

# EPF Position paper on eHealth

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19/12/2016

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## 1. Introduction

### 1.1 IMPORTANT NOTE

This paper was written following a consultation of the EPF Policy Advisory Group, and draws on the findings of various eHealth-related projects in which EPF has participated in over the last few years. The EPF Policy Advisory Group also requested for a survey to be carried out on eHealth/electronic health. After the first consultation held in April-May 2016, comments were integrated into a final draft for a final consultation held in November 2016 and the EPF board was consulted for approval before publication.

### 1.2 WHAT IS EHEALTH?

According to the WHO “eHealth is the use of information and communication technologies (ICT) for health. Examples include treating patients, conducting research, educating the health workforce, tracking diseases and monitoring public health.”<sup>1</sup>

eHealth can be used as a means to more effectively provide or exchange information, whether for healthcare professionals, patients, or citizens. It can also be aimed at improving the management of health systems, or the functioning of public health services.

eHealth services (including mHealth) encompass:

- Services and information tools focusing on electronic provision of health and wellness information to patients
- Services aimed at supporting healthcare providers and users, for example patient-accessible electronic health records or ePrescriptions tools
- eHealth homecare and telemedicine tools and services for patients with chronic diseases focusing on applications that allow citizens who are receiving healthcare to be supported in their personal environment, whether fixed or mobile, outside traditional healthcare facilities
- Services that allow to collect or manage data in order to advance research

### 1.3 WHY DOES EHEALTH MATTER FOR EU PATIENTS?

eHealth is often cited as a solution towards sustainability of healthcare, in a context of growing healthcare demand due to demographic change, and shortages of healthcare professionals.

In its eHealth action plan (2012-2020)<sup>2</sup>, the European Commission noted that eHealth could help improve chronic diseases and multimorbidity management, enhance patient centric

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<sup>1</sup> <http://www.who.int/topics/ehealth/en/>

care, foster cross-border healthcare, and increase efficiency of healthcare systems and equity of access.

While it could bring forward many benefits for patients, the action plan also acknowledges that healthcare has fallen behind in adopting ICT solutions effectively, compared to other sectors. Key obstacles mentioned in the eHealth action plan include technical (interoperability) and legal barriers, and lack of user-friendly tools and services. There is also a lack of awareness and confidence in eHealth solutions from patients and healthcare professionals.

## 1.4 EHEALTH POLICY AT EU LEVEL

Various initiatives at EU level have focused on eHealth:

- The eHealth 2012-2020 action plan is a roadmap that aims at addressing and removing these barriers. It clarifies the policy domain and outlines the vision for eHealth in Europe. It indicates key actions that the European Union intends to deliver to support Member States in the area of eHealth.<sup>3</sup>
- The Commission has also published a mHealth green paper in 2014, to consult stakeholders on steps to take to support mHealth deployment in the EU.<sup>4</sup>
- The eHealth Network is a voluntary network set up under Article 14 of Directive 2011/24 on the application of patients' rights in cross-border healthcare. The network brings together the national authorities responsible for eHealth from Member States to work on common orientations for eHealth. The aim is to ensure EU wide interoperability of electronic health systems and to ensure safety and continuity of cross-border healthcare. The network produces EU guidelines on eHealth, including a set of patients' data to be exchanged across borders, identification and authentication measures used in healthcare, and interoperability of e-prescriptions.<sup>5</sup>
- The European Commission has established an eHealth Stakeholder Group, which was renewed for the period 2016-2020, in which EPF is represented. It has also established a new working group for the development of guidelines on the quality and reliability of mHealth apps data.

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<sup>2</sup> <https://ec.europa.eu/digital-agenda/en/news/ehealth-action-plan-2012-2020-innovativeHealthcare-21st-century>

<sup>3</sup> idem

<sup>4</sup> <https://ec.europa.eu/digital-agenda/en/news/green-paper-mobileHealth-mhealth>

<sup>5</sup> [http://ec.europa.eu/health/ehealth/policy/network/index\\_en.htm](http://ec.europa.eu/health/ehealth/policy/network/index_en.htm)

The EU has also co-financed many projects on eHealth through various EU funding mechanisms including Horizon 2020, the CIP ICT Policy Support Programme, and the EU structural funds.<sup>6</sup>

## 1.5 EPF AND EHEALTH

EPF has been involved in various eHealth projects to collect more evidence base in this area, with a strong focus on patients' role in eHealth as well as needs and expectations of patients towards eHealth services and tools.<sup>7</sup>

Our major projects in this area include:

- **SUSTAINS - Support USers To Access INformation and Services:** The project aimed to develop and deploy a wide range of eHealth services linked to patients' access to Electronic Health Records (EHR) in 11 regions in 9 European countries. EPF played a key role in this project, especially in the work relating to patient requirements' identification and the assessment of patient empowerment as a result of using the SUSTAINS services.<sup>8</sup>
- **Chain of Trust:** EPF was the coordinator of this EU public health programme project. It assessed the perspective of the main end users of telehealth services across the EU to see whether and how views have evolved since the initial deployment of telehealth and what barriers persist in building confidence in and acceptance of this innovative type of services. For more information, see the [final report](#).
- **Renewing Health:** EPF was involved in the User Advisory Board of this project. The project implemented large-scale real-life test-beds for the validation and subsequent evaluation of innovative telemedicine services in nine European regions for patients suffering from three major chronic conditions, notably diabetes, cardiovascular diseases, and Chronic Obstructive Pulmonary Disease (COPD).<sup>9</sup>
- EPF was also involved in the project **SmartCare**, which aimed to promote a more integrated and effective approach to providing health and social care, and **Calliope** which was focusing on interoperability of eHealth infrastructures and services in the EU.<sup>10</sup>

The present position paper aims to build on the evidence base collected through these various projects to ensure eHealth policies and legislation that have an impact on eHealth in the European Union correspond to patients' needs.

