

Assessing the progress of the eHealth Action Plan for the period 2004 - 2010

Report

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Executive summary

This document examines the progress of the eHealth Action Plan (eHAP) within its projected lifetime of 2004 to 2010. Following an introduction to the main policy developments which took place during these years, the three main objectives of the Action Plan are examined in detail while they are separated into different actions. These are:

- ◆ addressing common challenges such as interoperability of health information systems electronic health records, patient identifiers and mobility of patients and health professionals;
- ◆ building pilots for accelerating implementation of eHealth information on, for example, health education and disease prevention as well as promoting the use of electronic health cards;
- ◆ working together and monitoring, benchmarking and disseminating best practices.

Progress on the implementation of each action is analysed by comparing the results achieved in comparison to the original intentions of the plan by using a variety of sources ranging from policy documents and studies to descriptions of the actual systems implemented at national and European levels.

Among other purposes, this report is to be used as input to the impact assessment exercise that the European Commission has to undertake in order to define the scope of the new eHealth Action Plan. To this end, a chapter on the legacy left by the outgoing eHealth Action Plan to the new plan (to appear by the end of 2011) is included. The proposed objectives of the new plan are set against the contribution which the existing plan has made. This then constitutes the starting point of the new plan. The new plan's proposed objectives are currently to:

- ◆ increase awareness of the benefits and opportunities of eHealth, and empower citizens, patients and healthcare professionals;
- ◆ address issues currently impeding eHealth interoperability;
- ◆ improve legal certainty for eHealth;
- ◆ support innovation and research in eHealth and development of a competitive European and global market.

Looking at the overall wide picture, the report adopts the thesis that although the Action Plan may not have managed to achieve some of its targets in the strict sense, it has succeeded in creating a strong legacy of concrete developments on which further progress can be based. If we take a look at the current state of eHealth in the Member States, we see that:

- ◆ All have elaborate strategies on eHealth
- ◆ Standards for Electronic Health Records (EHRs) have been developed: some Member States follow these, while the use of subsets of records such as Patient Summaries are underway in four countries
- ◆ National-level ePrescription services are a reality in three states and are in preparation in others
- ◆ Telemedicine is regionally applied at a pilot level with an emphasis in the Nordic countries, and is politically supported by a dedicated action plan (2008)
- ◆ Legal frameworks are under preparation in some countries and under consideration in most of them
- ◆ Large-scale pan-European pilot implementations on partial EHRs are progressing (through large scale pilots such as epSOS)
- ◆ Electronic European Health Insurance Cards services have been implemented on a pilot basis (in the context of the NETC@RDS project)
- ◆ Numerous studies on vital areas of eHealth have provided information, highlighted best practice and enriched the experience of all stakeholders
- ◆ Dissemination of best practice has become an online resource (ePractice.eu portal)
- ◆ An EU Public Health portal is a reality

- ◆ The creation of a market on eHealth products and services has become a long-term political aim (via the Lead Market Initiative and its action plan).

None of the above existed before 2004. They all are the concrete infrastructural results of the drive which the plan itself provided. Thanks to those, Europeans are richer in experience and knowledge. First, they have become aware of the difficulties which common action by all Member States presents. Second, they have gained an appreciation of the importance of functioning at European level.

It is this duality of gains – in experience as well as infrastructure – that can provide a stable platform on which the forthcoming action plan (2011 onwards) can build.

Main sources used for the assessment of progress of the eHAP belong to the following categories¹:

- ◆ Official policy documents and presentations by the Commission, such as the Communication on the eHAP, the Action Plan on eHealth under the LMI and the presentation on the progress of the eHAP to the i2010 sub group on eHealth in 2010
- ◆ Resolutions of the European Parliament
- ◆ Studies funded by the Commission, such as the 2011 reports on eHealth strategies and the 2010 reports on “Business Models for eHealth”
- ◆ Results of relevant Commission-funded projects such as epSOS, NETC@RDS and STORK

¹ References are listed in chapter 7 of the present document

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1 Introduction

It has become a widely accepted fact that healthcare costs are (and have been for – at least – the last twenty years) on an upward spiral. The 2009 mid-term report on the progress of the Lead Market Initiative (LMI) in Europe¹ claimed that, without significant reforms, health expenditure was expected to increase from 9% of the Gross Domestic Product (GDP) in 2009 to around 16% by 2020 in response to the challenges implicit in the ageing of Europe. The report proclaimed eHealth as a reform which would not only reduce expenditure but also encourage innovation, offer citizen-centric services and leverage growth in Europe in other market segments such as pharmaceuticals and medical devices. These concerns are indicative of the promise as well as the commitment needed to achieve effective use of ICT for healthcare.

The European response to the matter dates back to the eHealth Ministerial Conference of 2003, where ministers welcomed Commission initiatives to promote co-ordination at European level. They also proposed that the targets and objectives laid down in the eEurope Action Plan as well as the Programme of Community Action in the field of Public Health (2003-2008) – set out in decision 1786/2002 – were met in liaison with other Community initiatives. The importance of monitoring and benchmarking progress by developing an open method of co-ordination was also stressed at the conference.

Following the results of the conference, the European Commission issued Communication COM (2004) 356, to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, titled “e-Health - making healthcare better for European citizens: An action plan for a European e-Health Area”, on the 30th of April 2004. The Communication subsequently became known as the **eHealth Action Plan, 2004-2010**.

This plan for the period 2004-2010 aimed at enabling the European Union (EU) to achieve the full potential of eHealth systems and services within a European eHealth Area. Its focus was on three priority areas:

- ◆ addressing common challenges such as interoperability of health information systems electronic health records, patient identifiers and mobility of patients and health professionals
- ◆ building pilots for accelerating implementation of eHealth information on, for example, health education and disease prevention as well as promoting the use of electronic health cards
- ◆ working together and monitoring, benchmarking and disseminating best practices.

In what follows, we briefly mention the most important developments, at policy level, which have characterised progress on the content of the eHealth Action Plan, 2004-2010.

In June 2006, the ICT for Health Unit of DG INFSO adopted a **new strategy**² which was in line with the Commission’s new i2010 policy framework. This was anchored in the eHealth Action Plan (eHAP) and in a “new healthcare delivery model, based on preventive and person-centred health systems, which can only be achieved through proper use of ICT”. The approach also involved forward-looking research under the Seventh Framework Programme (FP7). It postulated that continuity of care could be assured at all points of need, whether in hospital settings or in ordinary living environments. This continuity would be facilitated by the deployment of interoperable eHealth services across Europe, which would enable access to a patient’s medical history and data from any location.

A report on the eHealth priorities and strategies of the Member States in April 2007 by the eHealth-ERA project⁴ found that good progress had been made in implementing the European Commission’s eHealth strategy. The report noted that this was not accompanied by progress in educational and socio-economic issues related to eHealth.

Progress of the eHealth Action Plan

In 2008, the European Commission unveiled plans to make eHealth one of the EU's first six **Lead Market Initiatives**, thus making it a strategic priority. The size of the market and its scope for innovation were cited as principal reasons for eHealth's selection in this role. To this end, the European Commission published an **Action Plan for eHealth**³ at the end of 2007 that pledged to assess the possibility of adopting a legal initiative for eHealth and telemedicine. It also noted the need for common standards in eHealth and the importance of interoperability. Greater cooperation on eHealth between the Member States was encouraged. The plan had actions which were similar to those of the 2004 eHealth Action Plan. A mid-term progress report¹, published in September 2009, found that the eHealth LMI was still at an early phase of implementation. Nevertheless, it recognised that the LMI could stimulate demand-side measures in the Member States even if its full impact would only be expected after five to ten years.

The **Action Plan for Telemedicine**²¹, was issued in a Commission Communication in 2008 and included a ten-point roadmap for promoting telemedicine in Europe. In October 2009, a follow-up of the plan²⁴ examined the progress achieved.

Finally, the 2011 **Cross-border Health Care Directive**ⁱⁱ sets an EU-wide framework for cross-border access to healthcare services. Article 14 on interoperability calls for the creation of a network on eHealth. In May 2011, this "European Voluntary eHealth Network" was launched during the European eHealth Ministerial Conference, as part of the eHealth Week.

1.1 Structure of the document

In what follows we examine the progress of the eHealth Action Plan (eHAP) within its projected lifetime of 2004 to 2010. The three main objectives of the Action Plan, as laid out above, are examined in detail, separated into the different actions. Progress on the implementation of each action is analysed by comparing the results achieved in comparison to the original intentions of the plan by using a variety of sources ranging from policy documents and studies to descriptions of the actual systems implemented at national and European levels (chapters 2-4).

Among other purposes, this report is to be used as input to the impact assessment exercise that the European Commission has to undertake in order to define the scope of the new eHealth Action Plan. To this end, a chapter on the legacy left by the outgoing eHealth Action Plan to the new plan (to appear by the end of 2011) is included. The proposed objectives of the new plan are set against the contribution which the existing plan has made. This then constitutes the starting point of the new plan.

Based on the previous findings, general conclusions on the overall execution of the 2004-2010 Action Plan and its legacy on eHealth developments in Europe are finally given in chapter 6.

