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GIHF AI

German Israeli Health Forum for Artificial Intelligence

GIHF-AI Review 2023

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The German Israeli Health Forum for Artificial Intelligence (GIHF-AI) connects experts from Germany and Israel in the field of digital health with a focus on artificial intelligence (AI) and machine learning (ML) and has a board of trustees aside.

Dear readers,

In 2023, the German Israeli Health Forum for Artificial Intelligence (GIHF-AI) was able to further expand its efforts regarding German-Israeli cooperation in the digital health sector. The highlights of the second year of the program included three new German-Israeli innovation partnerships that GIHF-AI was able to support. In addition to the initiation of collaborations between the Tel Aviv Sourasky Medical Center (Ichilov) and the University Medical Center Hamburg-Eppendorf (UKE), University Hospital Schleswig-Holstein (UKSH) and University Hospital Essen (UME), Charité-Universitätsmedizin Berlin and the Sheba Medical Center as well as the largest Health Maintenance Organization (HMO) Clalit continue to be among GIHF-AI's close partners.

Another milestone was the second annual GIHF-AI conference, for which ELNET brought a delegation of around 30 Israeli healthcare experts, innovation managers, startups, and representatives of the Israeli Ministry of Health to Germany. To kick things off, the delegates met around 20 high-ranking guests from the German Bundestag, the Federal Ministry of Health, the Israeli Embassy, and representatives from industry and the media at the ELNET office in Berlin.

The following day, the delegation traveled to Essen, where the conference commenced with a festive reception at Essen City Hall at the invitation of Lord Mayor Thomas Kufen. Dr. Yiska Weisband, Director of the Data Research Center at Clalit Innovation, presented the first results of the GIHF-AI study on trust in the use of health data in Germany and Israel. As part of the study, which she co-authored, 2,052 Germans and Israelis were asked about their willingness to share their health data in mid-2023. Prof. Dr. Sylvia Thun, Director of the Core Unit eHealth and Interoperability at Charité's BIH, and Prof. Dr. Ran Balicer, CIO & Deputy-DG at Clalit Health Services, acted as primary investigators of the study. Contrary to predictions, the differences between the countries were strikingly small. Dr. Weisband summarized that the majority of respondents in both countries had a positive attitude toward the sharing of anonymized health data for research and treatment.

The conference day was used by around 80 participants in Essen to deepen the discussion on the use of health data and to explore opportunities for cooperation between Europe and Israel. Dr. Yiannos Tolias, Legal Lead AI and AI-Liability in Healthcare & Member of the European Health Data Space (EHDS) Team of the European Commission, and Dr. Axelle Menu-Branthomme, researcher at the Health Data Hub France, added European perspectives to the discussions. Breakout sessions on regulation, medical collaboration, innovation, and market access complemented the extensive program.

In addition to the digital roundtables, several dialog events rounded off the annual program. These included a parliamentary breakfast on AI in health research and practice at the German Parliamentary Society and an event at the European Parliament on the EHDS and the European AI Act in cooperation with the Munich-based company Brainlab. In response to the October 7th attacks by Hamas and the ensuing war, GIHF-AI hosted a Digital Mental Health Roundtable on December 13, which focused on the impact of the events on the mental health of the Israeli population.

Furthermore, GIHF-AI again participated in the Digital Health Conference DMEA, where ELNET brought three Israeli digital health startups to Berlin with its second innovation program, the German Israeli Network of Startups & Mittelstand (GINSUM).

GIHF-AI was represented at numerous other dialog formats in 2023 and further strengthened its own German-Israeli expert status in the field of digital health by publishing policy briefings, statements, and reports with political recommendations for action.

The publications of the past year are summarized in this brochure. We hope you find it to be interesting reading and look forward to your suggestions and comments.

Carsten Ovens
CEO (DACH)

Summary

1. Background and method approach

The digitalization of medicine is currently one of the most relevant topics globally. In order to measure **the willingness to provide digital health data for research and care management**, **2,052 citizens in Germany and Israel were surveyed** in mid 2023 for a first direct comparison **in the context of GIHF-AI** (German Israeli Health Forum for Artificial Intelligence). **Prof. Dr. Sylvia Thun**, Director Core Unit eHealth and Interoperability at **Berlin Institute of Health at Charité** (BIH), and **Prof. Dr. Ran Balicer**, CIO & Deputy-DG at **Clalit Health Services** and Founding Director at **Clalit Research Institute**, served as **primary investigators to the study**. Additional authors were **Dr. Yiska Weisband**, Director of Data Research Centers at Clalit Innovation, and **Dr. Alexander Schachinger**, CEO of EPatient Analytics.

Clalit Research Institute and EPatient Analytics, the digital health market research agency, **designed a health data survey** and used the panel approach from **Kantar Global**, an international leading consumer panel provider, to survey a **controlled sample of 1,219 German and 833 Israeli citizens**. The project time of the panel survey was **May to July 2023**.

In addition to the current state of health, the main contents of the questionnaire included **socio-demographic information** of the participants, the **use of digital health applications, wearables or trackers, medical devices,** and the **willingness of the digital data donation** of one's own vital data for a wide variety of application scenarios with different actors, such as doctors, clinics, authorities, industry, and others.

2. Key findings

The sociodemographic participants structure is in its majority aligned to the social structure of the respective countries. In a first comparison visualized in the graphs below, the **age difference between Germany and Israel is quite apparent. The average age in Germany in 2020 was 44.7 years, in Israel 29.1 years (2022).**

2.1 Age of population

The different age structure is also reflected in the proportion of participants with chronic diseases: **41% of German participants have a chronic disease. In Israel, the figure is only 26%**.