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<sup>6</sup> <https://ec.europa.eu/digital-agenda/en/news/ehealth-projects-research-and-innovation-field-ict-health-and-wellbeing-overview>

<sup>7</sup> For more information on other eHealth projects EPF participated in please see: <http://www.eu-patient.eu/whatwedo/Projects/>

<sup>8</sup> A three-year project co-funded under the Competitiveness and Innovation Programme of the European Commission. <http://www.sustainsproject.eu/>

<sup>9</sup> The project was funded under the Competitiveness and Innovation Framework Programme (CIP). <http://www.renewinghealth.e>

<sup>10</sup> More information: <http://www.pilotsmartcare.eu/home.html> and <http://www.calliope-network.eu/>

## 2. Patient-centred eHealth

Patient-centeredness is increasingly recognised as a core component of high quality care. In addition, patient-centred care models have been shown to be cost-effective as well as to increase patient satisfaction and often clinical outcomes. Patients with chronic and long term conditions develop specific needs compared to the general population. An increasing number of patients also have multiple conditions.

One important element to take into account in the development of eHealth services is that care should be centred around the patient, not the disease. eHealth has the potential to bring care closer to patients' lives, and to ensure an improved coordination of patients' care through better exchange of information and data between healthcare professionals.

There are specific challenges for the implementation of patient-centred healthcare in eHealth. One example is telehealth: through the survey carried out with patients for the Chain of Trust project, trust was identified as a key enabler for (and lack of trust a key barrier against) uptake of eHealth services. Patients and healthcare professionals pointed out that telehealth is all too often driven by manufacturers and technology, not by the need of users. One of the recommendations of the report is to ensure that service developers and health organisations assess user requirements when designing, adopting or evaluating telehealth services.<sup>11</sup>

eHealth services can contribute to a shift in healthcare from disease-centred to patient-centred if they:

- help healthcare professionals maintain a closer eye on the health status of the patient and facilitate chronic disease management
- contribute to the sustainability and improvement of patient-healthcare professional relationships and do not replace direct patient-health professional contact
- are designed around the needs of the patient, are accessible, and user friendly
- help improve adherence to treatment and life-styles and enables concordance<sup>12</sup>
- facilitate/are accompanied by patient empowerment strategies.

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<sup>11</sup> Chain of Trust final report: main findings and recommendations <http://www.eu-patient.eu/globalassets/projects/chainoftrust/epf-report-web.pdf>

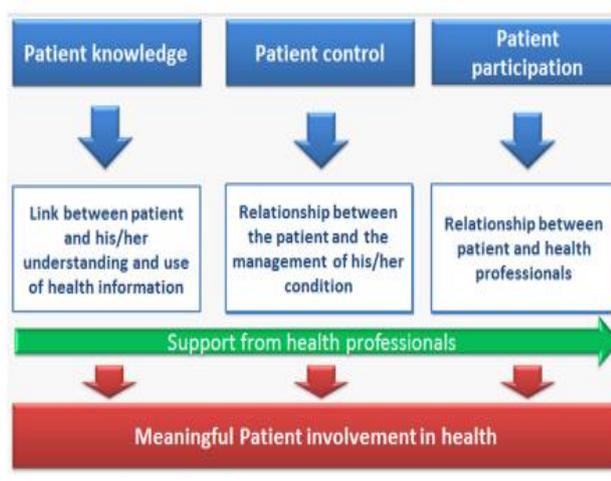
<sup>12</sup> <http://www.eu-patient.eu/whatwedo/Policy/Adherence-to-therapies-Compliance-Concordance/>

## 2.1 PATIENT EMPOWERMENT AND EHEALTH

EPF defines patient empowerment as “a multi-dimensional process that helps people gain control over their own lives and increases their capacity to act on issues that they themselves define as important.” Collective empowerment is “a process through which individuals and communities are able to express their needs, present their concerns, devise strategies for involvement in decision-making, and take political, social, and cultural action to meet those needs.”<sup>13</sup>

The Sustains project, which focused on patients’ access to electronic health records, developed a model for patient empowerment (see figure).

The Chain of Trust project also showed that 92% of patients who participated to the survey are willing to play a more active role in managing their own condition, but only 48% thought they were ready to handle the additional responsibilities presented by eHealth.<sup>14</sup>



Patient empowerment is both a precondition for the large scale implementation of eHealth and a potential outcome for eHealth. Patients need the necessary skills to access and use eHealth services.

All eHealth services entail some degree of responsibility shift from health professionals to patients. Giving patients more responsibility for their own care does not necessarily mean “empowering” them if they are not provided with adequate support.

eHealth services must be implemented in a way that is respectful of patients’ choices, capacity, and willingness to participate in shared decision making.

<sup>13</sup> For more information see EPF’s briefing on patient empowerment: [http://www.eu-patient.eu/globalassets/campaign-patient-empowerment/briefing\\_paperpatient-empowerment\\_final\\_external.pdf](http://www.eu-patient.eu/globalassets/campaign-patient-empowerment/briefing_paperpatient-empowerment_final_external.pdf)

<sup>14</sup> Chain of Trust final report: main findings and recommendations <http://www.eu-patient.eu/globalassets/projects/chainoftrust/epf-report-web.pdf>

To support patient empowerment, 3 components are needed:

- Healthcare professionals with the right skills to communicate with patients, to educate them and that welcome patients' participation,
- Health literacy, which is "The ability to make sound health decisions in the context of everyday life – at home, in the community, at the workplace, the healthcare system, the market place and the political arena."<sup>15</sup>, and digital health literacy,
- An enabling healthcare environment.