ⁱⁱ Vote of 19th January 2011 by the European Parliament.

2 Issue 1: Addressing common challenges

The first part of the eHAP addresses issues which affect all Member States such as planning for eHealth deployment at leadership level, interoperability, mobility of patients and legal frameworks. These are analysed in what follows.

2.1 Health authorities leadership

Following the Ministerial Declaration of the 2003 eHealth Ministerial Conference, the eHAP set a target for Member States to develop roadmaps for eHealth. In particular:

- ◆ *By end 2005, each Member State is to develop a national or regional roadmap for e-Health. This should focus on deploying e-Health systems, setting targets for interoperability and the use of electronic health records, and address issues such as the reimbursement of eHealth services.*

Implementation of the Action:

The Action did not specify the level of detail which these roadmaps should contain – which, indeed, reflects the Member States' own mandate in this matter. This detail was left open to interpretation by the various authorities of the Member States. Due to this, and to the different levels of “readiness” among the states, implementation was affected by varying delays compared to the target set of 2005. The survey conducted by the “eHealth ERA” coordination action⁴ during 2006, showed that, by the end of that year, the eHealth strategies of most Member States contained only high-level policy documents.

Reported eHealth activities	Total 2006 eHealth ERA	Total 2010 eHealth Strategies	Delta
Legal activities	14	22	8
Evaluation	5	21	16
EHR Patient Summary	27	27	0
ePrescription	16	22	6
Telehealth	23	27	4
Patient ID	24	26	2
Professional ID	13	22	9
Citizen card	22	25	3
Professional card	7	18	9
Standards (technical/semantic)	19	27	8

Source: eHealth Strategies study, 2010

Table 1. Comparison of national eHealth activities in EU-27, 2006 and 2010

(The “Delta” column shows the increase since 2006)

The situation has vastly improved by 2010, however. According to a study on eHealth strategies in Europe⁵, conducted on behalf of the European Commission, there has been considerable progress in all fronts. eHealth strategies have been produced by almost all states that contain goals, targets for interoperability and implementation measures. Table 1, compiled by the aforementioned study, is indicative of the progress made in the five-year period between 2006 and 2010.

The net result, regarding the implementation of the Action, has been positive. It indicates not only a high degree of “health authorities’ leadership” but also an awareness of the importance of eHealth at policy level.

2.2 Interoperability of health information systems

The eHAP emphasised the need for future open standards to solve interoperability concerns in a way that all stakeholders could benefit. In addition, it advocated the possible adoption of Open Source reference implementations for healthcare services and the exchange of similar experience among the Member States. The following two actions were proposed.

2.2.1 Patient identifiers

- ◆ *By end 2006, Member States, in collaboration with the European Commission, should identify a common approach to patient identifiers. This should take account of best practices and developments in areas such as the European Health Insurance Card and identity management for European citizens.*

Implementation of the Action:

The importance of patient identifiers at policy and strategy level has been recognised throughout the EU-27 as indicated in the results of Table 1. That said, the target of a common approach to patient identifiers has not been attained and there are ongoing challenges regarding the overall feasibility of such a goalⁱⁱⁱ. Instead, the focus has shifted towards achieving interoperability among different systems of patient identifiers⁶.

Evidence from the study on eHealth strategies in Europe⁵ suggests that there are currently different approaches to patient identifiers across the EU. Two different categories of identifiers can be distinguished in use today. They are:

- ◆ Purely healthcare (patient) IDs specifically created for electronic healthcare provision and facilitation of medical information storage and exchange. In Europe, such systems can be found in France, Germany and Greece.
- ◆ General purpose electronic cards (eCards), which, besides their ID management or insurance verification purposes, can be used for eHealth functions. The mode of use of these cards in Europe today is for verification of medical insurance entitlements⁵ only and not as eHealth cards managing the handling of medical information.

Given the unevenness in the approaches among the Member States, European Commission co-funded projects try to offer commonly accepted interoperable approaches. There are two examples of projects in this category, namely NETC@RDS⁷, epSOS⁸ and STORK⁹. NETC@RDS aimed for the initial deployment of an online service for the electronic European Health Insurance Card (eEHIC), therefore it cannot be considered as a patient's ID project in the strict sense. epSOS is an interoperability-oriented large-scale pilot aimed at cross-border exchange of medical information. STORK aims to establish a European eID Interoperability Platform for transactions across borders with the use of national eIDs. A liaison with the epSOS project has also been formed.

epSOS represents a much more relevant effort with respect to patient IDs, given that it deals directly with cross-border provision of medical data, including personal records. epSOS services rely on identification of both patients and health professionals. The project does not deal with the provision of these forms of identification themselves. Therefore, it cannot be considered as having had a direct effect on the scope of the original action which implied the identification of a common approach on patient identifiers. That said, however, epSOS does address cross-border interoperability among different national systems of identifiers. As such, it is considered to have had an important regulatory and "best practice" role in promoting the spirit of the Action. This orientation is also helped by the large scale of participation, which

ⁱⁱⁱ Similar difficulties have been encountered in the application of identification systems in Europe.

amounts to the involvement of 20 Member States and three other European states. Concrete results are expected to become available by the end of the pilot in December 2013.

2.2.2 Interoperability of electronic health records

- ◆ *By end of 2006, Member States, in collaboration with the European Commission, should identify and outline interoperability standards for health data messages and electronic health records, taking into account best practices and relevant standardisation efforts.*

Implementation of the Action:

The 2004 eHAP envisaged common structures and ontologies as a means to enable seamless exchange of health information across Europe. In response to this, the proposed action set a relatively short-term target (two years) for reaching a joint agreement on interoperability standards for messages and health records. The action did not explicitly specify the level of interoperability sought, but the mention of ontologies in the introductory text indicates a minimum requirement to address the technical and the semantic level^{iv}.

The situation at the end of 2006, as depicted by the “eHealth ERA” report⁴, showed that although many Member States had strategy documents addressing electronic patient records, the explicit mention of a life-long Electronic Health Record (EHR) as a strategic target was included only in the documents of Estonia and the UK. This, of course, leads to the conclusion that the action was not achieved within the set time targets.

As developments beyond 2006 show, implementation of an EHR for patients has proven to be a complex task. Following the study on eHealth strategies in Europe⁵, a patient's EHR is understood as being a “shared, integrated or interlinked (virtual) record of all his/her clinically relevant health and medical data independent of when, where and by whom the data were recorded”. As such, the full concept has not been implemented anywhere in the EU-27 yet; instead, partial implementations do exist. “Patient Summaries” or facility-centred “Electronic Patient Records” are found in Member States such as the Bulgaria, Czech Republic, Denmark, Finland, and regions of the UK such as Scotland. These systems, although useful at either a national or regional level, can only achieve cross-border exchange via commonly accepted standards for interoperability.

Follow-up activities by the Commission

It is important at this point to look at the various follow-up actions of the European Commission on the interoperability issue. The Recommendation¹⁰ of 2008 on the interoperability of EHRs offered a more realistic framework. First, it accepted subsets of EHRs, such as Patient Summaries and, second, it extended the target date for 2015. Another important pillar in support of the Recommendation is the Commission's Lead Market Initiative (LMI). As explained in the mid-term report¹ of 2009, the LMI is the framework policy initiative for the implementation of the Recommendation; it multiplies the political importance and impact of the interoperability for eHealth in the Member States.

The accompanying Mandate 403 was sent by the Commission to the European standards organisations (CEN, CENELEC and ETSI). It aimed to provide a consistent set of standards to address the needs of future healthcare provision. At the request of the Commission, the three organisations will define the standardisation process for effective interoperability at specific use cases via the eHealth-INTEROP¹¹ project. Phase 1 of the project was completed and approved in 2009: its corresponding report surveyed the European landscape and proposed a roadmap for the future. The launch of Phase 2 suffered a two-year delay and is currently under preparation. Its results are not expected before 2012.

^{iv} The Commission Recommendation of 2008 on cross-border interoperability of electronic health record systems specified that the Member States were invited to undertake actions at five levels, namely the overall political level; the organisational level; the technical level; the semantic level and the level of education and awareness raising.

Progress of the eHealth Action Plan

On the road-mapping side, the report¹² on “Semantic Interoperability for Better Health and Safer Healthcare” by the SemanticHEALTH Specific Support Action was funded under Framework Programme 6. It developed a longer-term research and deployment roadmap for semantic interoperability by identifying key steps across the whole health value system. Focus was on the needs of patient care, biomedical and clinical research, and public health through the re-use of primary health data.