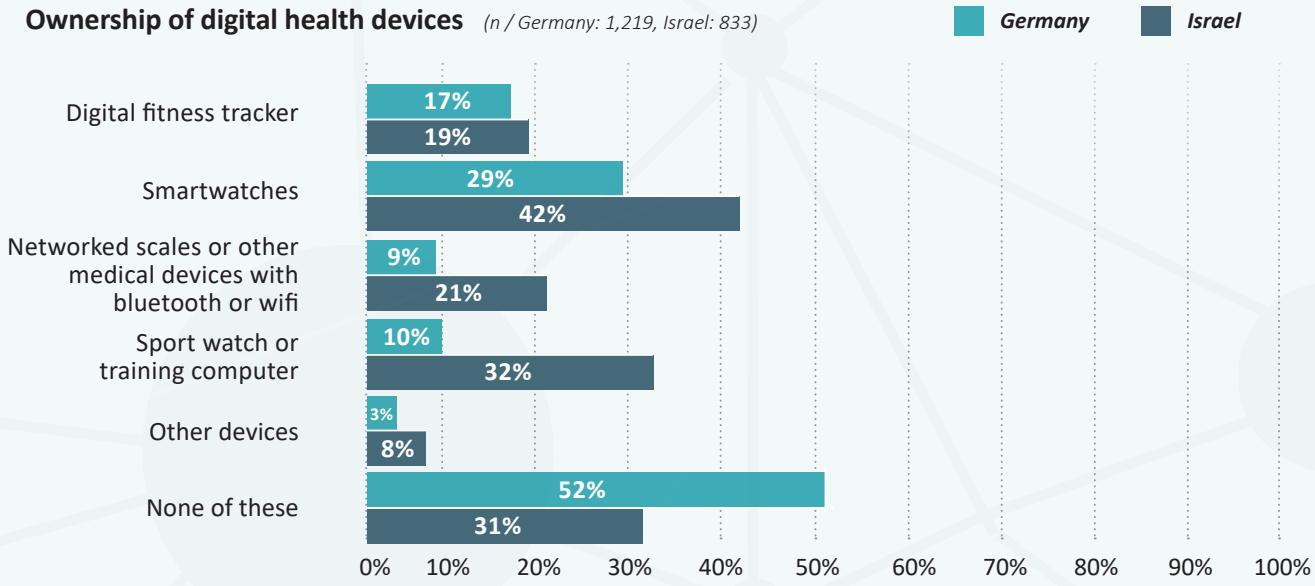
2.2 Ownership of digital health devices

As shown in table 1, **Israeli citizens own all digital health devices surveyed more frequently than Germans**. These differences are quite significant from a digital technology diffusion perspective. After adjusting for age and gender, use of some digital device is more common in Israel than Germany, IRR 1.28, 95% CI (1.14, 1.44), p<0.001.

However, **no difference was found in use of some digital health devices between chronic disease and not**, after adjusting for age and gender.

TABLE 1

Ownership of digital health devices *(n / Germany: 1,219, Israel: 833)*



2.3 Knowledge and readiness on using personal digital health data for research and care

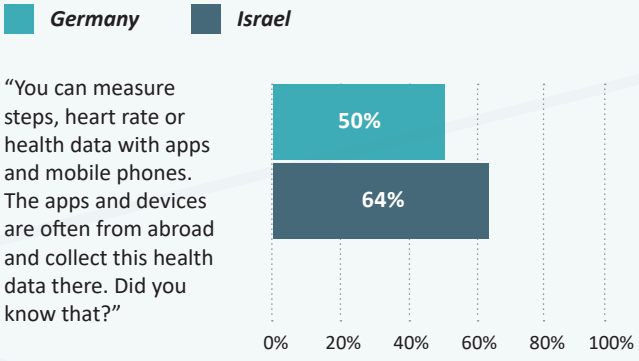
Participants from Israel have a higher knowledge of the digital ecosystem behind personal digital health data and its potential. This remained even after adjusting for age and gender, IRR 1.17, 95% CI (1.04, 1.32), p=0.01. Table 2 shows the results for two exemplary items.

Also, **Israeli citizens are more open to research and care scenarios** that are **based upon or using their personal digital health data**. This remained even after adjusting for age and gender, IRR 1.24, 95% CI (1.09, 1.41), p<0.001.

TABLE 2

Knowledge on the topic of digital health data (percentage of respondents who answered positively)

(n / Germany: 1,219, Israel: 833)



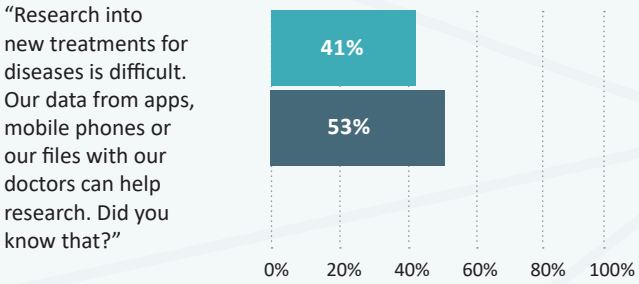


TABLE 3

Support data use for clinical purposes by clinical public entities (doctor, HMO, or clinic)

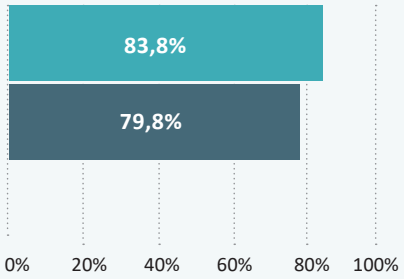
(n / Germany: 1,219, Israel: 833)

*Surveyed organization proposals (pro) were:

- industry
- health fund/insurance
- government
- non-profit-organization
- university
- hospital

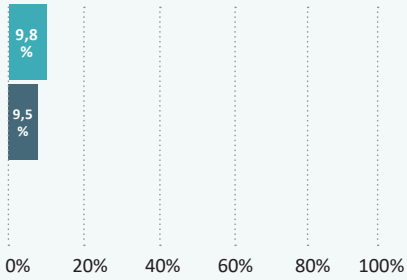
Germany Israel

"Imagine: your health data is stored digitally. This is intended to serve your health and improved treatment. But: Who would you trust with your digital health data? I support the use of my digital data for clinical purposes by some entity."*



IRR 1.11, 95% CI (0.99, 1.24), p=0.08

"I would not let any of these organizations use my data for clinical purposes."*



IRR 0.98, 95% CI (0.73, 1.31), p=0.9

2.4 Evaluation of digital health data scenarios

The **assessment of application scenarios in which personal digital health data is used, did not differ as clearly for the two countries as in the other questions raised**. This is noteworthy because the implementation of digital health data infrastructure in the care of citizens is quite advanced in Israel compared to Germany – whose health care system is practically still paper-based. Vice versa these results can be interpreted as a **digital health readiness of Germans** which **is more advanced than state-of-the-art political regulators think or act upon**.

TABLE 4

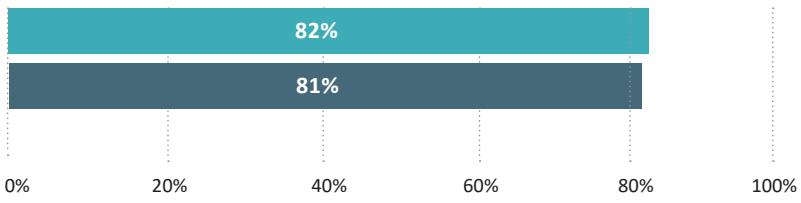
Evaluation of selected digital health data scenarios (percentage of respondents who answered positively)

(n / Germany: 1,219, Israel: 833)

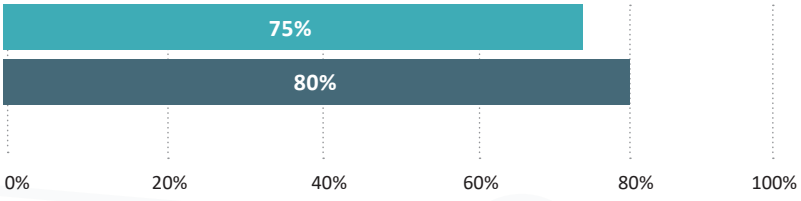
*Scenario evaluations in the survey were operationalized via 3 items: 1. pro, 2. con, 3. don´t know.

*Question answered positively** Germany Israel

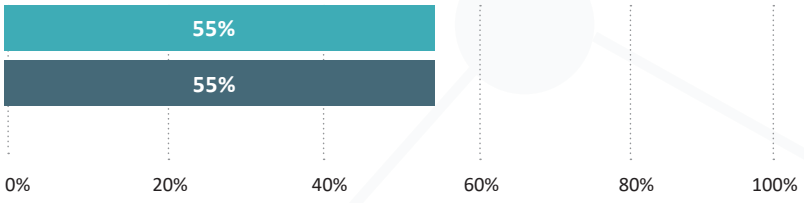
"In some countries there is already a central database with anonymized patient data. Medical research can use the data in compliance with data protection. What do you think about such a research database for Germany/Israel?"



