

**Executive Summary**  
to  
**eHealth-INTEROP Report**  
in response to  
**eHealth Interoperability Standards  
Mandate**

(SA/CEN/ENTR/000/2007-20 eHealth Mandate M/403 – Phase 1)

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**Summary of  
SA/CEN/ENTR/000/2007-20 eHealth Mandate M/403 – Phase 1 Report**

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**Editorial project team:**

20

Pantelis Evangelidis,  
Georg Heidenreich,  
Charles Parisot,  
Melvin Reynolds (lead editor).

**Please submit any comments on this document to:**

Ms Mary van den Berg Standardization administrator	<a href="mailto:mary.vandenberg@nen.nl">mary.vandenberg@nen.nl</a> Tel. + 31 152 690390 Fax + 31 152 690190	NEN-Healthcare Vlinderweg 6 NL-2623 AX Delft
Ms. Shirin Golyardi Standardization consultant	<a href="mailto:shirin.golyardi@nen.nl">shirin.golyardi@nen.nl</a> Tel. + 31 152690313 Fax + 31 152690563	

## Summary of the eHealth-INTEROP Report

### Background

Because this is a summary of the full Report a considerable amount of detail is necessarily omitted for the sake of brevity.

5 For those concerned with the day-to-day implementation of the European Commission (EC) Mandate M/403 (the Mandate), reading this Summary is not therefore a substitute for familiarity with the full Report, to which the numbered references refer.

10 The Scope (1) of the Report is defined by the *Terms Of Reference of the Project Team* appointed to carry out phase one of the Mandate. Familiarity is assumed both with the Mandate and with the 2007 *EU Study on the specific policy needs for ICT standardization*, which highlights many of the issues affecting the European standardisation scene across ICT in general.

### Where we are

The background (2) of previous advisory groups on eHealth standards is reviewed briefly, as are definitions (2.2) central to the topics covered in the Report.

15 Current activities in the 'standards' area impacting eHealth are reviewed (3) – recognising that not all such activities are undertaken by formally constituted standards development organisations.

A comparative review of the European standards organisations precedes descriptive reviews of the role and processes of other significant 'standards' development and adoption organisations.

20 The existing, and earlier, eHealth standards coordination efforts are reviewed briefly in 3.4 before the different deliverables and processes are described.

Barriers to adoption of standards are discussed in 3.7 and a preliminary (inevitably incomplete) inventory of relevant eHealth standards (Annex A) is then introduced.

A short section (3.9) examines the relationship of safety / security, privacy issues in eHealth to those impacting society as a whole and other e-Processes in particular.

### Surveying the route ahead

25 Having thus surveyed where eHealth interoperability is at present, we turn our attention in Chapter 4 to the route ahead: how, at a European level, it could be possible to establish processes to ensure mutual understanding, agreement and cooperation to meet the identified policy goals of EU health ministers.

30 Critical success factors of standards development, but more importantly of standards adoption and implementation in eHealth, are examined in some detail (4) in order to find the road to interoperability in eHealth (4.2). In particular, a use case based approach is recommended.

35 This is followed by a more detailed analysis of the different classes of standards-related specifications (4.4), which are divided into Base Standards, Profiles and Interoperability Specifications. We see that this provides the clarity necessary to achieve interoperability while offering sufficient flexibility to individual eHealth projects across Europe. We note too that achieving quality implementations needs to rely on widely available testing tools and processes to ensure conformance of implementations to Profiles and the referenced Base Standards.

40 Section 4.5 identifies the need for five major activities to ensure that the 'rules of the road to interoperability' are established and managed.

The Chapter concludes with a short survey of international experience of standards implementation for eHealth interoperability (4.6).

### Moving forward

45 Based on the use case approach outlined in Chapter 4, Chapter 5 deals with specific requirements. Using readily available examples, we look at requirements from the citizen; care provision and population health perspectives. Annex D provides a review of some example use cases corresponding to these groups.

The Mandate required us to address specific topics: patient and healthcare professional identifiers (5.3.2), and the patient summary and emergency data set (5.3.3).

50 For the patient identifier some clear (but not exhaustive) use cases and Profiles have been described. Annex B, provides detailed review of the use cases, Base Standards and Profiles available to address

patient and, to a lesser extent, healthcare professional identification needs.

