Europe, we have a problem! Challenges to health data-sharing in the EU

2022 18th International Conference on Wireless and Mobile Computing, Networking and Communications (WiMob) | 978-1-6654-6975-3/22/$31.00 ©2022 IEEE | DOI: 10.1109/WIMOB55322.2022.9941532

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***Abstract*— E-medical documentation is becoming an increasingly important tool that the European Commission recognizes and puts on the policy agenda, and it is expected to be created in the next few years. The main objectives of the EU Health Data Space Framework are to make the health sector more efficient and to advance scientific research in telehealth. One major hurdle is the way to ensure that it is used for the common good, but in the opinion of health professionals, this requires proper consideration of trust, ethics, and safety. For example, e-prescription will be a useful tool, but there are open questions about reimbursing cross-border costs. The potential danger and risks are that the use of eHealth data will affect the general rights of patients, especially the right to privacy and confidentiality under the European Charter of Patients' Rights and the General Data Protection Regulation. We are faced with the fact that not all countries have a national contact point for cross-border healthcare and the Regulation on Electronic Identification, Authentication and Trust Services (eIDAS). This ensures secure access to health data where patients should see who has visited their data in the hospital system or other health platforms, and in addition, may deny access to third parties. It remains challenging to receive reports from several EU countries to the Ombudsman for patients who can make visible data only to themselves through ID-certified health portals, but despite this, the hospital does not have this data and continues to use all the data.**

Keywords*— *European Health Data Space, GDPR, eHealth, eIDAS, Patient rights

I. Introduction

Digitalization is essential for the future of healthcare in the European Health Union. E- medical records are becoming an increasingly important tool and recognized by the European Commission and putting on the policy agenda, with a data space for health expected to be created at the EU level over the next few years [1].

The eHealth Digital Service Infrastructure [eHDSI] is an infrastructure ensuring the continuity of care for European citizens while they are traveling abroad in the EU. This gives EU countries the possibility to exchange health data in a secure, efficient, and interoperable way [2].

Digital health products and services are no longer novelties and digital transformation is crucial to provide better healthcare to the patients with the main goal of the new framework making the healthcare sector more efficient and advancing scientific research in the telehealth area [3].

Today, patients face challenges in exercising their right to control their health data, including accessing and transferring their data within the same Member State and across borders, despite the relevant rules, laid down in the GDPR [4]. EHDS is a health-specific ecosystem comprised of rules, common standards and practices, infrastructures, and a governance framework that aims at empowering patients to control their electronic personal health data, at the national level and EU-wide, and support their free movement [5]. Systems provide a consistent, trustworthy, and efficient set-up for the use of health data for research, innovation, policy-making, and regulatory activities [6]. It has also significantly accelerated the uptake of electronic health records, e-prescriptions, and sharing of research data [7]. Barriers across policy areas, however, hinder data-sharing and the development of digital health. One big hurdle is the protection of data and ways ***to*** make sure it is being used for the common good [8]. This imposes the need for cross-border identity verification and affects both the identification and authentication of health professionals and patients [9]. This requires an agreement between government authorities for national contact points for eHealth on the criteria required for the participation in cross-border eHealth Information Services [10].

This paper addresses challenges in implementing e-health, so far lacking in the scientific literature. The procedures of handling the data followed the suggestions of the International Council of the patient Ombudsman after the complaint of healthcare professionals from EU hospitals. To illuminate this uncharted area, we examined the Member States and their national situation concerning possible compliance of their national systems to the proposed Electronic IDentification, Authentication and Trust Services [eIDAS] and use in the health network [11].

II. eHealth Legal Implications

As of today, there is no common and assured interpretation of the legal implications of both the GDPR and eIDAS Regulation [11]. People cannot always easily access their health data electronically, and if they want to consult doctors in more than one hospital or medical center, they often cannot share the data with other health professionals [12]. At the moment, not even all countries have a national contact point for cross-border healthcare or use of the [eIDAS] Regulation which provides the basis for cross-border and presents a useful tool to ensure secure access to health data for European citizens where the patient is informed and have a right to see any time and any place who visited their health data in the hospital digital system or other health platform and as well, could deny access to third parties.

The situation becomes even more difficult when a patient visits a doctor in another country, their medical information [including diagnostic images] is often not accessible, which can lead to delays and errors in diagnosis or treatment. In most cases, doctors cannot see the patient's health data if they have undergone health interventions in another country. Continuity of care and rapid access to personal electronic health data is even more important for residents in border regions, crossing the border frequently to receive healthcare [13]. That's why the Member States were asked to investigate their national situation concerning possible compliance of their national systems to the proposed eIDAS Authentication (Table I). Over half of Member States do not have specific legislation on reusing electronic health data for research, policy-making, or regulatory purposes for instance, and rely on the general provisions of the GDPR, often using consent for processing health data. Not all Member States have set up systems to exchange electronic health records and there are significant deficiencies in the interoperability of the systems [14]. Patient summaries and e-prescription services exist in two-thirds of all Member States and are most frequently accessed via an online portal, but only in a few Member States can they be sent or received across borders [15,16].

