# EHEALTH INTEROPERABILITY:

# STATE OF PLAY AND FUTURE PERSPECTIVES

## AN ASSESSMENT OF EUROPEAN COUNTRIES' RESPONSES TO QUESTIONNAIRE ON RECOMMENDATION (COM(2008)594)

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This report aims to provide a better understanding of the status quo of the development of eHealth interoperability in Europe, the lessons learned so far and the actions that should be taken in the future to help speed up and facilitate interoperability. It responds to the invitation extended to Member States to report to the European Commission the measures they have taken in relation to the implementation of cross-border interoperability of electronic health record systems[1].

In compiling this report, twenty-two countries provided information on the status of their achievements with regard to eHealth interoperability, and stated their preferences for future activities that should be recommended to go ahead in this domain, either collaboratively among Member States or collectively at European-level.

Interactive discussions with Member States (through the i2010 sub-group on eHealth[2]) will provide further feedback on the responses received, and the ways in which the proposed ideas or initiatives should be carried forward.

This report was developed by Diane Whitehouse and Marc Lange from EHTEL and the data included in the report was analysed with the help of a small team of CALLIOPE[3] beneficiaries whose representatives volunteered their services: Catherine Chronaki (HL7-Hellas, Greece); Jacob Hygen, KITH Norway; Matic Meglič, Future Studies Centre, Slovenia; François Wisniewski, CRP Henri Tudor, Luxembourg; and Andreas Xyrichis, European Federation of Nurses.

CALLIOPE is a Thematic Network funded under the CIP ICT-PSP programme[4].

this report can be found on http://ec.europa.eu/information_society/activities/health/policy/interoperability



1 Article 18 of the Commission's Recommendation on cross-border interoperability of electronic health record systems (2008/594/EC) http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32008H0594:EN:NOT

2 http://ec.europa.eu/information_society/activities/health/policy/i2010subgroup/index_en.htm

3 CALLIOPE is a network of collaborating organisations mandated with the planning and implementation of eHealth. It comprises 17 organisations representing national governments and eHealth competence centres and 11 EU-level stakeholder organisations of health professionals, patients, health insurers and industry www.calliope-network.eu

4 http://ec.europa.eu/information_society/activities/health/cip_ict_psp/index_en.htm

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## *1. Executive summary*

***Background and context:*** As a follow-up[5] to the publication of the Commission Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems, a short questionnaire survey was sent to EU Member States[6]. Nineteen of the responses described here came from EU Member States; two were from European Free Trade Association countries; and one was from a candidate country (an observer to the i2010 subgroup on eHealth).

Given the ongoing work related to eHealth being carried out by epSOS, CALLIOPE[7], and the Member States themselves, the opportunity was also taken to ask a small number of questions related to how future developments in eHealth interoperability in Europe might progress.

***Analysis****:* Twenty-two countries outlined their accomplishments in this field. They also stated their preferences for future activities to be explored in this domain, whether collaboratively among Member States or collectively at a European level. Interactive discussions with the Member States (through the i2010 sub-group on eHealth and through higher levels of health ministry representatives) will provide further feedback on the responses received, and the ways in which their proposed ideas or initiatives should be carried forward in Europe.

***Main conclusions****:* The experiences of the Member States in relation to eHealth interoperability are extremely varied, However, most Member States have faced interoperability challenges of one type or another whether at the local, regional, or national level.

There is enthusiasm and a considerable degree of involvement, at least among the respondent countries, in the two eHealth interoperability pilots and studies, epSOS and CALLIOPE, as well as other related initiatives and projects.

Below is a snapshot of responses from individual Member States to facilitate the implementation of the Recommendation and take its objectives further:

**A snapshot[8] of proposals made individually by Member States to facilitate implementation of the Recommendation and take its objectives further.**

- **Create a** "**mutual trust enforcement policy**".[9]
- **Prioritise the recommendations, offer guidelines** on the "core" ones and provide advice via **a set of "starting" or "reference" points** for Member States.
- **Provide information** on ***where*** **Member States could** get advice and guidance on how to put into place all levels of the Recommendation as they relate to electronic health record systems.
- **Identify the specific legal and regulatory requirements** that relate to eHealth interoperability or electronic health record systems.
- **Indicate how the Member States could make progress on** creating electronic health record **systems that are semantically and technically interoperable**.
- **Focus on activities related to needs** such as: standards; personal and medical data; clinical data; use cases; good or best practices; identification, authentication, and database requirements.
- **Draw actively on the results or outcomes of CIP ICT PSP projects**, and ensure that there is a solid coordination developed between the relevant CIP ICT PSP projects.
- **Create incentives** or other measures **that will motivate the implementation of the priority recommendations**.

5 Article 18 of the Commission's Recommendation on cross-border interoperability of electronic health record systems (2008/594/EC)

6 EU 27 countries plus Iceland, Norway, Switzerland and Turkey were contacted

7 These are two of the current initiatives co-financed by the European Commission and Member States by the umbrella framework of the Competitiveness and Innovation Programme (CIP) Information and Communication Technologies (ICT) Policy Support Programme (PSP).

8 Summarised points as opposed to verbatim text

9 This suggestion is related to ICT standards (quality, integrity, security) but also more generally to correct ICT implementation (e.g., equivalences between countries) with the perspective that once requirements have been defined, the possibility of a self-certification process at a European level could also be considered.

The Member States individually also suggested a number of actions which could optimise future work towards eHealth interoperability and on electronic health records systems:

**Key areas for future emphasis suggested by individual Member States:**

- Focus on **high-level governance**, high-level cooperation, and joint action.
- Explore the notion of a **European competence network** or **centre**.
- Concentrate on legal and regulatory issues, **standards**, coordination of projects and their results, **semantics**/languages/terminologies[10].
- Expand the **application and impact** of large-scale pilots.
- Create a **project office** to coordinate or bring together the results of projects.
- Ensure and operationalise **stakeholder involvement and engagement**.
- Emphasise continuity and/or sustainability, and interoperability as **a process** (development, knowledge, resources, and support).

