

## IMPROVEMENT OF HEALTHCARE THROUGH EXCHANGE OF HEALTH DATA - BUT HOW?

### I. Introduction

In February 2020, the European Commission paved the way to leverage data in various areas by publishing a European Data Strategy<sup>1</sup> and a White Paper on Artificial Intelligence (AI)<sup>2</sup>. The objective of the Data Strategy is to guarantee the "flow of data within the EU and across sectors" and is based on the FAIR principles when it comes to the access, management, and use of data. It emphasizes the importance of the availability of large pools of data, an infrastructure to use and exchange data as well as appropriate governance mechanisms. One of the areas proposed is the creation of a "common European health data space".<sup>3</sup> A proposal is supposed to be published by the end of 2021. With the European Health Data Space, the Commission plans to promote better exchange and access to different types of health data, such as data from electronic health records, genomics data or data from patient registries to support healthcare delivery (primary use of data) but also for health research and health policy making purposes (secondary use of data).

### II. Advantages of exchange of health data

Health insurance funds and not-for-profit health insurers agree with the huge potential that a flexible use of health data has for patient centeredness as well as improving healthcare quality and outcome. A closer cooperation in the use of health data shall aim to improve patient's access to healthcare and allow to predict the costs of the treatments (the amount to pay and the part reimbursed by the health system) more easily. The use of real-world data can drive research, cost-effectiveness analysis, treatment, and care, identify inefficient spending and empower patients through access to their own data and records. The outbreak of COVID-19 has made clear that access to health data, notably real-world data, for scientific research and a coordinated interpretation is of utmost importance.

AIM members have the task of maintaining, restoring or improving the health of its insured persons. To be able to fulfil these tasks, they collect, process, store and use health and social data from their insured. These claims data, a form of administrative data, primarily collected for billing and reimbursement purposes, have the comprehensive potential for both, rational allocation of resources and for health services research to optimize healthcare provisions. Therefore, AIM welcomes the current and upcoming initiatives of the European Commission. The following recommendations focus mainly on billing data and contain proposals about which criteria should be followed in the collection, organization and sharing of health data<sup>4</sup>.

<sup>1</sup> COM(2020) 66 final, <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0066&from=EN>.

<sup>2</sup> COM(2020) 65 final, [https://ec.europa.eu/info/sites/info/files/commission-white-paper-artificial-intelligence-feb2020\\_en.pdf](https://ec.europa.eu/info/sites/info/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf).

<sup>3</sup> European Commission on a European health data space; [https://ec.europa.eu/health/ehealth/dataspace\\_en](https://ec.europa.eu/health/ehealth/dataspace_en) (assessed on 13 December 2020).

<sup>4</sup> The Belgian mutuels highlight their existing cooperation in data-sharing and analysis for research purposes foremost within the member state but also for cross-border academic research to improve patient centeredness and sustainability of healthcare systems as was demonstrated with participation in the EMRaDi- project. Actual cross-border sharing of data was largely hampered by several constraints mostly related to intra member state organization. Recommendations for decision makers <https://www.emradi.eu/assets/72b1b491-c733-4ce9-9c82-8de6707da4d6/finalreportemradipdf-en-md.pdf>.

## Recommendations for sharing of data, best practices, and methods between actors in healthcare

The benefit of the use of secondary data is the fast availability, which can be used for different purposes. Data can also be used to reach conclusions that are not in line with the opinions/point of views of the holders of primary data (e.g. health insurance funds and health mutuals). FAIR principles (Findable, Accessible, Interoperable, Reusable) should be followed, meaning the capacity of computational systems to find, access, interoperate, and reuse data with none or minimal human intervention. Because of the increase in volume, complexity and speed of data, humans rely more and more on these computational systems.

### Health insurance funds/not-for-profit health insurers support sharing of health data with the public sector

Health insurance funds and not-for-profit health insurers support the domestic and cross-border sharing of anonymized or pseudonymized health data within the public sector in the EU, **if it is lawful and data protection and security are safeguarded by a precise legal framework**. Cross-border data exchange between not-for-profit health insurance organizations within the EU should be processed at the level of national umbrella organizations and not of single carriers. Cross-border exchange of health data should only be processed, if there is a clear public health goal that requires cross-border use of data, or when the size of the population of a country is too small to facilitate research or when different treatment models need to be compared (subsidiarity principle for data<sup>5</sup>).

### Objective of health data partnerships must be to improve healthcare and patient centeredness

Health data partnerships should aim to improve access to healthcare and allow patients to know in advance the costs of the treatments (the amount to pay and the part reimbursed by the health system). Improved health outcomes such as new medicines or a new understanding of a disease and patient centeredness, should always be the primary purpose of using health data. It could include improved diagnostics, more effective treatments as well as early disease detection. These outcomes impact health of patients in a positive way.