However, we find that when we seek to apply the use case technique to the other topics they are sufficiently broadly scoped (i.e. set at policy level) that there is no shared European understanding of the specific requirements.

5 With that inconclusive outcome from Chapter 5 we set out in Chapter 6 to describe how, again at a European collaborative level, it could be possible to establish a mutually agreed strategic workplan to meet the policy goal of cross-border care, as well as enabling interoperability at a local (e.g. hospital or home) and at a regional/national level.

10 Existing organisations engaged in each one of these activities are reviewed and proposals are made for the Phase 2 of the Mandate in order to leverage their experience, and the need for an overall coordination at the European level is discussed (6.2).

Starting with the key policy use cases (6.3), seven use cases are proposed for consideration at the European level within the first year of Phase 2 consistent with the necessary ramp-up of European-wide stakeholder engagement in delivery of the eHealth Standards Mandate.

15 The proposed phased deliverables address regional/national patient summary and prescription use cases; two use cases (ordering and results distribution for radiology enterprise workflow allied to regional or radiology cross-enterprise information sharing); and then three new use cases for laboratory enterprise workflow, laboratory cross-enterprise information sharing and for ubiquitous care outside conventional care facilities, initially focussed on remote monitoring.

20 Recognising that other use case related needs may emerge, the main areas of Base Standard priorities are currently identified (6.4) as being:

1) Fill gaps; a) continue support for safety / security and privacy strategy, b) enable development of infrastructure for care outside conventional care facilities,

25 2) Facilitate semantic interoperability; a) enable support for terminological interoperability in support of use cases, b) enable safe semantic interoperability, and c) facilitate Maintenance arrangements,

3) Resolve inconsistencies, and

4) Increase European impact in international standardisation.

In Chapter 7 we gather together as Conclusions the "Anchor points" that have been highlighted throughout the Report.

## 30 **Proposals**

Our proposals are set out in full in Chapter 8 and are, in summary, as follows:

A "European eHealth Mandate Coordination Group" should set, and monitor, the high-level business objectives.

35 Structure activities around five entities to execute the core outcomes of the eHealth Standards Mandate and organise these activities so that they become effective in 2009 and sustainable after the end of the eHealth Standards Mandate, taking account of existing, and emerging, standard based solutions to ensure viability in a global market. The objectives set for each one of these five activities is discussed below.

### **1 Business use case definition and prioritisation**

40 For Phase 2 of the eHealth Standards Mandate, it is proposed to establish a small project team under joint oversight of i2010 (Member States) and Stakeholder Group (users and industry), in the context of and in cooperation with other similar initiatives, to analyse, consolidate and prioritise use cases for Profile Specifications in Phase 2 and thereafter.

45 The following specific proposals are therefore made as the basis for discussion, possible change, and agreement in Phase 2 (2009) 4 use cases for Profile Specifications focus, an additional 3 for Profile Specification in 2010 and a rolling plan thereafter.

#### **1.1 Two generic intra-country (2009) use cases**

Use eSOS driven cross-border cases to provide complementary intraregional/national use cases:

1. regional / national patient summary information sharing, and
2. regional / national prescription information sharing.

#### **1.2 Two high-priority additional (2009/2010) use cases**

1. radiology enterprise workflow, and

2. radiology cross-enterprise information sharing.

### 1.3 Three follow-on (2010) use cases

1. laboratory enterprise workflow,
2. laboratory cross-enterprise information sharing, and
- 5 3. for ubiquitous care outside conventional care facilities, involving the interoperability necessary from mobile and/or home-based monitoring devices.

## 2 Base Standards development

10 For Phase 2 of the eHealth Standards Mandate, rely on the existing harmonisation entities: CEN, CENELEC, ETSI ICT Standards Board (ICTSB) and Joint Initiative Council on SDO Global Health Informatics Standardization (JIC); and improve their efficiency by means of four identified actions.

### 2.1 Fill gaps in provision

Identify and fill gaps in the work Base Standards programme that need to be resolved at the European and International level in order to enable use case priorities to be met.

