2019-07-11

Project Plan for the CEN Workshop on guidelines for introducing tele-medical and pervasive monitoring technologies balancing privacy protection against the need for oversight and care

CEN/WS 102

1. Status of the Project Plan

- Initial draft Project Plan, to be further developed, prior to submission for approval
- Draft Project Plan to be approved at the Kick-off meeting of the Workshop
- Approved Project Plan

2. Background to the Workshop

2.1. Introduction to REACH project

The health expenditure in the EU is expected to rise by 350% by 2050 compared to an economic expansion of only 180% and the provision of Long Term Care (LTC) will pose an increasing challenge to the sustainability of public finances in the EU, due to an ageing population. REACH[1] therefore represents a solution that seeks to prevent elderly citizens from loss of function and a decline of being able to perform Activities of Daily Living (ADLs) independently leading ultimately to entering LTC. REACH is a personalized prevention and intervention system that promotes the activity of the elderly by monitoring and evaluating their daily habits, considering both personal medical history as well as real-time gathered data from a series of wearable and embedded sensors, in order to mitigate loss of function and to arrest associated and/or consequential morbidities via a number of physical and virtual activity intervention modules. REACH is an open solution that proposes its own innovative systems while remaining compatible with existing sensing systems and technologies[2]. In this context, it is recognized that guidance is needed to balance privacy against the need for oversight and care.

2.2. Motivation for the Creation of this Workshop

The GDPR and European national legislations impose limitations on introducing technologies that enable professional and informal care providers to monitor continuous information on a person's activities and actions even when such monitoring is conducted for the purpose of care. At the same time, sensor-based monitoring techniques can reduce the risk of, for instance,

[1] More information on the REACH (**R**esponsive **E**ngagement of the Elderly promoting **A**ctivity and **C**ustomized **H**ealthcare) project can be found under: http://reach2020.eu/

[2] Source: https://cordis.europa.eu/project/rcn/200425/factsheet/en

demented citizens wandering about and getting lost and becoming helpless or frail elderly citizens suffering bouts of incapacity at home without being noticed for possibly several days. Data on patients' vital parameters have been monitored and transmitted in tele-medical applications for many years; however, using pervasive sensing technologies, it is now possible also to monitor and capture (nearly) all daily activities and, for care purposes, critical deviations from expected patterns. Several countries have well-established regulations and codes of practice for geo-tracking demented citizens; but care organisations, including municipalities and hospitals that wish to monitor patients after discharge or when closer monitoring is needed, lack guidance on how to introduce, implement sensor-based monitoring technologies (SMT), including ensuring and obtaining informed consent from patients and citizens in need of care and rehabilitation. The workshop plans to provide this guidance.

2.3. The market environment

There is a rapidly growing range emerging technologies – part of the large market of Internet-of-Things and Smart Home technologies– that are becoming available as part of tele-health to care organizations in their effort to support an increasing care burden while controlling costs. Using SMT, care organisations may save staff time for physical visits and transport and, at the same time, provide peace-of-mind to frail citizens and their families, allowing earlier detection of critical events and changes of behaviour. It is desirable for care organizations (and, by extension, patients' rights associations and industries that develop and supply SMTs) to have a well-based and generally approved set of guidelines for navigating the trade-offs between infringing on/respecting privacy, ensuring high quality care with timely detection of critical events, and controlling costs of care.

2.4. The legal environment

The European GDPR has introduced the concepts 'Privacy by Design' and 'Privacy by Default', where Privacy by Designs holds that organisations need to consider privacy at the initial design stages and throughout the complete development process of new services involving personal data. Privacy by default means that whenever a system or service includes choices for the individual on how much personal data he/she shares with others, the default settings should be the most privacy friendly ones. The GDPR is being implemented in European national legislations.

2.5. Existing standards and standard related activities and documents

The most important existing standards for the Project Plan are listed in the following table. This list is non-exhaustive.

Number	Title
ISO 9001	Quality management systems - Requirements
ISO/TS 13131	Health informatics - Telehealth services - Quality planning guidelines
ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes

While security is excluded from the scope of the planned document, there are overlapping risk issues and we must take into risk and security management requirements and standards laid down in the following security standards:

Number	Title
ISO 22301	Security and resilience - Business continuity management systems - Requirements
EN ISO/IEC 27001	Information technology - Security techniques - Information security risk management
ISO/IEC 27005	Information technology - Security techniques - Information security risk management
ISO/IEC 27017	Information technology - Security techniques - Code of practice for information security controls based on ISO/IEC 27002 for cloud services
EN ISO/IEC 27002	Information technology - Security techniques - Code of practice for information security controls
EN ISO 27799	Health informatics - Information security management in health using ISO/IEC 27002
EN ISO/IEC 27002	Information technology - Security techniques - Code of practice for information security controls

Furthermore, the document “Telehealth Quality Group EEIG - International Code of Practice for Telehealth Services 2018/19” is of high interest.

3. Workshop proposers and Workshop participants

The original proposer of the Workshop is DTU, the Technical University of Denmark, a Danish partner of the REACH consortium. Other consortium partners such as the Technical University of Munich (TUM) and Eindhoven University of Technology (TU/e) will contribute and therefore be part of the Workshop.

DIN, the German Institute for Standardization, as a CEN national member will hold the workshop secretariat.