### 2.1.1 HEALTH LITERACY AND INFORMATION

Digital health literacy or eHealth literacy sets challenges. Though an increasing number of people in the EU use internet to find information about health<sup>16</sup>, digital health literacy is a wider concept that also encompasses the skills necessary to use eHealth tools.

There are various barriers to digital health literacy. A survey carried out as part of the Chain of Trust project showed that while patients who had used telehealth in the past thought it was easy to use, 32 % of the non-users of telehealth only believed it is easy to use, which could indicate a lack of confidence in their own knowledge and skills required for using telehealth.

Additionally, many healthcare professionals who participated in the survey had doubts regarding the ability of their patients to use telehealth.<sup>17</sup> Incentivizing professionals to use eHealth tools is a key challenge, for example for electronic health records or other means to share patients' health information more effectively with the healthcare team.

There are also particular challenges for specific groups of patients. (e)Health literacy of patients varies according to certain factors, including the local situation (eHealth is not developing evenly across the EU), financial stability, educational status, and family and social support of the patient. (e)Health literacy of older patients is of particular concern. Many older people are now using the Internet for different aspects of their lives, but some of them cannot or do not access the Internet<sup>18</sup>: this can be due to low income, lower education, or failing to understand the opportunity. This can be exacerbated by complicated

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<sup>15</sup> Kickbush and al, cited in <http://www.eu-patient.eu/globalassets/campaign-patient-empowerment/epf-briefing-paper--patient-empowerment.pdf>

<sup>16</sup> [http://ec.europa.eu/public\\_opinion/flash/fl\\_404\\_en.pdf](http://ec.europa.eu/public_opinion/flash/fl_404_en.pdf)

<sup>17</sup> <http://www.eu-patient.eu/globalassets/projects/chainoftrust/epf-report-web.pdf>

<sup>18</sup> According to Eurostat "one third (38 %) of the elderly population — defined here as those aged 65–74 — in the EU-28 used the internet on a regular basis, in other words at least once a week."

[http://ec.europa.eu/eurostat/statistics-explained/index.php/People\\_in\\_the\\_EU\\_%E2%80%93\\_statistics\\_on\\_an\\_ageing\\_society](http://ec.europa.eu/eurostat/statistics-explained/index.php/People_in_the_EU_%E2%80%93_statistics_on_an_ageing_society)

medical conditions and/or disability. There needs to be a better understanding of older people's situations, and of the common issues regarding the use of information technology.<sup>19</sup> Paradoxically, older patients have a strong need for more integrated care.<sup>20</sup> According to the CHRODIS project, 4 out of 5 people over 65 suffer from at least one chronic disease like diabetes or cardiovascular disease. 65% of this age group suffers from multimorbidity, i.e. two or more chronic diseases. This number rises to 85% for the 85-year-old group.<sup>21</sup>

On the other hand, the digital environment also has the potential to make health information much more accessible than before. For example, adolescence and early adulthood are a high-risk period for developing a mental illness, therefore mHealth apps have the potential to fill the lack of information and reach young people, who tend to use mobile apps daily. Such access to information can be important for example to encourage early intervention. The development of digital tools can also allow patients to network and seek support from their peers.

The Chain of Trust project also indicated that health professionals that had received training on telehealth had more positive views on the usability of eHealth services and the possibility to integrate them into care.<sup>22</sup>

Whether eHealth services will ultimately be adopted on a large scale is going to depend on users, including patients' perceptions of real benefits and interest in using them. Trust and user acceptance are important cornerstones for eHealth. Enhancing "eHealth literacy" of patients and carers is a key requirement for the acceptance and confident use of ICT-based tools.

For patients, adopting eHealth services in general will depend on: ensuring useful and quality services as well as how easy it is to find information about eHealth services or mHealth apps. In addition, using eHealth services may entail new responsibilities for the patient. Training and information for patients needs to become a more important focus in eHealth strategies.

Currently, patient organisations report that it is challenging to find quality information about reliable apps or eHealth services. However, there are some good practices in this area, for

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<sup>19</sup> [http://www.eu-patient.eu/globalassets/events/2011\\_rights\\_needs\\_older\\_patients/epf-fpp\\_warsaw\\_conference\\_report.pdf](http://www.eu-patient.eu/globalassets/events/2011_rights_needs_older_patients/epf-fpp_warsaw_conference_report.pdf)

<sup>20</sup> [http://www.eu-patient.eu/globalassets/policy/ageing/epf\\_position-paper\\_older-patients\\_jan14.pdf](http://www.eu-patient.eu/globalassets/policy/ageing/epf_position-paper_older-patients_jan14.pdf)

<sup>21</sup> [http://eurohealthnet.eu/media/chronic-diseases-and-healthy-ageing-experts-are-joining-forces-madrid#\\_ftn1](http://eurohealthnet.eu/media/chronic-diseases-and-healthy-ageing-experts-are-joining-forces-madrid#_ftn1)

<sup>22</sup> <http://www.eu-patient.eu/globalassets/projects/chainoftrust/epf-report-web.pdf>

example the NHS launched an app library which comprises free apps that were reviewed and recommended according to specific criteria.<sup>23</sup>

### 2.1.2 SELF MANAGEMENT

Self-management is a key element of patient centred healthcare: in chronic and long term conditions, the management of the condition is mostly handled by the patient at home and in the community. In EPF's perspective self-management implies a partnership between the patients and the healthcare team which support patients in living with their condition.<sup>24</sup>

The tender study EMPATHiE explored patients' and stakeholders' perception of eHealth and patient empowerment through a scenario whereby eHealth would be part of mainstream healthcare and European cooperation would focus on developing ICT resources for patients and professionals to support patient empowerment through self-management.<sup>25</sup> A survey carried out as part of the study with various health stakeholders including patients indicated that over half of the respondents think such a cooperation would be at least somewhat effective in supporting patient empowerment. Some respondents indicated that while technology can be an element contributing to patient empowerment and self-management, it should not lead to the conclusion that technology alone can lead to patient empowerment and self-management.