Additional activities by the Commission include funding provided via the Competitiveness and Innovation Programme (CIP) within the ICT Policy Support Programme. Important relevant activities are:

- ◆ The EHR-Q^{TN} Thematic Network¹³ deals with quality assurance and certification of eHealth products and EHR systems in particular. The project will also deliver two complementary reports. One is intended to address the EHR market in the Member States and another is to document possible roadmaps to sustainable certification, such as that which may be requested by a supplier on a national or cross-border basis. Expected results are to appear in January 2012.
- ◆ The epSOS⁸ project on cross-border interoperability, which is also making advances in semantic interoperability. These advances have taken into account existing developments such as SNOMED CT (Systematic NOMenclature of MEDicine, Clinical Terms) which is adhered to by ten European countries, with many more likely to join. The epSOS semantic services use key components such as the MVC (Master Value Set Catalogue), the MTC (Master Translation/Transcoding Catalogue) and the epSOS (reference) Ontology which provides a semantic backbone coded in OWL-DL based on the MVC. The ontology provides a linguistic reference to the terms of the epSOS value sets. The main objective is to prepare a formal representation of the entities of interest to epSOS and successively provide support and a consistency check to those parties filling in the MTC. It appears that epSOS currently represents a promising vehicle which forms a basis for resolving interoperability issues in eHealth and in relation to EHRs, in particular. Full results are expected at the end of 2013.
- ◆ Finally, the CALLIOPE Thematic Network^v completed its official mission at the end of 2010, with a focus on cross-border eHealth interoperability and the implementation of the Commission’s Recommendation in the Member States. The CALLIOPE Network¹⁴ developed an eHealth interoperability roadmap¹⁵ that was aimed at helping decision makers implement eHealth at national level. CALLIOPE comprised a dedicated forum for how to establish interoperable eHealth services. It established a successful collaborative platform for many actors in eHealth interoperability in Europe and supported considerably the first three years of activity of the epSOS large-scale pilot.

Current state of affairs

The result of all efforts at European level on EHR interoperability since 2006 is such that, at the end of 2010, the situation with regard to progress appeared much more promising. In fact, as the study on eHealth strategies in Europe⁵ notes, Member States are currently engaged in issues such as “standards development, interoperability and wider implementation actions, certification, conformance testing, maintenance of standards, management of their life cycle, and deployment support.” The main standards in use, shown in Table 2, are augmented by developments on specifications such as those of IHE (Integrating the Healthcare Enterprise^{vi}) and the Continua Health Alliance^{vii}.

^v CALLIOPE, Creating a European coordination network for eHealth interoperability implementation, http://www.calliope-network.eu/Portals/11/assets/documents/200901calliope_factsheet.pdf

^{vi} www.ihe-europe.net

^{vii} www.continuaalliance.org

Standard	Use in Europe
HL7 V2 and V3 (Health Level 7, version 2 and 3)	15 countries
CDA R2 (clinical document architecture, release 2; an HL7 V3-based standard)	8 countries
DICOM (Digital Imaging and Communications in Medicine standards)	8 countries
LOINC (Logical Observation Identifiers Names and Codes)	4 countries

Table 2. EHR-related standards in Europe⁵

An overall appraisal of this most important of issues for eHealth shows that, despite the delayed progress and the high expectations of the original action of the eHAP, European Member States are moving in the right direction. The contribution of the European Commission has been instrumental here. They did not hesitate to identify which policies on EHRs set out in the eHAP were too optimistic in their expectations and timeframes, hence they compensated via additional policy instruments (such as the LMI) and actions (such as the ICT Policy Support Programme).

We may even risk a prediction: aided by the forthcoming results of the epSOS large-scale pilot, the Member States will be in a position to adopt and apply common interoperability standards for a sizeable subset of an EHR (such as a Patient Summary) within approximately two years after the end of epSOS (which is in 2013). This is also in accordance with the Digital Agenda's Action 75 for eHealth²⁵ to promote pilot actions so as to equip Europeans with secure online access to their medical health data by 2015.

2.3 Mobility of patients and health professionals

At the point of its publication, the eHAP did not put a specific target for achievement of this objective within a time frame, but rather pointed to a number of proposals made in another Communication on patient mobility. These included improving the exchange of information, and establishing specialised reference centres on health information. Actually, the non-specification of a date was a perfectly reasonable approach, foreseeing the incremental, considerable, and steady efforts that it would take to come from a Communication to a stronger statement of mandatory application such as, for example, a Directive.

Indeed, the most prominent result in this direction is the 2011 Cross-border Health Care Directive^{viii} which sets an EU-wide framework to ensure cross-border access to healthcare services. Article 14 of the Directive refers to the promotion of interoperability for eHealth and calls for the creation of a voluntary network on eHealth, related to patient data protection and sharing.

A potentially important development is the transformation of the "eHealth Governance Group", which comprised state secretaries and director generals from the national ministries of health, into the "European Voluntary eHealth Network" specified by the Directive. The decision was taken during a meeting of the "eHealth Governance Group" at the May 2011 European eHealth Conference. This group has previously been an informal body affiliated to the European eHealth Governance Initiative (eHGI), which encompasses 39 eHealth beneficiaries including 26 Member States and various stakeholders.

2.4 Enhancing infrastructure and technologies

This action of the eHAP refers to the development of high-speed communication networks serving eHealth informational purposes. It sets a five-year period for support to their deployment.

^{viii} Vote of 19th January 2011 by the European Parliament

Progress of the eHealth Action Plan

- ◆ *During the period 2004-2008, Member States should support deployment of health information networks for e-Health based on fixed and wireless broadband and mobile infrastructures and Grid technologies.*

Implementation of the Action:

Progress in this area has occurred in two ways: certain countries developed dedicated healthcare networks, which may also be used for general eGovernment purposes while others use general-purpose lines of communication. An example of the first category is Sweden, where a fibre-optics network, the "Healthcare-digital-network", has been developed for eHealth purposes. The IP-based broadband network connects all Swedish hospitals, primary care centres and other health services and is separate from the Internet. Countries such as Belgium and Denmark have opted for Virtual Public Networks (VPN) implemented over the public Internet infrastructure⁴. Of the countries with no dedicated networks, the UK has a variety of networked eHealth information structures. These range from concrete telemedicine applications that are currently running in NHS England^{ix} to nationwide eHealth information services, such as the NHS-Direct website, which provides patients with access to a library of medical advice, and the NHS-Direct Telephone assistance service, which provides patients with a 24-hour phone support service. At the other end of the spectrum, countries such as Greece or Portugal have established no national eHealth networks so far.

Generally speaking, although we cannot say that all Member States have equally supported the development of network infrastructures for eHealth information between 2004 and 2008, there has been progress in the area and developments are ongoing. The commentary by the eHealth ERA project⁴ on this matter is noteworthy: "a clearer and more standardised means of reporting on the status of the network infrastructure of a country is needed if there is to be a reliable form of measurement of progress in this area."

2.5 Conformity testing and accreditation for an eHealth market

This section of the EHAP referred to the need for agreed attributes and norms beyond existing standards to define and accredit good quality products and services. Two actions supported this call.

2.5.1 Guidance

- ◆ *By mid 2005, the Commission should produce a summary of European best practices as guidance for Member States.*

Implementation of the Action

The European Commission has funded several studies on eHealth^x, which have also included best practice examples for use by the Member States. Although there was no summary of best practices produced as early as 2005 as the action suggested, the variety of studies thereafter more than compensate for this delay. Of particular note is the "Good eHealth" study¹⁶ which offered a comprehensive and continuous approach to dissemination and transfer of learning experiences. It identified the benefits of specific good practice examples, developing stronger approaches to sharing good practices and stimulating faster uptake of new eHealth systems and services. The knowledge base produced by the study covers 25 Member States, three Accession Countries, and three European Economic Area (EEA) nations as well as Switzerland.

^{ix} Whitehouse D. *et al*, eHealth Strategies Study, "Country Brief: England", European Commission, DG Information Society and Media, ICT for Health Unit, November 2010.

^x http://ec.europa.eu/information_society/activities/health/studies/published/index_en.htm

2.5.2 Conformity and accreditation

- ◆ *By end 2007, Member States should adopt conformity testing and accreditation schemes following successful best practices.*

Implementation of the Action

As referred to in the wording of the eHAP, countries such as Belgium and the UK have proceeded with accreditation of eHealth systems since at least 2004. Also the interoperability guidelines of the “Integrating the Healthcare Enterprise in Europe” initiative (IHE¹⁷) were quoted as an example of conformance testing and accreditation.

Indeed, it appears that the solutions provided by IHE have the acceptance of industry associations such as COCIR^{xi}. Specific IHE documentation relevant to individual European countries is contained within the national extension annexes to the IHE Technical Framework documents accessible through the respective IHE National Initiatives. These are present in seven Member States, namely Austria, France, Germany, Italy, Spain, the Netherlands and the UK.

Another related proposal by COCIR is public/private certification processes, linked to interoperability conformance testing activities.

The activities of the European Institute for Health Records (EUROREC¹⁸) on quality labelling and certification in EHRs, especially through projects such as the FP6 Specific Support Action Q-REC^{xii} and its successor the EHR-Q¹³ Thematic Network¹³, can be seen as being of particular help in achieving the objective of this action. Also, the ARGOS eHealth pilot project^{xiii} on common methods for responding to global eHealth challenges in the EU and the US is expected to produce some results in the certification of EHRs.

In general, conformity testing and accreditation have not progressed uniformly among the Member States and implementation of the action is still pending. That said, the above initiatives do supply a favourable environment, along with best practice examples, which can contribute to adoption by more Member States.