"The smartphone can measure and transmit data on movement, blood pressure, and pulse, e.g. to the doctor. In this way, patients can be treated better. What do you think about the possibilities of connecting your smartphone data with the doctor's patient record, thus ensuring better diagnosis and treatment?"



"For an easy data access for research: My data may automatically flow anonymously to an independent research institute or university."



3. Conclusion

Common wisdom suggests that the wide differences that exist between **Germany and Israel** in the legal framework and the **extent of health data usage** for clinical and research purposes are **driven by differences in public willingness to share such data**. The survey **results tell a very different story. In fact, support of such use is almost identical in both countries; and is moderately high when public-service clinical entities are involved**, while a small consistent minority of about 10% of those surveyed are categorically opposed to any such use in both countries.

KEY OUTCOMES

**The two sampled groups in both countries have major age differences – result comparisons are therefore age-adjusted.*

1 **High levels** (71.8% Germany / 72.8% Israel) **of reported awareness that data from apps, cell phones, and electronic medical records can be used to support research,** are reported in both Germany and Israel, with no significant difference between countries.

2 General **high level of willingness** (82.4% Germany / 81.4% Israel) to **establish anonymized datasets** of patient information to be used for research in both Germany and Israel, with no significant difference between countries.

2.1 *The age group with the lowest level of trust was 50-59 years old in Germany and 18-29 years old in Israel.*

2.2 *A small group exists that categorically refuse any and all data sharing and use, by any entity, even for clinical purpose. This subgroup is of identical size (~10%) in both countries.*

2.3 *Those with chronic disease were more willing to share their data for clinical use, in both countries (Israel 83.5% / Germany 88.7%).*

3 **The majority of respondents** in both Germany and Israel (53.5% Germany, 58.5% Israel), are **willing to actively donate one's data for research** (IRR 0.97, 95% CI (0.87, 1.07), p =0.5).

4 **Support of some clinical public entities** (at least on one of the following - doctors, clinics, or HMO) **using health data to improve clinical care is high** (79.8% Israel, 83.8% Germany), with no significant difference between countries.

5 **Agreement to share one's health data with one's Krankenkasse/HMO differs between the countries.** Nearly two thirds in Israel and slightly less than half in Germany (49.1% Germany 65,3% Israel). Differences are significant in age-adjusted analysis (IRR 1.27, 95% CI 1.12, 1.43, p<0.001).

6 **There is a low support for other (especially private) institutions in applying the data**. Here are **no relevant differences between the two countries** given. Pharmaceutical companies receive a relatively lower level of support for the use of personal health data for research purposes (30.7% Germany / 28.3% Israel). Big tech companies are evaluated even lower (4.4% Germany / 18.1% Israel).

RECOMMENDATIONS FOR ACTION

- **Support an unbiased use of patient data for research and medical care while safeguarding data privacy.**
- **Anonymized datasets of patient information should be used for valuable research in the public and private sectors.**
- **Engage in trust-building campaigns for the use of data by informing data holders about data usage, data protection, and data security.**
- **Communicate and inform transparently about data usage and its benefits for research and application.**

4. Summary and conclusion

A key finding is the relatively **advanced willingness of citizens in Germany to accept digital health scenarios based on their own health data**. This willingness is only **slightly less pronounced than in Israel**. Mind you: **In Israel, digital supply solutions based on individual vital signs, have been a reality for over 15 years**.

Against the background of a previously non-existent digital care structure in Germany, it can be deduced that the German population is more advanced in its acceptance of digital health than politicians and legislators or the regulators of the health system in Germany. This finding also **coincides with a comparable preliminary study from 2022**, in which 6,000 Germans were interviewed on this topic (see Self Tracking Report, EPatient Analytics GmbH, 2022).

Furthermore, it is easy to understand that **ownership and usage of digital health devices and applications in Israel are further developed by many years compared to Germany**. As indicated above, the **Health Maintenance Organizations in Israel have been offering these applications** to their policyholders and patients with a consistently digitally integrated database **for many years**. Germany should follow suit.

Primary Investigators:

Prof. Dr. Sylvia Thun, Director Core Unit eHealth and Interoperability, Berlin Institute of Health at Charité (BIH)

Prof. Dr. Ran Balicer, CIO & Deputy-DG, Clalit Health Services; Founding Director, Clalit Research Institute

Additional Authors:

Dr. Yiska Weisband, Director of Data Research Centers, Clalit Innovation

Dr. Alexander Schachinger, CEO, EPatient Analytics GmbH

Stand 15.01.2024

Prof. Dr. Ran Balicer:

"Our results are very encouraging. In Israel, patients greatly benefit from data-driven interventions for over a decade, and it seems the public is now overwhelmingly supportive of this happening in Germany as well."

Prof. Dr. Sylvia Thun:

”It‘s great that most citizens are willing to share their data with doctors and scientists, which represents enormous progress for medical research and patient care.“

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ELNET

GIHF AI

German Israeli Health Forum for Artificial Intelligence

16.12.2022

Report "GIHF-AI Conference 2022"

Healthcare of the Future

On November 28-29, 2022, the German Israeli Health Forum for Artificial Intelligence (GIHF-AI) held its first annual conference. At the invitation of the Israeli Ministry of Health, the conference took place in Tel Aviv as part of HealthIL Week. It kicked off with a conference reception at the Carlton Hotel Tel Aviv with Minister of Health Nitzan Horowitz on the evening of November 28, followed by a day-long conference with keynotes, workshops, and a panel discussion at the Tel Aviv Sourasky Medical Center (Ichilov) on November 29. Finally, on November 30, the conference participants attended the HealthIL Week Main Event together at EXPO Tel Aviv, giving them- after the theoretical exchange of the previous day- a practical insight into the Israeli digital health ecosystem. The following is a summary of the recommendations for action derived from the results. The following text summarizes the presentations of the conference, the video recording of which can be found on the ELNET YouTube channel.[1]

FACTS, FIGURES, DATA ON THE GIHF-AI CONFERENCE 2022

- Two-day conference (Nov. 28-29, 2022) with live stream
- Approximately 200 participants (online/offline).
- 3 breakout sessions followed by panel discussion
- Attended HealthIL Main Event with 1,750 participants, 25 delegations and country representatives, 310 startups, and 13 spotlight sessions
- Featuring Nitzan Horowitz (Minister of Health Israel), Dr. Asher Salmon (Director International Relations Department, Israel Ministry of Health), Esti Shelly (Director Digital Health, Israel Ministry of Health), Dr. Susanne Ozegowski (Director General for Digitalization and Innovation, Federal Ministry of Health Germany), and Thomas Renner (Head of Subdepartment Digitalization and Innovation, Federal Ministry of Health Germany).
- Keynote on the EHDS and the EU AI ACT by Dr. Yiannos Tolias (Legal Advisor AI and AI Liability in Healthcare & EHDS Team, EU Commission DG SANTE).
- Presentations by Prof. Dr. Sylvia Thun (Director Core Unit eHealth and Interoperability (CEI), Charité Berlin), Prof. Dr. Ronni Gamzu (CEO, Tel Aviv Sourasky Medical Center), Prof. Dr. Ran Balicer (CIO, Clalit Health Services).