The study identified that eHealth (including mHealth) services have the potential to support patients' self-management.

In EPF's position paper on adherence to treatment, patients also highlighted that technology can provide self-management support and motivation to patients and carers; patients can, for example, monitor their condition at home through wearable technology, and add information from their own observations to their shared electronic health record. Electronic health records can allow patients to have access to information usually only available to their healthcare team.<sup>26</sup> The paper provides some examples of good practices including:

- "My Diabetes My Way" information portal for diabetes (NHS Scotland) contains educational materials, videos and interactive tools supporting education and self-management; it allows patients direct access to their data via a novel electronic personal health record.<sup>27</sup>

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<sup>23</sup> <http://www.nhs.uk/tools/pages/toolslibrary.aspx>

<sup>24</sup> For more information on self-management please see: [http://www.eu-patient.eu/globalassets/campaign-patient-empowerment/briefing\\_paperpatient-empowerment\\_final\\_external.pdf](http://www.eu-patient.eu/globalassets/campaign-patient-empowerment/briefing_paperpatient-empowerment_final_external.pdf) p9-10

<sup>25</sup> See EMPATHiE final summary report 2015 <http://www.eu-patient.eu/whatwedo/Projects/EMPATHiE/>

<sup>26</sup> For more details, please see: [http://www.eu-patient.eu/globalassets/policy/adherence-compliance-concordance/adherence-paper-final-rev\\_external.pdf](http://www.eu-patient.eu/globalassets/policy/adherence-compliance-concordance/adherence-paper-final-rev_external.pdf) p14-15

<sup>27</sup> <http://www.mydiabetesmyway.scot.nhs.uk/>

- PatientView, allows British patients with certain conditions to access their healthcare records, including information about diagnosis and treatments.<sup>28</sup>

However, providing patients with access to information traditionally available only to healthcare professionals is not empowering on its own. To ensure that eHealth supports self-management and adherence, patients need to be involved, and their needs should be at the centre when developing ICT tools.

## 2.2 PATIENT INVOLVEMENT IN EHEALTH

Meaningful patient involvement in the development, implementation, and evaluation of eHealth services is an essential condition that needs to be met to achieve more patient - centred eHealth services. This requires more than carrying out a patient satisfaction survey once the service is deployed. In our project Value +, we had defined meaningful patient involvement as *“patients take an active role in activities or decisions that will have consequences for the patient community, because of their specific knowledge and relevant experience as patients. The involvement must be planned, appropriately resourced, carried out, and evaluated.”*<sup>29</sup>

Yet too often, users are not involved or only minimally involved.<sup>30</sup> This model of innovation is unsustainable, as it can result in waste of healthcare resources and can hamper the uptake of eHealth services by patients. The unique value of the patients’ perspective is still too often ignored. One recent example of this is the Joint Action on eHealth, which did not commit to meaningfully involve a patient organisation to bring the patients’ perspective into this EU wide cooperation.

Patients’ organisations often report that mobile health apps are frequently developed without an adequate needs assessment, without involvement of patient organisations, and are often of limited use to patients. For patients, it is a key principle that apps should be made to meet a demand. Apps are usually installed by patients when they will be used regularly.

In some instances, family carers can also play a key role in the coordination of patients’ care, and can be a key way to reach out to the patients. Therefore, family carer’s involvement in the development of eHealth services is also important and they should also be recognized as a key source of information on patients’ needs.

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<sup>28</sup> <https://www.patientview.org/#/>

<sup>29</sup> [http://www.eu-patient.eu/globalassets/projects/valueplus/doc\\_epf\\_policyrec.pdf](http://www.eu-patient.eu/globalassets/projects/valueplus/doc_epf_policyrec.pdf)

<sup>30</sup> This lack of involvement is notably highlighted in the eHealth Stakeholder group report on health inequalities: [http://ec.europa.eu/newsroom/dae/document.cfm?doc\\_id=5170](http://ec.europa.eu/newsroom/dae/document.cfm?doc_id=5170)

Examples of patient organisations involved in the development of an eHealth service include:

The European Federation of Allergies and Airways Diseases' Patient Associations (EFA) is a partner in the EU project "myAirCoach" which aims to support asthma patients to control their disease through mHealth. Within the project EFA established an Advisory Patient Forum, which is formed by 22 asthma patients that are volunteer and give up their time in order to make sure that the system under development will address their needs.<sup>31</sup>

The organisation Dystonia Europe developed the MyDystonia app for patients. MyDystonia is an electronic diary created for people with the neurological disease Dystonia. By answering predefined questions (e.g. symptoms like overactive muscles or pain and impact on daily living) the user is able to examine and to visualise his/her well-being according to the treatment schedule.

MyDystonia gives the physician a reliable overview ahead of the consultation, helping to save time. It also helps the patient keep track of their symptoms and how effective their treatment is. This has led to improved communication and treatment outcomes.

The App was initiated, designed and developed by patients for patients. Dystonia Europe has the 100% ownership of the project, the database includes collected data from users of the MyDystonia diary. The app is currently being rolled out in 10 countries.<sup>32</sup>

## 2.3 THE HUMAN AND COMMUNITY DIMENSIONS

The human dimension is key for eHealth. The Chain of Trust project showed that the issue of human interaction and its effect on the patient/healthcare professional relationship is often side-lined, while it is actually an important factor to building trust in eHealth.

