ICT CIP – Competitive and Innovation Programme

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Abstract

This document contains a short summary of the analysis and workshop delivered on 13th June 2014 to the U4H Project Assembly meeting in Kristiansand, Norway. Presenter was Bridget Moorman.

Key Word List

COCIR, Continua Heath Alliance, GSMA, Industry advisory team, interoperability, procurement, technology, telehealth, telemedicine, regulatory issues.

Executive Summary

This report discusses the development and execution of the workshop "Interoperability in practice: an Assessment" which comprises the deliverable D5.4. The workshop took place as part of the fourth United4Health project assembly on 13th June 2014 in Kristiansand, Norway, and was delivered to a plenary meeting in the morning over 45 minutes.

The IAT presentation provided additional information and analysis of the D5.2 document and pilot sites in terms of their compliance with medical interoperability standards as well as results of a survey of the pilot sites regarding their desires for standards-based solutions.

This report includes in the appendix a copy of the survey questions and the presentation delivered at the workshop.

Change History

Version History:

0.1	28th July 2014	Initial Version
0.2	29th August 2014	
0.3	1st September 2014	
1.0	12th September 2014	

Version Changes

0.1	Initial version
0.2	Updated with comments/edits from M.Strubin
0.3	Accepted comments from M Strubin and added dates of survey
1.0	Presentation slides added; version for issue

Outstanding Issues

None

Table of Contents

1. Introduction

1.1 Purpose of this document

This document is a written record of the fourth deliverable of the Industry Advisory team: Interoperability in Practice: an Assessment. It contains background information and the presentation delivered at the workshop.

1.2 Glossary

CHA	Continua Health Alliance, member of the IAT
COCIR	European Coordination Committee of the Radiological Electromedical and Healthcare IT Industry, member of the IAT
GSMA	GSM Association, member of the IAT
IAT	Industry Advisory Team
IHE	Integrating the Healthcare Enterprise
MDD	Medical Device Directive

2. Introduction

2.1 Background

The United4Health project is a large scale pilot to trial telemedicine solutions with more than 13,000 patients in 15 regions in Europe, focusing on patients with cardiovascular disease, chronic lung disease and diabetes. The project runs from 2013 to 2015 and is led by NHS Scotland.

To solicit and secure advice and support from industry, an Industry Advisory Team (IAT) was formed including representatives from the industry associations COCIR, the Continua Health Alliance and GSMA. The IAT will support the project and the participating regions with advice on technology, interoperability and regulatory compliance and with support on communication and outreach.

2.2 Preparations for the workshop

The purpose of the fourth deliverable, D5.4 "Interoperability in Action: An Assessment", was set out in the Description of Work to focus on interoperable solutions. The IAT's intent was to analyse the pilot sites' technical system implementations to determine if they were using interoperable and standards based solutions. In the project plan, the workshop was set up right after the pilot implementations, to determine if interoperable solutions were implemented and to give enough time to help the pilot sites re-direct their efforts, if desired, towards that direction.

3. The Workshop

The workshop took place as part of the fourth United4Health project assembly on 13th June 2014. It was the last session of the project assembly, and included a brief refresher on interoperability and how standards are used to bring about interoperability, a review of the standards used by the United4Health partners in their solutions, and the results of a survey regarding the United4Health partners' desires for standards at the different system interfaces. The goal was to identify where there was a gap between the desires of the pilot sites for standards-based solutions, and what they were deploying.

3.1 Interoperability Analysis

In preparation for the workshop, the IAT in early 2014 analysed the pilot site solutions described in D5.2 "Technical Documentation and Recommendations," for their use of standards based solution at the different interfaces along the transmission path. These include the interfaces at the medical device, the telehealth centre and the EHR. The standards identified were for physical, data, networking and messaging functions. In March 2014, after reviewing the analysis of the standards used in the United4Health systems, the IAT sent a brief survey to the pilot sites to determine their desire for standards-based solutions.

