Privacy in the Revision of the Swiss EPDG

Our Assessment of selected key privacy aspects

The Revision of the Swiss Electronic Patient Dossier(in German) (EPDG) is open for comment until October 19, 2023 and provides for a number of changes to improve on the deficiencies of the current law.

It will be mandatory for Healthcare service providers in general to update Electronic Patient Dossiers (EPD), thereby improving the richness and general utility of EPDs for the patient population at large. The federal government is proposed to be given the authority to define, implement and continuously grow the functionality and scope of a central database of structured data for research and quality assurance. Government can also use 3rd parties to implement these developments. Also, the use of this data by Health Applications is going to be permitted, if the respective person agrees. The possibility for pilot projects in a controlled context will be introduced, as well as delegation and guardian functionalities. It will also be possible to include administrative insurance documents.

Privacy Facts

Human Research Act

It may not be generally known that the Swiss Human Research Act, intended to protect the dignity, personality and health of human subjects in research, does not apply to anonymous nor anonymised health data (Art 2c, Human Research Act, HRA, or Humanforschungsgesetz (German), HFG) and therefore such data is generally accessible for research, subject to other laws applicable.

There is no guarantee that any de-identification of health data, colloquially referred to as "anonymisation", can not lead to re-identification of subjects, in particularly so, if combined with other data. Other laws that may apply, such as the Swiss Federal Data Protection Act (FDPA) therefore are key to understand how citizen health data is protected.

Federal Data Protection Act

Processing sensitive health data of human subjects without their express consent by private entities is a **breach of personality rights as per FDPA, however this may be lawful even against applicable principles and express wish of the subject, if justified by an overriding private or public interest, or by law (FDPA Art 31)**. **That same FDPA further clarifies that the controller in particular may have such an overriding interest, amongst other justifications, if data is not processed for purposes related to the specific person, in particular for research, planning or statistics** (Art 31 2e), whereby the controller 1) must anonymise data, or if impossible or disproportionate to do so, take appropriate preventive measures to prevent identification of subjects; 2) if sensitive data is disclosed to third parties this should be done in a non-identifying manner, and if not possible, the recipient must be obliged to process data only for not person specific purposes; and 3) ensure that subject cannot be identified from published results.
Health data processing by private entities for research, planning or statistics purposes, even against their express wish and if not specific person to a person, therefore is lawfully possible under an overriding interest such as research.

Proposed EPDG

Health Data of all Swiss residents who have not opted out of their Electronic Patient Dossier (EPD) is going to be aggregated in structured format and linked with the unique patient identifier at the national level without any further consent. This data can be shared in an anonymous manner with

3rd parties for research and quality assurance purposes. For purposes as per HFG, this personal health data can also be shared in non-anonymised form, if approved as required per HFG, or if consented by subjects. For other research purposes, this data can be shared in compliance with FDPA.

Operators of the EPD (Stammgemeinschaften) will provide patients with the **possibility to consent (no mention of withdrawal) to use of their data for non-anonymous research use per under the Human Research Act, and any other research and quality assurance under the data protection act FDPA (see possibilities to override above)**.

Federal government establishes a national register of opt-outs from the EPD, determines requirements and scope of central components and data held centrally, their operation and access thereto, and can transfer development, and operation of the central components to 3rd parties.

A central structured database holding personal health data of the whole Swiss data population is a large cyber security target, with high data protection risk exposure, regardless of protection measures taken. Breach would have substantial consequences on a potentially large scale. EPD patients have no opt-out from that database.

Patients cannot participate in EPD without their "anonymised" health data being used for research, planning or statistics or quality assurance. This comes as a bundle. Their personal health data will be included in the central database regardless. Patients can choose to not-consent to sharing their identifying health data for research, but that objection may be overridden for approved research as per Human Research Act or other lawful purposes per the FDPA, e.g. as per research, planning and statistic purposes by public and private entities (see above).

The Approach in the EU

In the EU **a similar approach was proposed with the Regulation for the European Health Data Space**. Similarly, it was proposed to not require a separate consent for secondary research for general interest purposes, research, consistent with the purposes listed in EPDG. This triggered resistance in parliament and a hot debate, during which it has become clear that a form of consent has to be included and **an approach whereby an opt-out for secondary research in general and an opt-in for highly sensitive data like genetic data may emerge**.

Our Viewpoint

In the proposed revision of the EPDG, we note an approach that anonymised health data can be used without consent of individuals. This may be valuable in the event of substantial public interest, such as in a health crisis where epidemiological data would be useful, and in general supports public interest purposes and general interest purposes such as research, planning and statistics, yet compromises personality rights of patients.

The hurdle for public and private entities to access this data for other purposes under the FDPA such as not person-specific research is quite low, even if this data is not anonymised. It is sufficient to ensure technical and contractual data protection measures and a justifying general interest as explicitly foreseen the data protection law (FDPA Art 31 2e).

The bundling of EPD use and personal health data being aggregated in a national database for various research, planning and statistics or quality assurance without an effective mean to block such use may deter patients and trigger them to opt-out of EPD all together.

By granting patients the right to choose 1) whether their data is included in the central database or 2) whether their data may be used in anonymised form, trust can be built. Neither of these options are currently foreseen in the proposal.

By including a condition to overriding a lacking consent or express wish of the subject, only if 3) a substantial public interest is present, such as a public health interest or emergency, or 4) the inclusion of non-consented data only if this is necessary to achieve the (research, planning or statistics or quality assurance) purposes at hand, the overarching interest of the community can still be ensured, while the hurdle to compromise individual rights can be elevated. Such a condition for health data re-use in EPGDG would have to be met in addition to the requirements of FDPA.

We believe that the combined inclusion of opt-in or -out for anonymous research (2) and a condition to overriding an absent or express wish of subjects only when necessary for the legitimate purposes listed (4), strikes a good and pragmatic balance, which is feasible in the legislative process, which does not compromise data visibility in a health crisis, maintains the ability to perform research, and maintains citizen rights, thereby also increasing trust and EPD adoption and political acceptance. This may in turn also lead to more research data made available by citizens.