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ELNET

GIHF AI

German Israeli Health Forum for Artificial Intelligence

Policy Briefing "Regulation"

A solid legal framework for the innovation-promoting use of health data

The development and use of artificial intelligence (AI) in healthcare depends to a large extent on the **availability and usability of health data**. The reason is obvious: An AI can only be as good and representative as the data available to train it. After the previous Policy Briefing by the German Israeli Health Forum for Artificial Intelligence (GIHF-AI) dealt with the technological and security aspects of this data, the focus of this briefing are the **most important regulatory mechanisms regarding primary use (use for health care) and secondary use (use for research and development) of health data** in Germany, especially focusing on the latter. For that, we draw a comparison to a country that is about 20 years ahead of Germany when it comes to Digital Health: Israel. The Middle Eastern country already has over 700 digital health startups and a thriving infrastructure of AI-based health applications, used by the majority of its population of just over nine million.[1]

When it comes to the use of health data, Germany is not in a legal vacuum. Quite the opposite: there is a large number of municipal, national and state-dependent regulations that influence the primary and secondary use of health data. **As part of the European Union, German legislation must furthermore be considered in an EU context, given that AI Made in Germany also means AI Made in Europe**. Many laws and requirements on health data are sensible and necessary, as we are dealing with highly sensitive data. Others, however, lead to legal uncertainty and overregulation, which in comparison (also in a European context) make it difficult for developers, startups and smaller companies in Germany to develop innovations and bring them to market. A **rapid implementation of the Health Data Use Act (GDNG)** planned in the coalition agreement for better scientific use of health data **in line with the EU's General Data Protection Regulation (GDPR)**, as well as the **rapid establishment of a decentralized research data infrastructure**, can provide a remedy.[2]

Legislation and the Status Quo in Germany

A milestone in the promotion of Digital Health in Germany was the **Digital Healthcare Act, known as Digitale-Versorgung-Gesetz (DVG)**, that came into effect in December 2019 and provided the foundation for the Digital Health Applications Regulation (DiGAV) and the Patient Data Protection Act (PDSG). In addition to extending the Innovation Fund with 200 million euros annually until 2024, it includes the obligation of pharmacies and hospitals to provide incentives for physicians, midwives, physiotherapists, as well as nursing and rehabilitation facilities to connect to the telematics infrastructure (TI). According to the German government's current digital strategy, the aim is furthermore to achieve widespread use of the electronic patient file (ePA). At least 80 percent of those with statutory health insurance

should have an ePA by 2025 and the establishment of the e-prescription should be the standard.[3]

However, prophecies that Germany, Europe's largest healthcare market, will become a global player in the digital health sector, have not yet materialized. Currently, **the digital health application directory by the Federal Institute for Drugs and Medical Devices (BfArM) lists just 33 applications**[4] and the absolute number of prescriptions is at merely 45,000 – an almost negligible number compared to the 444 million prescriptions for conventional drugs and medical aids.[5] In addition, there is the **almost non-existent uptake of the ePA**. Only 0.5 percent of respondents to a Bitkom survey conducted in November 2021, stated that they had used the electronic patient record, despite expressing great interest in it.[6]

Even though there are various reasons for these sobering numbers, ranging from inadequate education to a lack of trust, the **lack of a clear legal framework for the use of health data** is one of the most crucial ones. Recently, the Conference of State Health Ministers asked the Federal Ministry of Health to identify the reasons for the low uptake of digital applications (for instance the ePA) to evaluate the opt-out solution for the ePA, a demand by the 126th meeting of the German Medical Association.[7] This view is gaining increasing support and is shared by the German Council of Experts on the Assessment of Developments in the Health Care System (SVR), as well as the German Medical Association.[8] Another example is the increased urgency with which physicians, patients, health insurers, researchers, civil societies, and businesses call for the **swift implementation of the Health Data Use Act**, agreed upon in the coalition agreement. This law intends to ensure that health data can be better used for research while being in agreement with the EU's GDPR. At the same time, the misuse of data is to be prevented through higher technical data security and tougher penalties.[9]

As the signatories of the paper "Cornerstones for a Health Data Use Act" argue, **"the use of health data is based on the idea that in a solidarity-based health care system, the general availability of digital health data is an expression of a person's communal responsibility, insofar as personal disadvantages ensue"**.[10]

„Data sharing is caring": A European Health Data Space

In addition to the above-mentioned arguments, the wider use of the electronic patient file creates the basis for further standardized and open interfaces, such as the **connection to the European Health Data Space (EHDS)**. The EHDS can be seen as a regulatory framework for the use of health data in a pan-European context. It provides clear rules, common standards and practices, infrastructures, and a governance framework for the use of electronic health data for the benefit of patients, research, innovation, policymaking, patient safety, statistics, and regulation.