### A clear overarching governance framework for the use of health data

To ensure strong and sustainable accountability over data use, a **data surveillance body** should be established at European level. Such a body should work under the supervision of the European Data Protection Board (EDPB)<sup>6</sup> and in cooperation with the supervisory authorities of the member states (Data Protection Authorities – DPA's). The concept, introduced by articles 40 and 41 GDPR, which determines codes of conduct and “bodies” that can be accredited to monitor compliance with these codes of conduct, should also be used for the data surveillance body. The data surveillance body should be able to scrutinize and oversee any use of personal data and guarantee their protection. The organization should be responsible for decisions **about how and for which purpose health data is used**. It should collect the data from the individual data sharing bodies and **grant one permit for all, notably when it comes to multi-centered research at European level (e.g. COVID-19), to save time and costs**. The data surveillance body should include a governance structure with the participation of all relevant stakeholders that decides if a certain project is in the public interest (with power of veto for the non-profit health insurance organizations). It should oversee the policy framework and provide legal advice for health insurance funds and health mutuals as well as other organizations which enter data agreements. There should be clear rules concerning liability, cases of abuse/misuse of data, independent audits as well as penalties.

### **Transparency by listing all health data partnerships in a central register**

Information about all partnerships of health data hubs, health insurance funds and non-for-profit health insurers should be made available on a central register, which is part of the data surveillance body, to ensure publics' trust in sharing data. Short summaries on the partnerships' purpose, the data involved and how decisions have been made about them should accompany the respective partnership.

### **Need for clear rules to guarantee the quality of data**

Clear rules need to guarantee the quality of data. This also needs to be addressed in Member States before exchanging health data in the European Health data space can occur:

- o Data registration: Need to use international standards of clinical, epidemiological, and sociological information.
- o Uniform way of coding is necessary (the pandemic has shown the difficulty of exchanging information, when the information is not completely the same; for instance, the use of ICD10 but also of Orpha codes for rare diseases in Belgium or such as SNOMED and HL7 / FHIR in the Netherlands).
- o Need to create awareness with doctors and medical personnel to adhere to quality data registration. This requires more and continued attention to data registration in the curriculum and their career.
- o Need for clear rules on the way the data is kept and managed. Importance of safely storing, classifying, clustering and then sharing of data.

### **Reliable “health data partners” to ensure high quality data**

A strategy and criteria should be developed on how to motivate reliable “health data partners” to share their data and spend the required time and effort for putting qualitative data at the disposal of other partners. The sharing of quality data must be a legally binding objective for the partners involved, for example for mutual societies. The added value must be clear before sharing.

### **Sharing of the least complex datasets and combinations to ensure the personal privacy**

Efforts should be made to ensure that the least complex datasets and dataset combinations are used for specific projects as foreseen by the principle of data minimization in the GDP). Appropriate technical and organizational measures should be implemented to avoid re-identification of patients.(through combination of information of multiple databases). It should be forbidden to link the data with other (commercial) databases that are not as secure and anonymized.

### **A cost effectiveness analysis should be conducted**

Another objective must be the increase of efficiency and the saving of costs. A cost-effectiveness-analysis should be conducted. It should be analyzed what the added value of “big data” is compared to smaller databases.

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<sup>5</sup> Recital 170 GDPR, Principle of Subsidiarity and Principle of Proportionality, <https://gdpr.eu/recital-170-principle-of-subsidiarity-and-principle-of-proportionality/> (assessed on 16/12/2020).

<sup>6</sup> Articles 51, 68 GDPR.

## Enable public participation

The public should be involved in decisions about how health data is used. Patients should be involved in the so-called grey area/mid-range use cases, for which there will be a diversity of views and perspectives. The involvement should be limited to consultations.

## Consent for the use of data through patients necessary

It should be possible for patients to opt-out from the use of their health data. No health data sharing should be done without the permission of the patient/citizen (Principle of opting-in (GDPR), when articles 6.1.a and 9.2.a GDPR (also see Article 4.11) are used as the legal basis for data processing. The patient/citizen gives his/her consent).

## eHealth literacy should be promoted

The EU should promote the development of a basic understanding of e-health literacy and recommendations for member states, both for public at large but also with specific attention on healthcare professionals. It should be an obligation to have a basic understanding of eHealth literacy, when having access to health data. It should be discussed how eHealth literacy is used in the different countries and whether national variations can also be taken into account (e.g. use of personal data portals in the Netherlands, high digitization / consent rate in Estonia vs. critical attitude on privacy in the Netherlands).

## Shared health data must never be used against the interest of citizens

There should be a guaranty that shared health data will not be used against the interest of citizens (even when anonymized).



**AIM** Healthcare and social benefits for all

The International Association of Mutual Benefit Societies (AIM) is an international umbrella organisation of federations of health mutuals and other not-for-profit healthcare payers. It has 57 members from 30 countries in Europe, Latin America and Africa and the Middle East. 33 of its members, from 20 countries, are based in the European

Union. AIM members provide compulsory and/or supplementary health coverage to around 240 million people around the world, including close to 200 million people in Europe, on a not-for-profit basis. Some AIM members also manage health and social services. Collectively, they have a turnover of almost €300 billion.

AIM members are either mutual or health insurance fund.

They are: private or public legal entities; solidarity based; not-for-profit oriented organisations: surpluses are used to benefit the members; democratically-elected members play a role in the governance of the organisation.

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