In the workshop presentation, see Appendix A, the definition of interoperability was reviewed along with the different standards that can be used to bring about interoperability. The interfaces at which those standards apply were also presented.

Some history as to why non-standards based solutions were used in Renewing Health and United4Health were presented, as below.

For Renewing Health, the findings had been:

- Most pilot sites had to have existing systems, so that prohibited procurement of standards based systems outside of those already used.
- A procurement technical specification recommending and listing specific standards which aid in interoperability was provided to the pilot sites. However, it was only used by one pilot site (Finland), and they reported that the local market could not provide products that met the specification.
- Standards which are used tend to be in physical connectivity, networking, and some messaging realms, but not in the data realm.

For United4Health, the findings were:

- At the Vendor Fair with Interoperability Showcase (Ljubljana):
  - Limited interest from pilot sites.
  - Many pilot sites not procuring.
- As in Renewing Health, pilots sites with existing systems were not procuring, and were in the same interoperability and standards compliance state as before.

The following table shows what standards are used by the United4Health pilot sites, mainly physical and transmission standards. No messaging or data standards were used.

Table 1: United4Health Interface Standards Used

Country	Condition	Means of Transmission from Medical Device	Means of Transmission from Home
Spain, Basque Country	CHF	Bluetooth and manual entry (weight)	Landline (Internet-Web services), GPRS/3G
Finland, South Karelia	DM	Bluetooth 3.0	GSM, Internet (Web)
Germany, Berlin,	COPD	USB	Internet
Germany, Berlin,	DM	USB, Bluetooth	Internet
France, Nord Pas de Calais	HTN	Bluetooth	GPRS via Orange Business Services
Greece, Central Greece	DM	Bluetooth	GSM (GPRS)
Italy, Calabria	DM	USB	Internet
Northern and Southern Norway	COPD	Bluetooth	TeleNorway VPN tunnel
Slovenia	COPD, DM	Bluetooth 3.0 or higher	GSM, Internet
United Kingdom, Scotland	CHD, COPD, DM	BlueTooth and USB	GPRS, GSM, Internet
United Kingdom. Wales	COPD, DM	Bluetooth, manual entry	GPRS

The key finding from the analysis of the United4Health D5.2 document with regard to using interoperable solutions was:

- Where data is transmitted electronically, network transmission methods are standards based, while messaging and data formats remain proprietary.
- Physical and network standards are primarily driven by the commercial sector, while data and messaging are industry specific.
- Mobile phones and smart phones are important data hubs and transmitters.
- There remain important legal and regulatory barriers:
  - E.g. Norwegian laws do not allow a patient-acquired measurement to be directly and automatically transferred into an EHR that is government or healthcare organisation owned.
  - Medical device regulation acts to encourage closed end-to-end monitoring systems by placing responsibility for assuring safety on the suppliers.
  - E.g. Players in the mobile industry have expressed concerns, about the possibility that a mobile handset used in monitoring could be considered as falling within the scope of medical device regulations.
- Cost could also be a factor, because standards adoption is confined to the premium end of the market, and used as a differentiator.

- The idea of 'normalising' telehealth / telemedicine into the type of clinical care offered for chronic diseases is at an early stage. Meeting the clinical workflow and patient expectation requirements are currently the priority.
- There is continued limited availability of interoperability-compliant telemedicine solutions in the regions where U4H is being implemented.

3.2 Survey Results

The second element of the workshop was the presentation of the results of a survey which the IAT had conducted in April-May 2014 to see if the pilot sites truly did desire standards based interoperable solutions. The survey instrument is in Appendix B. The desire was scored from 1-5 with 5 being the most highly desirable.

Table 2 shows the results of the survey.