The responses of the Member States with regard to future directions for eHealth interoperability at a European level show, implicitly or explicitly, a degree of synergy with current discussions on governance in relation to eHealth. This is apparent whether at a high-level, at the level of a supporting strategy group, or at the level of an operational platform. Organisationally, a number of other propositions have been put forward: e.g., a coordination project office; competence networks or centres; and consultative/advisory bodies.

Concretely, many of the suggestions for action run parallel to those proposed in the Recommendation in terms of its plea for an organisational framework to cover cross-border interoperability of electronic health record systems (cf. Articles 6a, 6b, 6c, 7, 8, 9, and 14).

The responses indicate a small, but growing, interest in the notion of services, especially Web-based services. New fields for the exploration of interoperability would include medical devices or a pharmaceutical registry.

## *2. Introduction and background*

This section describes the reasons for the survey undertaken by the European Commission, and why and how CALLIOPE became involved. It constitutes a general introduction and background to the survey.

eHealth has long been a combined commitment of the European Commission and EU Member States. Since the 2004 publication of the European eHealth Action Plan[11], the challenge of the interoperability of eHealth systems and services in Europe has grown in importance.

On July 2, 2008, the European Commission published a Recommendation on the "cross-border interoperability of electronic health record systems" (COM (2008) 594)[12]. The Recommendation's article 18 commits the Member States to providing an update on their progress one year after publication. To this end, it was planned that a questionnaire survey would be designed and circulated twelve months following the publication of the Recommendation. Its aim was to facilitate an understanding on the part of both the Member States and the European Commission of the Member States' accomplishments with regard to the activities stipulated in the Recommendation.

In order to get a broader informed view of current activities and future perspectives, three additional questions were included in the questionnaire. They related to more collaborative activities among the Member States on eHealth interoperability, and opinions on new directions and activities for the future.

10 The key words of semantics and standards are underlined because these are those initiatives that were especially emphasised.

11 COM(2004)356 final e-Health – making healthcare better for European citizens: An action plan for a European e-Health area. Luxembourg: European Commission (30.4.2004)

The letter which accompanied the questionnaire, and the questionnaire text, are attached (see ANNEX 1).

### 2.1 Why CALLIOPE was involved in analysing the questionnaire responses

The CALLIOPE thematic network has three core responsibilities:

i. to propose a European Road Map for eHealth interoperability,

ii. to be involved in eHealth standardisation activities, and

iii. to contribute to the next steps which could be taken with regard to COM (2008)594 (the Recommendation on eHealth interoperability - hereafter, referred to as the "*Recommendation*").

The work involved in carrying out the questionnaire survey directly relates to core responsibility iii.

In its activities, CALLIOPE considers interoperability from the perspective of "integrated, connected and interoperable continuity of care for Europe[13]". CALLIOPE particularly encourages its range of stakeholders (i.e., competence centres; payers; health professionals; and patients) to contribute to the interoperability debate through the means of the thematic network. CALLIOPE also offers support to the interoperability initiatives of the Member States, as undertaken in the large-scale pilot, epSOS[14], facilitating best practice exchange and passing on key learnings, particularly to Member States in the early stages of eHealth development.

Considering the responsibilities and expertise of CALLIOPE, the European Commission – in full agreement with the Member States – endorsed CALLIOPE's contribution to the analysis of the questionnaires.

## *3. Format of the questionnaire*

This section describes the questionnaire, the number and range of responses, and the timelines over which they were received.

The questionnaire was divided into five questions which were accompanied by a small number of guidance notes.

The first two questions request the responding Member State[15] to describe the way in which its activities fit with those suggested by the Recommendation, and the extent to which the Recommendation has assisted the Member State in formulating or implementing those activities. A third question enquires about the way in which involvement in European Commission co-financed projects is helping that Member State move towards interoperability. The final two questions ask what the Member State would propose as potential, useful enhancements to the Recommendation and, where it would suggest that the European Commission should concentrate its efforts in the future.

These questions are outlined in Box 1 (below), and are also reproduced in ANNEX 1.

Twenty-two responses to the questionnaire were received by the Commission from EU Member States: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, Hungary, Italy, Latvia, Luxemburg, Malta, Netherlands, Portugal, Slovakia, Slovenia, Spain, Sweden, and the United Kingdom. Three additional responses came from Norway, Switzerland, and Turkey.

The responses to the questionnaire were received between early October 2009 and January 8, 2010.

**Box 1**

[13] This notion is one of keen interest to the Member States. A variant of this notion is being discussed under the framework of the Member States' exploration of eHealth governance issues.

[14] See www.epsos.eu (accessed 29.1.2010).

[15] Here the term 'Member State' is used. This is the descriptor used in the questionnaire, however, the questionnaire was responded to by two European Free Trade Association countries and by a candidate country. All three of the latter are countries associated with membership or observer status of the i2010 subgroup on eHealth.

**QUESTIONS ASKED BY THE EUROPEAN COMMISSION TO THE MEMBER STATES**[16]

1. To what extent has your national administration achieved the objectives outlined in the Recommendation on cross-border interoperability of electronic health record systems (2008/594/EC)?

2. To what extent does the Recommendation contribute to establishment of interoperability of electronic health records and eHealth in your own country?

3. How far are activities in your country contributing to achieving the objectives on the implementation of cross-border interoperability outlined in the recommendation? Please refer – among other activities – to your country's involvement in epSOS and/or CALLIOPE (if and when applicable).

4. What suggestions would your country make to the European Commission for improving, enhancing, or expanding the current set of recommendations?

5. On what services relating to the implementation of cross-border interoperability of electronic health records would your country suggest the European Commission should concentrate?

