

New possibilities of strengthening the preventive healthcare of workers through the secondary use of electronic health data

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Digital transformation in the field of healthcare

Digital solutions for healthcare can increase the well-being, help to promote health and prevent disease, including in the workplace. They can support the reform of health systems and their transition to new healthcare models.

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Access to data and the ability to use it are essential for innovation and growth. In line with the European Data Strategy², health is an area where European Union can benefit from data revolution, increasing the quality of healthcare, while decreasing costs.

So, one of the specific objectives of the EU-4Health Program for the period 2021-2027, established by Regulation (EU) 2021/522³, is strengthening the use and re-use of health data, including by supporting the creation of a European Health Data Space.

European Health Data Space

Healthcare authorities across Europe face common challenges such as diversity of electronic health records, lack of technical interoperability and access to digital health services, risks of privacy breaches, cybersecurity risks, as well as risks regarding the quality and reliability.

Fragmented and divergent legal and administrative rules, frameworks, processes, standards and infrastructure for reusing health data restrict researchers and innovators' access to health data. They also limit the availability of innovative health products and services⁴.

The aim of the European Health Data Space is establishing the rules, common standards and practices, infrastructures and a governance framework for the use of electronic health data⁵. Security and privacy are fundamental principles of the European Health Data Space, which is based on strong data protection and cybersecurity elements.

The development of a common European Health Data Space require actions at national and European level, along with strong

cooperation between public and private stakeholders (for example, national digital health bodies, public health institutes, data protection authorities, healthcare providers, health professionals, academic and research institutions, and patient associations).

European Health Data Space supports two distinct uses of health data – primary and secondary use.

Primary use of electronic health data

Primary use of electronic health data means the processing of personal electronic health data for the provision of health services to assess, maintain or restore the state of health of the natural person to whom that data relates, including the prescription, dispensation and provision of medicinal products and medical devices, as well as for relevant social security, administrative or reimbursement services⁶.

The primary use of electronic health data supports the use of data for better healthcare at national and cross-border level. Medical data is typically stored in electronic health records, containing segments of a patient's medical history (centrally or involving various healthcare providers). The European Health Data Space will allow people to access their health data and make their data available to a health professional of their choice, including when abroad and in the language of the health professional. That is how the patient can get a better diagnosis and treatment with fewer medical errors and avoid unnecessary diagnostics⁷.

To support data being shared between healthcare providers, mandatory requirements for interoperability, security, safety

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and privacy will be introduced, as well as mandatory self-certification of electronic health records covering interoperability and security.

Member States will be required to make priority categories of data available in a common European electronic health record exchange format, such as patient summaries, e-prescriptions, e-dispensations, medical images and image reports, laboratory results and discharge reports.

All Member States will be required to participate in cross-border digital infrastructure for the exchange of health data for health-care delivery (MyHealth@EU).

Secondary use of electronic health data

The secondary use of health data means using health data for purposes other than the primary reason for which they were originally collected. The secondary use can be, for example, research, decision-making, development and innovation, as well as education.

In this context, opportunities are opening up for improving and strengthening the preventive healthcare of workers through the secondary use of health data for the purpose of developing future health policies in the field of prevention of disease and work-related health problems.

According to the Proposal for a Regulation on the European Health Data Space, researchers, innovators, public institutions or industry, will have access to large amounts of high-quality health data under strict conditions. The access to such data by researchers, companies or institutions will require a permit from a health data access body, to be

set up in all Member States. Access will only be granted if the requested data is used for specific purposes, in closed, secure environments and without revealing the identity of the individual.

The health data access bodies will be connected to the new decentralised EU-infrastructure for secondary use (Health-Data@EU) which will be set up to support cross-border projects.

Data permit for the secondary use of electronic health data

In line with the Proposal for a Regulation on the European Health Data Space⁸, the health data access bodies shall ensure that access is only provided to requested electronic health data relevant for the purpose of processing indicated in the data access application by the data user and in line with the data permit granted.

The health data access bodies shall provide the electronic health data in an anonymised format, where the purpose of processing by the data user can be achieved with such data, taking into account the information provided by the data user.

Where the purpose of the data user's processing cannot be achieved with anonymised data, taking into account the information provided by the data user, the health data access bodies shall provide access to electronic health data in pseudonymised format.