Recommendations for Action

Interoperability and standardization

The standardization and interoperability of health data must be driven forward at full speed so that data can be made usable for research and, in particular, AI development. It is recommended to **introduce internationally common data standards such as FHIR, SNOMED CT and LOINC** to enable transnational science collaborations.

Opt-out based EHR

Digitization in healthcare requires central orchestration, especially with regard to data use. This includes not only the nationwide introduction of data standards, but also regulations such as the use of the EHR (ePA). A **nationwide introduction of an opt-out-based EHR (ePA)** that covers all relevant health data is indispensable.

Incentivization of data linkage

Policymakers must create concrete incentives for increased data exchange in the healthcare sector. This includes, above all, **breaking down existing data silos** in order to make data linkable. One way of incentivizing this would be, for example, to link the **awarding of subsidies to criteria such as the reusability of data** and to finance the **development of a data infrastructure**.

Investment in data infrastructure

Research and development in the area of data use and AI in particular require **more budget for investments in the data infrastructure**, as this is the basis for any research project. At the same time, **greater exchange should be sought between research institutions, healthcare providers, patient advocacy groups, payers and industry**. Instead of competition, the focus should increasingly be on collaboration.

Trust through regulation

In particular, it is important to gain the trust of physicians and patients in digitization and AI development. This requires a **clear legal framework** based on the regulatory ordinances of the European Commission. Any laws must be constantly monitored, evaluated, and adapted to the current circumstances. **Transparency and ethical guidelines for data exchange** also ensure greater trust and acceptance.

Digital literacy in healthcare

Digital health and AI must be given a higher priority in healthcare institutions and among healthcare providers and must be increasingly **included in the curriculum of medical students**. In hospitals, this can be achieved by **appointing data experts and CTOs**, and by establishing interdisciplinary innovation hubs that connect researchers, healthcare providers, and industry. The knowledge gained should be passed on immediately to the next generation of medical professionals.

Close cooperation in the field of digital health between Germany and Israel

In his welcome address at the conference reception on November 28, Israeli Health Minister Nitzan Horowitz emphasized the importance of the German Israeli Health Forum for Artificial Intelligence (GIHF-AI) for collaboration between Germany and Israel in the field of digital health and praised the good cooperation over the past year. Also Dr. Asher Salmon, Head of International Relations at the Israeli Ministry of Health, demonstrated how important international liaisons such as GIHF-AI are in the field of health in his welcoming speech on the conference day. Furthermore, he announced the opening of a Digital Health Center with the World Health Organization (WHO) in 2023/2024 for experts from all over the world in Israel. This will also be important for German Israeli cooperation.[2]

Future Hospital: Inside Tel Aviv Sourasky Medical Center

Prof. Dr. Ronni Gamzu, CEO of the Tel Aviv Sourasky Medical Center, emphasized how important it is to break down barriers that prevent the introduction of technological innovations in his presentation on the topic of smart hospitals. In particular, it is crucial to gain the trust of physicians for implementation, according to him. At the same time, hospitals need to invest in data experts. Among the limiting factors, he pointed to the excessive hierarchies in everyday hospital life, the lack of budgets for research and development, and regulatory hurdles. Professor Gamzu cited Israel's high emergence of disruptive technologies, the startup nation culture, the impact of the Corona pandemic, competition between healthcare providers (HMOs in Israel) and industry, and the Israeli Ministry of Health's support for innovations conducive to the development of smart hospitals, among other factors. As a next step, he said, it is important to create a culture for new ideas, to see research and development as independent entities, to initiate collaborations between academia and industry, and to pursue a strategy of open data use. Innovation hubs, incubators, and accelerators, as well as participation in private equity funds, would help bring applications to the healthcare market.[3]

Challenges in Developing and Deploying AI in Healthcare – EC Legislative Responses

Dr. Yiannos Tolias (Legal Advisor AI and AI Liability in Healthcare & EHDS Team, EU Commission DG SANTE) welcomed the initiative to link Europe and Israel in the field of AI use in healthcare, as this would lead to a wealth of healthcare data that is important in the field of AI development. Among the priority issues in the area of AI regulation in healthcare, he cited the interaction between physicians with AI, as well as resentments regarding the safety of AI use and a lack of trust in the new technology. The European Commission has launched several regulations and proposals over the past four years to provide a comprehensive legal framework to advance AI use and regulate secondary uses of health data. These regulations also govern what data can be used for product development and are therefore important not only for researchers but also for industry. Namely:

- the EU AI Act
- the proposal for a regulation on the European Health Data Space (EHDS)
- the adapted Liability rules on products and AI and Liability rules for AI
- the European Medical Devices Regulation (MDR)

An example of the interaction between the EU AI Act and the EHDS is the transfer of data by data owners, such as hospitals, to the relevant competent authority for health data. The EHDS provides for each member state to have such a focal point to coordinate the sharing of health data for secondary use. Certificates such as the Data Quality Utility Label (DQUL) of the EHDS are also intended to ensure data quality.[4]

Digital Health and AI: Two countries, two perspectives, one goal

Esti Shelly, Director Digital Health at the Israeli Ministry of Health, emphasized that the government alone cannot drive the change in healthcare, but

needs the collaboration of physicians. To do so, she said, they need a broad set of tools to use health data. At the same time, privacy and data security regulation is needed to avoid losing the public's trust. In the case of regulations on data availability, it is important to bear in mind that, on the one hand, restrictions can hinder innovation, but on the other hand, liberalism can lead to a loss of trust, and a viable middle ground must be found that considers the needs of all stakeholders. In addition, she said, the legislation must also be seen in an international context, since Israel also acts as a beta location for many countries for testing algorithms. With regard to interoperability and standardization, she emphasized that specifications should apply across borders.[5]

Dr. Susanne Ozegowski, Director General for Digitalization and Innovation at the Federal Ministry of Health Germany, emphasized that the digitization strategy for the healthcare sector is primarily concerned with disseminating the Electronic Health Record (ePA) to at least 80 percent of the population, including medication and laboratory data. Prioritization here would have to be on medication and laboratory data in particular. To achieve this, the opt-out would need to apply to primary and secondary health data. In theory, the data should automatically go to the Health Data Hub (FDZ) unless the patient opts out. Dr. Susanne Ozegowski also emphasized the importance of interoperability, but at the same time stressed that this would take time, since industry also played a key role. In addition, in her view, it is not only the standardization of data that is important, but also the standardization of regulation.[6]

Transforming Care through Data Driven Innovation: Cross-countries Perspective

According to Prof. Dr. Ran Balicer, CTO at Clalit Health Services, the main reasons for the low use of AI in healthcare so far are not a lack of budget, interoperability problems or data protection, but the conservatism of healthcare providers. However, to redress the imbalance between supply and demand, innovations need to be introduced proactively. Using Clalit's AI-based predictive model C-Pi – Clalit Proactive-Preventive interventions platform, as an example, he showed that it is already possible to provide physicians with AI-based decision support. During the corona pandemic, high-risk patients were identified by C-Pi using patient data from clinical and administrative records, and preventive work was done. As a result, hospital admissions due to COVID were reduced by 43 percent. In addition to increased patient safety, this also led to financial as well as personnel relief.[7]