Another important aspect that was highlighted by the Renewing Health project is that intrusiveness can be an obstacle for patients. While patients can perceive the benefit of using telehealth at home, they wouldn't want, for example, to have to change their routine because of tele home care duties. Thus it is important to design and test such services not only in a laboratory, but also at home in order to ensure it blends into the patients' environment.

Another dimension to take into account when deploying eHealth is the role of the community. eHealth needs to be adapted to the needs of different communities of patients, and deployment needs to take into account the community setting to be successful. For

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<sup>31</sup> <http://myaircoach.eu/myaircoach/>

<sup>32</sup> <http://www.mydystonia.com/index.php/App/index>

example, the eHealth stakeholder group highlighted that community institutions such as libraries have an important role to play in digital inclusion in some regions.<sup>33</sup>

Neglecting the human element is often highlighted as an important failure in the implementation of eHealth services.<sup>34</sup>

### Recommendations

We call on the EU to:

1. Set user involvement (including patients, family carers, healthcare professionals) as a criterion for EU projects related to ICT in Health;
2. Encourage research to set a model for meaningful patient involvement in eHealth services, from the design stage through to the final evaluation;
3. Put in place an EU patient empowerment strategy encompassing health literacy, including digital health literacy (see EPF campaign PatientsPrescribE)<sup>35</sup>;
4. Investigate further and address meaningfully with the users (including patients and healthcare professionals) the issues around user acceptance and awareness of eHealth services
5. Develop EU guidelines for developers of eHealth services on user requirements in eHealth (for example through the eHealth stakeholder group), and ensure mechanisms are in place to monitor implementation of such guidelines.
6. Set a clearer assessment at EU level of whether eHealth/ mHealth tools are medical devices or not, and provide a clear framework for well-being eHealth services that do not qualify as medical devices.
7. Develop a certification system at EU level for mHealth apps.

## 3. EHealth and patients' data

Undue disclosure of medical information can have very negative consequences for patients, whether at work or in other areas of their life. Stigma is still attached to some medical conditions in various EU countries.

In some countries, discrimination on the grounds of a health condition have been reported by patients, including discrimination and stigma coming from healthcare professionals. To build the necessary trust for eHealth to be taken up, healthcare systems need to tackle these forms of discrimination and ensure patients' rights to protection of personal data are applied.

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<sup>33</sup> eHealth Stakeholder Group "Health inequalities and eHealth" (report) February 2014, p16, <http://ec.europa.eu/digital-agenda/en/news/commission-publishes-four-reports-ehealth-stakeholder-group>

<sup>34</sup> <https://www1.imperial.ac.uk/resources/32956FFC-BD76-47B7-94D2-FFAC56979B74/>, p7

<sup>35</sup> <http://www.eu-patient.eu/campaign/PatientsprescribE/>

Patients' personal health and genetic data are protected under the General Data Protection Regulation, which is currently in the process of being adopted. This legislation gives a number of rights to patients including: the right to have information regarding the collection and use of their data, the right to access said data, to receive a copy of the data ("data portability"), to object to the processing of data, and the right to be forgotten.

The data protection rules also set key criteria for patients' consent to which eHealth service providers are subject. In principle, patients' consent is required to collect and use patients' data, except if it is part of the provision of care. Consent has to be informed, specific, freely given, and unambiguous. When consent for several matters is asked, consent for processing of data has to be presented clearly and separately from other issues.

Another issue is the secondary use of data collected originally through eHealth. Data contained in electronic health records or other platforms is increasingly used for other purposes than the original one. Once the new data protection regulation enters into force, patients will need to provide informed and specific consent to allow eHealth services to process their data, however there are some exceptions for health research or public health purposes.<sup>36</sup>

Some patient groups report that there is a mismatch between the amount of data required from patients for the use of mHealth apps, and the data that is truly needed for the running of the app.<sup>37</sup>

#### **Recommendations:**

1. EPF calls on the EU to monitor closely the application of the data protection regulation in the area of eHealth;
2. EPF recommends that eHealth service developers should consult patients to ensure they understand patients' privacy concerns and needs and to ascertain that information they provide, including for consent, is easy to understand and corresponds to patients' needs, in compliance with the Data Protection Regulation requirements for consent.
3. EPF recommends the application and monitoring of implementation of the mHealth assessment guidelines developed by a multistakeholder expert group including a patient organisation.<sup>38</sup>

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<sup>36</sup> <http://www.eu-patient.eu/globalassets/policy/data-protection/data-protection-guide-for-patients-organisations.pdf>

<sup>37</sup> Collectif Interassociatif de la santé (CISS) "Note de position commune sur le numérique en santé - Septembre 2016.", p 34

<sup>38</sup> The guidelines are foreseen to be available by end of 2016: <https://ec.europa.eu/digital-single-market/en/news/open-stakeholder-meeting-mhealth-assessment-guidelines-presentations-and-survey>

## 4. EHealth and access to healthcare

The potential of eHealth to reduce health inequalities and improve patients' access to healthcare is well recognized. eHealth is often mentioned as a solution in moving towards sustainable healthcare systems, because it can be part of the response to healthcare professional shortages.<sup>39</sup> Yet eHealth could also become a factor for health inequalities, if not supported adequately by policies that aim to make eHealth part of a strategy to tackle access barriers.

### 4.1 EQUITABLE ACCESS TO EHEALTH

The report on health inequalities from the eHealth stakeholder groups underlines that eHealth services can deepen existing health inequalities based on socio-economic status or for already affected minorities. In addition, it also creates a new divide.<sup>40</sup> Inequalities of access to internet and technology affect ability to access eHealth, though this will not ensure alone that patients can truly make proficient use of eHealth services. Regional inequalities also affect access to eHealth, for both the patients and for healthcare providers. There is also unequal infrastructure available to roll out eHealth in the EU, for example in some regions access to internet is still a challenge.