*What support services does your country believe that the Commission can provide that would have the most added value in this specific domain?*

## *4. Overall results of the questionnaire*

This section introduces the five questions to which the Member States responded. Wherever possible, illustrations, quotes, and graphics are used. No direct comparison is made, however, country-by-country.

The responses received to the five questions are categorised in this section into three separate sub-sections (4.1, 4.2, and 4.3).

Sub-section 4.1 covers the Member States' responses on their achievements in relation to the Recommendation and the way in which the Recommendation is contributing to their accomplishments on eHealth and eHealth interoperability.

Sub-section 4.2 concentrates on the Member States' involvement in various projects which are mostly either national or international (the term "international" here, in terms of reporting on activity 2008-2009 means principally European[17]).

Sub-section 4.3 deals with ways in which the set of recommendations could be enhanced by the European Commission and Member States' proposals for future services that could be supported by the Commission.

### 4.1 Responses to questions 1 and 2

Twenty-one of the twenty-two countries responded to these two questions[18].

The responses received cover a wide range that can be categorised in two ways:

- moving towards eHealth interoperability maturity
- developing a preliminary concept of eHealth interoperability.

As concerns eHealth interoperability, both categories tend to view the Recommendation and its usefulness differently.

[16] The States were also provided with detailed supporting notes that describe the kind of content which was expected from their replies to the European Commission.

[17] There is every likelihood that the degree of internationalism of activities on eHealth interoperability is likely to expand in the future as a result of current initiatives being undertaken between the European Commission, Organisation for Economic Co-operation and Development; and the World Health Organization as well as activities being funded by the European Commissions' Directorate-General on international relations (DG RELEX).

[18] In one case only, the response – while interesting – did not provide a direct match with the questions being posed.

## Moving towards eHealth interoperability maturity

This sub-section describes countries that appear to be indicating a greater level of maturity towards eHealth interoperability.

***Countries' views of the Recommendation***

Some Member States demonstrated a sound understanding of the content and orientation of the Recommendation. They were also well informed about the content of own national strategies and/or Roadmaps, and were able to report on them in detail.

They saw this EU-level document as one that raised overall many issues that were broadly comparable to what was happening at their own, national level. Individual countries were experiencing similar challenges and parallel problems to European Union-level "cross-border" challenges. These challenges could be taking place in a single country, e.g., between its own regions (or in the example of the United Kingdom, between its four home countries). Some countries (e.g., Luxembourg), given that they are based geographically at the crossroads of several different European countries, were experiencing daily the realities of cross-border interactions. Other cross-functional or cross-team challenges were occuring at several cross-organisational levels and across professional or occupational domains. They also reflected the general difficulties of ensuring interoperability of and between diverse systems and services.

These Member States indicated that the levels, layers, and structures that relate to health and eHealth that they were using in their own countries were often similar and even "strongly related" to those specified in the Recommendation.

Such Member States tend to see the Recommendation in a generally useful light. The Recommendation is a document that can be perceived as supportive. It can facilitate and reinforce the country's own national strategy or Roadmap. It can also act as a form of "background support", i.e., it can reinforce messages in a local context. It permits the transfer of information about what Europe as a whole is doing and what fellow Europeans are agreeing to do.

Whereas, there were few generic observations made about the organisational level of the Recommendation Member States nevertheless, stage-by-stage, have been moving towards a shared vision of what it means to make decisions on, and organise, eHealth interoperability in Europe[19]. In this regard, it should be noted that responses to the questionnaire (October-December 2009) preceded significant political developments on eHealth in the December 2009 Health Council and March 2010 Barcelona Ministerial Meeting and respondents were therefore unlikely to make pre-emptive statements on this subject. There will have also been significant developments in individual member states which may alter their approach to achieving widespread interoperability. For larger countries this may entail finding a new balance between services which should be provided centrally, or nationally, and other developments which arise from the bottom up to best reflect local considerations.

***How countries describe their own initiatives on eHealth interoperability***

A set of recommendations can help to mature a set of standards activities. Some countries (examples including Finland, Portugal, and the United Kingdom) made a special point of listing activities undertaken by their country at several levels. In terms of maturing the status of eHealth interoperability in a Member State, the Recommendation appears to play the following role:

• **Political level:** the Recommendation is very much in line with a country's own national strategy or plan; there is a high level of fit between the European approach and the country's own approach.

• **Organisational level:** Some countries mentioned the economics of financing eHealth interoperability; the budgetary aspects of commissioning equipment and services; and the means to secure seed funding.

[19] Health Council Conclusions December 2009 and Barcelona Ministerial Declaration March 2010 illustrate this point

• **Technical, semantic, certification, personal data protection, monitoring and evaluation, education and awareness**: Among these levels, those which received the greatest attention were related to standardisation and semantics.

• **Stakeholder involvement or engagement:** Some respondents made special mention of the importance of this aspect of activity in relation to eHealth cross-border implementation and deployment, for example, in terms of the composition of committees or task forces.

## Developing a preliminary concept of eHealth interoperability

This sub-section provides an initial overview of the way in which country respondents at an early stage of eHealth interoperability development view the Recommendation. It then progresses to consider how such countries described their own maturing initiatives on eHealth interoperability.

***Countries' views of the Recommendation***

A number of respondents viewed the Recommendation as "quite an exhaustive document". They saw the Recommendation as very comprehensive.

The Recommendation was construed as providing an excellent reference for the comparison of the national eHealth strategy with the eHealth vision at Community level. In these cases, the Recommendation was perceived as forming a foundation for cross-border interoperability; this foundation-stone has generally been taken into consideration when constructing the specific country's national eHealth endeavours[20].

Countries' objectives often included references to an action plan – particularly a national plan; cooperation and care; coordination; patients; systems; and standards.

It was, nevertheless, suggested that the Recommendation appears to have stimulated – perhaps too strongly – a set of somewhat long-term goals. It was also at times perceived as a "high level document" which might be difficult to use directly in the kind of concrete activities that would need to be applied directly to eHealth interoperability.[21]

However, some respondents did see the Recommendation as a document that, more concretely, "provides guidelines"[22].

