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eHealth Governance Initiative:

Joint Action JA-EHGov & Thematic Network SEHGovIA

DELIVERABLE

D6.3 Recommendations on patient health records, including patient access to health data

WP6 Trust and Acceptability

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ABSTRACT

The paper documents the evidence collected after deployment of the “patient access to data” service in Sweden (Uppsala) and Estonia and lists the key issues that need to be appropriately addressed at national and European levels.

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ABBREVIATIONS

EHR	Electronic Health Record
NHS	National Health Service
GP	General Practitioner



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1. Introduction and scope of the paper

This briefing paper covers several elements: it describes the national and international background to the need for patient access to electronic health records; it examines the existing evidence, drawing on two cases – those of Uppsala county in Sweden and of Estonia – and uses them to identify the benefits, lessons learned and functionalities relating to patient access; it then uses the same two cases to identify a range of seven open issues which still need consideration. The paper ends by identifying a set of proposed next steps to be taken by the eHealth Network with regard to patient access as a result of these open issues. This will involve the organisation of a formal workshop that brings together key projects and Member States. The workshop outcomes should provide the input for a formal recommendation to be submitted to the eHealth Network at an appropriate date.

Items that are outside the scope of the paper: First, apart from the question of access *per se*, the question of the modalities of control of access by the patient himself or herself, and the subsequent need for supplementary rules, are highly dependent on national public “culture”; this issue is not explored here. Second, questions related to topics such as consent, modulated access¹ and exclusions are related to the issue of authorisation and are therefore not dealt with specifically in this document. Third, while aspects of patient access associated with security, data protection, safe identification and the authentication of actors are considered to be essential prerequisites to patient access, they are also not discussed here.

¹ Capacity to limit access to specific information and/or HCP

2. National and international background to patient access

With the majority of Member States currently entering the phase of deploying wide-scale eHealth applications, two challenges arise: the question of access to data by the patient himself or herself sometimes remains unaddressed at national level, while the upcoming deployment of cross-border use cases requires consensus at the European level. There is now growing experience of wider-scale deployment.

The evidence accumulated, e.g. in the Swedish context, shows that resolving the question of patient access to electronic health records is not a side issue: it is an important prerequisite in order to support patient empowerment, citizen engagement and innovative approaches to health care.

Patient access to electronic health records is an important driver for the use of key eHealth applications. Recent experience in Member States demonstrates that the absence of provision for an active role for citizens/patients in the implementation of national eHealth roadmaps has often led to significant hurdles and delays.

Key Action 13 of the European Commission's 2020 *A Digital Agenda for Europe* aims at undertaking pilot actions to **“equip Europeans with secure online access to their medical health data by 2015”**. To support this objective, the European Commission funded two pilot projects entitled "SUSTAINS"² and "PALANTE"³. These projects were designed to equip Europeans with secure online access to their medical health data and, together, have involved over 20 regions in 12 Member States.⁴

With the financial support of the European Commission, pilot projects in integrated care are also being implemented in a growing number of European regions (see, for example, United4health, Smartcare, Carewell, Beyond Silos and Integrate).⁵ The use cases on which all of these projects are based assume some kind of access by the patient to his or her data.

² <http://www.sustainsproject.eu/>

³ http://ec.europa.eu/information_society/apps/projects/factsheet/index.cfm?project_ref=297260

⁴ Austria, Czech Republic, Denmark, Finland, Greece, Ireland, Italy, Norway, Slovenia, Spain, Turkey and UK (Scotland)

⁵ <http://www.integratedcarefoundation.org/project/project-integrate>

<http://pilotsmartcare.eu/home/>

<http://www.united4health.eu/>

<http://www.beyond-silos.eu/home/>

The wide-scale deployment of cross-border services, such as those piloted by epSOS⁶, furthermore requires a minimum consensus at the level of the European Union on the scope and modalities of patient access.

Overall: Access to patient data should be about making access to data meaningful and understood. It is about moving patient access from paper to the digital world. Creating convergence at the national level can also enhance and support access to patient data across borders or despite borders. Patient access needs to be complemented by the ability to access data across borders, and the associated value that benefits both the person (the patient as an individual) and the health system. These two outcomes are vital and complementary.

3. Existing evidence

The existing evidence has been tested, and documented, in the Swedish county of Uppsala via the SUSTAINS project. The results of the Uppsala initiative have proved to be sufficiently valid for Sweden as a whole to extend this service to the entire country. Estonia has been offering a patient access to data service since 2008. Meanwhile, the National Health Service (NHS) in England has been planning a roll-out of patient access to data from 2013 onwards.

