ICT CIP – Competitive and Innovation Programme

UNIversal solutions in TElemedicine Deployment for European HEALTH care

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Workshop: Regulatory Practices and Telemedicine
Version 2.0

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Abstract

COCIR conducted a workshop on the report D5.5 Telemedicine Legal and Regulatory Framework for the Consortium partners in Santiago de Compostella on 6th May 2015. The report itself was submitted to the Commission for the second annual review.

The purpose of the work-shop was to:

- Collect feedback and comments on the report D5.5.
- Have D5.5 "endorsed" by the consortium.

A pilot site assessment on procurement and use of technology was carried out on the basis site visits. Annex I reports the outcomes and findings.

Key Word List

Workshop; Regulatory Practices; Telemedicine; Procurement; Technology; Assessment

Executive Summary

COCIR conducted a workshop on the report D5.5 Telemedicine Legal and Regulatory Framework for the Consortium partners at the Project Assembly in Santiago de Compostella on the 6th May 2015. The report itself was submitted to the Commission for the second annual review, and was considered to combine useful information available on national and European levels in the context of legal and formal environment for telemedicine deployment.

The purpose of the workshop was to:

- Collect feedback and comments on the report D5.5, and its accuracy.
- Have the report "endorsed" by the consortium, i.e. "blessing from a wider community" than just the Industrial Advisory Team.

This document describes the discussions at the workshop on Regulatory Practices and Telemedicine.

A pilot site assessment on procurement and use of technology was carried out on the basis site visits, an activity in addition to the contracted WP5 activities, carried out by COCIR in collaboration with Continua Health Alliance. Annex I reports the outcomes and findings, and is summarised in section 3.

Change History

Version History:

0.1 12th March 2015
1.0 17th March 2015
2.0 17th June 2015

Version Changes

0.1 Initial version
1.0 Initial version describing plans for Workshop, for issue
2.0 Plans for Workshop replaced by description; Version for issue

Table of Contents

1. Introduction

1.1 Purpose of this document

This document describes the Workshop on Regulatory Practices and Telemedicine held on 6th May 2015 in Santiago de Compostella.

1.2 Glossary

ICT	Information and Communications Technology
Project Assembly	United4Health consortium's bi-annual project meetings with all partners attending
Telemedicine	Provision of healthcare services, through use of ICT, in situations where the health professional and the patient, or two health professionals, are not in the same location. It is an overarching definition covering Telehealth, Telecare and other 'tele-disciplines'.

2. Workshop: Regulatory practices and telemedicine

2.1 Context and content

Below summarises deliverable D5.5 Regulatory environment and good practice; this forms the contextual frame for the Workshop.

2.1.1 Summary of deliverable D5.5 Regulatory environment and good practice

The use of telemedicine as a tool to help support better-integrated care is on the rise. One of the ways to support this in Europe is to capitalise on the potential of technological advances in ICT, and accelerate the adoption by (1) establishing an appropriate legal and regulatory framework for telemedicine consistently applied by Member States and by (2) ensuring telemedicine is integrated into, and interoperable with, existing care delivery structures.

Telemedicine is at the crossroad of ICT, health policy and data protection. Under European law, it is both a health service and an information society service. As a health service, citizens have the freedom to seek and receive healthcare services from another Member State regardless of how that service is delivered. As an information society service, that service is normally provided by remuneration. Legal and regulatory challenges at the European and Member State levels need to be overcome to help deliver on the promise of telemedicine

A legal and regulatory framework needs to be established that is not only clear and simple, but also flexible and nimble, and that, as technological advances, allows for an ever-evolving variety of methods for patients, physicians, payers and regulators to interact.

Key recommendations for an effective legal and regulatory framework:

1. Integrate telemedicine into care delivery structures.
2. Enable citizens' access to their data.
3. Develop appropriate reimbursement strategies.
4. Establish a harmonised data protection regime that allows innovation.
5. Provide clear regulatory guidance.
6. Foster use of widely recognised standards and support mobile broadband policies.

2.2 Location and timing

The Workshop was held as part of the Project Assembly in Santiago de Compostella (Galicia, Spain) on the 6th May 2015.

2.3 Format

The format is threefold:

- Preparation.
- Workshop.
- Follow-up.

2.4 Preparation

The report D5.5 Regulatory Environment and Good Practice was sent to all attendees of the workshop, as well as to the responsible person from each deployment site.

The Consortium partners were asked to review D5.5 in detail in advance of the meeting, and to prepare and report feedback and comments either prior to the workshop or during the workshop.

The feedback received was reviewed and structured by COCIR with the support of WP5 and project management in advance of the meeting. COCIR received some comments from Greece, Scotland, Slovenia, Wales and Norway prior to the workshop; these were shared with the audience.

2.5 Workshop

At the workshop, Nicole Denjoy from COCIR presented both the content of the report as well as the feedback, and coordinated discussion with the participants. The presentation is attached in Annex 2.