For patients living in remote or rural areas, some preliminary studies have shown that eHealth can increase access to services across a range of medical specialties without any detrimental effects.<sup>41</sup> However, the regional differences in deployment of ICT can be an obstacle to this.

eHealth has potential for people with mobility difficulties, and with disabilities, though this is sometimes hindered by the fact that ICT tools are not very accessible.

The European Federation of National Organisations Working with the Homeless (FEANTSA) also highlighted that mHealth has the potential to support homeless patients with some of the challenges that they face in engaging with healthcare services, or in medication adherence for example.<sup>42</sup>

Apps can potentially raise the same issues of health inequalities as other eHealth technologies, as they require a smartphone, or may be subject to a fee. However, they also have the potential to reduce health inequalities as they can help reach specific populations of patients, like young patients or men that are more attracted towards new technologies.

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<sup>39</sup> COM(2012) 736 final, eHealth Action Plan 2012-2020 – Innovative healthcare for the 21st century

<sup>40</sup> eHealth Stakeholder Group "Health inequalities and eHealth" (report) February 2014, p16, <http://ec.europa.eu/digital-agenda/en/news/commission-publishes-four-reports-ehealth-stakeholder-group>

<sup>41</sup> <http://www.ncbi.nlm.nih.gov/pubmed/25303412>

<sup>42</sup> [http://www.feantsa.org/spip.php?action=acceder\\_document&arg=2138&cle=5357a31bfff17912c02d03de367787b4e57aed15&file=pdf%2Ffeantsa\\_mhealth\\_policypaper.pdf](http://www.feantsa.org/spip.php?action=acceder_document&arg=2138&cle=5357a31bfff17912c02d03de367787b4e57aed15&file=pdf%2Ffeantsa_mhealth_policypaper.pdf)

eHealth service developers tend to wrongfully perceive their users as homogeneous.<sup>43</sup> Inclusion of various underserved or vulnerable groups needs to be part of eHealth policy to ensure services don't reinforce current inequalities. In addition, as noted by the Inter-Association Collective on Health (CISS) in their position paper on eHealth, people have different needs and capabilities, depending on various factors such as "their level of social inclusion, their personal resources, the place that health occupies in their own value scales, the severity of their illness, and the intensity of their personal involvement in managing their live with an illness."<sup>44</sup>

Due to their role in the care of older patients, it is essential to include family carers in training and ensure the right legislation is in place to provide them with rights in eHealth. For patients who are not able to provide consent themselves, ensuring the carer can provide this as next of kin is essential.

For patients, affordability is a key dimension of access to healthcare services. It depends on the financing of healthcare services, pricing and the reimbursement decision, and whether patients are asked to contribute out of pocket. There is a lack of a reimbursement model for effective eHealth services in the EU, which could result in eHealth contributing to a "two speed" delivery of healthcare rather than reducing health inequalities. This lack of reimbursement or inclusion in the basket of care is perceived by the patient community to be a consequence of the lack of evaluation of eHealth services.

## 4.2 CROSS-BORDER HEALTHCARE

eHealth has an important role to play in cross-border healthcare and in ensuring continuity of care for patients. EU citizens are increasingly mobile; yet regional or national borders can be obstacles to continuity of care. Therefore, more actions in this area are needed to ensure patients' data are easily portable and transferable.

National health systems must work together to ensure smooth and timely sharing of information. These systems need to be interoperable in order to share patient records and medical information, exchange e-prescriptions, or provide e-consultations. The Directive 2011/24/EU established a voluntary eHealth network comprising authorities responsible for eHealth in Member States to work towards enhancing the continuity, safety, and high quality of healthcare. However, it doesn't include stakeholder representation. The network delivered guidelines on minimum dataset for ePrescriptions and for patient summaries.<sup>45</sup>

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<sup>43</sup> eHealth Stakeholder Group "Health inequalities and eHealth" (report) February 2014, p16, <http://ec.europa.eu/digital-agenda/en/news/commission-publishes-four-reports-ehealth-stakeholder-group>

<sup>44</sup> Translated from Collectif Interassociatif de la santé (CISS) "Note de position commune sur le numérique en santé - Septembre 2016.", p 4 [http://leciss.org/sites/default/files/160912\\_Note-Ciss-E-sante-Bon-Usage.pdf](http://leciss.org/sites/default/files/160912_Note-Ciss-E-sante-Bon-Usage.pdf)

<sup>45</sup> [http://ec.europa.eu/health/ehealth/key\\_documents/index\\_en.htm](http://ec.europa.eu/health/ehealth/key_documents/index_en.htm)

### 4.3 SUSTAINABILITY OF HEALTHCARE SYSTEMS

In the eHealth action plan, eHealth is identified as a sector with important growth potential and is also perceived as part of the solution for the sustainability of healthcare systems. According to the action plan, benefits have been demonstrated when it comes to managing chronic conditions according to the action plan. The study “eHealth is worth it” shows several case examples of successful eHealth projects and their economic impact as well as clinical and safety benefits.<sup>46</sup>

However, better quality evidence is needed to demonstrate costs and benefits of eHealth in order to enable decision makers to choose the most effective and sustainable strategies for eHealth systems’ development and implementation to ultimately maximize eHealth’s beneficial impact on health systems’ performance.

For example, it was reported that major investment in eHealth rarely includes the adequate focus on evaluation and the evidence of the impact of eHealth remains insufficient.<sup>47</sup>

The Renewing Health project also highlighted that the cost of treating patients with telemedicine is higher than conventional care. On average, the studies find that the cost per patient using telemedicine is 20% higher than the cost per patient in the control group. However, this project was a pilot and was not run over a sufficient period of time to determine the long-term cost or savings.

eHealth may require an important initial investment, and it is essential that later savings offset this initial investment.