This sub-section aims at summarising the main findings from two sources: the SUSTAINS project in Sweden, and the Estonian context (the English example is not documented here).

These two examples are used to provide the Member States with a list of the key open issues that surround patients' access to their own data.

The two examples also show that there are various commonalities among doctors' opinions in Member States as well as dissimilarities. The question of electronic access by the patient to his or her medical data is often considered to be a sensitive issue by public authorities.⁷ Numerous *a priori* legitimate questions are raised about this issue by health care professionals. However, the evidence to date in this limited number of countries shows that most of

⁶<http://www.epsos.eu/>

⁷ This position was taken by associations of medical doctors in Sweden but can certainly be extrapolated to associations of medical doctors in other countries.

these assumptions and fears are not justified. In Sweden, for example, doctors' anxieties that patients might be confused by the various sets of data have been shown to be unfounded. In fact, patients have been happy with the patient access service provided and they appreciate the degree of patient empowerment it enables. Opening up the electronic health record to the patient improves: the quality of the data available; the quality of communication between health care professionals and the patient; and long-term patient safety. In Estonia, there was also some initial resistance on the part of the hospital sector; it is now the treatment relationship between the health care professional and the patient that guides the degree of appropriate access to patient data; and, ultimately, it is the patients themselves who monitor/vet to what extent inappropriate access has taken place (which they are then able to report to Estonia's Data Protection Inspectorate).

3.1 Uppsala, Sweden

After nine years as a pilot at a general practitioner (GP)'s surgery, the "Read your EHR via the net" service was made available to the public on 8 November 2012. With a few exceptions, the service includes all the medical information from GP surgeries, open care and all hospital care in the county of Uppsala. The patient/citizen chooses whether to see his/her information as soon as the information is entered in the electronic health record (EHR) or within 14 days.

After one year of operation:

- 50,000 unique patients/citizens have used the service.
- Each patient has logged in five times on average, and in total there have been 250,000 logins.
- 98% of patients have chosen to read the information immediately.
- Females used the service slightly more than males: the share of those who had an EHR was 7.37% for females and 5.54% for males (after nine months of the service being operational).
- After one year, 9% of patients/citizens with an EHR in the county of Uppsala had used the service.
- Users were aged between 23 and 72 years of age.
- The typical user had a current medical problem and was a major consumer of health care.

At first, the doctors' union opposed the introduction of the service, mainly for the reasons given below. The union argued that:

- There will be a rush of patient questions that prevents work.
- Patients will not understand the information.
- Patients will be concerned about the information.
- There is a risk that health care workers will be threatened when patients read the log list of who has access to the data.

However, evidence collected from the Uppsala initiative shows that doctors' fears were unfounded. There was no rush of questions on the part of the patients, who did not experience any real problems in understanding the notes of the clinicians. Overall, the service has drawn extraordinarily wide media attention (more than 150 articles have appeared in newspapers and it has featured on TV and radio over 30 times).

On the whole, the "Read your EHR via the net" service has proved to be the most successful eHealth service introduced so far.

The Uppsala evidence from the SUSTAINS project indicates that the service has led to the following benefits:

- Improvement in quality of the information produced.
- Improvement of communication between the health care professional and the patient.
- Patient empowerment and a more balanced relationship between the health care professional and patient.
- Time gain for the health care professional through the reduction of administrative constraints.
- Better access to the services. The "read the EHR" service opens doors to other eHealth services.
- Potential benefits in terms of patient safety and adherence to treatment.

3.2 Estonia

A new version of the Estonian National Patient Portal was launched on 1 July 2013 (it was first introduced in the country at the end of 2008). It allows patients to log in using their ID card and/or Mobile ID. The services available to patients in the new portal include: electronic health records, links to medical images, electronic referrals, compilation and electronic signature of different types of "expression of will"⁸, access to health insurance validity, viewing and updating of personal data and contact details of a close relative, time-critical data, viewing of ePrescriptions, tracking usage of personal data, delegating

⁸ Regarding, for example, blood transfusion, usage of post-mortal body for scientific and education purposes, and post-mortal transplantation of organs and tissues

access to a trustee of personal medical data, and masking data or masking single medical documents to health care professionals/trustees.

The following functionalities have been considered as important drivers to foster a citizen's/patient's use and acceptability of the patient access to data service. They relate to the patient's capacity to:

- Consult his or her data.
- Mask certain data.
- Have access to all access logins.
- Book (or rebook) appointments.
- Direct a question to a specific health care professional.
- Fill in forms online.
- Request an e-Prescription.