***How the countries describe their own initiatives on eHealth interoperability***

The work on eHealth interoperability described was aligned with the political, organisational, technical, semantic, certification, personal data protection, and monitoring and evaluation levels of the Recommendation. Examples include:

- **Political:** legal frameworks; eHealth strategies.
- **Organisational:** road mapping.
- **Technical:** many countries have eHealth interoperability activities planned: these include standards, mapping, and ultimately eServices.
- **Semantics:** the International Health Terminology Standards Organisation (IHTSDO), HL7, the International Classification of Diseases (ICD), and the WHO[23]'s International Classification of Primary Care.
- **Certification:** Few countries have certification schemes underway.
- **Personal data protection:** around a quarter of the countries appear to be doing work on legislation, policies, solutions[24].

[20] For this to be the case, the country needs to have been working towards specifying its national stance on eHealth interoperability either during the time-period that the Recommendation was under formulation (i.e., 2007-2008) or once it was published (2008-2009).
[21] It should be noted that – in response to the question posed by the European Commission – no single response by any of these countries described a missing part to the Recommendation, cited a new element to add, or remarked on any barriers to its implementation.
[22] This observation should not be viewed as contradictory with the later desire expressed by Member States to see even more concrete guidelines developed.
[23] World Health Organization.

- **Monitoring and evaluation:** ongoing activities include feasibility studies and cost-benefit analyses.

### 4.2. Responses to question 3

This sub-section introduces the range of responses to question 3.

This question concerned the extent to which activities in each country were perceived as contributing to achieving the objectives of the Recommendation. Where applicable, the respondents were asked to make particular reference to any activity in which their country was involved in epSOS and/or CALLIOPE.

The Member States indicated that their contributions to cross-border interoperability largely took place through their involvement in, and support of, large-scale initiatives (which can be called pilots or projects) such as epSOS and CALLIOPE. Eight respondent countries mentioned involvement in some way in epSOS, and eleven mentioned involvement in CALLIOPE. Five respondent countries were involved in both epSOS and CALLIOPE.

CALLIOPE was particularly noted as an important arena for the exchange of ideas by countries which were themselves CALLIOPE members and participants.

Nine respondents referred to a wide range of other projects or initiatives. Among these were the following:

• *Projects:* EUROREC electronic health records, PEPPOL, STORK, Telemedicine

• *Initiatives and activities:* M403 (standardisation), pan-European or pan-international collaboration on semantics e.g., IHTSDO.

In addition, other countries mentioned spontaneously various other pan-European or collaborative initiatives that they are working on, e.g.:

- Diagnostic imaging.
- Working together with health insurers.

A large-scale pilot like epSOS is, of course, not open for involvement of all countries, since it is restricted to countries that are more advanced in a specific field of information technology development. This explains why some countries are not present in such a project.[25] CALLIOPE, on the other hand, is open to all Member States and European countries (and several are currently negotiating to enter it, or joined it only recently). CALLIOPE's role in disseminating the findings of an advanced large-scale pilot is an important area of interest.

The potential to get involved at European level is in fact much wider than either of these two projects. Opportunities are available through a wider range of initiatives and projects (several of which relate to other health-related areas e.g. telemedicine; imaging; methods of financing healthcare systems and services; and areas of eHealth standardisation. Initiatives which focus on the foundation stones for interoperability, such as identity management, accreditation, and certification are also perceived as beneficial by the European countries.

### 4.3. Responses to questions 4 and 5

This sub-section introduces the range of responses given to both questions 4 and 5.

There was little distinction made by many Member States in terms of their responses to questions 4 and 5. Overall, responses to the first of these two questions were more complete and informative. Relatively sparse information was put forward in responses to question 5.

[24] For a more dedicated source of information on the status of Member States with regard to data protection legislation and health-related data, the European Commission co-financed study published in 2009 is recommended *SMART 2007/0059 Study on the Legal Framework for Interoperability of eHealth in Europe. Final Report*. See also footnote 9.

[25] Further initiatives that focus on eHealth interoperability could nevertheless orientate themselves towards activities which could guarantee a wider level of implementation e.g., interoperability of emergency health telephone numbers and/or services.

Empirically, in relation to question 4, 19 out of 22 respondents replied directly[26]. In response to question 5, 21 out of 22 Member States replied.

A wide variety of insights were offered. Most responses were brief and targeted. Some of the comments were rather more high-level or conceptual. Other responses were more applied in their orientation.

## Responses to question 4

Among the responses, a number of Member States reinforced the importance of the need for a focus on high-level governance in relation to health and eHealth in Europe.

These responses seem to indicate that the Recommendation could be improved and enhanced by a focus on the "organisation" of eHealth in Europe. It is this level of emphasis that is noticeably missing in the text of the Recommendation and hence it could be considered somewhat reassuring that this desire for self-organisation is emerging progressively from among the Member States themselves.

The following box outlines seven key areas of activity identified individually by the Member State respondents:

**Key areas for future emphasis**

- Focus on **high-level governance**[27], high-level cooperation, and joint action.
- Explore the notion of a **European competence network** or **centre**[28].
- Concentrate on legal and regulatory issues, **standards**, coordination of projects and their results, **semantics**/languages/terminologies[29].
- Expand the **application and impact** of large-scale pilots.
- Create a **project office** to coordinate or bring together the results of projects.
- Ensure and operationalise **stakeholder involvement and engagement**.
- Emphasise continuity and/or sustainability, and interoperability as **a process** (development, knowledge, resources, and support).

These responses mirror the direction of high-level discussions taking place at EU-level incorporating health authority directors, policy makers, and politicians from EU Member States. Examples of recent high-level discussions include European annual high-level/ministerial conferences; EU-Presidency-led initiatives; and the current development of "e-Health governance" proposals for future high-level decision-making (i.e., in preparation for initiatives to be co-financed by various Directorate-Generals of the European Commission).