Interoperability is a key challenge to ensure eHealth services are sustainable, and to avoid waste both for patients and health services, like duplication of tests or information silos that are obstacles to the safety, quality, and continuity of care. The Calliope project developed an eHealth interoperability roadmap.<sup>48</sup> The EU has a particular role to play for interoperability as it requires common standards and legislations, as well as coordination of resources and common priorities.

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<sup>46</sup> <http://www.ehealth-impact.org/download/documents/ehealthimpactsept2006.pdf>

<sup>47</sup> Call to Action on Global eHealth Evaluation, Consensus Statement of the WHO Global eHealth Evaluation Meeting, Bellagio, September 2011 <http://www.ghdonline.org/search?q=Bellagio>

<sup>48</sup> CALLIOPE “EU Health Interoperability Roadmap” December 2010 [http://www.ehgi.eu/Download/European%20eHealth%20Interoperability%20Roadmap%20\[CALLIOPE%20-%20published%20by%20DG%20INFSO\].pdf](http://www.ehgi.eu/Download/European%20eHealth%20Interoperability%20Roadmap%20[CALLIOPE%20-%20published%20by%20DG%20INFSO].pdf)

### Recommendations

1. eHealth need to be integrated as part of national and European strategies to tackle health inequalities. Its deployment need to occur based on needs, not means;
2. The eHealth network created by directive 2011/24/EU should involve patients and healthcare professionals and take into account their needs when setting the work program of the network. All member states should participate in order to ensure that the potential of eHealth is harnessed for the benefits of EU patients, and to enable optimal continuity of care;
3. More research is needed on financing and reimbursement models for effective eHealth services for patient safety and quality of care;
4. The EU needs to develop an assessment framework for eHealth and/or look at the possibility to adapt health technology assessment for eHealth services;
5. The EU should take on a leading role in promoting development of appropriate interoperability of eHealth services across regions and countries.
6. The EU should have a supporting role in ensuring the development of appropriate infrastructure for eHealth in Member States and particularly in rural areas.

## 5. Safety and quality of eHealth services

For patients, the safety and quality of eHealth services is an important concern. eHealth services need to be as safe and offer comparable quality to conventional services. In addition, eHealth needs to demonstrate added value for the patients in terms of health outcomes and/or quality of life.

### 5.1 EU LEGISLATION

The safety and quality of eHealth services (including software) with a medical purpose is currently regulated by the EU medical devices directives until the new Regulation on medical devices will apply. This sets a number of obligations for developers of eHealth services:

- They must ensure their device functions according to the intended purpose;
- They must perform a clinical evaluation prior to obtaining the right to put their device on the market, which can take the form of a clinical investigation or study;
- They have obligations to keep track and respond to incidents that occur with their devices.

## 5.2 IS EHEALTH SAFE AND EFFICIENT?

Evidence collected with the Renewing Health project showed that proposed telehealth services were at least as safe as conventional care.<sup>49</sup> However, the project did not demonstrate additional benefits for clinical effectiveness of pilot services in comparison with conventional care.

There is some evidence that eHealth services have the potential to contribute to patient safety. For example, electronic health records can ensure that there is more comprehensive information available on the patient.<sup>50</sup>

A report by the Imperial College of London reviewing available literature indicated that there is limited rigorous evidence demonstrating that eHealth improves safety and quality of care.<sup>51</sup> Various factors are cited by the report as to why evidence is lacking: the evidence available is of variable quality, lacks focus on the human factors and need of end-users, and that, very often, developers evaluate the benefits of their technologies themselves (potential conflict of interest).

## 5.3 SAFETY AND QUALITY OF APPS

Mobile health comprises medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants, and other wireless devices.<sup>52</sup>

There are various types of use for mHealth devices:

- technologies to measure vital signs heart rate, blood glucose level, blood pressure, body temperature and brain activities;
- communication, information and motivation tools (medication reminder/ dietary advice);
- personal guidance systems.

Some mHealth apps and devices are aimed at patients, but others are aimed at healthcare professionals and the wider public.

Wellbeing apps for the wider public can be a particular challenge because they are not regulated by EU law and the validity of the information they provide or their safety and quality is not monitored. In addition, determining whether a mHealth app is a medical device can be a particular challenge and only non-legally binding guidelines exist to clarify the medical devices legislation.

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<sup>49</sup> <http://www.renewinghealth.eu/>

<sup>50</sup> <https://www1.imperial.ac.uk/resources/32956FFC-BD76-47B7-94D2-FFAC56979B74/>, pp 373-380

<sup>51</sup> <https://www1.imperial.ac.uk/resources/32956FFC-BD76-47B7-94D2-FFAC56979B74/>, pp 373-380

<sup>52</sup> World Health Organisation “mHealth – New horizons for health through mobile technologies, Global Observatory for eHealth series – Volume 3”, page 6

As highlighted by our member, the European Federation of Allergy and Airways Diseases Patients' Associations (EFA), "in the field of chronic disease, a low quality app could make you think you are doing fine in controlling your disease and this might lead to underestimation of symptoms".

### Recommendations

1. A framework for the evaluation of the impact of eHealth services on safety and quality of care need to be developed with the involvement of stakeholders, including patients;
2. eHealth pilot projects should be highly encouraged to evaluate impact on patient safety and quality of care, whether they are financed privately or with public funding at EU or national level. This evaluation needs to take into account patient relevant outcomes as well as clinical outcomes.