Table 2: United4Health Standards Desirability Survey Results

Pilot Site	Require Standard Solution	Physical	Network	Data	Message	Other
Basque					5	XML, web, real-time subscription services
Finland	Yes	5	4	5	3	To reporting
Greece	Yes	5	4	5	3	
Norway	Yes	2	4	5	3	Web
Scotland	Yes	5	2	4	4	Use of consumer devices
Slovenia	Yes	5	2	4	4	

Answers to the general questions supported some of the previous analysis. Only the Czech Republic used the technical specification that had been provided in their acquisition documents as many of the pilot sites did not procure solutions. Finland and the Czech Republic both noticed a lack of vendors who could meet the technical standards specifications (Finland used them in Renewing Health), and they both ended up changing their specification to not require the standards based solutions so that more vendors could compete.

Comparing Table 1 and Table 2 shows a disconnect with regard to what the pilot sites are implementing and what they desire. They desire solutions with data and messaging standards as well as physical and networking standards, and yet they are neither requiring nor implementing solutions using the data and messaging standards.

Speculations for this disconnect usually end up being iterative reasoning with regard to procurers' willingness to use standards based products and vendors' willingness to supply standards based products. Therefore, the IAT believes that the extension

of WP5 to include the fine-grained recommendations regarding “why” interoperable and standards based products are not procured will be of value to the overall healthcare industry.

3.3 Workshop and recommendations

In the workshop, the IAT presented the interoperability analysis and survey results, and invited the audience to react.

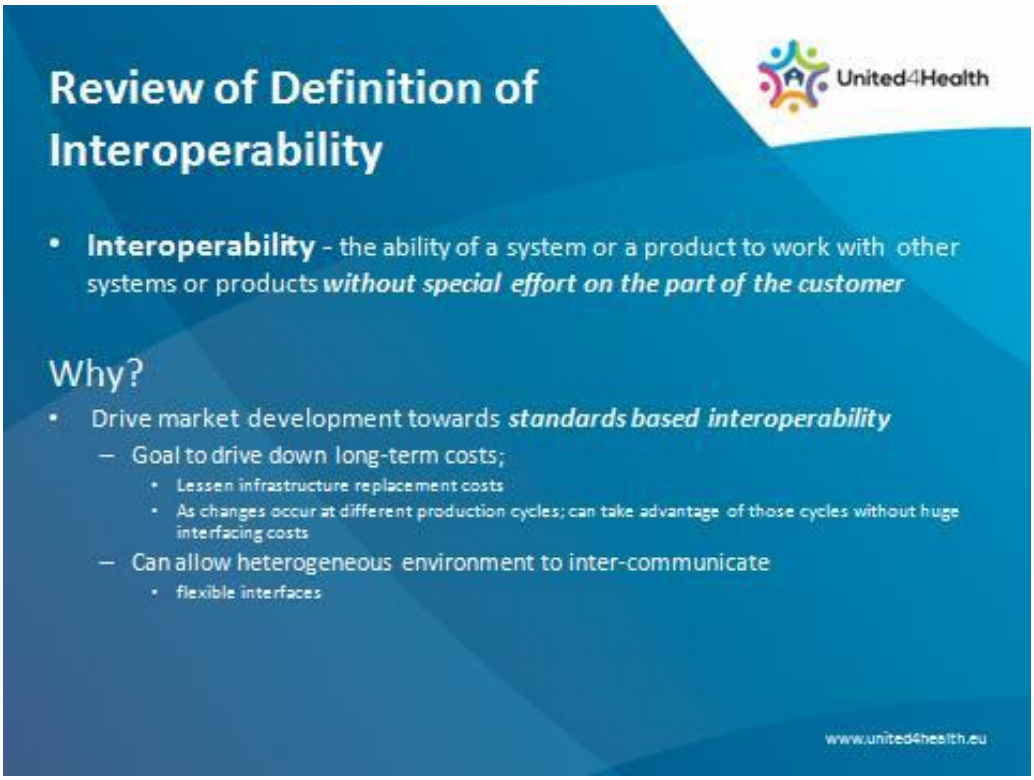
In the Q&A session, it was noted that there were many reasons as to why the standards-based interoperable solutions were not procured, ranging from general to regional issues. The IAT determined after the first review to embark on another deliverable which would study in depth the reasons why the interoperable solutions were not implemented, by visiting a large cohort of the pilot sites and doing a question based and inspection of the site. COCIR, with the assistance of CHA, will be visiting seven sites before December 2014 with a detailed set of questions for each site.