2.6 Leveraging investments

The eHAP called for a shared approach among Member States to support and boost investment in eHealth. Examples of European regional funding mechanisms such as INTEREG and the European Investment Bank were also quoted. The stated goal was:

- ◆ *By end 2006, a collaborative approach should be undertaken among Member States to supporting and boosting investment in e-Health.*

Implementation of the Action

With the exception of claims for funding provided through the Framework Programmes for Research and Development such as FP6 and FP7, there has been no evidence of other

^{xi} The COCIR eHealth Toolkit (http://www.cocir.org/uploads/documents/1185-1185-ehealth_toolkit_link2.pdf) was published in 2011 by the European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR). It “encourages public or private certification entities to make use of the openness of IHE’s flexible and proven solutions to adapt conformity testing to local needs”.

^{xii} Q-REC project, http://www.eurorec.org/RD/pastProject_Q-REC.cfm

^{xiii} ARGOS project, under the framework of “Pilot Projects on Transatlantic Methods for Handling Global Challenges in the European Union and the United States”, created via a European Parliament initiative, 1/1/2010–1/6/2011, DG RELEX, <http://argos.eurorec.org>

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collaboration among Member States to leveraging investment in eHealth. European regional and structural funds have been used, however. For example, the European Regional Development Fund (ERDF) supported eHealth-related infrastructure and services in Hungary and Lithuania⁵. For the period 2007-2013, European Structural Funds support ICT systems for medical services, and productive investment in areas including medical equipment and the exchange of good practice. The Convergence Objective of the ERDF supports structural adjustment of regions whose development lags behind.

Initiatives funded by the Commission, such as the “Business Models for eHealth” study¹⁹ and the “Financing eHealth” study²⁰ provide guidance and information on these matters for the Member States.

The first study analyses business modelling approaches aimed at making eHealth applications financially and operationally sustainable in the longer term, with particular attention paid to ICT applications for chronic diseases management and to research activities in the field under the support of the European Commission.

The second study was commissioned specifically to support this specific action of the eHAP in boosting and leveraging investment in eHealth. It assesses different financing opportunities to apply vis-à-vis the financing needs of eHealth investment.

2.7 Legal and regulatory issues

Legal and regulatory issues encompass professional status, liability, privacy, data protection, confidentiality, and even costing of eHealth services. Given the need for cross-border arrangements, this represents a most challenging field. The stated goal of this action was:

- ◆ *By end 2009, the European Commission, in collaboration with Member States, should undertake activities to:*
 - *Set a baseline for a standardised European qualification for e-Health services in clinical and administrative settings.*
 - *Provide framework for greater legal certainty of e-Health products and services liability within the context of existing product liability legislation.*
 - *Improve information for patients, health insurance schemes and providers regarding the rules applying to the assumption of the costs of e-Health services.*
 - *Promote e-Health with a view to reducing occupational accidents and illnesses as well as supporting preventive actions in the face of the emergence of new workplace risks.*

Implementation of the Action

At country level there are no general legal frameworks covering the domain of eHealth, as yet. Specific parts of eHealth have been the subject of legislative regulation; for example France and Scotland on the UK have done so for telemedicine. The dominant status in EU-27 today is that most countries rely on existing laws covering issues such as patients' rights, data protection (via Article 8 of the Data Protection Directive), professional licensing and conduct.

Consensus however has been achieved regarding the importance of such legislation. As reported by the study on eHealth strategies in Europe⁵ only seven Member States – Denmark, Estonia, Finland, France, the Slovak Republic, Sweden and the UK (England and Scotland) – are currently designing a new legal framework for eHealth. At the opposite end of the scale, five Member States (Austria, Cyprus, Latvia, Malta and Portugal) have no specific regulations on eHealth. It is important to note, however, that the situation is bound to change: As the above study reports, 22 Member States are being active in the examination of eHealth-related legal frameworks.

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As reported by the same survey-based study, most of the current thinking regarding legal certainty for eHealth in Europe centres on EHRs, ePrescriptions and telemedicine. For EHRs, legislative interventions appear easier to implement in the near future since similar frameworks cover existing paper-based records. Preparation of ePrescriptions regulation focuses on identification and authentication issues (such as eSignature), patient consent and electronic pharmaceutical records. The status of preparation for telemedicine legislation appears less advanced due to the complexity presented by cross-border accreditation and liability issues.

At the level of the EC, the Communication on Telemedicine²¹, adopted on 4th November 2008, addresses issues on the legal clarity of the existing EU law applicable to telemedicine. As the mid-term progress report¹ of the LMI for Europe pointed out in 2009, “the Commission came to the conclusion that regulation at the EU level regarding Health is in principle applicable also to eHealth. Thus no legally binding measure is foreseen to be adopted by the EC in the near future and the soft law instruments will be considered in line with the principle of proportionality as instruments to boost deployment of eHealth services and products.”

Other activity by the EC includes funding for various studies and projects on the legal support for eHealth. Of these, there was a study²² on the “Legal Framework for Interoperable eHealth in Europe”, completed in 2009. It describes comprehensively the legal status of eHealth in Europe and concentrates on EHRs, ePrescriptions and telemedicine. The study concludes that “the health sector in Europe necessarily needs to be seen as a very fragmented landscape and that this fragmentation will not be eliminated in the near future. A European regulatory framework for eHealth should therefore not only take this diversity into account but it should fundamentally be based on it.”

In addition, the study demonstrates the complexity of the issues and recommends that this can best be tackled via more specific case studies, where more practical and workable legal guidelines can be provided.

The part of the action referring to the contribution of eHealth to occupational health has not been implemented, the objective probably was far too specialised to be achieved by ICT expertise alone. The issue later became part of the responsibilities of the DG for Health and Consumers^{xiv}.

Finally, it is important to mention the latest boost to eHealth-related legislation at European level, the Cross-border Health Care Directive²³ adopted by the European Parliament on 19th January 2011. A general reference to eHealth is found in Article 14, with calls for the promotion of interoperability and the creation of a voluntary network on eHealth, related to patient data protection and sharing. Specific regulatory measures for telemedicine state that:

- ◆ For the purposes of care via telemedicine, “healthcare is considered to be provided in the Member State where the healthcare provider is established”, and
- ◆ Treatment of costs for care via cross-border telemedicine is the same as that of any other cross border healthcare (Article 7).

The Directive provides for reimbursement of patients for healthcare services received in another Member State. This, combined with Article 7, partially addresses the third part of the Action on the supply of information regarding the assumption of costs of eHealth services. There has been no other activity regarding the realisation of that part of the Action.

It is of interest that further calls on the Member States to equate the status of the professional quality of telemedicine services and the protection of patients with the status of similar non-electronic healthcare services was removed from the final text. This is indicative of the

^{xiv} http://ec.europa.eu/dgs/health_consumer/index_en.htm

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scepticism and the reservations which exist among parliamentarians and the Member States they represent.

Recapitulating, it can be inferred from the implementation of this specific action that there has been considerable activity both in the Member States and the Commission on legislative issues which, however, has demonstrated the complexity of the matter and the need for further study. At the same time, progress has been made both in European legislation (Cross-border Health Care Directive) and in the “mindset” of the Member States, with 22 Member States being active in the examination of eHealth-related legal frameworks.

3 Issue 2: Pilot actions: accelerating beneficial implementation

3.1 Information for citizens and authorities on health education and disease prevention

The following actions essentially announced the establishment of a European Union-wide public health portal to provide reliable information and serve as a single point of access. The portal was the result of action based on the Commission's Public Health Programme.

- ◆ *By end 2005, a European Union public health portal will give access to European level public health information. Health portals shall offer dedicated information on safety at work and workplace health risks.*
- ◆ *By end 2005, there will be a strengthening of early warning, detection, and surveillance of health threats through enhanced information and communication technologies tools.*

Implementation of the Actions

These two actions were implemented by DG Health and Consumers in the guise of the Health-EU Portal^{xv} which is the official public health portal of the EU. Under separate sections presented on the portal's home page, it provides an early warning system at national as well as at Community level that offers surveillance results with regard to diseases (HIV, infectious, influenza and others), including non-communicable diseases, and bioterrorism threats. A special section on "Health in the EU" outlines policies, health indicators in the EU, research and statistics.

As an example, the portal's section on statistics^{xvi}, presents information from various databases as well as the data collected on Healthy Life Years (HLY), which measures the number of remaining years that a person of a certain age should be able to live in good health. This is a solid indicator for monitoring health as a productivity/economic factor. Moreover, the European Commission, via the Innovation Union Communication^{xvii}, has set the doubling of the average value of the HLY indicator as a target for 2020.

The website of the EC's Directorate for Public Health and Risk Assessment^{xviii} is directly accessible from this portal. The site provides thematic information on policies and decisions taken at European, national and international levels and provides links to databases of public health statistics.

3.2 Towards integrated health information networks

The eHAP envisaged online services for health supplied through health information networks linking hospitals, laboratories, social centres and other stakeholders. This action set a target for 2008 for implementing a number of services in Europe.

