

CROSS-BORDER EXCHANGE OF HEALTH RECORDS

The European Union (EU) has long aspired to support the freedom of movement of its citizens between member states by facilitating the transfer of their health records across borders. This is not as simple as might first seem, because few countries have a robust legal basis for such a transfer, records in different European countries are often in different languages, and the structure of health records varies greatly from country to country. At present most exchanges are informal and unstructured; hardly the best formula for safe and efficient healthcare.

Cross-border exchange of personal health data was first piloted during the epSOS (European Patient – Smart Open Services) project. This was a large-scale pilot that ran from 2008 to 2014 and involved not only most EU countries but also Norway, Switzerland and Turkey. It focused on how to transfer patient summaries and ePrescriptions when citizens need unplanned health care while travelling outside their home country. Malta took part from 2011 onwards, and succeeded in exchanging patient summaries with various countries, including Italy, Portugal and Slovenia. The epSOS project drew up specifications for other use cases, such as transfer of a health care encounter report back to the patient's home country, and direct patient access to the cross-border data. However, these use cases have not been widely tested yet.

The European Commission is now encouraging countries to set up cross-border health data exchange as a routine service, and is supporting this by making funds available from its Connecting Europe Facility (CEF).² A call for applications opened in November 2015, inviting proposals from EU member states interested in connecting to the EU's new eHealth Digital Service Infrastructure (DSI). The call closed in March 2016 (CEF-TC-2015-2);³ twenty countries submitted a proposal, and it is expected that the eHealth DSI will go live in the first quarter of 2018.

In parallel, the EU has been actively cooperating with the US in the specification and testing of an International Patient Summary standard that draws upon EU epSOS and the US Meaningful Use experience.⁴

e-SENS (ELECTRONIC SIMPLE EUROPEAN NETWORKED SERVICES)5

The European Commission is keen on integrating the outputs of various projects into its Digital Service Infrastructures. One of these projects is e-SENS, which included an eHealth component that focused on using European e-ID services to improve access to eHealth services. The aim is to help EU citizens not just identify themselves when accessing health services, but also demonstrate their entitlement to care and facilitate access to their cross-border health records in real time. Estonia and the Netherlands are the first countries testing the e-SENS online processes which allow the checking of health insurance entitlements of visiting citizens in real time by communicating with that citizen's own member state.

MOBILE HEALTH (MHEALTH) APPLICATIONS

In the past few years, the increasingly widespread possession of smartphones has led to a veritable explosion in the number of mobile apps available to the man in the street. More than 100,000 of these are related to health and lifestyle. A more recent trend is the increase in wearable devices, especially smartphones and fitness bracelets; this has further fuelled interest in mHealth. Jurisdictions around the world are trying to keep up with this rapid evolution. The challenge is to reap the benefits without losing sight of crucial factors such as safety, privacy and efficacy.

In April 2014, the European Commission issued a Green Paper on mobile health (mHealth) to help identify the right way forward to unlock the potential of mHealth in the EU. The summary report of the consultation, issued in January 2015,6 makes for interesting reading; it addresses points such as the need for certification in order to generate trust in specific mHealth apps, and the role of standards in the generation of "big data" from such apps.

More recently, the European Commission has facilitated the creation of an industry-led **Code of Conduct** on mobile health apps, covering the topics of privacy and security. The objective is to foster citizens' trust in mHealth apps and to raise awareness of and facilitate compliance with EU data protection rules for

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app developers. It covers issues such as user consent, purpose limitation, data retention, disclosure of data to third parties and data gathered from children. The Draft of this Code was published on 7 June 2016,⁷ and it is now being looked at by the Article 29 Working Party on data protection.

Another recent EU policy initiative is the preparation of mHealth app assessment guidelines. In February 2016, the European Commission appointed a working group to draft these guidelines. The group includes representatives of patients, health professionals and providers, payers, industry, academia and public authorities. The group is seeking to provide common quality criteria and assessment methodologies that could help different stakeholders, in particular end-users, to assess the validity and reliability of mobile health applications. The guidelines are expected to build on existing initiatives and best practices in Europe. The latest draft may be downloaded from the dedicated web page.⁸

RESEARCH AND INNOVATION IN CHEALTH

Through its Horizon 2020⁹ Programme, the EU provides substantial funding for research and innovation projects in the field of ICT for health and wellbeing. A few examples of such projects¹⁰ are:

- A Decision Support System incorporating a validated patient-specific, multi-scale Balance Hypermodel towards early diagnostic Evaluation and efficient Management plan formulation of Balance Disorders (EMBalance)
- Clinical Intervention Modelling, Planning and Proof for Ablation Cancer Treatment (ClinicIMPPACT)
- Wearable Sensing and Smart Cloud Computing for Integrated Care to COPD Patients with Co-morbidities (WELCOME).

New research & innovation actions that will open in November 2016 and close in March 2017 include "In-silico trials for developing and accessing biomedical products" (SC1-PM-16-2017) and "Personalised computer models and in-silico systems for well-being" (SC1-PM-17-2017).¹¹

ehealth week in Malta: May 2017

From Tuesday 9th to Friday 12th May 2017, a series of eHealth events known collectively as "eHealth Week" will be jointly organised and hosted in Malta by the Maltese Presidency, the European Commission and HIMSS-Europe. Health Week is an annual gathering of the top eHealth policy makers and practitioners in Europe. It is estimated that around 2,000 delegates will attend from Europe and beyond.

These events will be held in Malta because, since 2007, the EU member state holding the first-semester Council Presidency and the European Commission have hosted a High-Level eHealth Conference. Almost every year since 2010, this has been co-located with a Health IT conference and exhibition organised by HIMSS-Europe, the European branch of HIMSS, a global not-for-profit organization focused on better health through

IT. Since 2012 the European Commission has also organised a meeting of its eHealth Network alongside these conferences.

The main conference and exhibition will be spread over the three days from 10th to 12th May. It will include daily plenaries and parallel education sessions covering several themes. A particular feature is the SME Competition organised by the European Commission, which aims to recognise and reward SMEs that are leaders in the development of health IT applications. HIMSS also organises "matchmaking" sessions, which are opportunities for health IT companies, health providers and other stakeholders to meet.

Since January 2016, the Ministry for Health has been working on the thematic content of the Conference. It is planned to take forward discussions on the following themes:

- Giving patients direct access to their own data;
- Using data for personalised medicine, health technology assessment and analytics;
- Moving personal health data across borders (even for migrants);
- Supporting European Reference Networks¹⁴through eHealth;
- Joining up patient data from different sources;
- Improving safety and privacy of mobile health;
- Moving health data safely onto cloud infrastructure.

Visitors will be able to see Malta's eHealth systems in action, including the new version of the myHealth portal and other local Health IT deployments. A central theme in eHealth Week 2017 will be how to keep IT at the service of patients, citizens and society in general.

eHealth Week 2017 will be a golden opportunity for local healthcare providers and health IT companies to network with health IT leaders from all across Europe. For more information on this series of events, or on other eHealth matters, readers are encouraged to contact the Ministry for Health's Information Management Unit on digitalhealth@gov.mt.

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