This workshop provided more justification for the more in-depth approach due to the results: no standards based solutions were implemented, but there was a desire for these. Norway also brought up the issue of ensuring secure data and pathways for the data as it was transmitted from the home to the healthcare location.

In the meantime, the following recommendations were agreed:

- Timing for pilot education on standards and interoperability needs to occur six months to one year before procurement activity.
- Procurers need to insist on and buy standards based products, or the market will not respond.
- A top-down approach may be required such that there are government regulatory mechanisms demanding standards be used. If this occurs, the market (product manufacturers and healthcare organisations) should be prepared to adhere.

Appendix A – Presentation


Review of Definition of Interoperability
United4Health
• Interoperability - the ability of a system or a product to work with other systems or products without special effort on the part of the customer
Why?
• Drive market development towards standards based interoperability
– Goal to drive down long-term costs;
• Lessen infrastructure replacement costs
• As changes occur at different production cycles; can take advantage of those cycles without huge interfacing costs
– Can allow heterogeneous environment to inter-communicate
• flexible interfaces
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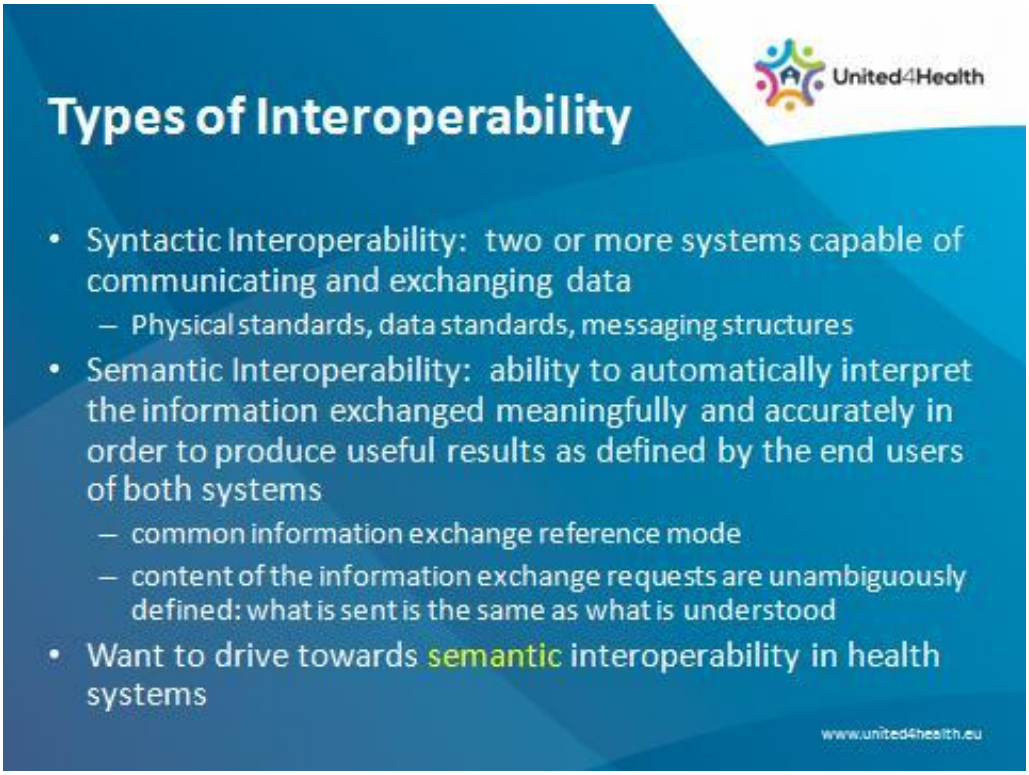
Types of Interoperability
United4Health
• Syntactic Interoperability: two or more systems capable of communicating and exchanging data
– Physical standards, data standards, messaging structures
• Semantic Interoperability: ability to automatically interpret the information exchanged meaningfully and accurately in order to produce useful results as defined by the end users of both systems
– common information exchange reference mode
– content of the information exchange requests are unambiguously defined: what is sent is the same as what is understood
• Want to drive towards semantic interoperability in health systems
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Review of Standards Available for Remote Monitoring Systems in Healthcare

