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[1] and a White Paper on Artificial Intelligence (AI)[2]. 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".[3] 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).

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 claims data and contain proposals about which criteria should be followed in the collection, organization and sharing of health data[4]:

[1] COM(2020) 66 final, https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52020DC0066&from=EN.
[2] COM(2020) 65 final, https://ec.europa.eu/info/sites/info/files/commission-white-paper-artificial-intelligence-feb2020_en.pdf.
[3] European Commission on a European health data space; https://ec.europa.eu/health/ehealth/dataspace_en (assessed on 13 December 2020).
[4] The Belgian mutuals 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.

Executive summary

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

1. Sharing data with the public sector

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, **in accordance with the GDPR and 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 the national umbrella organizations, competent for exchange of health data in every member state, and not of single health insurers.

- **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 heath 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)[5] 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.

[5] Articles 51, 68 GDPR.

- Transparency by listing all health data partnerships in a central register

Information about all cross-border partnerships of health data hubs, health insurance funds and health mutuals 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:

  - Data registration: Need to use international standards of clinical, epidemiological, and sociological information.
  - 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).
  - 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.
  - Need for clear rules on the way the data is kept and managed. Importance of safely storing, classifying, clustering and then sharing of data

- Motivating health data partners

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 quality data at the disposal of other partners. The sharing of quality data must be an objective for the partners involved, for example for mutual societies and health insurance funds. The "FAIR Guiding Principles for scientific data management and stewardship" can be used (findability, accessibility, interoperability, and reusability). Financial means must be provided to enable this work. 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 organisational 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 anonymised.

- 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.

- Investing in digital health literacy is a prerequisite for the European Health Data Space

An EU Joint Action on Digital Health Literacy should invest in and promote the equal development of a basic understanding of digital health literacy and skills (e-health, m-health literacy) in the member states for the public at large to empower the citizen in healthcare and the citizen's knowledge on their health data.

Digital health literacy and skills should be promoted in the formation for healthcare professionals and a point of attention in (continued) education. Researchers and academics should be aware of the legal framework that applies to the digital exchange of health data.

The EU could increase attention for measuring and monitoring the level of health literacy (via population survey) by including it as an indicator in the social scoreboard.

The ambitious target in the European Pillar of Social Rights Action plan to attain basic digital skills by 2030 for 80% of those aged 16-74 as a precondition for inclusion and participation in the labour market and society in a digitally transformed Europe, should be extended to digital health literacy, not leaving the most vulnerable (and older) citizens behind.

It should be discussed how eHealth literacy is perceived and promoted in the different countries and whether national perceptions 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).

2. Sharing data with the private commercial sector

As sharing of health data with the private sector is regarded critically by the members of AIM, it should – if any- only be conducted under a set of additional criteria:

- **Precise legal framework and clear legal mandate**

There must be a precise legal framework on sharing of health data with the private sector that meets the high need for protection of health-related data. Prerequisite for any sharing of data by health insurance funds and health mutual is a clear legal authorization/mandate to do so.

It must be assured that there is no obligation for health insurance funds and not-for-profit health mutuals to share health data (with the exception of legal obligations). A possibility to opt-out of the data-sharing contract must be given, if there is a reasonable suspicion that the health data is not used to improve health or in the public interest.

Robust standards on transparency and reporting will increase public trust. When data from publicly financed research agencies or partners are used, the research questions and the detailed methodology should be made public.

The data surveillance body as a supervisory authority on the use of health data has a role to ensure protection of general interest by guaranteeing these research questions and resulting data are rendered public on transparent and objective rules.

- **Development of standard contracts/templates and guidance**

The data surveillance body should develop standard contracts and guidance. It should provide tools and products including good practice guidance and examples, standard contracts, and methods for assessing the value of different partnership models. When the private sector is concerned, a template must be developed to assess the use of data. The data surveillance body should have the authority to conduct audits on the application of the contract.