By March 2014:

- More than 1.2 million persons had seen the medical documents stored in the central health information system via the National Patient Portal.
- The Estonian National Patient Portal had more than 66,000 unique users; the number has grown over the four years since it was first launched and the number of unique users is increasing.
- More than 1,000 delegations of access had been compiled in the National Patient Portal and sent to the central information system.
- More than 1,500 expressions of will had been compiled in the National Patient Portal and sent to the central information system.

Evidence collected in Estonia shows that the launch of its patient access to data service has not caused any major problems other than some initial resistance from the hospital sector. Use of the service is directly related to the amount of information available and the availability of services, with added value for the citizen/patient. The service is mainly used by young females (aged 21-40 years), while its use by the male population remains marginal. During the first three years of the health information service deployment, most efforts were dedicated to the involvement of health care providers and physicians as they were considered "the source of health care data". Although patients have been involved from the first day of the health information service, it can be concluded that during the first years of its deployment not enough data was produced to attract a majority of patients to use the service. While, overall, the lessons learned are quite positive, additional incentives are needed to achieve a more complete digital documentation in the national health information system, and hence for more data and possible applications to be available to patients.

4. List of key open issues and currently proposed solutions

Seven key open issues are listed below. Where proposed solutions to the specific issues are available, they are mentioned.

4.1 Direct or health care professional-mediated access

In the case of health care professional-mediated access, it is the health care professional who decides for each individual patient whether to provide him or her with access to his/her data. Optionally, the health care professional can also decide to provide partial access to the patient. The principle of mediated access is in contradiction with the principles of patients' rights legislation in most Member States, but it can be seen as an intermediary step in countries where there is cultural sensitivity to patient access. Mediated access, however, seems to remain necessary for certain categories of people (e.g. teenagers) or activity (e.g. "clinical thoughts"; see Section 4.5).

4.2 Delayed or immediate access

The assumption is that it might be better to give patients (bad) news about their medical results before they have access to the data themselves. Evidence shows, however, that when given the choice, patients usually opt for immediate access to the data. Providing the patient with the option to choose is important.

4.3 Default rules for access by children and teenagers

Parents (or official guardians) are by default allowed to have access to the data of their children (up to 12 years old). Teenagers (up to 18 years old) have no default access to their own data except when they are affected by a chronic disease (and this access occurs only if the doctor in charge assesses the individual teenage patient's maturity and the need is very strong). Thus, access is decided on a case-by-case basis when maturity is assessed as sufficient and indication is very high.

4.4 Vulnerable patients or patients under influence

These patients are to be provided with the option of voluntarily suspending their access to data. Only a formalised procedure would allow them to regain access.

4.5 Health care professionals' personal notes

These notes are by default not accessible to the patient. The situation requires that these notes are specifically “tagged” in the electronic health record as the personal notes of the health care professional. “Clinical assumptions and thought” are considered to be information which should be shared between health care professionals, but should not be directly accessible to patients. Evidence collected from the Open Notes⁹ project in the USA tends to demonstrate that – when shared – such specific pieces of information are highly valued by the patients, and have a demonstrated impact on use of the service and patients' adherence. Evidence from Uppsala, Sweden shows that the use of “personal notes” by doctors is very rare (i.e. in less than 0.01% of all notes).

4.6 Issues relating to trust and acceptability

A number of other critical issues that directly affect trust and acceptability need to be further considered. Below is a non-exhaustive list:

- Give the patient the option of providing data (both “objective and subjective” data, and both structured and unstructured) as input for the health care professional.
- Provide guidance to avoid uncontrolled proliferation of patients' portals.
- Develop and/or select appropriate technical and semantic standards to improve data readability and understanding by the patient.
- Invest in mass and targeted information and education campaigns about patient access to electronic health records for the citizen/patient.
- Include mobility aspects for the patients.

4.7 Mandates management service

The availability of a secure “mandates management service” guaranteed by the public authorities is seen as an important complementary service which should add the necessary flexibility to the system.

⁹<http://www.nejm.org/doi/full/10.1056/NEJMp1310132>

5. Next steps (towards a mandate to be adopted by the eHealth Network)

In view of the strategic importance of this issue, and the availability in the coming months of supplementary evidence emerging through projects such as SUSTAINS and PALANTE, it is proposed that a formal workshop on the issue of patient access to data should be organised. The workshop should bring together key projects and Member States, with the results providing the **input for a formal recommendation** to be submitted to the eHealth network at an appropriate date.