^{xv} <http://ec.europa.eu/health-eu>

^{xvi} http://ec.europa.eu/health-eu/health_in_the_eu/statistics/index_en.htm

^{xvii} Communication from the Commission to the European Parliament, the Council, the European economic and Social Committee and the Committee of the Regions, "Europe 2020 Flagship Initiative, Innovation Union", SEC(2010) 1161, Brussels, 6.10.2010, http://ec.europa.eu/research/innovation-union/pdf/innovation-union-communication_en.pdf#view=fit&pagemode=none

^{xviii} http://ec.europa.eu/health/about/index_en.htm

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- ◆ *By end 2008, the majority of all European health organisations and health regions (communities, counties, districts) should be able to provide online services such as teleconsultation (second medical opinion), e-prescription, e-referral, telemonitoring and telecare.*

Implementation of the Action

With the exception of ePrescription, most of the activities mentioned in the action are now grouped under telemedicine. The action specified the target date of 2008 for these services. Although online services on telemedicine are actively pursued throughout the EU at either pilot stages or at local level, deployment at large (which is close to the spirit of the wording of the action) has not materialised yet in Europe. A number of underlying causes is responsible for this, ranging from legal to organisational to financial hindrances. The outlook, however, is promising. All Member States include some telemedicine pilot in their eHealth arrangements. The study on eHealth strategies in Europe⁵ reports that wider application of telemedicine among the Member States has taken place in the Nordic countries, i.e. Denmark, Finland and Sweden; countries such as Italy and Spain have regional activities; while Poland plans a move from local pilots to large-scale regional pilots within a year of the publication of the document. Two relevant pilot developments of interest were also singled out by the study:

- ◆ At national level, the “Whole System Demonstrator” (WSD) programme^{xix} in the UK (England) is a two-year research project funded by the Department of Health to find out “how technology can help people manage their own health while maintaining their independence. The WSD programme is believed to be the largest randomised control trial of telecare and telehealth in the world to date”.
- ◆ At European level, the RENEWING HEALTH (REgioNs of Europe WorkINg toGether for HEALTH) project^{xx}, partially funded under the ICT Policy Support Programme (ICT PSP), aims at implementing large-scale real-life test beds for the validation and evaluation of innovative telemedicine services. Nine regional authorities or regional healthcare providers supported by eHealth Competence Centres participate in the project, which started on 1st February 2010 and finishes at the end of September of 2012. It represents one of the largest-scale efforts in reference to telemedicine so far at EU level.

ePrescription online services, which were included in the action, have followed a rather different route. As reported by the study on eHealth strategies in Europe⁵, there is a small number of Member States which have implemented full ePrescription services or offer regional or partial services. However, the majority of Member States is still at the planning stage. In particular, Denmark, Estonia and Sweden offer full services, while the Netherlands, Portugal and Spain have regional implementations at different levels (whether physician or hospital environments). Portugal has recently established a legal regime for ePrescriptions, under Ministerial Order no. 198/2011, of 18th May 2011. The Order also defined the period of transition for the digitisation of manual prescriptions.

Overall, the situation on ePrescription appears more advanced when compared to that of telemedicine, where only pilot stage implementations exist. Full-scale examples such as those of Denmark, Estonia and Sweden can act as show-cases for countries with regional-only implementations or strategic intentions.

In conclusion, while the original target of the eHAP for services by 2008 may not have been reached, the dynamics of implementation are evident. The advantages of services such as telemedicine and ePrescription are hard to ignore these days. Despite its optimism for more

^{xix} http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_100946

^{xx} <http://www.renewinghealth.eu/>

concrete implementation, the eHAP has succeeded in raising awareness and in setting the foundations for accelerated future developments. Any full-scale deployment of such online services will have to be supported by an enabling legal and regulatory framework, an issue which is far from straightforward (see section 2.7).

At the level of the EC, the political will to achieve widespread deployment of telemedicine services is there. A specific ten-point **Action Plan for Telemedicine**²¹ was issued in 2008. The 2009 follow-up of the plan²⁴ set the target that, by the end of 2011, the EC, in cooperation with the Member States, will issue a policy strategy paper on how to ensure interoperability, quality and security of tele-monitoring systems based on existing or emerging standards at European level.

Wide-scale deployment of telemedicine services, however, has a longer-term horizon. The Digital Agenda, via Action 75 sets the target date at 2020²⁵.

3.3 Promoting the use of cards in health care

This part of the eHAP referred to the two types of cards – health cards containing information similar to an EHR and health insurance cards – which offer evidence of participation to an existing health insurance scheme. The Action was worded as follows:

- ◆ *Promoting the use of cards in the health care sector. Adoption of implementation of an electronic health insurance card by 2008.*

Implementation of the Action

With regard to health cards, the eHAP did not set any target date for their promotion. Indeed, the complexities of the issue and its close association with EHRs and patient identifiers has been dealt with in section 2.2.1 of this report, in the context of the relevant action on a common approach towards patient identifiers.

Regarding the more concrete target of a health insurance card, the decision to introduce a European health insurance card²⁶ set the 1st of June 2004 as its deployment date. The card was supposed to replace paper forms needed to benefit from medically-necessary care while on a temporary stay. The card was supposed to have been followed by an electronic equivalent card, the eEHIC. Its implementation has been plagued by delays caused by the Member States. These were due mainly to differences in existing systems and the necessary interoperability requirements.

At European level, a pilot implementation of an eEHIC – and the closest initiative to applying the action – was undertaken by the NETC@RDS⁷ project under the “Initial Deployment” phase of the eTEN programme. More specifically, the project enabled health practitioners to check foreign patients' entitlement to health care. It was based on an agreement between health insurance organisations to provide easier access to cross-border healthcare for citizens travelling inside the EU and EFTA. The service can be provided via an optically readable EHIC card, a national health insurance electronic card, or via certain national eID chip cards issued by the responsible government authorities.

The initial deployment provides healthcare access for European citizens who provide evidence of entitlement in any of the upcoming 260 Service Units and around 500 Service Points across the 16 participating countries (14 from the EU and two from EFTA).

The results of the NETC@RDS project are expected to be of significant help towards full deployment of the eEHIC across Europe. However, issuing a specialised eEHIC for all European citizens is not necessarily the most efficient way to achieve the full benefits of eHealth. The newer trend of using multi-purpose eCards, which encompass eID, eSignature and eHealth, appears to be a more effective way of achieving a more inclusive, citizen-friendly means of identification. These cards can potentially achieve the full benefits of

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extended eGovernment, eParticipation and eHealth services for all citizens. The drawback is that the larger scale of integration of the different functionalities poses new challenges in the fields of security, legality and privacy. Consequently, it lengthens the debate and the corresponding implementation horizon. On the other hand, this longer horizon may prove beneficial as it may allow for more efficient and diverse means of identification and authentication, for example the new generation of mobile telephones.

4 Issue 3: Working together and monitoring practice

The aim of the eHAP here is to help develop a European eHealth Area by highlighting and disseminating best practice examples, regular monitoring of progress and fostering cooperation with countries around the world.

4.1 Disseminating best practices

The eHAP places the EC at the centre of the distribution and sharing of best practice examples throughout the EU on a variety of eHealth-related issues covering all the areas highlighted in the eHAP. Of particular interest is the emphasis on approaches which ensure interoperability “while respecting the multi-cultural and multi-lingual tradition of European health care systems”. Targets were set through the following three-tier action.

- ◆ *In 2004, a high level e-Health forum should be established, the role of which will be to support the Commission services. It should involve all necessary stakeholders, including at national, regional, or local hospital authority levels, thereby enhancing the understanding of the Commission services with regard to the current and planned status of development of e-Health in Member States. Its task should be to follow up the various roadmaps, and to identify further actions including a strong focus on users and access for all to e-Health, as well as to develop a strong evidence basis for the case for e-Health. The work of the e-Health forum will also be closely associated with the implementation of the Community Public Health Programme.*
- ◆ *During the period 2004-2008, Member States with the support of the European Commission will organise special events such as high level conferences in order to disseminate best practices.*
- ◆ *In parallel, by the end of 2005, the European Commission, with contributions from Member States, should establish an effective way of disseminating best practices and supporting actions within the European e-Health area.*

Implementation of the Action

The high-level eHealth forum was achieved by an experts group called the “eHealth Stakeholders Group”, established in December 2005 by the EC. The group’s mission was to support and enhance work being done on eHealth interoperability. The group later created two subgroups, namely the eHealth Users’ Stakeholders Group with membership ranging from key decision-makers and health professionals to hospital representatives, patients and citizens, and the Industry Stakeholders’ Group. The experts group became an Advisory Group of the i2010 Subgroup on eHealth working under the coordination of DG Information Society and Media. It is expected to be included in the European eHealth Governance Initiative (eHGI), which encompasses 39 eHealth beneficiaries including 26 Member States and various stakeholders.

Another high-level advisory group is the European Task Force on eHealth, which includes health care professionals, patients’ representatives, people from the medical, pharmaceutical and ICT industries, legal experts and policy makers. The Task Force advises the EC on how to unlock the potential of eHealth and on how to achieve interoperability of eHealth services and technologies across the EU. It explores the relationships between eHealth, telemedicine and social policy initiatives and suggests ways for ICT to be applied to promote innovation in healthcare. The first meeting of the Task Force was held in Budapest, during the May 2011 eHealth conference.

