Heales
HEALTHY LIFE EXTENSION SOCIETY

NEWSLETTER HEALES

Massive health data and longevity. European developments. | February 2022 | N°155 | The death of death

These actions will be funded by the EU4 Health (...) and Horizon Europe programmes, with the aim that by 2025 (...) citizens in all Member States will be able to share their health data with healthcare providers and authorities of their choice (...). This extract from a [Commission Communication to the European Parliament (Fostering a European approach to artificial intelligence)](#) means, if put into practice, that every citizen will be able to share this data with scientists (with data protection guarantees, of course). This would be a very big step forward for longevity research and for health in general.

Theme of the month: Massive health data and longevity. European developments.

Introduction

Health "Big Data" is everywhere: it seems it represents 30% of the total mass of data available in the world. Today, in a country like France, almost all medical activities are at some point recorded by computer.

The issue of accessibility of health data for researchers has already been addressed in a [letter of September 2020](#). This letter details recent developments, hopes and limitations at the level of the European public.

The hopes

1) The acceleration of digitalization in health during the pandemic and massive data

First of all, we are already in the era of Medicine 4.0. At the same time, as a result of government measures in the fight against the Covid-19 pandemic, the digitization of health care has accelerated worldwide: the debate about personal data for medical purposes is spreading among the population.

This pandemic has affected us so much and, at the same time, has forced us to think about public and individual health. No responsible decision-maker would want to repeat this physical and moral restriction without a scientific understanding of the causes. Therefore, many will

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reflect on the importance of sharing "big data" in order to obtain a faster and more efficient measurement of results, for drugs, vaccination or prevention. Finally, Covid-19 was an opportunity to realize the usefulness of sharing massive data in health.

2) Institutional work in the post-Covid-19 era

In this context, the European Union is taking an initiative to create a common platform between the Member States: the European Commission is considering the creation of a European Data Space including the field of health for the period 2019-2025.

In December 2021 the European Parliament and the Council of the EU announced their agreement on the Data Governance Act (GDA). This agreement aims to facilitate altruistic data practices between public and private organizations to support scientific research.

As for scientific research, a new regulation of the European Parliament and of the Council concerning clinical trials for human use, Regulation No 536-2014, came into force on 31 January 2021. It envisages the creation of a CTIS platform, Clinical Trials Information Systems. This is an optimistic first step towards sharing data for research purposes. It is only the beginning of a project that will bring about change within the European area.

3) Innovative state systems in the European Union

Regarding the system of sharing massive health data at state level, there are several states in the European Union that have made a platform available. For example, Denmark has had the "Medcom" system for 25 years, and in Sweden the Swedish National Data Service also exists for the re-use of data for research purposes. It is the trend towards the re-use of health data at state level that could influence other Member States.

In this context, the joint TEHDAS project for the re-use of health data brings together 25 European countries. This consortium plans to start in 2022.

4) The notion of data altruism

In discussions on data management in general (not only health data), some have advocated for the concept of "altruism" for organizations that would be data controllers. The idea is to create a category of organizations that present guarantees of efficient processing on the one hand, and of processing in accordance with the objectives on the other. For example, in the case of health research, this would mean that it would be inaccessible in law and in fact to insurance companies, employers, etc., but accessible

to researchers.

The difficulties

1) The Health Data Hub in France and the RGPD

In France, the temporary failure of the Health Data Hub project (L1462-1 Code de la santé publique) became apparent in December 2021. The government's withdrawal of its request for authorisation from the CNIL is a consequence of a political strategy before the presidential election in 2022. The choice of a suitable cloud is essential. For the sharing of massive data, this is a big obstacle.

According to the judgment of the Court of Justice of the European Union of 16 July 2020 (the Schrems II judgment), transfers of personal data from the EU are contrary to the RGPD as well as to the Charter of Fundamental Rights of the European Union. Unless there are additional measures or transfers are justified under Article 49 of the GDPR (paragraph 5: "*In the absence of an adequacy decision, Union law or the law of a Member State may, on important public interest grounds, expressly set limits on the transfer of specific categories of personal data to a third country or to an international organization.*")

Therefore, the Health Data Hub project has to be postponed as announced to the end of 2021.

The Health Data Hub is also arguably something of a white elephant. Despite the nice plans to share data, the practical situation is that only a few of the hundreds of requests from scientists for access to data are successful.

2) Fear of influence by US giants

A European cloud project, Gaia-X, was launched in 2019, based on collaboration between France and Germany. It aims to establish an autonomous system in the face of American and Chinese competition. It provides a framework for data exchange. This gives hope, for example, to solve the problem of choosing the cloud for the Health Data Hub, as mentioned above.

3) Limited EU intervention in health for Member States

Despite the existence of several programmes and work by the European institutions in the field of health data sharing, the realization of data sharing does not seem to be close. One of the causes of this difficulty is the fact that the shared competence of the European Union in health matters is limited as follows: TFEU Article 168 paragraph 4 a,b,c.

Except in these limited matters, the EU can intervene in a non-binding

way even if the data shared are health-related: it is up to the Member State to decide whether to make such a measure available.

4) The GDPR and the limiting provisions related to privacy

In theory, the famous General Data Protection Regulation does not prevent scientific research. In practice, it is clear, particularly in times of Covid, that there is a kind of mechanism of fear mongering - sometimes not very rational - in particular towards public health authorities. This mechanism leads to a great slowness in authorisation procedures, or even refusals, with many useful research projects being delayed.

5) Technical difficulties

Beyond the complexities of policy decisions and privacy issues, there is a need to ensure data interoperability. This is complex, especially at the European level, as IT systems and data come from very different sources. 'Trash in, trash out' situations, i.e. incorrect (or incompatible) information 'corrupting' other data, must be avoided.

In conclusion

There are countless initiatives to share data, especially for scientific purposes.

An ideal solution would be a system:
- Having the trust of the citizens
- Managed by a public institution (or non-profit organization)
- Allowing by default (opt-out) the use of all health-related data (anonymized or pseudonymized)
- For scientific research (not for other uses).
- Ultimately enabling everyone to live longer and healthier lives.

The European Union is currently the most appropriate place to develop this.

Good news of the month. Major advances in xenotransplantation.

Under normal circumstances, a transplant of a pig heart or kidney into a human body leads to immediate rejection, sometimes even before the operation is completed. For the first time, these two operations have been performed on two patients. This is very promising. For more than a month, David Bennett has been living with the heart of a pig and since September 2021 another patient has been living with the kidney of a pig. To make this possible, the animals were genetically modified. This means considerable progress for gene therapy as well as for xenotransplantation. And so in what may be a short time, it is very useful for research into healthy longevity.

For more information:

- See: heales.org, sens.org, longevityalliance.org and longecity.org.
- Source of the image