- **Understanding the landscape**

The data surveillance body should build relationships and credibility with the research and industry community, regulators, health insurance funds and mutuals and patient organizations. That is necessary to understand the demand for specific health data that is used for public health, or private purposes, to explore new data sources and to promote the use of available data.

- **Data from private insurance funds and private hospitals for the general view of health status**

For the sake of completeness, it would be important to include the private health sector, especially private insurance funds and private hospitals, in this data sharing exercise to combine the data to the public health sector and as a consequence get a general view of status of health. AIM health insurance funds and health mutuals would be ready for collaboration in this matter.

II. Better use of data between health insurance funds/mutuals and other actors in the healthcare system can transform healthcare

Health insurance funds and health mutuals 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 more easily predict the costs of the treatments (the amount to pay and the part reimbursed by the heath system). 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. Through data collection, their organization as well as the regulation of their access and use, it is possible to develop and implement national and European strategies for AI in healthcare. 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. Moreover, a European health data hub would increase the competitiveness of Europe in a world, where other regions are developing at high pace in this area, sometimes under less stringent data protection regimes than that of Europe.

1. Clinical data used for research vs. public health data

Clinical data is a main resource for most health and medical research and is either collected during the course of ongoing patient care or as part of a formal clinical trial program. These data are about the individual. Clinical data falls into six major types: Electronic health records, administrative data, claims data, patient/disease registries, health surveys and clinical trials data.[6] Health insurance funds and health mutuals deal mostly with claims data. It helps them to design the services and programs needed for the insured and to guarantee affordable healthcare in the long-term. Public health data is needed to improve and to protect public health. Timely access to high-quality information in order to formulate appropriate action is indispensable. In an increasingly globalized world, sharing of data is often sensitive across borders. During the COVID-19 pandemic it showed that successful public health data sharing can prevent a disease from becoming established or facilitate a robust and timely response.[7]

2. Genomic data

Genomic data is the study of our genes, which are made up of DNA. It is a "key source of data within most discipline of healthcare".[8] By donating blood, participating in genetic research of having genetic tests online, genetic data will be added to the personal data that is already online or offline. The COVID-19 pandemic has demonstrated that sharing data can improve clinical outcomes for patients, but only few healthcare organizations are participating in data-sharing initiatives.[9]

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[6] Data resources in the health sciences, https://guides.lib.uw.edu/hsl/data/findclin, assessed on 14/12/2020.
[7] Strengthening data sharing for public health data, https://www.chathamhouse.org/about-us/our-departments/global-health-programme/strengthening-data-sharing-public-health, assessed on 14/12/2020.
[8] We need to talk about big data and genomics. Here is why - and how, https://www.weforum.org/agenda/2020/07/why-we-need-a-public-conversation-about-big-data-and-genomics/.The COVID-19 pandemic has demonstrated that sharing data can improve clinical outcomes for patients, but few healthcare organizations are participating in data-sharing initiatives.
[9] Idem.

A federated data system can enable sensitive data sharing across borders and ensure data security, patient privacy and data interoperability. Genomic data as such does not give a lot of insights, but larger data sets linked to de-identified clinical health records and phenotypic data can improve information on diseases immensely.[10] However, data might be de-identified and anonymity cannot be absolutely guaranteed. Health information, for instance, can always be linked to other personal information that is also available on the web.[11] It is important that experts provide full transparency about ongoing discussions and the risks, but patients also must take on responsibility.

The European Commission launched in April 2018 the "One million Genome Initiative", aiming to develop a mechanism by which genomic data bases across Europe can be assessed and linked for analytical purposes with a robust governance model and in full compliance with data privacy regulation.

The Commission plans to contribute to improved health outcomes and to support the long-term sustainability of the EU's health and care systems by exploiting the potential of new digital technologies, such as big data analytics, AI, and high-performance computing. It directly contributes to implementing key political priorities, such as the European Health Data Space and the Commission's plan to beat cancer. It will enable to make more efficient use of scarce resources from cancer, to rare diseases, brain related diseases or prevention. As a consequence, better diagnostics can be made, prevention will receive a boost and better diagnostics can be made. prevention, and make more efficient use of scarce resources from cancer, to rare diseases, brain related diseases or prevention. At the same time, there are privacy issues, such as the identification of persons and their families based on DNA.