United4Health

- Interfaces
  - Personal or Peripheral Area Network (PAN)
  - Local Area Network (LAN)
  - Wide Area Network (WAN)
  - Health Record Network (HRN)
- Physical, Data and Messaging, Network Protocol
  - Physical: DB9, DB22, USB
  - Data: IEEE 11073, SNOMED, LOINC
  - Messaging: HL7 (V2.x, 3.0)
  - Network Protocol: NFC, Bluetooth, ZigBee, GSM, WiFi (IEEE 802.11)



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Bit of history

United4Health

- Findings in Renewing Health about interoperability and standards:
  - Most pilot sites had to have existing systems, so that prohibited procurement of standards based systems outside of those already used
  - A procurement technical specification recommending and listing specific standards which aid in interoperability was provided to the pilot sites, however, it was only used by one pilot site (Finland) and they reported that the local market could not provide products that met the specification
  - Standards which are used tend to be in the physical connectivity, networking and some messaging realms but not in the data realm

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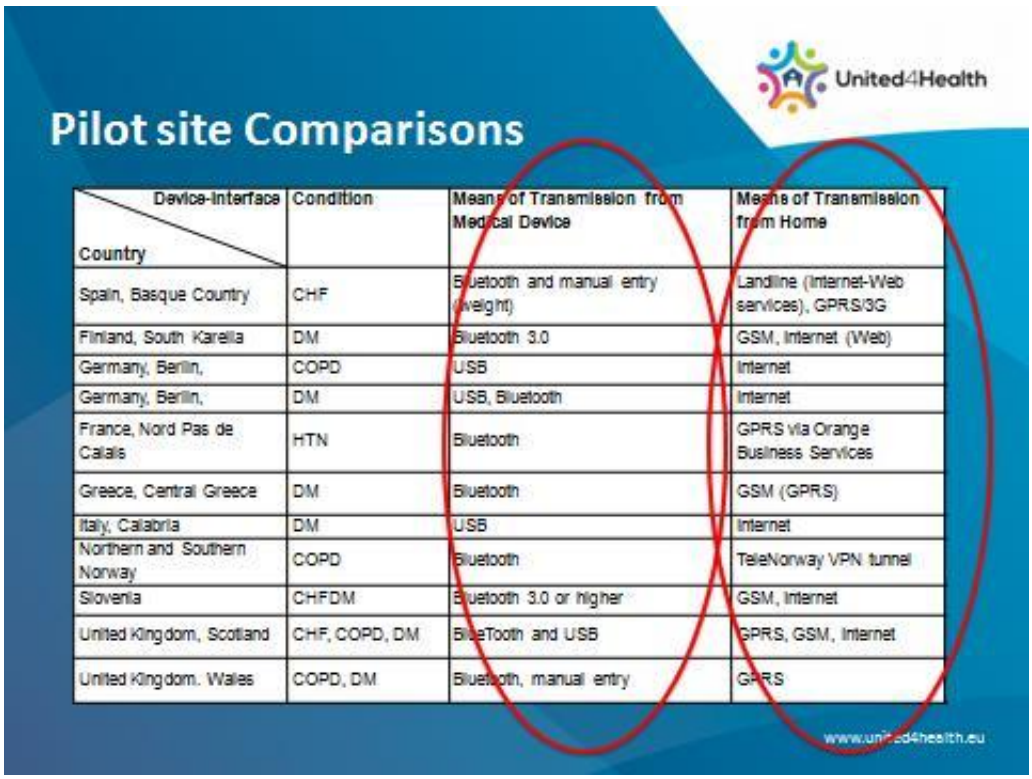