Outlook for 2023: Introduction to upcoming GIHF-AI Study

Prof. Dr. Sylvia Thun, Director Core Unit eHealth and Interoperability (CEI) at Charité Berlin, presented the upcoming GIHF-AI study. The study is being conducted by EPatient Analytics and is a collaboration between Charité - Universitätsmedizin Berlin and Clalit Health Services, under the direction of Prof. Dr. Ran Balicer. It will compare Germany and Israel on the topic of trust in the use of health data. The results of the study will provide decision-makers in both countries with a barometer of public sentiment that can be used to derive policy recommendations. In preparation for the study, Sylvia Thun presented the results of the current EPatient Survey, Germany's largest eHealth survey, with the aim of providing stakeholders with valuable information. According to the survey, the population has more confidence in the use of ePAs than politicians. 65 percent of the population would support the efficient use of health data for research, and 78 percent of the population would welcome the work of the health data hub. At the same time, health data literacy, or the competence to handle health data, is very low at 12 percent. Based on this, the GIHF-AI study will give an important picture of the population's opinion regarding health data use.[8]

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GIHF AI
German Israeli Health Forum for Artificial Intelligence

10.03.2023

Policy Briefing "Technology & Security"

With FHIR to more use of artificial intelligence in medicine

Building on the first policy briefing of the German Israeli Health Forum for Artificial Intelligence (GIHF-AI) on the topic of interoperability of healthcare data, this briefing addresses the implementation of FHIR standards in healthcare institutions based on use cases. The main focus is on the FHIR-based interoperability platform of Charité - Universitätsmedizin Berlin and Vivantes as well as a project of Maccabi Healthcare Services (MHS) from Israel. In his guest article, Dr. Uri Lerner, Project Manager at MHS, presents the FHIR implementation program, which was initiated in 2021 with the support of the Israeli Ministry of Health.

The **use of artificial intelligence (AI) in medicine stands or falls on the quantity, quality, and especially the interoperability** of health data used for training and testing AI. In this regard, there is now broad consensus from the scientific, medical, nursing, informatics, political, and business communities.[1]

In order to develop recommendations on standards, profiles and guidelines, the **Coordination Office for Interoperability was established at gematik, Germany's National Digital Health Agency, in November 2021**. The **task** is to **promote interoperability in the German healthcare system** on the basis of identified and prioritized needs. The coordinating body is advised by the Interop Council chaired by Prof. Dr. Sylvia Thun, Director of the Core Unit eHealth and Interoperability (CEI) at Charité.[2]

During its fourth meeting in **August 2022, the Interop Council made it clear that the implementation of FHIR (Fast Healthcare Interoperability Resources) is essential for digitization in healthcare**. The use of the standard is therefore also a central component of the **criteria catalog** adopted by the council. It serves as an important roadmap for politics and industry, which should also be guided by it in regulatory terms.[3]

The Interop Council's decision to designate the use of HL7-FHIR as a prerequisite for standardization is also important for international scientific cooperation. In **collaboration with highly digitized countries such as Israel**, which is particularly interesting for collaborative projects due to its richness of medical data, **FHIR acts as a common language**. There, the story of FHIR standard implementation began around 2018, when Maccabi Healthcare Services, Israel's second largest health maintenance organization (HMO), announced it would use FHIR resources as the basis for its new data model. Unlike Germany, the electronic patient record (ePA, eng.: EMR) has been established in Israel for over 20 years, leading to FHIR being implemented not only for data from inpatient care, but equally for data from outpatient care.[4]

Looking at the **European Health Data Space (EHDS), international data standards such as FHIR are also**

essential in the EU context. In addition to data delivery and structure, there is also an absolute need for uniform nationwide regulation of access authorizations for data use. Patient Consent Management, which plays an important role especially in the context of data protection and thus legal certainty, can also be easily mapped using FHIR. The **Health Data Use Act (GDNG)** envisaged in the coalition agreement of the German government **should therefore adopt the recommendation of the Interop Council on the use of FHIR**.[5]

The Medical Informatics Initiative and The German Portal for Medical Research Data

To enable data from standard care to be made usable based on FHIR, German university hospitals are working together with numerous partners in the **Medical Informatics Initiative** (MII), which is funded by the German Federal Ministry of Education and Research (BMBF), to **establish a nationwide data infrastructure**. Within this framework, **data integration centers (DIZ) have been established at the university hospitals**. They ensure both the technical and organizational prerequisites for data exchange between hospitals and research based on FHIR in compliance with data protection regulations and across locations and institutions. The tasks of the DIZ include **data extraction from the primary systems, data annotation and preparation, as well as data stewardship and data provision for use in medical research**.[6]

Scientists can access **data from the 20 DIZs via The German Portal for Medical Research Data (FDPG)**. In addition to an overview of all data holdings for cross-site research, there is the option to submit feasibility requests for available data and biospecimens. Furthermore, the portal offers a **standardized process for requesting data and biospecimens, standardized contractual regulations for uncomplicated data use, central coordination of data provision, and transparent presentation of research projects in the project register**. Currently, the FDGP contains **basic data on almost 8 million patients**, more than 85 million diagnoses, over 150 million laboratory values and over 140,000 biospecimens. In addition, there are almost 38 million data on procedures and 46 million drug prescriptions.[7]

FHIR-based interoperability platform of Charité – Universitätsmedizin and Vivantes

The **IT cooperation between Charité and Vivantes** is an example of the successful implementation of FHIR in healthcare facilities in a clinical context. After Charité, with over 100 clinics at four sites, and Berlin's largest maximum care provider Vivantes, with nine sites, introduced a joint digital treatment record in 2021, the **shared IT infrastructure was expanded in 2022 to include an interoperability platform for structured, granular data based on HL7-FHIR**. Supported by specialized consulting firms and IT service providers, the IOP-CDR suite (ICS) was implemented. It provides the basis for data sharing for hospitals, research as well as patients and, in perspective, also for non-stationary care providers. The outstanding advantages for the patient journey are the avoidance of medication errors and duplicate examinations, improvement of treatment quality, and reduction of waiting times.[8]

Initially, specific use cases were implemented in infection management and intensive care medicine. **Data protection and data security requirements were addressed and consistently implemented from the outset of the project**. In the infectious diseases use case, the hygiene databases of Vivantes and Charité were networked with each other and additionally with the database of Labor Berlin- Charité Vivantes GmbH. This enabled the treating staff to see whether a patient was a carrier of a multiresistant pathogen at an early stage, for example - even if the data had not originally been entered in the patient's own hospital. In the area of intensive care medicine, the main issue was the **provision of central vital signs and laboratory parameters in the event of a transfer between Charité and Vivantes**.[9]

As part of the IT cooperation, existing patient data is transferred to the receiving hospital before the transfer and can be transferred to the systems. Transfer and treatment can thus start without delay.

