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COMMISSION OF THE EUROPEAN COMMUNITIES

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DRAFT RECOMMENDATION OF THE COMMISSION

on cross-border interoperability of electronic health record systems

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty Establishing the European Community, and in particular Articles 3 [1. (p) - “high level of health protection”], 14 [“free movement ... persons, services, ...], 95, 152 [“Public Health”, ... “measures designed to ... improve human health”] and 211 thereof,

Whereas:

(1) The strategic initiative i2010 – a European Initiative for Growth and Employment – builds on information and communications technology policies, regulation, and research and innovation to contribute to the goals defined in the Lisbon Strategy. The i2010 strategy promotes the European Information Society for all citizens, and encourages provision of better public services, including eHealth.

(2) The 'Council Conclusions on Common Values and Principles in European Union Health Systems' summarise the goals and priorities of Member States in the field of healthcare as *universality, access to good quality care, equity, and solidarity* - all of which constitute a set of overarching values that are shared across Europe.[1]

(3) Resolving contemporary and future challenges to these European healthcare values is possible, at least partly, through deployment of proven information and communications technology -enabled solutions (eHealth). A major requirement to harness benefits of eHealth is an improved cooperation regarding interoperability of Member States’ eHealth systems and applications.

(4) Interoperability of health information systems such as electronic health record systems should enable improved access, quality and safety of patient care throughout the European Union (EU) by providing patients and health professionals with relevant and up-to-date information while respecting data privacy and confidentiality. Enhancing cross-border cooperation in the domain of eHealth requires cooperation between providers, purchasers and regulators of different Member States.
At the same time any measure on interoperability need not necessarily lead to the harmonisation of laws and regulations of the organisation and delivery of healthcare in Member States.

(5) Interoperability is one of the major hurdles for realising the social and economic benefits of eHealth in the European Union. Market fragmentation in eHealth is exacerbated by the lack of technical and semantic interoperability. The current health IT systems and standards used in Member States are often incompatible and do not facilitate access to vital information for provision of safe and good quality care.

(6) In accordance with the principles of subsidiarity and proportionality, Member States have the prime responsibility for protecting and improving

[1] Document (2006/C 146/01), published in the Official Journal of the European Union on 22 June 2006, pp. 1 - 5

the health of their citizens. As part of that responsibility, it is for them to decide on the organisation and delivery of health services and medical care. When they exercise these competences, Member States have to comply with Community law including the case law formulated by the Court of Justice of the European Communities concerning free access of citizens to healthcare in another Member State.

(7) The Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of Regions entitled: *eHealth – making healthcare better for European citizens: An action plan for a European eHealth Area*, presented on 30 April, 2004[2] presents the potential of eHealth and major challenges for wide deployment. The Action Plan of this Communication calls for joint European Union and Member State action on interoperability of electronic health record systems.

(8) The High Level EU eHealth Conference 2007 Declaration[3] acknowledged the importance of starting joint initiatives among Member States by strengthening a range of activities related to interoperability of electronic health record systems.

(9) The European Commission responded to the 'Aho[4] report' on *Creating an Innovative Europe*[5] with the Lead Market Initiative[6] that aims at the creation and marketing of innovative products and services in promising industrial and social areas such eHealth. One of the main targets of the proposed programme is stimulating the interoperability of electronic health record systems.

(10) The European Parliament, on 23 May 2007, passed a Resolution on health services in relation to the internal market, particularly the Services Directive. The Resolution invites the Commission to encourage Member States to actively support the introduction of eHealth and telemedicine, particularly of interoperable systems allowing the exchange of patient information between healthcare providers in different Member States[7].

(11) A robust European legal framework is already in existence at least in relation to data protection (i.e., the Directive 95/46/EC). Any activity recommended is without prejudice to the existing *acquis communitaire* on the protection of personal data and on the provisions that health services must respect fully the fundamental rights to privacy and the protection of personal data (cf. articles 7 and 8 of the Charter of Fundamental Rights of the European Union).

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[2] COM(2004)356 final. *e-Health – making healthcare better for European citizens: An action plan for a European e-Health Area.*

[3] See http://ec.europa.eu/health-eu/news/ehealth/ehealth2007_en.htm

[4] Esko Aho chaired the working group which first drafted and published this report on innovation in Europe. It is his name which has since been used to refer to the report.