Sharing 'genomic data' is different than, for example, claims data, especially because anonymity cannot be guaranteed. This requires an opt-in construction, but the question arises, whether that is workable. The privacy issues that are being discussed are essential and need to be resolved.

3. eHealth literacy

Electronic tools such as a common health data space provide little value, if the intended users do not have the skills use information technology to promote health and eHealth. E-Health requires a skill set, or literacy of its own. The ability "to seek, find, understand, and appraise health information from electronic sources and apply the knowledge gained to addressing or solving health problems"[12] is not sufficiently there. The EU should promote the development of a basic understanding of e-health literacy and recommendations for member states.

4. Already existing health data hubs

Research partnerships consisting of several actors in healthcare such as academics, researchers and clinicians can provide health insurance funds and health mutuals with a lot of expertise and new resources. It can speed up research for new medicines and treatments and support more timely diagnoses, which can help to save lives. Some health data spaces already exist at European and national level but they are not very numerous. Moreover, the different systems in the European Union are not interoperable. But they give many opportunities and can serve as good examples for the future work regarding a European health data space.

[10] We need to talk about big data and genomics. Here is why - and how, https://www.weforum.org/agenda/2020/07/why-we-need-a-public-conversation-about-big-data-and-genomics/.The COVID-19 pandemic has demonstrated that sharing data can improve clinical outcomes for patients, but few healthcare organizations are participating in data-sharing initiatives.
[11] Idem.
[12] eHealth literacy: Essential skills for consumer health in a networked world, J Med Internet Res. 2006 Apr-Jun, Cameron D Norman, PhD corresponding author and Harvey A Skinner, PhD, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1550701/ (assessed on 16/12/2020).

International Health Data Hubs to fight pandemics

If a pandemic occurs, scientists all over the world will try to combat this new epidemic by understanding this disease and developing treatments and vaccines. A major challenge in this fast-moving situation is to share data and findings in a coordinated way. International health data hubs can help to facilitate data sharing and analysis and to accelerate research. During the outbreak of the coronavirus, for example, the European Commission and the EMBL's European Bioinformatics Institute (EMBL-EBI together with EU Member States and research partners) launched in April 2020 a European COVID-19 Platform to enable the rapid collection and sharing of research data[13] .

National Health Data Hubs to respond to and to speed up treatments and prevention of diseases

In most Member States health data hubs do not exist yet, but more and more countries implement them: In 2019, three countries brought health data hubs on the way: the UK, France, and Finland.

United Kingdom: Seven health data hubs focusing on specific diseases

In the UK, seven health data hubs[14] were launched, focusing on improving the lives of people with specific diseases.[15] The hubs are formal collaborations between the NHS, academic organizations, patients, charities and industry and are expected to provide and maintain data and offer services for research and innovation. [16] With the available information the search for cures for diseases like cancer, asthma and mental illnesses should be accelerated by giving researchers access to data about which patients get ill in the first place and who responds best to certain treatments. Researchers and pharma firms that are granted access will be able to search, discover and request access to the data, which they will be able to use to develop therapies. The data will be completely anonymized.

France : « Plateforme des Données de Santé »to promote Artificial Intelligence in healthcare

In France, the Health Data Hub represents a strategic tool to serve innovation and promote AI in the health sector. All French health data is concentrated in one place and can be used by researchers, health professionals, care institutions, industrials, social security schemes, health insurance funds and not-for-profit health funds, startups as well as MedTech companies. It will ease the access to relevant data for health actors as well as expand the scope of data available and provide the means needed to analyze these data. The data platform is a place to share knowledge, as users, data providers and citizens will be able to interact with each other and benefit from each other's expertise to serve a common interest, namely innovation. Another objective is also to open the door to international databases, while staying in a secured and regulated environment.[17]