Some respondents particularly emphasised that these suggestions for shared and high-level leadership should be made within a particular socio-economic context. Europe is facing multiple economic, social, and demographic challenges to the continued quality, accessibility, and generally high-level standards of its health systems and services. It is in this context that Europe and Europeans are particularly aware of the constraints related to, and difficulties with, continued financial expenditure in the health domain.

A set of simple, concise messages can be drawn from the Member States' responses in terms of ways to enhance and improve the Recommendation.

These proposals are laid out in the box below. They deliberately do not imply which actions need to be taken by the European Commission or by the Member States which is not the role of this report.

[26] A respondent which simply noted that it had nothing to add is not counted here.

[27] Words which are emboldened by the editorial team are those which appear to have been given the greatest emphasis either quantitatively and qualitatively by the respondents.

[28] The extent to which this concept should – if considered useful by the Member States - be created as a network or as a centre is a matter for consideration and debate.

[29] The key words of semantics and standards are underlined because these are those initiatives that were especially emphasised by this second group of Member States.

Once a series of eHealth interoperability aims and goals can be agreed among the Member States – in line with their commitment towards the development of eHealth governance - it will presumably be possible to allot a more precise distribution of responsibilities and tasks to all the various parties concerned – for example, as part of a road mapping exercise.

The suggestions below include the need to reinforce prioritised information-sharing, and to concentrate on a core set of activities e.g., legal and regulatory; trust; semantics; and technical challenges.

**A set of proposals made by Member States to facilitate implementation of the Recommendation and take its objectives further *Direction and guidance*[30]**

- **Create a** "**mutual trust enforcement policy**".[31]
- **Prioritise the recommendations, offer guidelines** on the "core" ones and provide advice **via a set of "starting" or "reference" points** for Member States[32].
- **Provide information** on ***where*** **Member States could** get advice and guidance on how to put into place all levels of the Recommendation as they relate to electronic health record systems.

***Building blocks***

- **Identify the specific legal and regulatory requirements** that relate to eHealth interoperability or electronic health record systems.
- **Indicate how the Member States could make progress on** creating electronic health record **systems that are semantically and technically interoperable**.
- **Focus on activities related to needs** such as: standards; personal and medical data; clinical data; use cases; good or best practices; identification, authentication, and database requirements.

***Mechanisms***

- **Draw actively on the results or outcomes of CIP ICT PSP projects**, and ensure that there is a solid coordination developed among the relevant CIP ICT PSP projects.
- **Create incentives** or other measures **that will motivate the implementation of the priority recommendations**.

These levels of proposal for enhancement and improvement of eHealth interoperability have been classified broadly into three domains:

- The first domain needs **prioritised decision-making** that is based on advanced **information or information-sharing**
- The second domain is a list of a set of activities that are very specific and concrete in their delineation ("building blocks"). Examples include legal, regulatory, trust, semantics, and technical building blocks.
- The third domain includes some examples of incentives or actions that can support *either* the high level of decision-making *or* the operationalisation of the building blocks.

A set of choices therefore arises for the Member States:

- First, can the Member States develop an approach whereby these several levels can be mutually self-supporting?[33]

[30] This list includes *either* ways and means to operationalise the Recommendation *or* to take its underpinning concepts further.

[31] To date, these trust-oriented concepts have not been expressed in terms of documentation. "This [notion] is of course related to ICT standards (quality, integrity, security) but also to correct ICT implementation of other discussions (e.g., equivalences between countries). Once requirements *[are]* defined, consider also the possibility of a self-certification process at a European level."

[32] Examples of applications on which to focus included identification, authentication, and databases. Examples of concrete illustrations include describing what a good electronic health record system is by presenting an example system or showing a form of good ("best") practice.

- Second, should they concentrate in the immediate future on building a structure and approach to shared decision-making and information-sharing?
- Third, should they concentrate on various concrete domains of activity (legal, regulatory, and so on)? By sharing this information between themselves, could they help improve progress on those core, specific challenging areas?

## Responses to question 5

Question 5 is associated with those services which each specific country would suggest that the European Commission should concentrate and that relate to the implementation of cross-border interoperability of electronic health records.

Overall, the responses to question 5 can be regarded as a kind of "spill-over" set of answers. In many cases, they represent a serious of miscellaneous observations that the respondents have not found the opportunity to express otherwise or elsewhere in responding to the questionnaire.

Twenty-one responses were received. Most of the respondents did not focus their responses very specifically on the notion of "services" but, rather, they spoke of actions, activities, and initiatives more generally. Nor did the responses focus on electronic health records and their interoperability very precisely. Only light indication was given that any work should focus on patient summary and ePrescription: a single respondent referred specifically to patient summaries, ePrescribing, and standardisation activities such as the M403 initiative.

Several of the respondents emphasised the need for actions that would be **particularly helpful for small Member States**. Several commented that the precise focus of the various items outlined in the Recommendation could be better developed (e.g., technical, semantic, and standardisation issues) and that there should be a far greater concentration on more technical and applied actions. Other suggestions included appropriate research support, and financial support for specific project calls.

Perhaps the most ambitious proposal was for the European Commission to concentrate on the setting-up of a **consultative body or organisation** (which would provide advice and guidance on needs and process). A plea was made for it to be especially helpful to small Member States and/or new Member States.

In terms of process, one respondent in particular emphasised that, in any action undertaken, input and advice from three levels is to be welcomed: Member States, stakeholders and industry.

In relation to services, one respondent put forward an overall vision of: "**Enabling better services for citizens**".

It was felt that the European Commission should concentrate on the following initiatives. These five specific concepts were raised in relation to services:

- cross-border **services**;
- health and social **services** (together);
- Web **services**;
- **services** for the transfer of data (including such data as demographic, contact, basic medical information, ePrescription, and telemedicine – around which it was suggested the real "value-added" lies);
- semantic **services** (especially to develop a Road Map for semantic services).

