Management Standards

About Safety

- D.LGS. 81/08 e s.m.e i., Testo Unico sulla Sicurezza
  [EU Commission Regulation no. 1275/2008]
- CEI 64-8: Impianti elettrici e utilizzatori
- CEI 74-2: Apparecchiature per la tecnologia dell'informazione)

Italian Ministry of Health: workgroup on mHealth (hyperlink)

8. European Regulation

The European Commission put forward its EU Data Protection Reform in January 2012 to make Europe fit for the digital age. More than 90% of Europeans say they want the same data protection rights across the EU – and regardless of where their data is processed.

Everyone has the right to the protection of personal data.
Under EU law, personal data can only be gathered legally under strict conditions, for a legitimate purpose. Furthermore, persons or organisations which collect and manage your personal information must protect it from misuse and must respect certain rights of the data owners which are guaranteed by EU law.

Every day within the EU, businesses, public authorities and individuals transfer vast amounts of personal data across borders. Conflicting data protection rules in different countries would disrupt international exchanges. Individuals might also be unwilling to transfer personal data abroad if they were uncertain about the level of protection in other countries.

Therefore, common EU rules have been established to ensure that your personal data enjoys a high standard of protection everywhere in the EU. You have the right to complain and obtain redress if your data is misused anywhere within the EU.

The EU's Data Protection Directive also foresees specific rules for the transfer of personal data outside the EU to ensure the best possible protection of your data when it is exported abroad.

But how?
There are different laws related to software security and privacy in EU. Think about EU data protection laws and Guidelines, International and EU security standards, Member states' laws for healthcare and Hospitals' specific requirements. However, these are only some of them, meaning that complying with EU regulations is expensive and time-consuming.

The Health Data Security Platform for EU Devs & Enterprises Chino.io has created an overview of only a limited list of points which needs to be taken into account when working with healthcare services, eHealth apps, medical devices and wearables and IoT.

Figure 3: Source: https://www.chino.io/software-compliance

Changes in the EU digital health and data protection in 2015

In one of the blogs written by Jovan Stevovic of Chino the changes that 2016 would bring for digital healthcare in the EU were outlined and summarized here below.

Privacy related changes
First of all, the EU General Data Protection Regulation was finally approved. More than 90% of all Europeans said that they would like the same data protection right in the EU. Now their dream is coming true. The GDPR is adopted and every organization will need to comply with it by 2018. It will replace the European Data Protection Directive of 1995 and will finally introduce one single law for all 28 EU Member States, changing the digital health market and it's security.
Secondly, the "Safe Harbor" agreement was cancelled with the decision of the European Court of Justice. Before being cancelled, the agreement promised to protect EU citizens' data (including their health data) if they were transferred to companies located in the USA. This agreement was necessary because EU privacy laws forbid transfer of such data outside of the EU. Exception could be done only in case if the transfer is done to a location with privacy protection in line with the European. And now this is not possible anymore.

Cybersecurity related changes
Speaking about security of eHealth data, Jovan Stevovic refers to the new Network and Information Security (NIS) Directive. This Directive has been recently approved and aims at making EU eHealth services more secure. It rules that healthcare providers have to take necessary security measures and notify national authority about serious cyber incidents. National authorities, in turn, will be able to impose sanctions on companies which fail to adopt needed measures.

A lot of changes took place also in the narrow mHealth field targeting specifically mobile apps. EU Commission in 2015 was continuously working on this issue, publishing related documents such as its Opinion titled "Mobile Health. Reconciling technological innovation with data protection". This Opinion looks closely at types of data processed in the mHealth context and design of mHealth apps.

The EU security advisory body ENISA is also working on security of eHealth systems in each EU Member State. Last year ENISA published a report on each country status in this field. Finally, at national level the Member States themselves have started analysing the possibility of regulating mHealth, as it happened in case of Italy.

Relevant and related resources concerning digital health and data protection:

- European Commission - Data protection documents
- EU Data Protection Directive on Wikipedia
- EU General Data Protection Regulation (final)
- EU General Data Protection Regulation approval news
- Agreement on Commission's EU data protection reform will boost Digital Single Market
- The Guardian: Safe Harbor declared invalid by EU Commission
- NIS directive: More cybersecurity for eHealth
- EU Data Protection Supervisor: Opinion 1/2015 on Mobile Health
- ENISA: Security and Resilience in eHealth Infrastructures and Services