## 6. Electronic health records

Electronic health records (EHR) are "A comprehensive medical record or similar documentation of the past and present physical and mental state of health of an individual in electronic form and providing for ready availability of these data for medical treatment and other closely related purposes"<sup>53</sup>.

EHR can provide important benefits for patients: it can improve exchange of information between their healthcare professionals, save time for more interaction, and improve integration of care. If EHR are accessible to patients, it can also contribute to patient empowerment and involvement in their care and shared decision making.

However, EHR is deployed unevenly across the EU. While it became the norm in some countries such as Denmark, in other countries it is only at the stage of pilot projects. Deployment is not always successful, as several projects have been delayed or interrupted in countries such as France or the UK.

EPF gained knowledge about user requirements and challenges in this area for electronic health records through the Sustains project, which made key recommendations in this area.<sup>54</sup>

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<sup>53</sup> [http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2007/wp131\\_en.pdf](http://ec.europa.eu/justice/data-protection/article-29/documentation/opinion-recommendation/files/2007/wp131_en.pdf)

<sup>54</sup> [http://www.eu-patient.eu/globalassets/projects/sustains/sustains\\_user-requirement-recommendations.pdf](http://www.eu-patient.eu/globalassets/projects/sustains/sustains_user-requirement-recommendations.pdf)

## 6.1 INFORMED CONSENT

A recent study comparing electronic health records in the EU shows that many Member States do not require informed consent of the patient to establish an electronic health record, or for the sharing of the record with other healthcare professionals.<sup>55</sup>

## 6.2 OWNERSHIP OF INFORMATION

Ownership of the information in the EHR is an important question. This information is personal data of the patients and as such, it grants them rights under the data protection legislation (see section 3). However healthcare providers input the data and provide their medical knowledge.

## 6.3 WHO CAN HAVE ACCESS AND INPUT IN THE RECORD?

Privacy is a key concern when it comes to keeping patients' health (including potentially genetic) data in electronic format. It is important to define who can have access to the record to avoid breaches and undue disclosure and to maintain trust. But restrictive access can also hinder patients' care: it can often be restricted to certain professions (medical doctors). Pharmacists do not always have access or the right to input in the EHR but granting them access could have benefits (monitoring issues around medicines' interaction etc.).

Another important question is patients' access to their own electronic health records. Often, they have the right to access their own record, but there may be other obstacles, for example if they can only get access through a healthcare professional, or if they do not have internet access and no other means to access it. Patients do not always have the right to download the data. In addition, medical language can be an issue.

Patients are rarely granted the right to modify or input their electronic health records, due to liability issues and because ensuring the correctness of the data could be an issue if they erase important information. However, solutions exist to allow patients to input comments, or provide a space for patients to make their own notes and remarks.

For some patients, e.g. people with dementia or children, an informal or family carer may need access to provide support to the patient.

## 6.4 MASKING OR WITHOLDING DATA

Patients may have the possibility to mask some sensitive data from their electronic health records.<sup>56</sup> It is essential to discuss the modalities (what information can be masked or cannot for safety reasons, should healthcare professionals be notified that some information

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<sup>55</sup> [http://ec.europa.eu/health/ehealth/docs/laws\\_report\\_recommendations\\_en.pdf](http://ec.europa.eu/health/ehealth/docs/laws_report_recommendations_en.pdf)

<sup>56</sup> [http://ec.europa.eu/health/ehealth/docs/laws\\_report\\_recommendations\\_en.pdf](http://ec.europa.eu/health/ehealth/docs/laws_report_recommendations_en.pdf)

has been masked, etc.) that need to be decided with the involvement of appropriate stakeholders including patients and healthcare professionals.

Similarly, health professionals may have the right to withhold certain medical information from patients. EPF believes this is justified in some situations, for example in order to ensure the patients' diagnosis is delivered face to face. However, the rules should also be set with appropriate involvement of both patients and healthcare professionals to ensure provisions that allow withholding information are not used unduly.

## 6.5 WHAT INFORMATION NEEDS TO BE IN THE RECORD?

A recent study comparing electronic health records laws in EU Member States showed that there are differences in the amount and type of data required. A minimum dataset is not always required. Ensuring quality data is collected is essential to ensure the safety and quality of care of patients. Format of the data and interoperability are two key issues that need to be addressed. From the patients' perspective, it is important to remove technical barriers to the sharing of the data (while ensuring security). In addition, some common terminologies have been developed, such as SNOMED<sup>57</sup>.

### Recommendations

1. The EU should play a more important role in tackling interoperability issues, developing and encouraging the uptake of common standards for electronic health records;
2. Common ethical guidelines and principles should be set up at EU level with the involvement of appropriate stakeholders, including patients' organisations for various aspects of the development and management of electronic health records.
3. More research is needed in order to better understand and implement user requirements at EU and national level.

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<sup>57</sup> <http://www.ihtsdo.org/snomed-ct>

## 7. Conclusions

While eHealth holds many promises for EU patients and healthcare systems, EPF calls on the EU institutions and Member States to foster patient-centred development of eHealth, with equity of access, patient safety, and quality of care as key pillars.

## 8. Glossary

Terms often used when discussing eHealth are telehealth, telemedicine, and mobile health.

Telemedicine refers to the delivery of healthcare at a distance, using information and telecommunications technology and specially-adapted equipment. It allows health professionals to diagnose, treat, care, assess, and monitor patients without requiring both individuals to be physically in the same location.

Telehealth includes surveillance, health promotion, and public health functions. It is broader in definition than telemedicine as it includes computer-assisted telecommunications to support management, surveillance, literature, and access to medical knowledge.

Mobile health (hereafter “mHealth”) covers “medical and public health practice supported by mobile devices, such as mobile phones, patient monitoring devices, personal digital assistants (PDAs), and other wireless devices”.



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