#### 2.1.1 Enable development of integrated safety / security and privacy strategy

15 Standards for safety / security and privacy in eHealth should continue to be developed, in concert with those for other e-Processes, with a clear plan for accommodating the needs of existing related sector-specific arrangements.

#### 2.1.2 Enable development of integrated infrastructure for care outside conventional care facilities

20 In accordance with the motivating Rationale of the Mandate, enable timely use of key communications infrastructure components (such as body and personal area networks) needed for integrated ubiquitous care (monitoring, well-being, assisted living).

### 2.2 Facilitate semantic interoperability

25 The longer-term goal should be to enable harmonisation among the various national terminologies and the adoption of consistent (at least) pan-European terminologies.

#### 2.2.1 Enable consistent terminological representation in support of use cases

30 Recognising that heterogeneity of classifications and terminologies will remain for several years in European healthcare, expand effort in Europe to achieve terminological interoperability in the context of the identified use cases.

#### 2.2.2 Enable support for safe semantic interoperability

Continued urgent effort is needed to ensure that the internal relationships in, for example, communication structures are unambiguously linked to the appropriate archetypes, templates, terms, codes, identifiers and/or value sets.

#### 2.2.3 Facilitate maintenance arrangements

35 Provide sufficient resourced impetus to establish real-time, "gold-standard" resources to support semantic interoperability in support of existing and emerging semantic requirements in eHealth.

### 2.3 Resolve inconsistencies

40 Resolve the inconsistencies, or at least facilitate co-existence, between Base Standards based on fundamentally different principles (e.g. Electronic Records exchange formats using either CEN 13606 or HL7 RIM based documents).

### 2.4 Increase European impact in international standardisation

Increase the coordinated contribution of Europe into international standardisation efforts to meet European needs within internationally accepted standards (e.g. for acute and home care device communications with IEEE, terminologies with WHO and IHTSDO, etc.).

## 3 Profile development and maintenance

45 For Phase 2 of the eHealth Standards Mandate, accredit an entity to ensure that the prioritised and documented Business use cases are broken down into Technical use cases, and specific Base Standards are selected and profiled. For this activity three success factors are identified:

- 50 1. the ability to scope the Technical use cases so that the specified Profiles are reusable across several Business use cases;

2. have the credibility to attract a good mix of industry, large medium and small and health professional organisations; and,
3. specify the Profiles supporting each Technical use case in an open and timely fashion (no more than nine months from the Business use case availability).

5 Profiles should cover all layers of interoperability, from transport, through messaging services, to data structures and terminologies; these last two are two of the major elements necessary to provide semantic interoperability in health.

It is recommended to use the processes defined by ISO TR28380 to develop internationally agreed, or Europe specific, Profiles.

#### 10 **4 Profile quality assurance, test plans and tools**

This activity is to ensure, for Profiles, the development of conformance test plans and test tools under a coordinated process among the various contributors and users. Users include industry which is implementing interoperability in its products, local, regional and national projects, care delivery organisations such as hospitals, clinics, laboratories, pharmacies, imaging centres, general practitioners, etc., for which three key success factors are identified.

- 15 1. the ability to develop these test plans and tools in a timely fashion so that they could be made available no later than four months after a Profile is recognised for trial implementation;
2. coordinate contributors resources to ensure that quality plans and tools are developed and maintained; and,
- 20 3. ensure open access to these test plans and tools and an effective maintenance process engaging the broad range of users.

For Phase 2 of the eHealth Standards Mandate, it is proposed to accredit IHE-Europe in partnership with ETSI, Continua (assuming its capability is proven in time), and possibly others. It is important to link this activity with the existing national testing efforts in some of the European countries, and with international arrangements.

#### 25 **5 Sharing of best practices in deploying eHealth project**

This activity is to give every national, regional or local project a European-wide forum to share experiences and publish best-practice guides that offer guidance in conducting the deployment activities of eHealth projects. In particular, this best practice forum should address the policies for safety / security and privacy in eHealth in concert with those for other e-Processes, with a clear plan for accommodating the needs of existing sector-specific arrangements.

For Phase 2 of the eHealth Standards Mandate, It is proposed to rely on EHTEL and the CALLIOPE project to conduct these activities for 2009 and 2010. Beyond 2010, a permanent accredited European entity needs to be designated to conduct these activities.

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