During the lifetime of the eHAP there have been a lengthy series of high-level events and high-level conferences organised jointly by the Member States and the EC which have concentrated on eHealth and the dissemination of best practice, for example, the annual

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European eHealth Conference and eHealth Week. The EC has also organised activities which were similar to those of the “forum” described in the action. These can be epitomised in studies monitoring roadmaps for eHealth deployment set by the Member States^{4, 5}.

Although only “dissemination” appears in the title of this group of actions, the activities envisaged for the “eHealth forum” were wider. One of them was following up of roadmaps on eHealth-related issues. As no other roadmap-related activity was included in the eHAP, we deem it suitable to refer here two such activities sponsored by the Commission in the form of two supplementary action plans.

- ◆ The **Action Plan for Telemedicine**²¹, issued in 2008, included a ten-point roadmap for promoting telemedicine in Europe. The Communication took its final form after an in-depth stakeholder consultation process. Actions for the years ahead were separated into three levels: actions at Member States’ level, actions by the Member States supported at EU level and actions by the European Commission. In October 2009, a follow-up of the plan²⁴ examined the progress achieved.
- ◆ The **Action Plan for eHealth**²⁷ was developed in the framework of the LMI for Europe. The plan represents a roadmap leading to measures which can further stimulate a market for innovative eHealth solutions in Europe. Actions such as standardisation of information exchange formats or certification of interoperable systems could effectively solve interoperability problems, while other measures within the framework such as clarification and guidance to apply the legal framework, networking of public procurers, and supply of information to users, doctors, health managers and public authorities on eHealth benefits could transform the eHealth landscape in Europe. A mid-term report on the progress of LMI in Europe¹, issued in 2009, also included information on the state of execution of the Action Plan for eHealth.

Finally, the last tier of the action on the dissemination of best practice was not achieved in 2005, as originally planned, but a few years later with the ICT for Health section^{xxi} of Europe’s Information Society Thematic Portal and the ePractice.eu portal. This is more oriented towards the submission and dissemination of real-life good practice cases^{xxii} in eHealth. Besides cases, the ePractice.eu portal offers support for two thematic communities of stakeholders, namely:

- ◆ The **eHealth Procurers’ Forum**^{xxiii}, a community open to practitioners in eHealth procurement from European national and regional administrations, public and private organisations, academia and research centres.
- ◆ The **Telemedicine Forum**^{xxiv}, a community to help all practitioners involved in telemedicine services in Europe to meet and share their experiences and knowledge, and to ask and to provide support.

4.2 Benchmarking

The eHAP refers to benchmarking as a monitor of progress on issues such as awareness of eHealth, effective and efficient use, and added value to existing health challenges, like the

^{xxi} http://ec.europa.eu/information_society/activities/health/index_en.htm

^{xxii}

http://www.epractice.eu/cases/view_all?filter=1&content_type=case_type&Countries=All&domain=102&Sector=All&Status=All&Type_of_initiative=All&Regular_Case_Awards=All&search=&form_build_id=form-c254e150c349f9b3bf25606e11b376f5

^{xxiii} <http://www.epractice.eu/en/community/ehealthprocurers>

^{xxiv} <http://www.epractice.eu/en/community/telemedicine>

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ageing population, access by all, escalation of costs of care and others. Specific targets were set by the following two-tier action.

- ◆ *During the period 2004-2010, every two years, the European Commission will publish a study on the state of the art in deployment, examples of best practices, and the associated benefits of e-Health.*
- ◆ *By the start of 2005, Member States, in collaboration with the European Commission, should agree on an overall approach to benchmarking in order to assess the quantitative, including economic and qualitative impacts of e-Health.*

Implementation of the Action

Since 2005, a number of studies has been commissioned and published by the EC on the state of various components of eHealth as well as on cases representing best practice. Some of the most important of these studies are examined below.

A general survey on the strategies and state of eHealth among the Member States was conducted by the “eHealth ERA” coordination action⁴ at the end of 2006. The survey gave a first appraisal of the progress of the eHAP in the two-year period to which it applied (2004-2006) among the Member States. The project^{xxv} had multiple responsibilities: it supported innovation-oriented eHealth RTD, identified opportunities for multilateral joint activities, and aided further integration of eHealth deployment and implementation across countries.

The 2006 study was followed by another report called “eHealth Strategies in Europe”. This was a more focused survey on the state of eHealth in Europe⁵, inclusive of individual country profiles. The study was completed early in 2011; it included the entire period of application of the eHAP.

The “Good eHealth study”¹⁶, conducted between 2006 and 2008, offered a comprehensive approach to dissemination and transfer of learning experiences by identifying the benefits of specific good practice examples, developing stronger approaches to sharing good practices, and stimulating faster uptake of new eHealth systems and services. The knowledge base produced by the study covers 25 Member States, three Accession Countries, and three EEA nations as well as Switzerland.

The “Methodology to assess Telemedicine Applications” (Metho Telemed) study²⁸, conducted between 2009 and 2010, provided up-to-date information on telemedicine applications in use in Europe, with a particular focus on cross-border solutions. It also identified enablers and obstacles to deployment and provided an initial overview of national policies in telemedicine. The study also provided a basic methodology to assess telemedicine solutions. This methodology will be validated at European level, in the pilot set up by the RENEWING HEALTH (REgionNs of Europe WorkINg toGether for HEALTH) project^{xxvi}, partially funded under the ICT Policy Support Programme (ICT PSP). The pilot aims at implementing large-scale real-life test beds for the validation and evaluation of innovative telemedicine services. Nine regional authorities or regional healthcare providers supported by eHealth Competence Centres participate in the project, which started on the 1st of February 2010 and is to finish at the end of September 2012. So far, the project represents one of the largest-scale efforts in telemedicine at EU level.

^{xxv} The “eHealth European Research Area” (eHealth ERA) project (<http://www.ehealth-era.org/indexold.htm>) was an FP6 IST Coordination Action, conducted between April 2005 and June 2007.

^{xxvi} <http://www.renewinghealth.eu/>

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More specific studies on eHealth can be found at the Europe's Information Society Thematic Portal^{xxvii} under "ICT for Health".

Regarding benchmarking, there have been three phases of the EC-led activity under the name "eHealth Benchmarking" I, II and III.

- ◆ Phase I was a survey among General Practitioners of medicine in EU-27 regarding the use of eHealth
- ◆ Phase II included a collection and appraisal of eHealth Benchmarking sources in Europe and other states
- ◆ Phase III resulted (May 2011) in the publication of a report on the use of eHealth by hospitals.

Phase I was concluded in 2008 with a study²⁹ on "ICT and eHealth use among General Practitioners in Europe", using data collected during 2007.

Phase II was achieved by a study³⁰ completed in March 2009, which aimed to collate and analyse existing eHealth monitoring and benchmarking sources in order to identify best practice in data gathering and to develop a framework for EU-wide eHealth. Sources included healthcare associations and bodies, international organisations such as the OECD and the WHO, IT industry, national statistical institutes and authorities at regional and national level.

Phase III included a survey³¹ completed and published in April 2011 on the use of eHealth by hospitals in Europe. The following results are worth noting:

- ◆ While more than 90% of European hospitals are connected to broadband and 80% have electronic patient record systems, only 4% of hospitals grant patients online access to their electronic records. European hospitals are more advanced than US hospitals in terms of external medical exchange, but they lag behind in using eHealth to view laboratory reports or radiology images. eHealth applications have a growing role in Europe's hospitals, but there are still wide variations in take-up, with Nordic countries taking the lead. Large, public and university hospitals are generally more advanced in eHealth terms than smaller, private ones.

The benchmarking study is accompanied by a treatise on methods for benchmarking eHealth deployment in hospitals³².

We should also note that benchmarking activities for eHealth have also been supported by the LMI¹ of the EC. The LMI was the main driving force behind the study on business models for eHealth¹⁹, where benchmarking was proposed as the solution for more accurate market data.

In conclusion, the activity of the EC in achieving the action has been consistent and extensive and has produced useful results for the assessment of the overall state of eHealth in the EU. What appears not to have been achieved is the part of the Action which refers to a commonly accepted overall approach to benchmarking among the Member States. That said, the funds allocated by the Commission for benchmarking phases I, II and III have also included studies on the development of benchmarking approaches^{xxviii}.

^{xxvii} http://ec.europa.eu/information_society/activities/health/studies/index_en.htm

^{xxviii} See web pages for phase I (<http://www.ehealth-indicators.eu/>), phase II (<http://www.ehealth-benchmarking.eu/index.htm>) and the study in reference [32]

4.3 International collaboration

The purpose of the eHAP was to link European efforts to those of other nations and international organisations such as the United Nations and the World Health Organisation. Although only a first step in this direction, the action was probably ultimately too specific and narrow in scope.

- ◆ *An assessment of e-Health developments should be completed ahead of the second part of the World Summit to be held in Tunis in 2005.*

Implementation of the Action

The action was implemented successfully. Indeed, the progress report³³ on the eHAP in 2005 had already collected information on the latest developments on the eHAP by the time the World Summit on Information Systems was held in Tunis in November 2005.