Finland: Secondary use of health and welfare data provided by one authority

In March 2019, the Finnish Parliament accepted the act on the secondary use of health and social care data, which brings all regulations related to the secondary utilization of health and social care data under the same law. It opens unique possibilities for scientific research, drug and health technology development and knowledge-based management in social and health care. All services related to the

[13] COVID-19 Data Portal, https://www.covid19dataportal.org/.
[14] The seven hubs include a cancer hub, an eye health hub, an inflammatory bowel disease hub, an acute care hub, a clinical trials hub, a respiratory hub, an hub that aims to use real-world data to improve understanding of many long-term conditions.
[15] NHS Digital: Blog, Welcoming new health data research hubs, 12 September 2019 (https://digital.nhs.uk/blog/transformation-blog/2019/welcoming-new-health-data-research-hubs).
[16] Idem.
[17] https://www.opusline.fr/health-data-hub-an-ambitious-french-initiative-for-tomorrows-health/.

secondary use of health and welfare data will be provided by one authority, based on "one-stop-shop" principle. Health and welfare data can be harnessed by public and private providers for broader use, such as for the development of personalized medicine, medical technologies, and digital health solutions, or optimizing services.[18]

5. Good data management

In Europe, 80% of the data remains unstructured[19] after being collected. In most Member States data is stored in several separate and often incompatible silos. Compatibility between States is an even more complicated matter. Challenging is a homogeneous definition of data that has to be shared and the subsequent correct interpretation of these shared data. For example, the lack of homogeneity in definition COVID-19-deaths between countries can lead to questions, whether only serologically confirmed cases or also suspected cases are included. Does the definition only cover deaths in hospitals or also in elder's homes and private homes are covered by the definition. In addition, it is often argued that the data is of insufficient quality. Finally, when it comes to personal health data, there is an expectation from citizens and patients that the data will be governed in an appropriate, safe and accountable way. The use of personal data by public research institutions (universities, hospitals, mutual) to improve public health might be acceptable to most citizens. It is unclear how citizens feel about the use of their personal data for for-profit research (with a public health impact).

Good data management is important to get knowledge discovery and innovation. However, the existing digital ecosystem prevents from extracting maximum benefit from research investments. The FAIR guiding principles (Findable, Accessible, Interoperable, Reusable) for better data management and stewardship began in a few European academic institutions and have now burgeoned to include endorsements by global organisations such as G7[20] and national governments and science funding agencies including the European Commission[21] and National Institutes of Health in the USA[22] as a useful framework for thinking about sharing data in a way that will enable maximum use and reuse.

III. Recommendations

AIM and its members manage access to health data information very carefully. Robust and ethical frameworks are indispensable to maintain public trust in rapidly developing technologies. This is particularly important in the fields of health data and patient data, where data is profoundly personal. Irresponsible use can undermine the foundations of trust and legitimacy that goes with the social value of that data.[23] The use of patient data should be visible, understandable, and trustworthy for patients, the public and health professionals.[24] As health insurance funds and health mutuals mostly deal with claims data, the following recommendations focus mainly on claims data and contain proposals about, among which criteria should to be followed in the collection, organization and sharing of health data:

[18] Finnish model.

[19] Adam Rogers, the 80% Blind Spot: Are You Ignoring Unstructured Organizational Data? https://www.forbes.com/sites/forbestechcouncil/2019/01/29/the-80-blind-spot-are-you-ignoring-unstructured-organizational-data/#7e42dfe9211c, assessed on 01/10/2020.

[20] http://www.g8.utoronto.ca/science/2017-annex4-open-science.html

[21] http://ec.europa.eu/transparency/regexpert/index.cfm?do=groupDetail.groupDetail&groupID=3464

[22] https://commonfund.nih.gov/commons/awardees

[23] The foundations of fairness for NHS health data sharing, 12 March 2020, https://www.adalovelaceinstitute.org/the-foundations-of-fairness-for-nhs-health-data-sharing/.

[24] Idem.