The workshop is open to any interested party or entity that is willing to support the aims of the project plan.

All registered participants at the kick-off meeting are listed in Annex A.

4. Workshop scope and objectives

This Workshop will develop a CEN Workshop Agreement (CWA), which will define guidelines for introducing, implementing and operating sensor monitoring technologies into the private homes of citizens who are in need of care and for the purpose of detecting critical events and trends.

The guidelines will describe and exemplify the processes and procedures to support an ethically responsible balance between, on the one hand, respect for the autonomy and privacy of the citizens in need of care and, on the other, the obligation to provide quality care of typically frail citizens. The guidelines will not include issues of security or technical requirements for availability of information to relevant parties. The guidelines will not include management of or procedures for handling monitoring data.

The primary target groups of the workshop are care organizations (public or private) that are responsible for delivering social care and health care to citizens.

5. Workshop programme

In the following the work plan as well as work already delivered will be presented.

5.1. Work plan

The overall timeframe for the envisaged CWA can be seen in Figure 1. This project plan can be commented by anyone in the given timeframe. The comments will be collected by the secretary. At the Kick-off meeting each of the received comments shall be discussed and considered.

The Kick-Off meeting will be held in Berlin on 11th of July 2019. Any planned meeting can be a virtual meeting – to be decided at the kick-off meeting. The timeframe for the workshop is limited to the REACH project runtime. The Elaboration of the Draft CWA is planned from July to end of November 2019. The final draft will be ready by December 2019. It is aimed to publish the CWA by January 2020.

The CWA will be drafted and published in English.

	2019										2020
	3	4	5	6	7	8	9	10	11	12	1
Preparation of Project Plan											
Public availability of Project Plan											
Kick-off Meeting											
Elaboration of Draft CWA											
Finalisation and Approval of CWA											
Publication of CWA											

Figure 1 Gantt chart of the workplan

5.2. Work already delivered

The content of this workshop is to

(A) outline current practices for establishing agreement on privacy protection between patients/citizens and care providers for tele-medical implementation;

(B) demonstrate risks of violations of privacy when remote monitoring and AI pattern recognition technologies are implemented;

(C) demonstrate risks of patient harm when opportunities for monitoring are not utilized;

(D) outline end-goals for a process of balanced and consensual trade-off between privacy and needs for monitoring and care;

(E) outline project workplan for describing the required elements in the process of establishing consensual agreement on monitoring obligations and limitations.

6. Workshop structure

6.1. Workshop Chairperson and Vice-Chair

The Workshop Chairperson has five main responsibilities. If necessary or if assigned to him/her, the Workshop Vice-Chair may take over these duties from the Chair.

- Presides at Workshop plenary meetings;
- Ensures Workshop delivers the agreement in line with its Project Plan;
- Manages the consensus building process, decides when the Workshop participants have reached agreement on the final CWA, on the basis of the comments received;
- Interface with CEN-CENELEC Management Centre (CCMC) and CEN Workshop Secretariat regarding strategic directions, problems arising, and external relationships;
- Ensures information exchange with the Workshop Secretariat.

6.2. Workshop Secretary and Vice-Secretary

The Workshop Secretary has five main responsibilities. If necessary or if assigned to him/her, the Workshop Vice-Secretary may take over these duties from the Secretary.

- Formally register Workshop participants and maintain record of participating organisations and individuals;
- Offer infrastructure and manage documents and their distribution through the electronic platform;
- Prepare agenda and distribute information on meetings and meeting minutes/follow up actions;
- Initiate and manage CWA approval process upon decision by the Chairperson;
- Advise on CEN rules and bring any major problems encountered (if any) in the development of the CWA to the attention of CEN-CENELEC Management Centre (CCMC).

7. Resource requirements

Registration and participation at this CEN Workshop are free of charge, but each participant shall bear his/her own costs for travel, accommodation, and subsistence.

The administrative costs of the CEN Workshop will be covered by the REACH project, which received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 690425. The copyright of the CWA will be with CEN.

8. Related activities, liaisons, etc.

Related technical committees:

- CEN/CLC/JTC 13 – Cybersecurity and Data Protection
- CEN/TC 251 – Health informatics
- CEN/TC 431 – Service Chain for Social Care Alarms
- ISO/TC 215 – Health informatics
- ISO/TC 314 – Ageing societies

9. Contact points

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Annex A

Name	Organisation	Participation (Kick-off meeting)	Approved project plan
Aarnout Brombacher	TU Eindhoven	Yes	Yes
Barbara Schäpers	Schön-Klinik	Yes	Yes
Clare Harney	Digital Health Transformation at the Irish Medical and Surgical Trade Association (IMSTA)	No	Yes
Gottfried Endel	Hauptverband der Österreichischen Sozialversicherungsträger	Yes	Yes
Henning Boje Andersen	DTU Lyngby	Yes	Yes
Kristofer Petraeus	Secretary of CEN/TC 431 Service Chain for Social Care Alarms, Swedish Institute for Standards (SIS)	Yes	Yes
Maj Siercke	Copenhagen University Hospital	Yes	Yes
Thomas Linner	TU München	Yes	Yes
Lydia Vogt	DIN e. V.	Yes	–
Anja Seeliger	DIN e. V.	Yes	–