Purposes for which electronic health data can be processed for secondary use, according to the Proposal for a Regulation on the European Health Data Space, Article 34, are following:

- activities for reasons of public interest in the area of public and occupational health, such as protection against serious cross-border threats to health, public health surveillance or ensuring high levels of quality and safety of healthcare and of medicinal products or medical devices;
- to support public sector bodies or Union institutions, agencies and bodies including regulatory authorities, in the health or care sector to carry out their tasks defined in their mandates;
- to produce national, multi-national and Union level official statistics related to health or care sectors;
- education or teaching activities in health or care sectors;
- scientific research related to health or care sectors;
- development and innovation activities for products or services contributing to public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;
- training, testing and evaluating of algorithms, including in medical devices, AI systems and digital health applications, contributing to the public health or social security, or ensuring high levels of quality and safety of health care, of medicinal products or of medical devices;
- providing personalised healthcare consisting in assessing, maintaining or restoring the state of health of natural persons, based on the health data of other natural persons.

Secondary use of electronic health data for the purpose of improving health protection at work

Good quality data on occupational accidents and diseases are very important to design an effective prevention strategy on occupational health and safety, both at the national and European level. Reliable data are indispensable for identifying hazardous sectors and occupations, which require prioritizing and formulating effective legislation, policies and programmes, as well as identifying priorities for setting the right targets towards reducing occupational accidents and diseases⁹.

The intensification of migration flows, the ageing of the workforce and the increasing numbers of workers in temporary, casual or part-time work and precarious employment, do not only increase their disposition to accept unsafe working conditions but also makes them invisible to adequate health surveillance, and recording and notification of occupational diseases, all of which are required for the effective implementation of preventive strategies. Many occupational diseases, such as occupational cancers, are characterized by long latency periods and are, therefore, difficult to recognize until the clinical manifestation of their symptoms. The increased movement of workers to different jobs, their exposure to various agents during their working life, along with non-workplace factors associated with the emergence of a disease, can make it difficult to determine the occupational origin. Additionally, some workers may have exposure to substances that have not yet been identified as hazardous. The nature of occupational diseases is altering rapidly: technological and social changes, along with global economic condi-

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tions are aggravating existing health hazards and creating new ones. Work-related stress is often reported work-related health problem. In addition, work-related stress can also contribute to musculoskeletal disorders and other health disorders, such as hypertension, peptic ulcers, and cardiovascular diseases.

The fact is that emerging risks are increasingly linked to new technologies developed and implemented without enough consideration given to occupational health and safety aspects, to new types of workplaces, including remote work, and to social and organizational changes.

In this context, the secondary use of health data can contribute to new insights and benefit developing future health policies in the field of prevention of disease and work-related health problems.

Projects and activities

There are ongoing projects and joint actions within the EU4Health Program aimed at preparatory activities for the European Health Data Space.

Croatian Health Insurance Fund is participating in TEHDAS project (Towards European Health Data Space), which develops joint European principles for the secondary use of health data and is focused on:

- engaging other European projects and policymakers in a dialogue about the European Health Data Space;
- ensuring sustainability of the secondary use of health data in Europe;

- developing a governance model for cross-border co-operation in the secondary use of health data between European countries;
- promoting the reliability and compatibility of and access to health data for secondary use;
- clarifying the role of individuals in the secondary use of health data and including them in dialogue about the use of health data for research and policymaking.

Within the EU4Health Program there also possibilities of awarding direct grants to the Member States' authorities in order to accelerate the establishment and capability enlargement of health data access bodies across Member States and the rollout of connections for the future European Health data Space infrastructure for secondary uses (HealthData@EU). Where services and infrastructures of health data access bodies have already been established, this action will also support Member States in enlarging the capabilities of such bodies, including the design of new services and their further development.

We hope that above-mentioned projects and activities, in line with the Proposal for a Regulation on the European Health Data Space, will contribute to the development of a common European Health Data Space built on the principles of strong data protection and cybersecurity, and enable the secondary use of health data in order to improve health protection at work, too. ●

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1. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society, accessible at <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52018DC0233&from=EN>
2. Accessible at <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52020DC0066&from=EN>
3. Accessible at <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32021R0522&from=EN>
4. Communication from the Commission to the European Parliament and the Council: A European Health Data Space: harnessing the power of health data for people, patients and innovation, accessible at <https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52022DC0196&from=EN>
5. Proposal for a Regulation on the European Health Data Space, accessible at https://health.ec.europa.eu/publications/proposal-regulation-european-health-data-space_en
6. Proposal for a Regulation on the European Health Data Space, Article 22.(d)
7. Communication from the Commission to the European Parliament and the Council: A European Health Data Space: harnessing the power of health data for people, patients and innovation.
8. Proposal for a Regulation on the European Health Data Space, Article 44
9. International Labor Organization regarding prevention in the field of occupational health and safety