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GIHF AI

German Israeli Health Forum for Artificial Intelligence

Report "Regulation"

Health Data Policies in Israel and Germany's Digitalisation Strategy for Health and Care – Shaping the Future of Healthcare

On June 14, 2023, the German Israeli Health Forum for Artificial Intelligence (GIHF-AI) hosted its second Digital Health Roundtable on the topic of "Regulation". Distinguished experts from the German and Israeli healthcare sectors exchanged views concerning the regulation of health data use. In their keynotes, Yoel Ben-Or, Head of Policy for Digital Health from the Israel Ministry of Health (MOHI), and Marejke Talea Tammen, Senior Policy Advisor from the German Federal Ministry of Health (BMG), presented the latest developments concerning health data use policies and digitalization strategies in Israel and Germany.

The subsequent workshop was led by the keynote speakers as well as Tamar Tavory, Senior Counsel at Arnon, Tadmor-Levy, and Prof. Dr. Fruzsina Molnár-Gábor, Chair of International Health and Medical Law and Data Protection Law at the University of Heidelberg. On this occasion, participants discussed, developed ideas for the regulatory process in both countries, and jointly worked on recommendations for action. The report complements the June 13, 2023 GIHF-AI Policy Briefing "New digitalisation strategy in Germany and current draft law in Israel"[1] which was published in preparation for the roundtable and includes background information on the policymaking process presented.

Below is an initial summary of the main recommendations for action developed in the workshop. They shall contribute to the establishment of healthcare ecosystems with more heterogenous and better data – which is a prerequisite for AI in healthcare. The text that follows sums up the key messages from the keynote presentations as well as the workshop. The video recording of the first part of the Digital Health Roundtable (excluding the workshop) can be found on the ELNET YouTube Channel.[2]

> *"A world in which everyone can securely access and use the right health data when and where they need it."*
>
> Yoel Ben-Or, Head of Policy, Digital Health, Israel Ministry of Health

Recommendations for Action

Patient-Centricity and Benefit-Orientation

Health data use should follow a patient-centered and benefit-oriented approach. Patients are the ultimate beneficiaries of new technologies and innovations in healthcare springing from research. Thus, health data should be made accessible and usable for research and innovation, following an opt-out procedure. User-friendly regulation on data access is necessary both in the national as well as international context (such as the EHDS).

Tailormade Regulation

Tailormade regulation, following best practices, will lead to innovation rather than a "one size fits all" approach that tries to predict and pre-regulate every possible scenario. Since technological progress will always move faster than regulatory processes, one needs to think of the future when making regulations today. By using examples of certified, feasible cases in addition to a one-on-one decision, it is possible to react both timely and practicably.

Interdisciplinary Cooperation and Communication

Interdisciplinary cooperation and the involvement of relevant stakeholders in the development of strategy processes are recommended. Participatory processes in the development of a digitalization strategy, involving all relevant players, such as patients and their relatives, healthcare providers, researchers, industry, and cost carriers, will not only lead to more trust and acceptance but also to more interdisciplinary knowledge and better solutions.

Incentivisation and Motivation

A culture of incentives and motivation for creating and enabling innovation for the benefit of patients should be preferred to a culture of prohibition. **The government should design a framework (regulatory incentive) that enables researchers and developers to innovate while offering incentive programs** for needed solutions. Also, caregivers need an inducement to support change since they may be affected by increased documentation efforts during the transformation process.

Communication Campaign

It is recommended to initiate a broad communication campaign on digital health and health data use to gain trust and improve the digital health literacy of citizens. This needs to include information about the benefits of data use and transparency about how data is being stored, used, and shared.

International Cooperation

A regular exchange about regulatory processes on an international scale is crucial. Questions about international terminologies and data exchange standards, as well as consent models, are shared across the globe. E.g., as was discussed in the last GIHF-AI Digital Health Roundtable, shared standards like FHIR, are crucial for cooperation across borders.

Health Data: From Strategy to Implementation

Based on the presentation of Yoel Ben-Or, Head of Policy, Digital Health, Israel Ministry of Health

Starting of with a vision of **"a world in which everyone can securely access and use the right health data when and where they need it"**, Yoel Ben-Or presented the evolvement of policymaking in Israel with regard to the use of health data while stressing that this vision is shared amongst many countries. Three decades ago, Israel already had its first Electronic Medical Record (EMR) in place. Since it is outdated now and the regulation of health data use needs to be adapted to the patients' needs, the **Ministry of Health started taking on a new role as the driving engine for the optimal use of health data**. The goal is for patients to have better access to their data and more say in how their data may be used.