[5] See http://ec.europa.eu/invest-in-research/pdf/download_en/aho_report.pdf

[6] COM(2007) 860 final. For details, see: http://ec.europa.eu/enterprise/leadmarket/leadmarket.htm#1

[7] European Parliament resolution of 23 May 2007 on the impact and consequences of the exclusion of health services from the Directive on services in the internal market (2006/2275(INI)), See http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P6-TA-2007-0201+0+DOC+XML+V0//EN&language=EN

(12) It is to be observed that regulatory harmonisation should be limited to essential requirements that accord with the concept of 'New Approach' directives. The basis for this view was laid down by the Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 that outlines a procedure for the provision of information in the field of technical standards and regulations and of rules on information society services, and which was amended by the Directive 98/48/EC (the 'Information Society Services Directive').

HEREBY RECOMMENDS

Aim

1. This Recommendation provides a set of guidelines for developing and deploying interoperable eHealth systems, in particular electronic health record systems, allowing for the cross-border exchange of patient data such that healthcare providers and other health-related services can collaborate effectively and efficiently when a citizen is in need of healthcare while in another country.

Scope

2. The scope of the Recommendation refers specifically to electronic health record systems, including elements such as patient summaries, emergency data sets, and medication records facilitating ePrescription solutions.

Definitions

3. For the purposes of this Recommendation the following definitions are applied:

a) "Electronic health record" represents a repository of information regarding the health of a subject of care, in computer-processable form[8].

b) "Electronic health record system" represents a system for recording, retrieving, and manipulating information in electronic health records[9].

c) "Patient summary" refers to a clinical document which contains a minimum set of patient data which would provide a health professional with essential information needed in the event of unexpected or unscheduled care. It is stored in repositories with cumulative indexing systems and secure access by authorised personnel.

d) "eHealth" refers to information and communications technology-enabled systems and solutions which benefit health. These may be for storage, retrieval, sharing and optimal use of health related data, information and knowledge for decision making, for communication between relevant actors including citizens and patients, and ultimately for better health provision. Examples of applications include health information networks, electronic

[8] according to the standard ISO/TS 18308:2003
[9] EN 13606

health record systems, telemedicine services, and personal wearable and portable devices for monitoring and supporting patients.

e) "ePrescription" means a medicinal prescription as defined by the Directive 2001/83/EC issued and transmitted electronically.

f) "Interoperability" means the ability of information and communications technology systems and of the business processes they support to exchange data and to enable the sharing of information and knowledge[10].

g) "eHealth interoperability" includes not only the technical definition of "interoperability" that relates to connecting systems and exchanging data and information, but also recognises the concept of connecting people and diverse health service providers to support their collaboration for the optimal delivery of health-related services to citizens whenever and wherever in need, thereby also taking into account the relevant semantic, social, political, regulatory, business/industry, and organisational factors. In other words, realising eHealth interoperability will allow linguistically and culturally disparate clinicians, patients and other actors within and across jurisdictions to exchange, understand and act on patient and other health information and knowledge in a collaborative manner.

General

4. Realising and sustaining cross-border eHealth interoperability will concern managing a continuous process involving permanent change and the adaptation of a multitude of elements and issues within and across Member State health systems and their electronic infrastructures necessary to exchange information, to interact and collaborate in caring for the health of European citizens. It will require a complex set of framework conditions, organisational structures and implementation processes involving all relevant stakeholders.

a) To achieve this, Member States are invited to undertake together and in cooperation with the Commission actions at four levels, namely, the overall political, the organisational, the technical and the semantic levels.

b) Underpinning these activities will be a commitment to comply with national as well as EU legal frameworks on data privacy, confidentiality and data security, and to implement mechanisms for education of both citizens and professionals as well as for the evaluation and monitoring of activities.