Device-Interface / Country	Condition	Means of Transmission from Medical Device	Means of Transmission from Home
Spain, Basque Country	CHF	Bluetooth and manual entry (weight)	Landline (Internet-Web services), GPRS/3G
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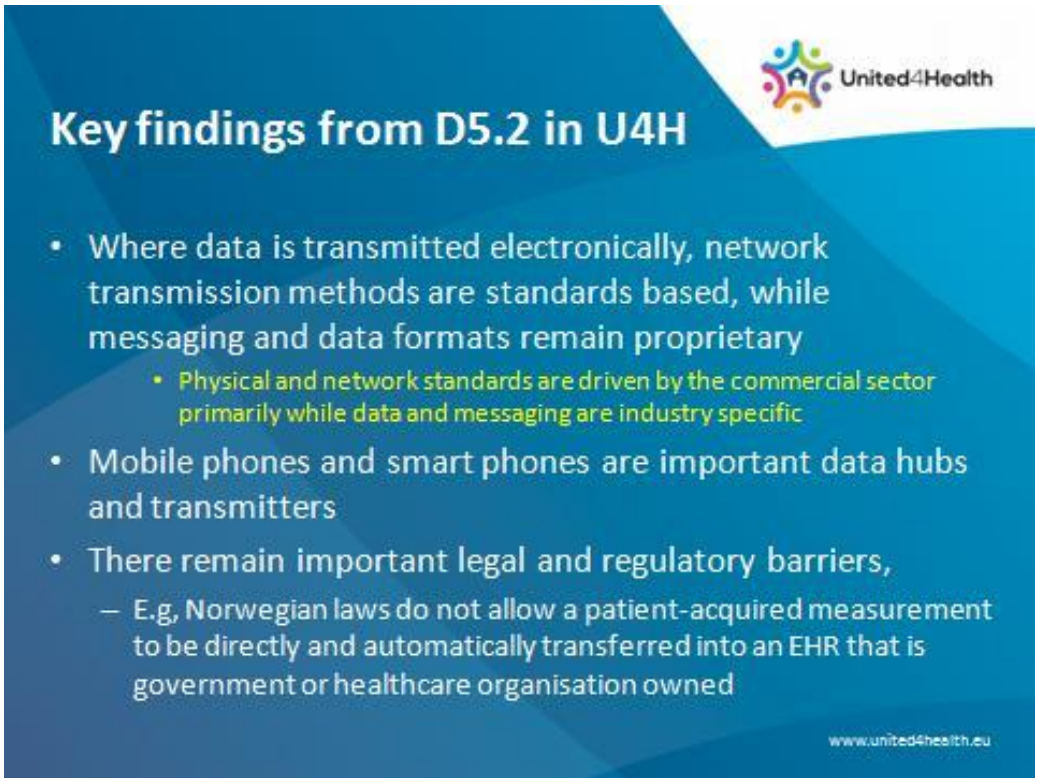
Germany, Berlin,	COPD	USB	Internet
Germany, Berlin,	DM	USB, Bluetooth	Internet
France, Nord Pas de Calais	HTN	Bluetooth	GPRS via Orange Business Services
Greece, Central Greece	DM	Bluetooth	GSM (GPRS)
Italy, Calabria	DM	USB	Internet
Northern and Southern Norway	COPD	Bluetooth	TeleNorway VPN tunnel
Slovenia	CHFDM	Bluetooth 3.0 or higher	GSM, Internet
United Kingdom, Scotland	CHF, COPD, DM	BlueTooth and USB	GPRS, GSM, Internet
United Kingdom. Wales	COPD, DM	Bluetooth, manual entry	GPRS