To achieve excellence in data quality, the MOHI started its first **incentives program in 2022 aiming to implement SNOMED CT** as common terminology. It also put more emphasis on **managing the national health data catalogs and enforced their use**. To further interoperability, the ministry continued supporting the **broad implementation of Fast Healthcare Interoperability Resources (FHIR)**, as was discussed in the previous GIHF-AI Digital Health Roundtable[3] on the implementation of FHIR in healthcare. Currently, the main discussion in health data policymaking in Israel is about **how to share health data and especially the role of patients hereby**. Starting in 2014, there is currently a closed network between Israeli Health Maintenance Organizations (HMOs) and hospitals. The **goal today is to create an open network that gives patients more sovereignty**. The **Draft Medical Information Portability Law published in 2023** aims to answer questions in that regard.

Balancing patients' rights and maintaining privacy and security are among the main challenges. Concerning privacy, **getting the consent of the patients to share their data with third parties is crucial**, as is in Germany. Next to multiple aspects of consent, like depth of data history, what data from which data holder may be used, and whether the consent is given for a limited or unlimited period, consent options like opt-in and opt-out or all or nothing, the time difference between consent giving and service need to be taken into consideration. To summarize, there **won't be a "one size fits all" policy but rather a tailored solution to different scenarios**.[4]

Going Digital: Germany's Digitalisation Strategy for Health and Care

Based on the presentation of Marejke Talea Tammen, Senior Policy Advisor, German Federal Ministry of Health (BMG)

The **German Federal Ministry of Health (BMG) recently published its Digitalisation Strategy for Health and Care**. It is part of the coalition agreement with the objective of a "focus on solving problems in healthcare provision and on the user perspective"[5]. The **development of the strategy was based on a participatory process** involving relevant stakeholders in the health and care system, inter alia, patients, people in need of long-term care, and their family members. The participatory process took place from August 2022 until December 2022. **Next to a kick-off event it involved expert interviews, online surveys, and specialist forums**. The strategy was publicly presented by the Federal Minister of Health, Prof. Dr. Karl Lauterbach, in March 2023.

Similar to Israel's approach, the **ultimate goal is to achieve a people-centric digital healthcare ecosystem** through adequate use of digital and analog healthcare resources, user-focused digitally supported healthcare provision and administration, and health literacy. To achieve this, it is crucial to have **high-quality data** which is needs-based, simplified, and can be securely accessed. Furthermore, the **data needs to be structured and interoperable as well as interconnectable for healthcare provision (primary use) and secondary use (including research and innovation)**. The electronic patient record (ePA) is supposed to serve as an individual digital healthcare platform for the insurance hold-

er. By 2025, 80 percent of statutory insurance holders are supposed to have an ePA and by the end of 2025, 80 percent of ePA users are supposed to have a digital medication plan.

Telemedicine becoming increasingly important due to demographic change and a growing shortage of specialists in rural areas, the strategy foresees to support the **establishment of respective healthcare arrangements**. The goal is that by 2026, 60 % of **underserved regions will have assisted telemedicine access points**. This is supposed to be done by lifting restrictions on telemedicine to 30 percent of consultations, setting up access points with non-medical health professionals (e.g. in pharmacies or health kiosks) as well as designing and establishing digital disease management programs (dDMP). To support the digitalization process in the field of care, the strategy includes the **plan to set up a Competence Centre for Digitalisation and Care** and make digitally assisted, interoperable care documentation the standard in care.

Furthermore, **by 2026, 80 percent of communication processes are supposed to be paperless**. Concerning health data use, by the end of 2026, no less than **300 research projects shall be conducted or initiated with data from the German Health Data Lab (HDL)**.

An **updated regulatory framework** is supposed to set the ground rules to achieve the strategy's goals, one of them being the **Digital Act**. It's supposed to **introduce the opt-out ePA and e-prescriptions as standard** applications in healthcare. It also includes a **binding commitment to uniform technical standards**. Timely implementation as well as parallel transformation processes will be challenging and need to be addressed.