The overall political level of cross-border interoperability of electronic health record systems

5. At the overall level of feasibility of and commitment to eHealth interoperability, it is recommended for Member States to:

[10] The term originates from the European Interoperability Framework (EIF) (2004:5) of the Interoperable Delivery of European eGovernment Services to Public Administrations, Businesses and Citizens (IDABC) Programme of the European Commission, http://europa.eu.int/idabc/. See also http://www.i2-Health.org/

a) Commit politically and strategically to the implementation and cross-border interoperability of regional and national electronic health record systems.

b) Implement such electronic health record systems interoperability as an integral part of regional and national eHealth strategies.

c) Consider the inclusion of eHealth in national and regional strategies for territorial cohesion and development. Encourage inter-regional and cross border eHealth cooperation projects and explore eHealth further at the levels of eHealth policy tools and financing.

d) Explore the risks, barriers or missing elements in achieving cross-border interoperability of electronic health record systems, and identify the necessary pre-conditions and relevant incentives.

e) Reserve adequate resources to invest in the eHealth area, in particular in electronic health record systems including time, management capabilities, training of users and financial resources.[11]

f) Consider the creation of other financial incentive mechanisms to enable the adoption, acquisition, and/or modernisation of interoperable eHealth systems, in particular electronic health record systems.

g) Plan ahead for at least 5 years (such a timeline is intended to ensure policy consistency – which is often a precondition for increasing investment and innovation – and is also due to the substantial sunk costs and long cycles often needed to realise a net benefit.[12]

h) Build on stakeholder involvement, public-private partnerships, and public procurement in the health sector.

i) Accompany electronic health record systems implementation by a strong involvement of users and other stakeholders in the setting up of adequate governance, planning, implementation, evaluation, training, information and education, and change management.

The organisational level of cross-border interoperability of electronic health record systems

6. It is essential to create an organisational framework (or 'process') that will enable cross-border interoperability of electronic health record systems. In initiating the basic pillars, processes and structures of eHealth interoperability in Europe, the following activities are considered necessary**.** The European Commission and Member States should:

[11] For many Member States, healthcare budgets may be spread across a range of ministries or authorities that encompass, for example, social care, industry or innovation, education or sport, research, and so on. For budgetary purposes, and as a rule of thumb, the earmarking of at least 3.0% of the annual health budget may be considered as a valuable indicator in order to achieve successful eHealth deployment. Despite this, the figure is given as indicative; the actual budgets from which the proposed sum is extracted may differ according to Member State.

[12] For example the English National Programme for IT strategy involves a 13-year timescale and is perceived as a fundamental enabler of healthcare reform. See also 'eHealth is Worth it - The economic benefits of implemented eHealth solutions at ten European sites': http://europa.eu.int/information_society/activities/health/docs/publications/ehealthimpactsept2006.pdf

a) Develop and agree a roadmap that reflects the above-mentioned minimum-5 year timeline, and outlines more precise details with regard to the milestones listed below.

b) Agree on the measures necessary for achieving the interoperability of electronic health record systems across health systems (namely at a cross-border level), and promote these in each Member State.

c) Agree on guidelines for the basic privacy, security, authentication, and traceability framework that would allow for interoperability, namely at a cross-border level, respecting the fundamental right to the protection of personal data in accordance with the applicable law.

d) Agree on guidelines concerning responsibility (accountability, liability, follow-up, and redress).

e) Agree on guidelines for nomenclatures, classifications, registries, accreditation and semantic interoperability.

f) Explore the use of the European health insurance card as a common approach to help to facilitate patient mobility in accordance with the eEurope 2005 plan, approved by the Seville European Council and suggested by the Parliamentary Report on patient mobility and healthcare developments in the European Union.[13]

At the level of technical interoperability

7. The European Commission and Member States together with the European Standard Development Organisations should:

a) Undertake a comprehensive survey of existing technical infrastructures and standards that may support cross-border health delivery and the provision of services throughout the European Union, especially those related to electronic health records and exchange of information.

b) In order to increase the safety of individual patients, take into account the interoperability of electronic health record systems along the full continuum of care including ambulatory care.

c) Take into account and make use of the existing standards[14] that are related to electronic health records and exchange of information. Bear in mind, in particular, the notions of scalability and extendibility.

d) Use information models defined by standards when designing the electronic health record systems and services solutions. Where appropriate, make use of

[13] Response of the EP to the Commission's April 2004 Communication on Patient Mobility. It highlights the urgent need for a proper framework to facilitate 2004/2148 (INI).