The participants, besides the presenter, were:

Victoria Hunter	NHS24
Bridget Moorman	CHA
Claire Hurlin	NHS Wales
Marc Lange	EHTEL
Julie Bjerregaard	EWMA
Drago Rudel	SB-SG
Diane Whitehouse	EHTEL
Michelle Brogan	NHS24
Helene Richardsson	COCIR
Stanislav Pušnik	RAVKOR
Mariangela Contenti	ARSAN
Zdenek Gütter	UPOL
Anna Rydlewska	JPII
Michał Harańczyk	JPII

Agnieszka Piwowarczyk-Bargieł	JPII
Damiano Colombo	Veneto
Lena Collins	NHS Lanarkshire
Morag Hearty	NHS Lanarkshire
Rachelle Kaye	AIM
Janice Kinnaird	NHS Greater Glasgow & Clyde
Professor George Crooks	NHS24
Pedro Marcos Velázquez	Galicia
Undine Knarvik	UNN
Helene Richardsson	COCIR

2.5.1 Discussions in general

During the discussion, it was obvious that not all of the audience had read the report, and therefore questions were asked and answers provided inviting the audience to consult the report while having the discussions.

Discussions took place around the definition of telemedicine, and whether such definition was considered stable. In addition, discussions took place on the importance of interoperability. The audience agreed that there was not a lack of standards, but there was lack of acceptance, support and implementation as well as significant differences between those that exist, e.g. between the US and the EU.

2.5.2 Dialogue at end

The audience appreciated that the supporting presentation provided a good understanding of the detailed compiled report.

The members of the workshop were asked to submit their feedback in writing so that the report could be updated and finalised.

Some discussions took place on procurement frameworks, which were considered as the best enabler for telemedicine.

Key points were considered as possible issues:

- Flow of data as an enabler.
- How to integrate systems together.

Discussions also included the importance of integrated care and how to use ICT tools more effectively. The following was generally agreed among the participants:

- Policy and legal recommendations are needed to encourage the development of telemedicine.
- Removing regulatory and technical barriers.
- Focusing on operational aspects and deployment.
- Choosing the appropriate technology.

2.6 Follow-up

Based on the feedback received both in advance of the Workshop and during the Workshop itself, D5.5 Regulatory Environment and Good Practice could be updated and distributed to all sites.

The members of the workshop were asked to submit their feedback by return to Nicole Denjoy so that the report could be updated and presented in its final version.

3. Deployment Site Assessment Report - Annex I

For full report, please see D5.6 Annex I v1.0 U4H Deployment Site Assessment Report.

3.1 Background

Based on the first European Commission Review report, and after consultation with the members of the Industry Advisory Team (WP5), the Project Co-ordinator (NHS 24), and further discussions at the Project Assembly meeting in Norway in June 2014, it was decided that COCIR would coordinate 5-7 site visits with the support of Continua Health Alliance, with the objective to openly discuss the various aspects of decisions making on the choice of technology at the deployment sites.

The purpose of the report is to give an overview of the current situation regarding procurement processes, the use of technology in the U4H deployment sites, as well as other aspects.

3.2 Summary

The sites visited were: (1) Galicia in Spain, (2) Cosenza in Italy, (3) Slovenj Gradec in Slovenia, (4) Olomouc in the Czech Republic, (5) Wales, (6) Scotland in United Kingdom, and (7) Lappeenranta in Finland. Kristiansand in Norway was visited earlier, and therefore the interview was conducted via a teleconference.

Having collected all the data from these sites, there are three areas that had key implications based on the answers to our questions. They are:

- Scalability and sustainability.
- Knowledge sharing:
  - Different levels of understanding telemedicine / telehealth.
  - Knowledge sharing within the pilot sites.
  - Knowledge sharing between the different sites.
- Governance:
  - Complex model to have all projects move toward a common goal.

3.3 Relationship to Workshop on regulatory practices and telemedicine

The deployment site assessment report is a separate piece of work that was found useful to conduct for the consortium, the EC and across Europe, in order to capture and document systematically the experiences with procurement process, the use of technology, and wider aspects in relation to this.

Consequently, the report and hence the Annex is not directly associated with the Workshop on Regulatory Practices and Telemedicine, although legal and regulatory aspects of deploying telemedicine services in health and care systems link to procurement and technology implementation and usage.

However, by including it as an Annex to a contractual report within the same WP and responsible partner, the report is technically submitted for review. It should be noted that whereas the document on the Workshop is a public report, Annex I is marked as confidential. This will be resolved as follows:

- Final report of D5.6 Workshop: Regulatory practices and telemedicine, completed after the Workshop, is available for publication, without Annex I
- Outcomes of the Deployment Site Assessment Report (Annex I) will be included as Lessons Learned outputs in a different deliverable than the current report version.