Despite the fact that the action only targeted the Tunis meeting, efforts to strengthen international cooperation in eHealth have continued. Support to Resolution WHA58.28 on eHealth^{xxx} (2005) of the World Health Assembly, paved the way to participation in other activities of the World Health Organisation (WHO). Since that date, the WHO, via the Global Observatory for eHealth^{xxx}, has also conducted two massive surveys worldwide^{xxxi} on the status of implementation of eHealth, in 2005 and 2009.

On the research side of eHealth, participation of non-EU countries has expanded steadily through FP6 and FP7.

A latest announcement^{xxxi} (on 17th December 2010) was a Memorandum of Understanding (MoU), signed between the European Commission and the United States (US) Department of Health, on the promotion of a common approach on the interoperability of electronic health records and on education programmes for information technology and health professionals. The aim of the MoU is to create new markets and growth opportunities for industry in the eHealth sector in both the EU and the US.

Following the MoU, together with the Office of the National Coordinator for Health Information Technology in the US, the European Commission organised a workshop in Brussels to present "ongoing and planned actions" in April 2011.

^{xxx} http://apps.who.int/gb/ebwha/pdf_files/WHA58/WHA58_28-en.pdf

^{xxx} <http://www.who.int/goe/en>

^{xxxi} <http://www.who.int/goe/data/en>

^{xxxi} <http://europa.eu/rapid/pressReleasesAction.do?reference=IP/10/1744&format=HTML&aged=0&language=EN&guiLanguage=en>

5 Progress with respect to the new Action Plan

The eHAP, which finished in 2010, is to be followed by a successor plan that will cover the time-period from 2011 onwards. In view of this new plan, the European Commission launched a consultation survey at the beginning of 2011. It sought the opinion of respondents along the following four axes:

1. Increase awareness of the benefits and opportunities of eHealth, and empower citizens, patients and healthcare professionals
2. Address issues currently impeding eHealth interoperability
3. Improve legal certainty for eHealth
4. Support innovation and research in eHealth and development of a competitive European and global market.

These axes are expected to form the consolidated objectives of the new plan, which is to appear later in 2011. Classifying these objectives, three different paths (or approaches) along which the new plan wants to deploy eHealth can be distinguished:

- ◆ A user-centric approach to attract and empower both ends of the spectrum, i.e. citizens, patients and healthcare professionals (objective 1)
- ◆ A thematic approach to lower the main barriers to eHealth deployment, such as interoperability and legal certainty (objective 2 and 3)
- ◆ The creation of a favourable environment to boost eHealth, which comprises support for research and development (R&D), innovation, and market development (objective 4).

A comparison of the objectives of the new plan and those of the original eHAP identifies a difference of orientation. The original eHAP followed an organisational view of matters. Its targets were tactical: common challenges (such as interoperability, mobility, and law), pilots and instruments (cards), and supplementary activities (like monitoring and sharing of best practice). The new plan appears to concentrate on functionality and effectiveness rather than organisation. This is not unreasonable, given that the experience acquired via the seven years of executing the eHAP has highlighted those issues which are pending alongside their relative importance. Actually, the shift towards a more functional approach to define eHealth can be traced back to 2007, when the Lead Market Initiative (LMI) Action Plan on eHealth²⁷ appeared.

In what follows, we will examine the three paths to the new plan (user-centricity, barrier-lowering, and favourable framework environment) as compared to the legacy left by the application of the 2004 eHAP. This will assist in an effort to appraise the initial starting point of the new plan.

5.1 User-centric approach

The new plan focuses on two areas: awareness and empowerment. Against those, we set the results of the actions of the eHAP.

5.1.1 Awareness

Awareness was directly or indirectly served by various actions of the eHAP. At a strategic level, the action on the development of national strategies (section 2.1) has resulted in

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strategy documents for all Member States. This means that awareness of eHealth has been built within the ranks of major policy decision makers and officials. At a mid-level too, the operation of the various committees on eHealth from 2005 onwards served to inform mid-ranking officials of development and progress, and they, in turn, briefed their senior policy makers. In this way, this strategic awareness of eHealth was gradually "grown" upwards to a higher senior level in the period 2005-2011. This is also shown by high level schemes such as the eHealth Governance Initiative and its political counterpart the European Voluntary eHealth Network (previously called the "eHealth Governance Group"),

The action on patient identifiers (section 2.2.1) has also served to create awareness of the benefits and the difficulties of the use of eHealth cards among those officials directly involved with the implementation of such systems. This awareness also extended to the fact that cards need not be the only means of identification and authentication. Indeed, the Commission's Recommendation¹⁰ on Interoperability of EHRs of 2008 refers not to cards but to reliable systems of identification and authentication. A further spread of awareness was brought by partially applied systems of eCards in some European countries; although not eHealth cards, these cards offer some identification functionality for health insurance services purposes.

Awareness, mainly among professional health workers, has also been enhanced through the deployment of eHealth information networks in many countries, under the action on infrastructures. As remarked in section 2.4, the development of such an infrastructure is uneven throughout the EU; therefore its effect on awareness is non-uniform among the Member States.

The second general objective of the eHAP on pilot actions included a large proportion of awareness-raising activities.

The calls on information on public health and the surveillance of health detection threats (section 3.1), which resulted in the official public health portal of the EU, had a profound awareness-raising effect on the general public and healthcare specialists alike regarding the possibilities of ICT-assisted health.

Even more targeted was the action on online services, such as telemedicine and ePrescription (section 3.2). These resulted in pilot and regional implementations of telemedicine, but in no widespread application, and in full implementation of ePrescription in three Member States and pilot or regional applications in another three. Awareness here was served in two ways: direct awareness for those involved (healthcare and other professionals, users and citizens at large in the three states where ePrescription systems operate) and indirect awareness of those to whom the results of these efforts were disseminated.

Finally, we should mention the wave of awareness brought about by the activities of the European Commission, which have been spread throughout the lifetime of the eHAP and has been laid out in chapters 2 to 4 of this document, spanning nearly all the actions. Of particular mention are the instruments for research, development and ICT policy support, such as Frame Programme 7 and eTEN, which have provided new knowledge, raised awareness through dissemination activities and through projects such as NETC@RDS, epSOS and CALLIOPE and others in their efforts to provide eHealth solutions of pan-European applicability. These projects involved large numbers of multi-stakeholders. CALLIOPE, in particular, focused on dissemination and promotion of eHealth awareness.

Other continuing Commission-led activities are the creation of informative portals such as ePractice.eu, with its active communities, and the series of high-level eHealth conferences from 2003-2011. These attract not only high-level policy makers and decision-makers but also a wide range of multi-stakeholders. The resulting multiplicative effect, has led to a growth of conferences and workshops in the field which has exploded since the mid-2000s. Although not necessarily all sponsored or co-financed by the EC, their success manifests that the market can still bear this degree of interest in knowing more about eHealth.

These effects on awareness must not be underestimated. In 2004, when the eHAP appeared, many of the difficulties of implementing and deploying eHealth solutions were only shared by small groups of individuals. This was reflected in the optimistic dates set by the eHAP actions. At the same time, the original eHAP needed to have ambitious goals and tight deadlines (particular at its beginning) so as to embed the starting actions in the minds of policy makers and stakeholders. The years of execution have not only managed to build an awareness of the benefits, but also an appreciation of the problems and the difficulties to be encountered in the future.

5.1.2 Empowerment of the users

User empowerment is a prerequisite for the success of any online service. The eHAP had no specific provisions here, although indirect effects can be seen in the actions on information of citizens (section 3.1), which led to an empowering users with information on the status of public health. Another related issue was included in the action for mobility of patients and professionals (section 2.3), which resulted in the “Cross-border Health Care Directive”^{xxxiii}, lunched in early 2011, and which enhances the rights of cross-border patients under certain circumstances.

That said, real empowerment of users as citizens and patients, in the sense of, for example, being able to 'own' or to consult their own electronic medical record, and even make efforts to self-manage their own health conditions, is still pending. From this point of view, its inclusion in the new plan is mandatory.

5.2 Lowering barriers

The main barriers to widening the use of eHealth were identified by the new plan as interoperability and legal certainty. Both were also focal points of the 2004 eHAP.

5.2.1 Interoperability

The eHAP centred on patient identifiers and EHRs. Both relevant actions of the eHAP (section 2.2) were set relatively short implementation dates, namely 2006. The fact that these dates were not achieved shows the optimism of the eHAP and possibly its incomplete knowledge of the actual conditions needed for implementation. That said, the actions did provide a solid foundation for future work, in the later years of the last decade of the 20th century, on interoperability. Although no common approach on patient IDs has been achieved, Member States such as France, Germany and Greece have created dedicated ID systems for healthcare. Other systems in Europe offer such IDs via general purpose eSignature or eID eCards, mainly aimed at medical insurance verification. Progress on cross-border approaches to eHealth have also advanced through the operation of EC co-funded projects such as NETC@RDS and epSOS, as well as funding via INTEREG and various structural funds programmes. Also, the STORK large-scale pilot on interoperability has used health as one of its fields of focus and has closely coordinated with epSOS.

Similar implementations of partial EHRs, such as “Patient Summaries”, have been implemented in Bulgaria, the Czech Republic, Denmark, Finland and various home countries of the UK such as Scotland.