Concepts that had been raised previously elsewhere by the respondents were reinforced in answer to this question. Here, the main messages were: consolidate the political messages and build from

33 That is, can core policy directions/decisions be made that fit around the appropriate building blocks and use appropriate incentivisation methods? It is assumed that this would be an appropriate direction in which to progress when considering the decisions to be made by a high-level eHealth governance process, supported in turn by a strategy group, and by an operational platform which liaises with all the actual, relevant, areas of deployment/implementation/operationalisation.

presidency-to-presidency; focus on what is concrete and can be applied (e.g., standards; trust[34]; use cases; and actual practices of the highest possible quality and impact):

- Detailed political goals with documented benefits (a good example of a model for this was cited as having been the Swedish presidency report published in July 2009[35]).
- "Mutual trust enforcement operational strategies"[36].
- Standards and standardisation.[37]
- Pilot projects that would be oriented towards 1) standardisation 2) concrete use-cases (e.g., medication information; benefits of interoperability/eHealth).
- Good or best practices (select specific examples of good practice that would be made available to Member States).

In addition, Member States concentrated their additional responses on notions that were either *not* laid out in detail in the Recommendation (or only superficially e.g., training orientations).

These included:

- Planned care[38].
- Medical Device Directive.
- European registry of pharmaceuticals[39].
- Training and/or capacity-building for various occupations and professions e.g. lawyers, health (care) professionals, technical staff[40].
- Classification mechanisms, and data sets.
- Profiling[41].

Ideas that have been around for some time, but which were reinforced in this set of responses, include the need a) to pay some attention to what can be achieved in small countries or small states (which often bear considerable similarities to regions of much larger countries) and b) what can be achieved in near-border circumstances (i.e., those parts of countries which are most likely to experience the mass of cross-border travel and hence, possibly, cross-border use of a wide variety of health services (e.g. sport, health, medical, optical, or dental).

[34] The emphasis placed on trust in this specific answer is in relation to various practical, applied methods and mechanisms to support electronic services.

[35] See http://www.sweden.gov.se/content/1/c6/12/98/15/5b63bacb.pdf (accessed 29.1.2010)

[36] "Mutual trust enforcement operational strategies" are directly complementary to the concept of the "mutual trust enforcement policy" mentioned elsewhere in this report. They involve governance, certification schemes, development / maintenance of a multi-lingual terminology server, (cross) validation of national official sources, common reference model for evaluation and monitoring.

[37] Including the coordination of standardisation bodies, minimum interoperability standards in the EU, framework of commonly agreed European standards (e.g., technical, semantic), security, legal issues (EU and national), mutual acceptance of authorisation mechanisms, standards for electronic health records and terminology, electronic medical records/vendor certification schemes, identity management.

[38] eHealth interoperability within the focus of the Recommendation is on unplanned care, i.e., of persons working, living, studying, or travelling abroad who need access to health treatment. Planned care might involve e.g., planned surgery abroad or planned reliance on expertise in other countries e.g. for people who experience rare conditions or diseases.

[39] Such a registry might facilitate orientation towards interoperability particularly in terms of cross-border provision of prescriptions.

[40] The Member States did not mention individuals, citizens, patients, or their families or carers, but this might form an obvious extrapolation of such a notion.

[41] In this context, profiling is considered to refer to 'user profiling' (a collection of personal data associated to a specific user / digital representation of a user's identity) or 'system profiling' (investigation of a programme's behaviour using information gathered as the programme executes). Since profiling is at the core of the previously-proposed M403 (eHealth standardisation) solutions, it was remarked that it is "NOT exclusively an activity that the standards organisations can or should do. Moreover, profiling is NOT an industry-only driven activity. It should be a cooperation between industry-driven groups and user-driven groups. Thus, it should be brought to live in a cooperation of various *[Directorate-Generals]* within the EU".

## *5. Main findings*

This section describes briefly the main themes and trends of the survey. Several are explored further in the analysis which follows.

The experiences of the Member States in relation to eHealth interoperability are extremely varied. However, most Member States have faced interoperability challenges of one type or another whether at the local, regional, or national level.

There is enthusiasm for and a considerable degree of involvement in, at least among the respondent countries, the two eHealth interoperability pilots and studies, epSOS and CALLIOPE. So too, Member States are involved in a somewhat wider range of related initiatives and projects. Some countries appear to be enthusiastic participants in multiple initiatives.

The responses of the Member States with regard to the future direction of eHealth interoperability at a European level, implicitly or explicitly, parallel current EU-level discussions on governance in relation to eHealth. This is apparent whether at a high-level, at the level of a supporting strategy group, or at the level of an operational platform.

Organisationally, a number of other propositions have been put forward: e.g., a coordination project office; competence networks or centres; and consultative/advisory bodies.

Concretely, many of the suggestions for action mirror those proposed in the Recommendation in terms of its plea for an organisational framework to cover cross-border interoperability of electronic health record systems (Article 6a) and its focus on commissioning or "procurement" (Article 6b); a speed-up of standardisation processes (Article 6c); technical issues, including standardisation (Article 7); semantics (Article 8); certification or conformity testing (Article 9); and Europe's legal framework (Article 14).

The responses indicate a small, but growing, interest in the notion of services. Equally, a number of new ideas which lie outside the "box" of interoperability or which push its parameters further (into fields such as medical devices or pharmaceutical registry) are also cited.

## *6. Analysis*

This section provides an analysis of the main findings

The responses demonstrate the commonalities among the Member States but also their variety and diversity. This diversity relates to e.g., their size; volume of population; types of health systems and services; types of financing or reimbursement system for health (and other similar services e.g. care or pensions) or resources; and stage of development and deployment of the country's eHealth systems or services.