On May 3, 2022, the European Commission published a regulation proposal, which the EU Commissioner for Health and Food Safety, Stella Kyriakides, sums up as follows: "Today we are putting in place another pillar for the European Health Union. Our vision is becoming a reality. The European Health Data Space is a fundamental game changer for the digital transformation of healthcare in the EU. It places the citizens at its center, empowering them with full control over their data to obtain better healthcare across the EU. This data, accessed under strong safeguards for security and privacy, will also be a treasure trove for scientists, researchers, innovators and policy-makers working on the next life-saving treatment. The EU is taking a truly historic step forward towards digital healthcare in the EU."[11]

The basic principle of the EHDS is that EU citizens can jointly use and profit from health data, while at the same time, the rights of the individual are protected. This principle is based on the GDPR, the proposal of the Data Governance Act, the draft of a data law, and the NIS Directive.[12] It has three main objectives: First, **users throughout the EU should be able to control their personal health data**. For instance,

by accessing data like their medical history, test results or prescriptions and be able to share them with hospitals and practitioners, as well as between member states. This would change the primary use of data, as it gives patients significantly more rights and possibilities to use their data. Second, it strives to create a **coherent framework for the use of individuals' health data for research, innovation, policymaking and regulation**, i.e., for secondary use. This too will have significant benefits for patients, as the use of data on vaccination effects during the Covid pandemic in Israel exemplified. Third, unleashing the data economy by promoting a single market for digital health services and products (EHR systems) will have a significant positive impact on AI Made in Germany and AI Made in Europe. This required a more effective law enforcement in the field of AI, however, for instance through the enactment an EU regulation for Artificial Intelligence (EU AI Act).[13]

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>
> Stella Kyriakides, EU Commissioner for Health and Food Safety[11]

Looking beyond the horizon: Handling health data in Israel

The **German top-down** strategy in terms of regulation stands in contrast to the **Israeli bottom-up** approach. Long before the introduction of an electronic patient file was seriously discussed in Germany in 2017, Israel had already digitized its population's health data for the last two decades and used it for healthcare and the research and development of innovative digital health apps and wearables.[14]

Israel began with the digitization of patient data as early as 1995, in the wake of its National Hospital Insurance Law. The 1996 Law for the Protection of Patients' Rights also established binding standards of conduct for the protection of patient data. However, the data in question was held exclusively by one of the four health maintenance organizations (HMO). There was a lack of regulation by the state, as well as a lack of coordination in cross-insurance data sharing. In consequence, the HMOs engaged in a high level of competition and tried to succeed each other in developing and investing in digital health applications. However, data was fully available for research and privacy issues occurred.[15]

Therefore, **Israel's use of data for research** purposes was very low, according to the 2013 OECD report on the connectivity of health data in member countries. Regulatory adjustments, such as the **National Program for Promoting the Digital Health Field**, adopted in 2018, marked a turning point, highlighting the viability of a solid regulatory framework. Particularly secondary use of health data has been facilitated through the related **development of Big Data platforms and data sharing platforms by the Israeli Ministry of Health** such as "PSIFAS". Especially in relation to rare diseases, personalized medicine and general development of medicines, the benefits of using big data cannot be denied.[16]

In addition to continuous regulatory adjustments in the secondary use of data, the Ministry of Health in Israel is eager to establish the legal framework for the primary use of health data. The laws for the protection privacy and medical data were enacted in the 1980s and most recently amended in the 1990s. **Existing patient data should be protected even better in the future, in line with the GDPR**.

In addition, access to one's own data is to be improved. In particular, the use of health data for the research of Covid vaccines by a pharmaceutical company recently led to an increased desire among the Israeli people for **transparency regarding their own patient records**, even though the consensus on sharing data was very high among the population and the data was completely anonymized any-

way. Ironically, the legislative changes pushed by the Ministry of Health have been delayed by COVID-19. Also, the proposal for a change in the law published by the Ministry of Justice last summer has so far failed to achieve any significant success.[17]

Conclusion and Outlook

Health data is much more than a collection of laboratory values, X-ray findings and doctor's letters. Their use has the potential to revolutionize medical care because they act as **fuel for innovative treatment options**. Due to their high sensitivity, they are rightly considered to be particularly worthy of protection in the GDPR. The individual wellbeing and self-determination of each person must have top priority.

However, when regulating the use of patient data, one should not forget, that this data is also a **common good**, as the research results on corona vaccinations from Israel show. A health data use law in line with the GDPR, the introduction of an opt-out solution for the ePA, and an integration into the EHDS, may be useful measurements to adopt a **sustainable regulatory framework** that promotes **solidary data use**, conducive to research and ultimately health care.

In addition, there should be **legal certainty for AI-based applications and confidence in AI Made in Europe** through the swift enactment of an **EU Artificial Intelligence Act (EU AI Act)** and clear supplementary guidelines. In this context, it should generally apply that a **solid legal framework** for the innovation-promoting use of health data may replace the existing overregulation.

Excitingly, Germany and Israel face similar issues about the use of patient data, even if Israel is miles ahead when it comes to implementation. This is another reason why **close cooperation and knowledge sharing** on this issue are so **central and should be promoted and encouraged**.

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