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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, **in accordance with the GDPR and 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 the national umbrella organizations, competent for exchange of health data in every member state, and not of single health insurers.

- **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 heath 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. Indirect impacts are reducing costs; providing additional revenue for health insurance funds and health mutuals, increasing administrative efficiency and reducing waiting times.

For health insurance funds and health mutuals, three aspects are particularly important:

- Sharing data should allow valid evaluations on the needs of certain groups (e.g. self-employed in general, certain professional or vulnerable groups).
- Better data concerning treatments (including diagnosis in ICD-10 format) provided by the institution of the Member State of residence under Article 35 of Regulation (EC) No 883/2004 and the corresponding provisions in the Implementing Regulation (e.g. through more differentiation within the billing data provided by the "assisting" institution of residence to the competent institution via EESSI) is needed. There is a blind spot concerning the needs of this significant group of secured persons which does not allow integrating them well in prevention programs.

It would be important to make the current insurance status of a person available to avoid the abusive claiming of benefits in other Member States by using the European health insurance card.

- **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)[25] 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 cross-border health data partnerships of health data hubs, health insurance funds and health mutuals 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. A central register would also reduce the risk of creating an internal market for data partnerships, making it harder to get a fair deal that benefits the wider health system.[26] The data surveillance body should offer free operational advice and guidance in order to help organizations get the fairest health data partnerships possible, taking into account that public interest and benefit goes beyond financial returns.[27] It should also determine specific topics to be followed. Therefore, health indicators should be constructed, which allow policy makers to take actions. The European Research agenda[28] should also be considered.

- 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:

- Data registration: Need to use international standards of clinical, epidemiological, and sociological information.
- 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).
- 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.

[25] Articles 51, 68 GDPR.
[26] The foundations of fairness for NHS health data sharing, 12 March 2020, https://www.adalovelaceinstitute.org/the-foundations-of-fairness-for-nhs-health-data-sharing/.
[27] Idem.
[28] Communication on a renewed European Agenda for Research and Innovation - Europe's chance to shape its futureEuropean Research (COM(2018) 306 final), https://ec.europa.eu/info/publications/renewed-european-agenda-research-and-innovation-europes-chance-shape-its-future_en

- Need for clear rules on the way the data is kept and managed. Importance of safely storing, classifying, clustering and then sharing of data

- **Motivating health data partners**

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 quality data at the disposal of other partners. The sharing of quality data must be an objective for the partners involved, for example for mutual societies and health insurance funds. The "FAIR Guiding Principles for scientific data management and stewardship" can be used (findability, accessibility, interoperability, and reusability). Financial means must be provided to enable this work. 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 organisational measures should be implemented to avoid re-identification of patients. Sufficient sample sizes should be used to avoid 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 anonymised.

- **Enable public participation**

People believe that the public should be involved in decisions about how health data is used.[29] Much of data-driven technology in healthcare will rely on using data that originates from people's health records and their interactions, so they naturally have an interest in how it is used. Patient involvement should not hinder positive developments because of an overly complex or bureaucratic system. 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.[30] It should be possible for patients to opt-out from the use of their health data. No health data sharing without the permission of the patient/citizen should be allowed.

- **Investing in digital health literacy is a prerequisite for the European Health Data Space**

An EU Joint Action on Digital Health Literacy should invest in and promote the equal development of a basic understanding of digital health literacy and skills (e-health, m-health literacy) in the member states for the public at large to empower the citizen in healthcare and the citizen's knowledge on their health data.

Digital health literacy and skills should be promoted in the formation for healthcare professionals and a point of attention in (continued) education. Researchers and academics should be aware of the legal framework that applies to the digital exchange of health data.

The EU could increase attention for measuring and monitoring the level of health literacy (via population survey) by including it as an indicator in the social scoreboard.

The ambitious target in the European Pillar of Social Rights Action plan to attain basic digital skills by 2030 for 80% of those aged 16-74 as a precondition for inclusion and participation in the labour market and society in a digitally transformed Europe, should be extended to digital health literacy, not leaving the most vulnerable (and older) citizens behind.