United4Health
Key findings from D5.2 in U4H
Where data is transmitted electronically, network transmission methods are standards based, while messaging and data formats remain proprietary
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Key findings from D5.2 in U4H (cont)
The idea of 'normalising' telehealth / telemedicine into the type of clinical care offered for chronic diseases is at an early stage;
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Players in the mobile industry have expressed concerns, about the possibility that a mobile handset used in monitoring could be considered as falling within the scope of medical device regulations
Cost could also be a factor, where standards adoption is confined to the premium end of the market and used as a differentiator
Continued limited availability of interoperabliity-compliant telemedicine solutions in the regions where U4H is being implemented
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United4Health
U4H Survey results
Question
Did you use the technical specification we provided to you in your procurement documents?
If you did, did it limit the number of vendors you could acquire systems from?
Did you change your acquisition criteria to enable more vendors to compete (i.e. not require the standards for interoperability in the specification)?
What are some of the issues you see with the current state of interoperable solutions?
Are you willing to tell a vendor they must quote interoperable solutions?
What types on interoperability are most important to you: 5- very important; 0- not important
Data?
Messaging?
Transmission protocols?
Connectivity interfaces?
Other types of interoperability?
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United4Health
U4H Survey Results
• Use of Technical Specification Provided – Czech only, all others no (many did not procure systems)
• Limitation of offerers based on technical specification – Czech, yes; Finland (from Renewing Health), yes.
• Did they change acquisition documents to enable more offerors to compete (not require standards based solutions)– Czech, yes; Finland, yes
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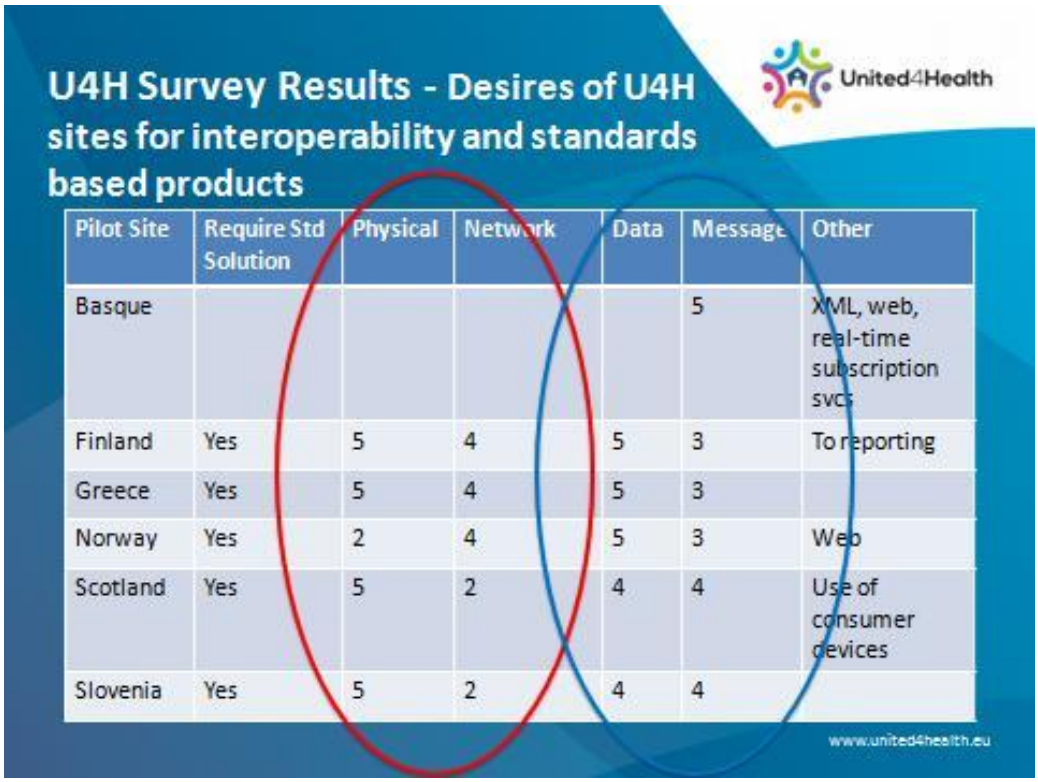