There were considerable differences among countries. For example, some Member States found the Recommendation useful because it was a policy-oriented or high-level document, whereas others found it less useful because it did not provide a precise set of guidelines, exact recommendations or guidance, "recipes" or "prescriptions".

There are broad differences between countries with more mature approaches to eHealth interoperability in relation to electronic health records and ePrescribing and countries with less mature systems and services. Whereas some may see this as a potential source of "tension" between Member States which are already in a deployment phase and Member State which are still in a preparation phase, it can more positively be viewed as: an opportunity: Member States at an advanced stage are able to share their expertise and learning with others as a result of their many years of trial and error; Member States at similar stages of development can benefit from mutual learning; and countries which share a number of their institutional or system or budgetary contexts in common and can hence benefit from a degree of critical mass.

It is likely, therefore, that several methods of sharing good practice will be beneficial and an open method of coordination should thus provide such opportunities. Likewise, the wide range of political, financing and co-financing, regulatory, technical, behavioural and normative mechanisms available to EU

Member States may provide a degree of differentiation that can appeal to each single Member State on its own.

Overall, the Recommendation corresponded to what several countries are actually doing in terms of eHealth interoperability. Overall, it is not surprising that there would be a fit between the Recommendation and the situation in Member States. This is due to (a) the close level of involvement of the Member States (through the mechanism of the i2010 sub-group on eHealth) in the early interoperability discussions in 2006-2007 that led to the publication of the Recommendation in 2008, and (b) the closely associated set of stakeholder groups which represented both industry and users and which in turn gave input to the Member States' discussions.

The organisational level of the Recommendation is most absent from the feedback. For many of the Member States, it is possible that they foresee the organisational level evolving as part of the shift towards the creation of a more formalised governance structure.

Timing was an issue mentioned by only a few Member States. The socio-economic climate was by some seen as a potential inhibitor, brake or constraint to rapid progress on the introduction or implementation eHealth interoperability throughout Europe. In one case, a ten-year timeline was seen as realistic (the Recommendation identifies a five-year time horizon; see cf. article 6(a)).

Lastly, there was no evidence of any country which replied in a negative manner or which criticised the Recommendation.

## *7. Conclusions*

The responses of the Member States to this short questionnaire survey can be used in various ways by the Member States and by the European Commission since:

- they represent a view of a large number of EU Member States with regard to their accomplishments in the field of eHealth interoperability;
- they are provided at a useful and opportune moment in terms of decision-making for both the Member States and the European Commission;[42]
- they illustrate a set of reflections of directions in which future activities on eHealth interoperability may head in the future.

This report can therefore be viewed as a useful representation of a "snapshot in time". It provides information and ideas that, it is hoped, will have interest and utility for the Member States and the various European institutions.

In many ways, the observations offered reflect and have synergy with a number of other Member States' activities that are currently underway, and which are increasingly coming together in harmony.

The questionnaire has also resulted in a set of informed ideas on how to move forward at EU-level on eHealth interoperability in relation to electronic health record systems (made initially in the Recommendation). However, **the methods** through which this should take place have not yet been consolidated.

The means through which future eHealth interoperability activities can be carried forward in Europe are in the process of being identified by CALLIOPE. They could be developed in the context of the eHealth interoperability Roadmap that is being formulated by CALLIOPE in conjunction with representatives of national health ministries, following endorsement by State Secretaries in March 2010.

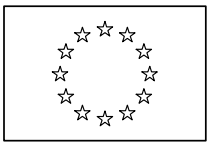
The implementation of various instances of European-wide eHealth interoperability are also being operationalised in the large-scale pilot, epSOS[43], and are being planned for in its successor – which will be proposed in mid-2010.

[42] At the end of 2009, there was: the entry into force of the Lisbon Treaty; the publication of a set of conclusions in the Health Council which will permit a focus on a renewed set of health priorities (including eHealth); the appointment of a new set of European Commissioners with a new portfolio of activities; and the establishment of a new European Parliament. 2010 is, to date for the Member States, coloured by a desire to move forward through the creation of a more collaborative framework and platform which focuses on needed eHealth actions.

The eventual involvement of the stakeholder community in this process of reflection and decision-making will be vital both in terms of stakeholders' input to the actual ideas and concepts; their constructive criticism of the proposals under development; and their capacity to help put into place the resulting initiatives.

[43] http://www.epsos.eu/

## ANNEX 1: LETTER AND ASSOCIATED QUESTIONS SENT TO MEMBER STATES ON JULY 17, 2009



EUROPEAN COMMISSION
Information Society and Media Directorate-General

ICT addressing Societal Challenges
**ICT for Health**

Brussels, 17 July 2009[44]
INFSO H1 /MP/bv D(2009)

**Subject:** **Implementation of the Recommendation on cross-border interoperability of electronic health record systems**

Dear Member State eHealth representative,

According to point 18 of **the Commission Recommendation of 2 July 2008 on cross-border interoperability of electronic health record systems (2008/594/EC)** (hereinafter the Recommendation):

> "Member States are invited to report, on a yearly basis, to the Commission on the measures they have taken in relation to the implementation of cross-border interoperability of electronic health record systems. The first report should be presented by Member States one year following the day of publication of this Recommendation".

In order to continue the EU-collaborative approach to this process, a plenary and two parallel sessions were held at the recent i2010 sub group on eHealth meeting. Discussion took place on if and how the points in the Recommendation have been implemented. Progress in the deployment of interoperable electronic health record systems was also overviewed at Member States-level.
It was generally felt by attendees that it could be useful to the Member States to collate evidence on the degree of interoperability of eHealth systems achieved by themselves at national level, and that the Member States would wish to share this information among themselves.
As a result, the i2010 subgroup on eHealth gave its authorisation for:

- the Commission services to send out a revised version of the questionnaire following the meeting
- the Commission services to collate and analyse the results of the questionnaire
- CALLIOPE multi-stakeholder platform (thematic network) to incorporate the results in an appropriate way in the deliverable that it has been mandated to produce entitled: "eHealth Interoperability Recommendation Review: Report on status and proposed revision". Member States should indicate whether they wish the EC not to share the questionnaire responses with CALLIOPE.