The **Core Unit eHealth and Interoperability (CEI) of Charité** took over the semantics subproject to **identify data-generating systems, to make specifications for an initial data exchange scenario, and to determine suitable FHIR data structures for the use case**.[10]

The implementation of FHIR in Israel

During the GIHF-AI Roundtable on September 20, 2022, on regulating the use of healthcare data in Europe, Germany, and Israel, **Yoel Ben-Or**, Head of the Digital Health Department at the Israeli Ministry of Health, **emphasized that in the medical field today there is no way around the gold standard FHIR developed by HL7**. In Israel, there is a voluntary incentive structure for FHIR implementation. Numerous projects by various healthcare institutions attest to its benefits. Additionally, **legislation** is being worked on to make **implementation mandatory for HMOs**.[11]

Already in 2019, the **Israeli Ministry of Health established a FHIR team**, based in the Digital Health Department, which began an exploratory process with hospitals and HMOs. This illustrated that the healthcare stakeholders were not familiar with FHIR at that time. An exception even then was **Maccabi Healthcare Services**, which had already gained some practical experience with the standard and was willing to **provide insights to the ministry on the topic**. Since then, the cooperation between the Ministry of Health and Maccabi on FHIR implementation has been successively expanded and has led to major use cases, such as in diagnosis management.[12]

Rough Waters to Smooth Sailing: Medical Record FHIR representation - Diagnosis Management Use Case

Guest article by Dr. Uri Lerner, Project Manager, Maccabi Healthcare Services

Maccabi Healthcare Services (MHS) is a not-for-profit medical organization and second-largest Health Maintenance Organization (HMO) in Israel, providing outpatient care to over **2.6 million members** nationwide. With over 6.000 physicians and 22 million medical encounters annually, MHS's central data repository retains over 20 years of comprehensive patient demographic and clinical data, stored for all patients according to their unique national identification or passport number. The **organization uses a unified electronic medical record (EMR) that is accessible to all physicians, nursing, and paramedical staff** and also receives data from external sources such as hospitals, private laboratories, and radiology centers.

In **2021, MHS launched a strategic FHIR implementation program** to coincide with Israel's national effort to implement FHIR across various health organizations. To achieve this implementation, dedicated teams were established within the Technology and Digital departments and clinical/medical domain. MHS devised a two-pronged approach: f**irstly, initiating small-scale projects to implement interoperability use cases based on the FHIR paradigm and data model**. Those use cases enabled MHS to take its first steps in adopting the FHIR paradigm into wide range of teams/systems and boosted the change management and education processes within the Technology and Business units regarding data and interoperability transformation.

Secondly, a perennial, wide-scope effort to **perform a "Medical Record FHIR Representation" process**. This process involves **converting and enhancing core data from various data sources, including EMR, to FHIR resources in the FHIR server**. The latter process has provided the chance for correcting historical "mistakes" in data management. These mistakes emerged during the EMR's development, either due to technical limitations or business decisions that prioritized saving time or simplifying medical visits. The **diagnosis management use case was the first project in this endeavor**, as it is a fundamental part of any future interoperability process. **Reorganizing MHS's core diagnosis data structure to FHIR was a complex process that involved clinical, technological, and terminology-related considerations**.

The process was initiated by first **mapping the data**

sources and usage scenarios of diagnoses within MHS's ecosystem. Several different **organizational data sources** were identified: the first was MHS's **EMR, Clicks®,** where diagnoses were stored either as encounter-specific or active (constant) medical conditions. These diagnoses can also include up to two additional attributes, describing physical lo-cation, severity, or added descriptors (e.g., status-post, suspected, etc.).

Another **internal data source was the claims authorization system**, where the eligibility of a patient to receive certain medications is diagnosis dependent. In addition, **diagnoses** were also received **from hospitals where the patient was admitted** or underwent various procedures. The **data was digitally transmitted to MHS through two channels** – **clinical data** and also a **financial report** for billing purposes.[13]

This **vast array of sources created a challenge** in the design of the FHIR resource, as each source includes other data elements in **different structures and even different coding systems for diagnosis coding**. Also, each data source had its own considerations to be taken. Among others, as previously mentioned, **diagnosis' characteristics given in MHS's EMR were saved in one or two designated fields in the data structure, disregarding different meanings**.

When **converting to FHIR, a decision was made to correct this approach for interoperability purposes, transforming all attributes to an FHIR-based approach** (see figure 1) and using **international (versus local) terminology** (**SNOMED CT** was chosen where no required Valueset is defined by HL7).

For the aforementioned reasons and the **complexity** that arose, this being the **first large-scale FHIR project** to be developed in MHS, the **mapping, design and development stages of the FHIR resource were fairly long**. A multidisciplinary technological and clinical team, including 3 FHIR Analysts, Medical Informatics specialists and family physicians, serving as clinical advisors to the project, all worked together for more than a year towards this goal.

Once the **detailed conversion design was completed alongside with the structure and set of supporting technology and data architecture design**, a **multi-stage development process** was initiated, bringing on board other teams within the technology and digital department. The data was streamed directly from source systems to MHS's integration layers, **based on event-driven architecture**. Each data source was converted and enriched to be compatible with FHIR and eventually stored as a resource in FHIR Server.

Nowadays, the project is approaching completion. It is worth mentioning **two other projects** coinciding in MHS: One is the **planning and implementing of data quality monitoring processes**, and the second is the initiation of a **system-wide terminology change for diagnosis coding**, translating from local diagnosis codes (based on ICD-9) to SNOMED CT, as part of a national terminology initiative.[15] When all three projects are completed, all **MHS's diagnoses data will be available and interoperable, upon patient's request, to any authorized party who requires the data to benefit patients**. Obviously, diagnoses are just the beginning, and more of **MHS's data will be "on FHIR"** as soon as possible.

clinicalStatus	?! Σ I	0..1	CodeableConcept	active | recurrence | relapse | inactive | remission | resolved Condition Clinical Status Codes (Required)
verificationStatus	?! Σ I	0..1	CodeableConcept	unconfirmed | provisional | differential | confirmed | refuted | entered-in-error ConditionVerificationStatus (Required)
category		0..*	CodeableConcept	problem-list-item | encounter-diagnosis Condition Category Codes (Extensible)
severity		0..1	CodeableConcept	Subjective severity of condition Condition/Diagnosis Severity (Preferred)
code	Σ	0..1	CodeableConcept	Identification of the condition, problem or diagnosis Condition/Problem/Diagnosis Codes (Example)
bodySite	Σ	0..*	CodeableConcept	Anatomical location, if relevant

Figure 1: FHIR elements used to describe diagnosis' characteristics (Source: HL7 FHIR).[14]

To sum up: in retrospect, Maccabi faced several major **challenges** during this project's lifetime, the first being the **technical** one elaborated upon earlier.

However, almost equal in effect were **organizational challenges**. Like every health organization, there were many **issues to be handled, new projects to integrate**, and the **resources are always at a limit**. Since this is the **first organizational-wide FHIR project**, with undefined implications apart from the true representation of the data itself, its **importance and potential benefits weren't clear to all parties** in the early stages. The responsible team invested quite a lot of effort to **gain organizational engagement**. This was crucial to **creating the commitment to invest in the project**. The **promotion of FHIR on the national level was also a key success factor**. FHIR is supported in Israel by the highest levels of the Ministry of Health and is presented at every health-related conference, demonstrating the true potential of FHIR-based medical record data.

Conclusion and Outlook

Through a government-driven **incentive structure for FHIR implementation, as well as the establishment of a FHIR team in the Israeli Ministry of Health**, FHIR gained visibility and support in Israel in a very short period of time. Exemplary of this are **synergies with healthcare organizations**, such as Israel's second largest HMO, Maccabi Healthcare Services, in the above example.