Secondly, the **Act on Health Data Use (GDNG)** is supposed to **improve the availability and secondary use of health data** including research and innovation. The GDNG aims to create a **decentralized infrastructure for health data** and is also supposed to **set the conditions for a data-driven machine learning system**. The negotiations on the EU level for a **European Health Data Space (EHDS) need to be closely taken into consideration for the GDNG to work**. A hurdle, that also needs to be taken into consideration, is the often too-restrictive interpretation of data protection law in Germany. Both laws are expected to come into play in 2024.[6]

Discussion and Conclusion

The keynotes and the following workshop showed that both **Israel and Germany are currently finding themselves in a transformative time** with regard to the use of health data for primary and secondary use. The fast pace of technological development in the health sector, including the use of innovative digital solutions based on AI, poses a great chance for the transformation of healthcare. The Covid vaccine research which relied heavily on big quality data, Israel was able to provide, served as a use case and accelerator alike. At the same time, this development poses a great challenge for regulators. In order **not to prevent innovation by unnecessary bureaucracy, regulators need to understand that it will not be feasible to think of every possible case in advance and pre-regulate it**.

The **Israeli approach, looking at scenarios and finding tailor-made solutions, could be a good option**. By learning from good practices and creating a sort of catalog of possible scenarios to turn to as a regulator, the process should be flexible, yet not too complicated and time-consuming, since technology companies need to move fast. In the framework of the **Draft Medical Information Portability Law**, the Ministry of Health Israel tries to **make sure that every solution that has a real benefit for healthcare will be able to enter the market and get licensed in a timely manner, even if it's an unprecedented case**. Good new solutions, not thought of before coming from developers not lawmakers, should be also promoted by the government while safeguarding citizens' rights and trust. The government isn't aiming to create the solutions itself but rather encouraging industry and HMOs to do so, providing them with the right framework. A practicable consent model may be developed by a non-governmental entity for example and applied by the government afterwards. **Germany's DIGA and DIPA**

regulations may be models for Israel on the other hand and have been adopted in other European countries already.

This flexibility is also crucial with regard to data privacy and protection. There was consensus amongst the participants that **consent by patients is important if you wish to integrate third-party applications for the benefit of patients**. This patient-centered approach is supposed to give people the option to decide how their data can be used. At the same time, **health data should not only be seen as an individual good but also as a common good**. In order to make this good useable and foster innovation while maintaining patients' rights, such as manifested in the GDPR in Europe or by the Helsinki Committee in Israel, **regulation needs to follow a cost-benefit approach**.

Looking to the **European Union**, the discussion of how to handle patients' consent and inform patients better about the use of health data, is ongoing. The question of **whether the opt-out solution will apply only to primary use or also to secondary use in Germany will hopefully be answered in the EHDS and the GDNG**. Once in play, it will be **challenging to connect national data spaces** and access points within but **creates a great benefit for stronger cross-border cooperation** in medical care and research. Since all **Israelis have an EMR already**, meaning there is no question of opt-in or opt-out for primary use, the **issue is rather, how patients can be given more possibilities to use and share their data**. For that reason, Israel looks closely at the European regulation and may adopt parts of it. Next to the question of dealing with consent, **medical ethics play a big role and will be discussed in the EHDS negotiations**. The German perspective on data privacy is comparatively conservative and seen by many experts as unbalanced and not sufficiently considering patient safety. A communication campaign for the public could foster trust in health data use, which is needed in order to deal with consent issues and may be conducted before, during, and after lawmaking.

To sum up, the **involvement of and cooperation between all relevant players** like patients and their relatives, doctors and nurses, researchers, industry, and HMOs is **key to designing practicable regulations and getting consent**. Since data can't be linked without interoperability, **implementing standards like FHIR needs to play a crucial role** in any framework regarding health data use. Furthermore, next to creating a regulatory framework, incentives to follow them should be thought of by the government. Since problems which might appear in the future need to be solved now, a pragmatic and benefit-oriented approach toward regulation needs to be taken. **Technology moves faster than lawmaking**, especially with regard to AI-based technologies, making it indispensable to always have the answer ready. **Flexibility and openness to new solutions** are key to benefit from the great potential of digital health. Finally, **learning about different systems is important to develop and implement a national strategy**, making **international cooperation like the one between Germany and Israel so fruitful**.

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