III. The New Framedwork Presentation of Electronic Health Records in the EU

In all EU countries, Electronic Health Records in cross-border health services are being introduced with ePrescription and eDispensation [17]. ePrescription allows EU citizens to obtain their medication in a pharmacy located in another EU country, thanks to the online transfer of their electronic prescription from their country of residence where they are affiliated, to their country of travel. Additionally, there are some potentially open questions about the validity of prescription or medical rapports and required repeated visits to the residence country. For example, e-prescription and reimbursement of cross-border healthcare. At the moment, a situation does not permit all countries to admit the validity and linguistic barriers.

Patient Summaries provide information on important health-related aspects such as allergies, current medication, previous illness, surgeries, etc. Potential Hazard and risks are that using e-health data will affect general patient rights, especially the Right to Free Choice and Right to Privacy and Confidentiality from the European Charter of the patient rights, and the GDPR. According to health professionals, this requires proper consideration of trust, ethics, and security [18].

IV. Examples and Disputes From Cinical Practice

From the clinical practice, we demonstrate a report from a patient that was treated for a depressive episode in the psychiatry department in the same hospital where he works as a nurse. He asked us for the intervention against the hospital that was not able to delete his medical records, and he knew that head of a department can access his file. And the same situation happened in another EU country where the doctor that works in the hospital becomes a patient in beacuse of the symptoms of multiple sclerosis, and she was very worried that their superiors will find out that and that will have an impact on her work even she was fully recovered. The recent legal action was against hospital staff, beacuse the medical records from the patient that is a public person were shared with the journalist. The most dangerous situation we faced was the abuse of the digital system for the Covid certificate from the nurse who recorded false covid vaccination in the patient medical record for the money.

V. Conclusion

A still unsolved question is whether patient access to own data is enough critical and not often accounted for in the health data management systems. Simultaneously, while digital technologies are frequently designed to be used at the individual level, a system-level approach is required to fully understand the breadth and depth of how digital technologies can shift or augment a [public] health system [19].

This assumption is supported by the fact that many EU countries, still report that patients make visible only to themselves through my health portal verified with the ID, and at the same time, the hospital doesn't have this information and could use this data. This is indicative of a lack of awareness of the patient and human rights and appears to become more often a case of juridical process and report to the court of human rights. The main achievements, including contributions to the field, can be summarised that is a special interest and challenge to have all processes the same in all EU Member States, where should everyone be equal.

Beyond the political aspects, there is a scientific challenge to identify older people's incapacity to craft technologies.

Further work is certainly required to disentangle these complexities around digital accessibility concerning the present inability of technology to cover the diverse types of disabilities. This provides a good starting point for discussion and further research. Our evaluation suggests that we still have a long way to go to implement digitalization in eHealth Network with full respect for the fundamental rights and patients' preferences.

VI. Abreviations

- EU: European Union
- EHDS: European Health Data Space
- GDPR: General Data Protection Regulation
- eHDSI: The eHealth Digital Service Infrastructure
- eIDAS: Electronic IDentification, Authentication and trust Services

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TABLE I. REVIEW OF THE SERVICES AVAILABLE IN COUNTRIES ACCORDING TO THE EUROPEAN COMMISSION – ELECTRONIC CROSS-BORDER HEALTH SERVICES: https://health.ec.europa.eu/ehealth-digital-health-and-care/electronic-cross-border-health-services_en

Health data of citizens from the countries below	**can be consulted by doctors from the countries below, using the Patient Summary**
Czech Republic	Luxembourg, Croatia, Portugal, France
Malta	Luxembourg, Portugal, Croatia, Czech Republic, France
Portugal	Malta, Croatia, Luxembourg, France, Czech Republic, Spain
Croatia	Malta, Portugal, Czech Republic, Luxembourg, France
Spain	Portugal
Doctors from the countries below	**can access health data of citizens coming from**
Croatia	Czech Republic, Malta, Portugal
Luxembourg	Czech Republic, Malta, Portugal, Croatia
Malta	Portugal, Croatia
Portugal	Malta, Croatia, Czech Republic, Spain
Czech Republic	Croatia, Malta, Portugal
France	Czech Republic, Malta, Portugal, Croatia
Spain	Portugal
The Netherlands	Czech Republic, Portugal
Croatia	Finland, Estonia, Portugal
Estonia	Finland, Croatia
Finland	Estonia, Croatia, Portugal
Portugal	Estonia, Finland, Croatia
ePrescriptions of citizens from countries below	**can be retrieved in pharmacies in**
Croatia	Finland, Estonia, Portugal

Estonia	Finland, Croatia
Finland	Estonia, Croatia, Portugal
Portugal	Estonia, Finland, Croatia
Pharmacists of countries below	**can dispense ePrescriptions presented by citizens from**
Croatia	Finland, Estonia, Portugal
Estonia	Finland, Croatia, Portugal