In **Germany**, too, there are numerous **FHIR-based implementation projects** and **FHIR-based scientific collaborations**. These include the **Medical Information Objects (MIO) for the electronic patient record**. The **Interoperability Coordination Office harmonizes the various players in the development and implementation of interoperability specifications based on FHIR**. This is done in the context of national as well as **international cooperation**, and in the future increasingly **in the context of the EHDS**.[16]

To further establish FHIR, **consolidation by policymakers** is needed also in Germany, as well as an **incentive structure like that in Israel**, so that additional stakeholders from the healthcare sector promote and support the necessary transition to FHIR.

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GIHF AI

German Israeli Health Forum for Artificial Intelligence

30.03.2023

Report "Technology & Security"

Implementing FHIR in Healthcare

On March 14, 2023, the German Israeli Health Forum for Artificial Intelligence (GIHF-AI) hosted its second Digital Health Roundtable on the topic of "Technology and Security". Distinguished experts from the German and Israeli healthcare sectors exchanged views implementing the Fast Healthcare Interoperability Standard (FHIR) in healthcare organizations. In their keynotes, Prof. Dr. Sylvia Thun, Director Core-Unit eHealth and Interoperability (CEI) at Charité, and Dr. Uri Lerner, Project Manager at MHS, presented the status quo and use cases of FHIR-implementation in Germany in Israel. The subsequent workshop was led by both keynote speakers and gave participants the opportunity to ask questions, develop ideas for cooperation, and jointly work on recommendations for action. The report complements the March 9, 2023, GIHF-AI Policy Briefing "With FHIR to more use of artificial intelligence in medicine" which was published in preparation of the roundtable including background information to the use cases presented. The following is an initial summary of the recommendations for action developed in the workshop. The ensuing text 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) is available on the ELNET YouTube Channel.[1]

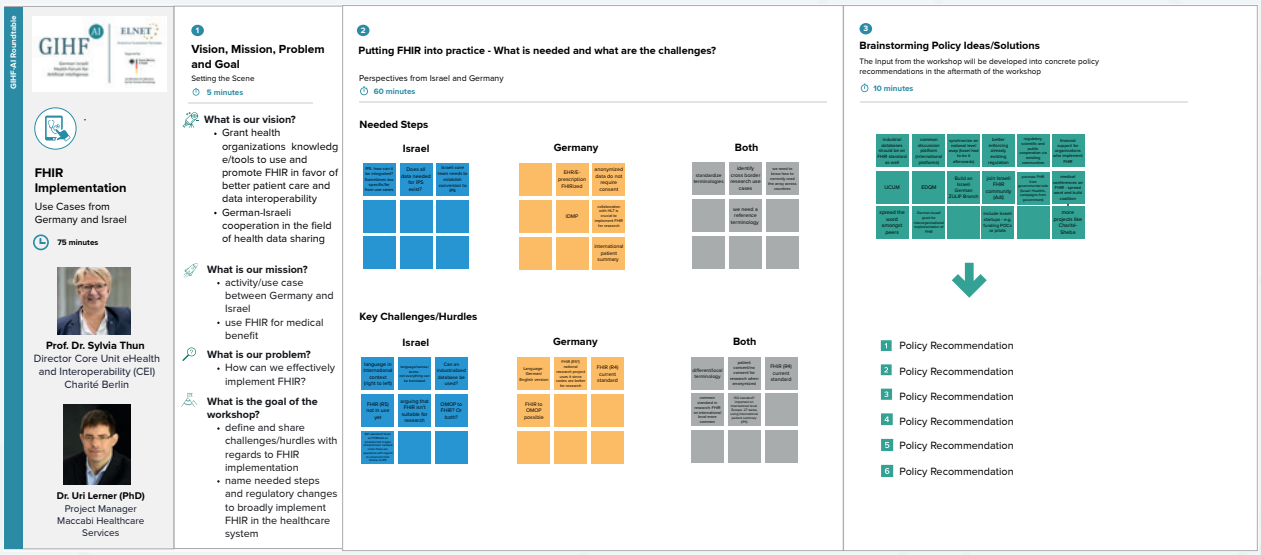

Figure 1: Mural Board produced at the Workshop.

Recommendations for Action

Standardization on international scale

FHIR should be introduced as the prominent international standard for exchanging healthcare information **together with international terminologies and imaging standards**. The implementation and enforcement of existing regulation on FHIR should be improved. FHIR is the key to a coherent health data ecosystem such as the European Health Data Space (EHDS) and it enables cooperation across European borders.

Promotion by government

The **implementation of FHIR must be strongly promoted by the government** to achieve interoperability on a national scale, both in public and in industrial databases. **Timely synchronization of standards** (including terminology in various clinical fields) is crucial to prevent the need to regulate and adjust after health data is fully digitized in various standards.

Financial support for healthcare organizations

Financial support should be granted to organizations who use or want to use FHIR to incentivize the broad implementation of FHIR in public as well as private hospitals, outpatient clinics and practices. Creating the infrastructure and know-how necessary for FHIR-implementation is costly and time-intensive for medical service providers, which is why support is needed.

Promotion and funding of existing initiatives

Existing FHIR-communities, teaching, and conferences on FHIR should be promoted and funded to broaden regulatory, scientific, and public exchange and cooperation via existing communities as well as to spread the word about the advantages of FHIR. International FHIR platforms can serve as facilitators and strengthen ties between the international FHIR-community.

German-Israeli FHIR grant

A German-Israeli grant for interorganizational implementation of FHIR should be set up to pave the way for common projects. This can lead to both more collaboration between German and Israeli hospitals as well as the inclusion of Israeli Digital Health startups. The goal should be the identification and implementation of bilateral research use cases.

Integration of HL7

Health Level 7 International should be closely integrated in the decision-making and regulatory processes. For the purpose of stronger German-Israeli collaboration, it is also recommended to connect the German and Israeli HL7 communities and develop shared projects.

"FHIRizing" without Interfering: Maccabi's Diagnosis Management with the help of FHIR

Based on the presentation of Dr. Uri Lerner, Project Manager, Maccabi Healthcare Services

Israel's second largest Health Maintenance Organization (HMO), **Maccabi Healthcare Services (MHS)**, with 2.6 million members, was the **first HMO in Israel to engage in implementing FHIR**. In order to successfully do so, MHS followed a roadmap that focused on a **small-scale project in the beginning** in order to **learn how to implement FHIR on a large-scale, namely Maccabi's entire Electronic Medical Record (EMR)**. Maccabi's vision for FHIR implementation includes a structured mapping process consisting of three steps: Firstly, **mapping all components of the medical record** (clinical, administrative, services). Secondly, **mapping all data sources** (internal and external). Finally, **FHIR is supposed to be adapted in the entire medical record** resulting in highly flexible and interoperable medical record capabilities.[2]

The presented **diagnosis management use case** started with **understanding the existing internal medical (EMR) and financial data, as well as external clinical and financial data**. EMRs with around 55 million yearly messages, and financial data, with around 1.6 million yearly messages, are coded with local MHS-codes. **External data**, such as medical data from hospitals, with around 3.5 million messages, **can be confidential in part, and will not be shared with the entire organization** (but should be stored as FHIR resource, classified accordingly). Billing data from hospitals and other independent suppliers, with around 880.000 yearly messages, can be coded in ICD-9 and-10 as well as modified ICD-9 codes or unknown codes.[3]