[14] European Standardisation Organisations: European Committee for Standardisation (CEN), www.cen.eu,European Committee for Electrotechnical Standardisation (CENELEC), www.cenelec.org,European Telecommunications Standards Institute (ETSI), www.etsi.org, International Organisation for Standardisation (ISO) www.iso.org and other standardisation bodies

the approaches and achievements of past and existing initiatives and industrial groupings[15].

e) Where appropriate, apply existing real-life exemplars of eHealth interoperability. These exemplars will later include the experience gained from the Large Scale Pilots on 'EU wide implementation of patients' summaries/Emergency Data Set to support continuity of care' and 'Electronic medication records' and 'EU wide implementation of ePrescription solutions to support continuity of care[16].

f) Commit to the development of any necessary additional standards, preferably on a global scale, with the relevant European and international standardisation bodies in the key areas that are identified as gaps or missing elements.

g) Explore the possibilities of adopting an initiative on interoperability in eHealth based on the 'New Approach' concept.

8. With regard to the certification of electronic health record interoperability in Europe, it is considered that there is a need for a single certification process that is valid throughout the European Union or which acts as a means of mutual recognition of each Member State's certification mechanisms. Therefore the European Commission and Member States should:

a) Put into place a joint or mutually recognised mechanism for certification of interoperable electronic health records and other eHealth applications, such as the techniques and methodologies offered by various industry consortia. Where appropriate, make use of the approaches and achievements of the EuroRec Institute and its Q-Rec initiative.[17]

b) Ensure that industry self-certification and/or conformance testing activities act as a possible mechanism to reduce delays in bringing interoperable eHealth solutions to the market.

c) Take note of national and international practices, including those which exist outside Europe

Semantic interoperability

9. In order to coordinate efforts towards semantic interoperability activities it is essential to agree on common priorities (through agreed 'use cases'), to share results and experiences, and to identify and use suitable eHealth standards that apply to the representation and communication of clinical meaning. The Member States should:

a) Agree on standards for semantic interoperability that will be used to represent the relevant health information involved in a particular use case (such as

[15] Integrating the Healthcare Enterprise (IHE), Continua Health Alliance, European Coordination Committee of the Radiological and Electromedical Industry (COCIR), European Institute for Health Records (EUROREC), European Health Telematics Association (EHTEL) etc.

[16] See clear descriptions on these proposed Large Scale Pilots which are to be found in the Competitiveness and Innovation Programme (CIP) ICT Policy Support Programme documents: http://ec.europa.eu/information_society/activities/ict_psp?index.en_htm, http://ec.europa.eu/information_society/activities/ict_psp/library/ref_docs/docs/cip_ictpsp_wp.pdf

[17] For further information see http://www.eurorec.org

coding terminology and archetype, template and ontology standards). Wherever possible, the suitability of international terminology and classification standards and various patient safety terminologies should be considered.

b) In technical terms, ensure a future semantic interoperability by formally defining clinical information represented through data structures and terminology systems, i.e. formally define: data elements (registered in a comprehensive metadata dictionary and mapped to a Reference Information Model value sets to guarantee a mapping to terminologies such as SNOMED CT[18]; clinical data sets, and clinical pathways.

c) Establish an appropriate mechanism to involve national research centres, relevant industries, and stakeholders involved in the development of health ontologies and semantics to further advance scientific and technical work in the applications field.

d) Consider the need for: a dynamic, language-independent, sustainable reference terminology; multi-lingual dictionaries that take into account the difference between professional healthcare languages and lay terminologies as well as services and tools for cross-language information retrieval, translation and provision of abstracts and extracts of healthcare-related information (including extracts from patient records).