You are asked to:

- respond to the questionnaire by Monday October 12, 2009
- send your response to _____
  *[email address removed]*

To assist in your answering of the five questions, please see the guidance notes provided in annex. If you have any further difficulties in responding to questions, please contact INFSO H1 for guidance.
The Commission services intend to collate and analyse the responses by mid-December 2009.
Thanks in advance for your cooperation.
Kind regards,

*signed*

Mike Palmer and Flora Giorgio

[44] NB. The font of this letter has been vastly reduced so as to enable the text to fit on a single page.

Responding Country: ……

Contact name: ……..

**QUESTIONS TO BE ANSWERED BY MEMBER STATES**

**1. To what extent has your national administration achieved the objectives outlined in the Recommendation on cross-border interoperability of electronic health record systems (2008/594/EC)?**

**2. To what extent does the Recommendation contribute to establishment of interoperability of electronic health records and eHealth in your own country?**

**3. How far are activities in your country contributing to achieving the objectives on the implementation of cross-border interoperability outlined in the recommendation? Please refer – among other activities – to your country's involvement in epSOS and/or CALLIOPE (if and when applicable).**

**4. What suggestions would your country make to the European Commission for improving, enhancing, or expanding the current set of recommendations?**

***Please focus in particular on what actions, services, or themes should be prioritised among the current set of recommendations. Indicate any major omissions. Highlight what processes would be used best to achieve this progress. You may also make suggestions for the ways in which the recommendation could be taken further or next steps could be started.***

**5. On what services relating to the implementation of cross-border interoperability of electronic health records would your country suggest the European Commission should concentrate? What support services does your country believe that the Commission can provide that would have the most added value in this specific domain?**

**GUIDANCE NOTES FOR MEMBER STATES**

1. **When there is particular information that you wish to share with the Commission services and not with calliope, please identify this material clearly (e.g., by placing it on a separate page or by sending it in a separate document).**

2. **In answering the five questions, please note the following:**
   - Q 2 aims at gathering information on interoperability activities within your own Country, also referred to as "national interoperability activities"
   - Q 3 aims at gathering information on cross border interoperability activities also referred to as "European/international interoperability"
   - It should be understood that interoperability of Electronic Health record systems refers to the provision of services which use the application
   - The working definition of "electronic health record system" used in the Recommendation (3d, p14) is: "a system for recording, retrieving and manipulating information in electronic health records".

3. **With particular regard to questions 1 and 2, you may find it useful to outline measure(s) taken nationally at the different levels identified by the recommendation:**
   - Political (see point 5 of the Recommendation)
   - Organisational (see point 6)
   - Technical (see point 7)
   - Semantic (see point 8)
   - Certification (see point 9)
   - Personal Data Protection (see points 10-15)
   - Monitoring and evaluation (see point 16)
   - Education and Awareness (see point 17)

4. **Please consider the following points for each of the identified levels of actions/activity:**

**POLITICAL**
- *Political and strategic commitment to the implementation of EHR interoperability at local, regional and national level*
- *Consultation mechanisms with relevant stakeholders such as regional and local authorities, health professionals, patients and industry on the topic of interoperability of EHR systems – specific mechanism in place*
- *Financing mechanisms considered to support interoperability of EHR systems*

**ORGANISATIONAL LEVEL**
- *European governance process for developing, implementing and sustaining cross-border interoperability of EHR systems*
- *Organisational mechanisms to support cross-border interoperability of EHR systems*
- *Policies and incentives for procuring eHealth services to enable interoperability of electronic health record systems*

**TECHNICAL LEVEL**
- *Activities undertaken in your country related to development of technical standards for EHRs*
- *Any change in the use of existing standardised information models and standards-based profiles when developing and implementing interoperable electronic health record systems and services solutions*

**SEMANTIC LEVEL**
- *Establishment of an appropriate mechanism (e.g. national research centres, relevant industry players and stakeholders) for the development of health semantics*
- *Any change in the use of international medical-clinical terminologies, nomenclatures and classifications of diseases, including those for pharmacovigilance and clinical trials*

- *Industry self-certification and/or conformity testing activities as a means to reduce delays in bringing interoperable eHealth solutions to the market*
- *Joint or mutually recognised mechanism for conformity testing and certification of interoperable EHR systems*
- *Impact of certification to enhance the confidence of users in eHealth standards*

**PERSONAL DATA PROTECTION**

- *Specific legal safeguards to protect the personal data recorded in EHR systems*
- *Involvement of the national data protection supervisor in your country in reviewing the legal regime required for interoperability of EHR*
- *Use of the guidance on EHR systems provided for in the Working Document 131 of 15 February 2007 on the processing of personal data relating to health in electronic health records (Article 29 Committee document)*
- *Identification and authentication of patients and health professionals*
- *Auditing requirements for the purpose of ensuring compliance with data protection obligations, such as data access logging, documentation of all processing steps, duration of maintaining the auditing information, effective back up and recovery systems*
- *Patient's autonomous and freely taken decisions as to which personal data concerning health are to be stored and disclosed to whom in his or her electronic health record*

**MONITORING AND EVALUATION**

- *Benefits and risks assessment (including economic benefits and cost-effectiveness) of interoperable EHR systems. Please include any quantitative and qualitative assessment of activities in which your Member State has been involved*

**EDUCATION AND AWARENESS**

- *Awareness about the benefits and risks of EHR systems and their interoperability among producers and vendors of information and communication technologies, healthcare providers, patients and citizens, public health institutions, insurers and other stakeholders*
- *Any requirements for education and training with regard to health policy-makers, health professionals and patients*