The key trio of activities of the EC at policy level, the Recommendation³⁴ of 2008 on the interoperability of EHRs, the subsequent Mandate 403 and the inclusion of eHealth in the LMI have not only increased awareness and paved the way for more funding at European level but encouraged large-scale promotion and action on interoperability efforts. Notable examples are the epSOS large-scale pilot and its growing focus on semantic services, the CALLIOPE Thematic Network with its focus on a roadmap on European eHealth interoperability, and the

^{xxxiii} Vote of 19th January 2011 by the European Parliament.

EHR-QTM Thematic Network with its focus on quality assurance and certification of eHealth products and EHR systems in particular.

Overall, one of the most important contributions of the eHAP to interoperability has been the realisation of the size of the problem at hand: interoperability is probably the most important barrier to cross-border services on eHealth and also the most difficult to overcome. The new plan will commence from a much more stable step, based on the knowledge, experience and political will acquired and built up in the Member States. This is a much more realistic way to overcoming and tackling effectively such serious challenges as standards and semantic issues.

5.2.2 Legal certainty

As stated in section 2.7, activities stimulated by the eHAP did not result in a concrete achievement of the targets set. Despite this apparent failure, gains do exist. The eHAP demonstrated the complexity of the issue and the need for further study. Progress in European legislation also resulted in the Cross-border Health Care Directive and its provisions in Article 14 on eHealth (although these did not go as far as initially expected by stakeholders or the EC).

Thanks to the pressure from the eHAP, the “mindset” of the Member States has been changed: consensus on the need for such legislation now exists. Although only seven Member States, Denmark, Estonia, Finland, France, the Slovak Republic, Sweden and the UK are currently designing a new legal framework for eHealth, 22 Member States are reported to be active in the examination of eHealth-related legal frameworks. Dominant legal issues identified for eHealth purposes include EHRs, ePrescription and telemedicine.

5.3 Creation of a favourable environment

The eHAP placed its focus on deployment and implementation. Unlike the eHAP, the new plan addresses research and innovation directly. In contrast to the “hands-on” approach taken by the eHAP, the proposals for the new plan appear to recognise the importance of pre-implementation or pre-production phases in eHealth deployment, particularly building a bridge between the commissioners of health services such as local, regional and national authorities and the industrial or commercial producers of services which are provided electronically.

Indeed, experience with efforts to progress the interoperability of EHRs, and of trying to achieve common approaches towards patient IDs, has shown that these issues could not be handled by the Member States alone. Intervention at European level was needed. This is where the role of the EC has been decisive. Initiatives such as the ICT Policy Support Programme and the former eTEN, which have co-funded large-scale projects such as epSOS and NETC@RDS, have had a decisive impact on the realisation that eHealth at European has a lot to offer and is in need of further support.

At the same time, studies commissioned by the EC, for example those on “Good eHealth”¹⁶, “Business Models for eHealth”¹⁹, “eHealth Strategies” and on other topics have offered clarity on the status and the opportunities provided by eHealth, as well as identifying a considerable range of good practice eHealth cases. These were accompanied by constructive benchmarking studies in terms of the use of eHealth in both primary and secondary healthcare domains in accordance with issue 3 of the eHAP on “Working together and monitoring practice”.

Another European level activity, the LMI, is also a manifestation of a European-level action, which has managed to draw enhanced political support for eHealth. The role of the LMI in various areas of the eHAP has been described in sections 2.2.2, 2.7, 4.1 and 4.2 of this document. This role is expected to be increased under the auspices of the new plan’s objective to develop a competitive European and global eHealth market.

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In conclusion, the eHAP has indeed succeeded in creating a favourable supporting framework environment for eHealth. This is thanks to activities that have spanned policy support, monitoring and benchmarking but also implicitly and gradually research and innovation. This activity has demonstrated the benefits of acting at a European level. It is these results which will enable the new plan to achieve its heightened and specific objective in research, innovation and market development.

6 Conclusions

At a first glimpse, the implementation of the eHAP could appear to be incomplete. Nearly all actions of importance were delayed and some have not been fulfilled at all. The following targets have not been reached. These include those actions which are the most massive in their implications and in their scale (and are indeed those which could be considered closest to the shift towards a European eHealth area):

- ◆ identification of a common approach among the Member States for patient identifiers;
- ◆ identification of interoperability standards for EHRs among the Member States;
- ◆ adoption of common schemes for conformity testing and accreditation;
- ◆ creation of a framework for greater legal certainty of eHealth products and services;
- ◆ provision of online services in telemedicine and ePrescription by the majority of European health organisations and health regions.

Overall, initially, the 2004 eHAP appears to be characterised by naivety and buoyancy: most of the dates set were unjustifiably optimistic, and so were many of the actions. This, of course could have been a deliberate “push” on behalf of the Commission in order to mobilise the Member States and start the ball rolling on eHealth.

That said, the question remains: when faced with a general appraisal of an action plan such as the eHAP, are the results outlined in this document, the only criteria by which its success and its wider impact can be assessed? The answer is no.

Success is measured by both direct and indirect criteria. These include – and are not limited to – a growth in awareness, impact on policies, the strengthening of political will, infrastructural development, contribution to knowledge and experience, promise for the future, a build-up of expectations among citizens, practical implications on a market-based economy. The eHAP succeeded on all these fronts and more.

If we take a look at the state of eHealth now in the Member States, we see that:

- ◆ All have elaborate strategies on eHealth
- ◆ Standards for EHRs have been developed: some Member States follow these, while the use of subsets of records such as Patient Summaries are underway in four countries
- ◆ National-level ePrescription services are a reality in three states and are in preparation in others
- ◆ Telemedicine is regionally applied at a pilot level with an emphasis in the Nordic countries, and is politically supported by a dedicated action plan (2008)
- ◆ Legal frameworks are under preparation in some countries and under consideration in most of them
- ◆ Large-scale pan-European pilot implementations on partial EHRs are progressing (through epSOS)
- ◆ Electronic European Health Insurance Cards services have been implemented on a pilot basis (in the context of NETC@RDS)
- ◆ Numerous studies on vital areas of eHealth have provided information, highlighted best practice and enriched the experience of all stakeholders
- ◆ Dissemination of best practice has become an online resource (ePractice.eu portal)
- ◆ An EU Public Health portal is a reality
- ◆ The creation of a market on eHealth products and services has become a long-term political aim (via the LMI and its action plan).

None of the above existed before 2004. They all are the concrete results of the drive which the eHAP provided. Thanks to the eHAP, Europeans are richer in experience and knowledge; the Union and Member States are now on a stable footing from which the objectives of the new action plan can be achieved (see chapter 5).

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Despite its obvious “misses”, in our opinion, the significant contribution of the eHAP lies in two specific areas:

- ◆ **Appreciation of the difficulties to common action by the Member States.** The eHAP placed high expectations on common action by the Member States on challenges such as interoperability standards, legal frameworks and cross-border services like telemedicine. The fact that this common action did not materialise fully is indicative of the differences (legal, organisational, economic and others) among the Member States and regions in the Union and the need for an alternative approach. Perhaps new initiatives, such as the European Voluntary eHealth Network, supported by the political mandate of the new Directive on cross-border healthcare, will strengthen collaboration ties among the Member States in the near future.
- ◆ **Realisation that action taken at European level is important.** Centralised actions led by the EC have had considerable success. Large-scale pilot actions such as epSOS and NETC@RDS have shown the feasibility of interoperable cross-border services and the value of embedded applied research and innovation. Policy initiatives such as the Action Plan on Telemedicine and Mandate 403 provide the necessary strategic direction and reinforce political will in the Member States. Best practice and benchmarking studies present accurate pictures of the state of eHealth in various domains. Last, but not least, portals such as ePractice.eu and the EU Public Health website continue to offer reliable and timely information for a variety of users. The value of action at EU level has also been recognised by the EU Presidency Declaration³⁵ of 10th May 2011, which emphasises “the need for, and benefits of, investment in eHealth and telemedicine and of strengthened coordination of all policies related to eHealth.” The creation of the new eHealth Task Force is a crucial manifestation of this recognition.

The eHAP may not have managed to achieve a number of its targets in the strict sense. Nevertheless, it has succeeded in creating a strong legacy of concrete developments on which further progress can be based and on which the new action plan can build. Two general objectives were laid out in the conclusion of the eHAP as its desired outcomes for the end of 2010:

- ◆ “the European Union will be well placed to measure the impact of eHealth in terms of better access and better, more efficient, services as well as on the overall productivity of the healthcare sector;
- ◆ eHealth will have become commonplace for health professionals, patients and citizens; and eHealth will be adequately resourced within healthcare budgets, and contribute to boosting wider objectives, such as competitiveness, jobs and cohesion.”

With the exception of eHealth becoming common for all involved in health, which seems to be taking longer to achieve, the essence of these two objectives has indeed been fulfilled.

Positively, the action plan itself (simply by its existence) put the notion of eHealth on the map. It attached dates to specific developments, which, even if not kept, were acknowledged and acted upon. It created a reference point on which Member States and health authorities could base their vision and efforts to achieve better quality and provision of healthcare.

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