Data privacy, confidentiality and data security

10. Under the umbrella of the requirements for an appropriate legal framework for eHealth interoperability, a number of initiatives – particularly in relation to data privacy, confidentiality and security issues – are outlined here. There is a need for the Member States to:

a) Identify the scope of relevant stakeholders (e.g., national statistical institutes, hospitals, social services, and all the relevant healthcare professionals), and assess the kinds of data and access that they use and/or need.

b) Agree on the common principles concerning identification of patients, healthcare professionals, and health institutions independent of particular carriers.

c) Agree on proven, robust, and appropriate means to ensure privacy protection design, technologies, validation and certification to both process and protect all relevant personal health data in respect of the Directive 95/46/CE of the European Parliament and of the Council of 25 October 1995 on the protection of individuals with regards to the processing of personal data and on the free movement of such data (Personal Data Protection Directive).

d) Identify under which conditions or events health data can be accessed, by whom, including the security that should be assured while accessing and/or transmitting health data, and specify these issues as policies that can be practically applied and technically implemented. Among the possible

[18] SNOMED (Systematized Nomenclature of Medicine), is a systematically organized computer processable collection of medical terminology. See http://www.ihtsdo.org/

mechanisms to be considered are: electronic identity cards, tags, bar coding, mobile telephonic equipment, and other devices.

e) Identify auditing/tracing needs (e.g., data access to be logged, and logged information, and how long the auditing/trace information must be maintained), and enforce the adoption of these auditing/tracing measures or solutions according to identified good practices for data handling.

f) Consider the adoption of incident detection and management processes when security or identity mechanisms are breached (i.e., identifying security incidents or violations promptly and effectively and ensuring measures or solutions are in place to manage such incidents, including informing and involving the appropriate stakeholders).

g) Promote the adoption at national level of good practices and solutions for security-related architectures, privacy management, de-identification, and stakeholder education about confidentiality.

Monitoring, evaluation, and education

11. In order to ensure activities at the level of the monitoring and evaluation of, and education about, EHR system cross-border interoperability in Europe the European Commission and Member States should:

a) Consider the possibilities for setting up a European Union EHR system interoperability monitoring exercise that would monitor, benchmark, and assess progress on forms of interoperability. The activities could be oriented towards the separate, but associated, activities, outlined below.

b) Undertake a number of measurement and assessment exercises. These could include defining the quantitative and qualitative criteria, and milestones; measuring the eventual benefits (including economic benefits and cost effectiveness) of increasing EHR interoperability throughout health services across and between Member States and assessing the benefits achieved by the systems and services developed by such practical demonstrators as the 'Large Scale Pilots ('Pilot Actions A') that are incorporated within the Competitiveness and Innovation Programme Policy Support Programme.

12. In terms of education and training, the Member States should:

a) Consider a high-level educational process with regard to eHealth policy-makers.

b) Consider the appropriate and/or necessary training and education needs of healthcare professionals (including both doctors and nursing staff) in the appropriate recording, sharing, storing, governance of clinical data, sensitive medical and personal information, and appropriate knowledge including evidence-based information; also with regard to gaining informed consent; safe sharing of information, and understanding of information governance requirements.

c) Provide parallel information and training for citizens and patients (thus, ensuring that they are 'informed' and 'empowered'). Such an approach would enable the more effective use of health information as patients move between

a variety of healthcare providers, along the continuum of care, and receive increasing amounts of treatment, care, and data in their own homes.

Follow-up

13. Member States are invited to report, on a yearly basis, to the Commission on the measures they have taken in relation to this Recommendation and the implementation of cross-border interoperability of EHR systems.

14. The Recommendation will be rigorously followed up in the meetings of the relevant policy groups on eHealth[19], and the various supporting stakeholders' groups. It will also have a major influence on the eHealth part and future directions of the Competitiveness and Innovation Programme of 2008 and 2009, and thereafter.

15. The Commission intends to assess, on a continuous basis, the development, the implementation and the impact of cross-border interoperability of EHR systems in the light of this Recommendation.

16. The Commission will consider, on the basis of the recommendation 7f and the assessment referred to in point 14, the need for further action at Community level.

Addressees

16. The Recommendation is addressed to all Member States, but it also has relevance for the European Economic Area (EEA) countries, and for the appropriate suppliers, buyers, and stakeholder associations that operate in the eHealth field within the internal market of the European Union.

Done at Brussels, XX XXX 2008.

For the Commission
Viviane Reding
Member of the Commission

[19] Such as the i2010 sub-group on eHealth