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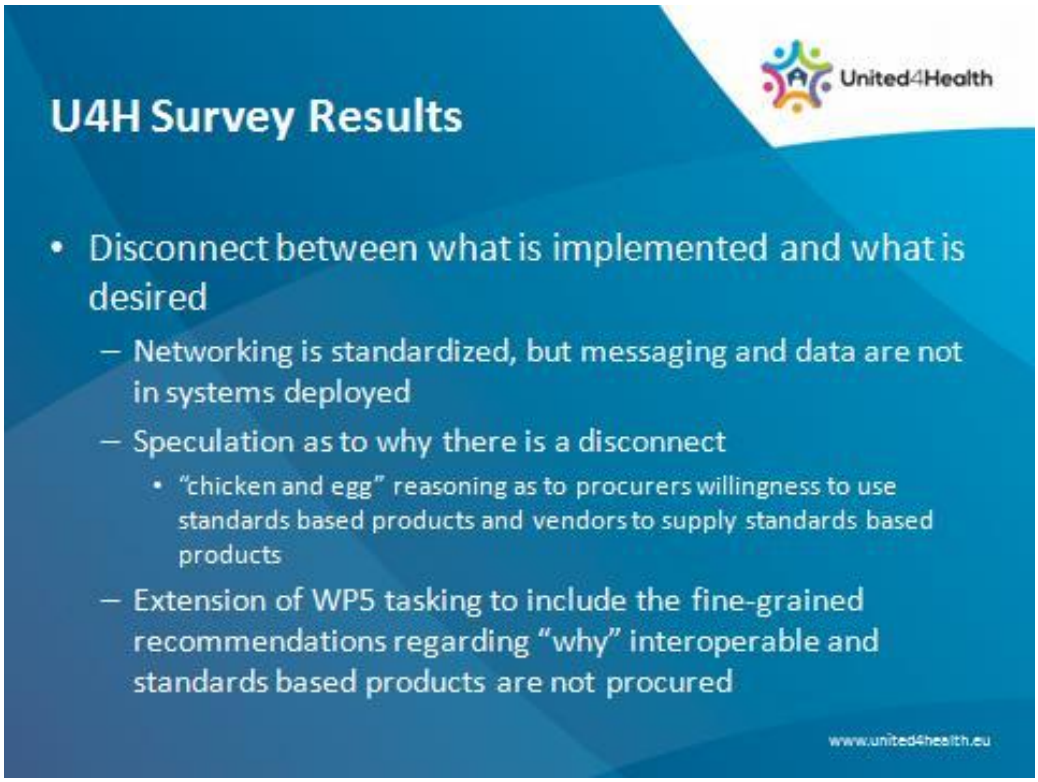


United4Health
Initial Recommendations
• Timing for pilot education on standards and interoperability needs to occur 6 months to 1 year before procurement activity
• Procurers need to insist on and buy standards based products or market will not respond
• May require top-down approach (government regulatory mechanisms for demanding standards)
– Market (product manufacturers and healthcare organizations) should be prepared to adhere
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Appendix B – Survey Instrument

Questions

Did you use the technical specification we provided to you in your procurement documents?

If you did, did it limit the number of vendors you could acquire systems from?

Did you change your acquisition criteria to enable more vendors to compete (i.e. not require the standards for interoperability in the specification)?

What are some of the issues you see with the current state of interoperable solutions?

Are you willing to tell a vendor they must quote interoperable solutions?

What types on interoperability are most important to you:
5- very important; 0- not important

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Other types of interoperability?