[29] The foundations of fairness for NHS health data sharing, 12 March 2020, https://www.adalovelaceinstitute.org/the-foundations-of-fairness-for-nhs-health-data-sharing/.
[30] Idem.

It should be discussed how eHealth literacy is perceived and promoted in the different countries and whether national perceptions 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).

2. Sharing data with the private commercial sector

Social Security Schemes, health insurance funds and not-for-profit health mutuals have an obligation to protect patient data. Therefore, in general they are skeptical about sharing anonymized or pseudonymized health data with the private sector. Insisting on anomization and/or pseudonymazation is very important.

At the same time health insurers should also make best use of health data. Working with partners across the healthcare system or even across healthcare systems in Europe can improve outcomes and make health insurance funds and health mutuals more efficient and cost effective. It allows them to make data-driven scientific advances in healthcare. New techniques and processes – such as cloud computing and machine learning – make it possible to collect, use and link more data. Data-driven technologies are rapidly emerging in health, relying on collaboration between the health insurers and researchers in both public and private sectors. Many of the new technologies cannot be implemented. Therefore, health insurance funds and health mutuals also see the possible benefits of a collaboration between all actors in the healthcare sector, including industry. One could think of strictly regulated public private partnerships.

AIM members are committed to making the EU the leader in data driven healthcare. They are eager to be part of turning this ambition into reality by having their say with regards to the frameworks of research collaborations. Their ultimate goal is to make sure that the benefits will reach the public and the individual patient and/or fulfill the general public interest.

Besides the mentioned criteria for data sharing with the public above, AIM thinks that sharing of health data with the private sector should – if any- only be conducted under a set of additional criteria:

- **Precise legal framework and clear legal mandate**

There must be a precise legal framework on sharing of health data with the private sector that meets the high need for protection of health-related data. Prerequisite for any sharing of data by health insurance funds and health mutual is a clear legal authorization/mandate to do so.

It must be assured that there is no obligation for health insurance funds and not-for-profit health mutuals to share health data (with the exception of legal obligations). A possibility to opt-out of the data-sharing contract must be given, if there is a reasonable suspicion that the health data is not used to improve health or in the public interest.

Robust standards on transparency and reporting will increase public trust. When data from publicly financed research agencies or partners are used, the research questions and the detailed methodology should be made public.

The data surveillance body as a supervisory authority on the use of health data has a role to ensure protection of general interest by guaranteeing these research questions and resulting data are rendered public on transparent and objective rules.

- Private commercial sector must give a quid pro quo for the use of data and must be transparent

While access to a large data pool is being created for the private commercial sector, it must be ensured that the "innovations" of this sector meet the urgent needs of the health sector. This could be reached, for example, by requesting a quid pro quo from the commercial sector and/or that use of the data is made transparent.

- Development of standard contracts/templates and guidance

The data surveillance body should develop standard contracts and guidance. It should provide tools and products including good practice guidance and examples, standard contracts, and methods for assessing the value of different partnership models. When the private sector is concerned, a template must be developed to assess the use of data. The data surveillance body should have the authority to conduct audits on the application of the contract.

- Understanding the landscape

The data surveillance body should build relationships and credibility with the research and industry community, regulators, health insurance funds and health mutuals as well as patient organizations. The data surveillance body should build relationships and credibility with the research and industry community, regulators, health insurance funds and mutuals and patient organizations. That is necessary to understand the demand for specific health data that is used for public health, or private purposes, to explore new data sources and to promote the use of available data. New Data sources need to be explored and the use of available data needs to be promoted. It should identify and communicate opportunities for agreements that support data-driven research.

- Data from private insurance funds and private hospitals for the general view of health status

For the sake of completeness, it would be important to also include the private health sector, especially private insurance funds and private hospitals or data of mobile health apps, in this data sharing exercise to combine the data to the public health sector and as a consequence get a general view of status of health. AIM health insurance funds and health mutuals would be ready for collaboration in this matter.

Brussels, 19 April 2021

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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