Among the **key learnings from the use case** was that **coding particularities need to be modified for the FHIR conversion**. This enables the inclusion of all the data. Furthermore, there **may be data overlap from the different sources which needs to be taken into consideration**. A challenge during the FHIR modelling process was **how to "FHIRize" without interfering the data flow** since the data needs to be used during the process. The conversion to FHIR had the positive side effect that the existing data was improved during the process. Lastly, **FHIR implementation comes with a terminology change to SNOMED CT** for example, where mapping is available or manageable within the project's timeframe.[4]

In conclusion, **FHIR implementation needs to be conducted in an organized and well-structured way**. The process needs to be mapped, including business and tech aspects. **Smaller projects in the beginning help to understand FHIR better and conserve scarce resources**. The outcomes can be used for large-scale FHIR implementation later on. One of the most **crucial aspects is the involvement of experts from clinical, medical informatics and digital teams**, as well as the constant promotion of the advantages of FHIR within the organization.[5]

Implementing FHIR on a large-scale in Germany thanks to institutionalized processes

Based on the presentation of Prof. Dr. Sylvia Thun, Director CEI at Charité

Since there are **just a few Electronic Health Records (EHR/EPA) and comprehensive digital EMR in hospitals and outpatient care in Germany** yet, the implementation process of FHIR is quite different than in Israel, where EMRs exist for over 20 years. In comparison to Maccabi's use case and vision plan with the goal to map and transform existing data to FHIR, **Germany has the chance to structurally map data to FHIR from the beginning**. The recently published German digitization strategy from the Federal Ministry of Health emphasizes the need for interoperable data, preparing the ground for broad implementation of FHIR.[6]

One of the **main organizations implementing interoperability in Germany is the Interop Council**. The Council's **roadmap for 2023 and 2024** includes the decision that **new specifications should be based on HL7 FHIR**. The council already uses ICD-

10 and soon ICD-11 as well as SNOMED and LOINC, paving the way for smooth implementation of FHIR. However, **mapping old specifications to FHIR is difficult** since the specifications aren't as detailed as on FHIR. The Interop Council makes sure to **include both patients and doctors** in order to develop the best outcome for all stakeholders involved. Decisions will be made **under the recommendations of ISO, the Joint Initiative Council (JIC) and the World Health Organization (WHO)**, both making sure that FHIR will become the global standard.[7]

The first project of the JIC was the **International Patient Summary (IPS)**. It started off as a **European project** called European Patient Smart Open Services (epSOS*), **initiated in 2008** in order to build an EHR for Europeans. After being **bridged with US specifications within the EU-funded Trillium Bridge project, the IPS became an ISO Standard (ISO 27269:2022)** based on SNOMED ICD-10 and HL7 Clinical Document Architecture (CDA). Today the JIC is working on **mapping to FHIR and also the European Health Data Space (EHDS)** proposal points to IPS on FHIR, setting regulatory framework for data standardization in Germany.[8]

Amongst use cases in Germany specifying FHIR is the **Core Data Set, which is built on the International Patient Summary**. Also, the **German Corona Consensus Dataset (GECCO)** for the standardization of COVID-19 research is based on FHIR, using SNOMED and LOINC. The **EU project ORCHESTRA** (Connecting European Cohorts to increase common and effective SARS-CoV-2 Response) applies GECCO as well.[9]

A successful example of **FHIR implementation in the hospital setting is the IT-cooperation between Charité – Universitätsmedizin Berlin and Vivantes**, enabling exchanging FHIR-based data between all hospitals linked to Charité and Vivantes. One of the biggest use cases of FHIR implementation in Germany is the development and progression of the **German EHR, the so-called elektronische Patientenakte (ePA), which is supposed to be mapped on FHIR**. The 2.0 version from 2022 includes data from prenatal care, vaccinations, dentistry, and pediatrics. Its successor, the ePA 2.5 from 2023, will also include data from Digital Health Applications (DiGA), laboratories, telemonitoring and disease management.[10]

Hence, **using FAIR (Findable, Accessible, Interoperable and Reusable) data, enhancing the reusability of data, extracting the maximum benefit from digital data sources, and allowing automatic processing (e.g. by AI) with the help of FHIR,** aids the democratization of medicine. Through the application of FHIR, health technologies will be made accessible globally, healthcare will be improved, innovations fostered, and translational medicine enabled.[11]

Conclusion

The keynote speeches as well as the workshop leads to the **conclusion that although mapping FHIR can be challenging**, especially when health data is already digitized in an EMR like in Israel, it is **worth the effort**. The **FHIR standard is key to a democratic and coherent international health data ecosystem** and will help **improve healthcare and foster innovations such as the use of AI in healthcare**, which is dependent on interoperable data. Therefore, the **implementation of FHIR must be strongly promoted and supported by the government as well as the industry**, which tends to be reluctant in many cases. Use cases have shown that **mapping to FHIR can be dealt with easier by developing roadmaps and focusing on smaller projects** first in order to understand the process better. This **paves the way to large-scale implementation such as in EMRs and EHRs**. In order to convince peers to use FHIR and share experiences, it is necessary to **spread the word and promote the advantages of FHIR**. Furthermore, it is recommended to **join national and international FHIR-communities**, **connect the German and Israeli HL7 communities**, and **develop shared projects**.[12]

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GIHF AI

German Israeli Health Forum for Artificial Intelligence

13.06.2023

Policy Briefing "Regulation"

New digitalisation strategy in Germany and current draft law in Israel

Building on the first policy briefing of the German Israeli Health Forum for Artificial Intelligence (GIHF-AI) on regulation for innovation-enabling use of health data in the European and Israeli context, this briefing highlights recent regulatory developments in Germany and Israel. Adv. Tamar Tavory, Special Counsel at Arnon, Tadmor-Levy, addresses the Israeli Ministry of Health's current Draft Medical Information Portability Law in her guest contribution. This is contrasted with the main contents of the Digitalisation Strategy for Health and Care presented by the BMG at the beginning of March, with a focus on the topic of healthcare data use.

"**Germany's healthcare system is decades behind in digitalization. We can no longer justify this**. That's why we're making a fresh start - opening up electronic patient records for everyone, making electronic prescriptions suitable for everyday use, and facilitating research based on health data. **Modern medicine is based on digitalization and data**. Harnessing their benefits makes treatment better."[1], said Federal Minister of Health Professor Karl Lauterbach at the Federal Press Conference as part of the presentation of the Digitalisation Strategy for Health and Care in March 2023.

Especially with regard to the application of AI in healthcare, the question of data use for care and research is of great importance and is also reflected in the Regulation for a European Health Data Space (EHDS) and the European AI Regulation (EU AI Act), which will be discussed extensively in the context of the GIHF-AI.[2] In the following, the aspects of the digitalization strategy with regard to legislation on the use of healthcare data will be discussed. It also looks at the current legislative situation in Israel, which is decades ahead of Germany in terms of digitalization of healthcare[3], as highlighted in the publication by ELNET on "Digitization and Innovation in German and Israeli healthcare: An inventory".[4]

The Digitalisation Strategy for Health and Care

Among other things, the digitalisation strategy addresses the question of how care processes, data use and technologies must evolve by the end of the decade in order to improve healthcare. **Two legislative projects that will make a key contribution in this context are the planned Digital Act and the Health Data Use Act.**

The Digital Act

As part of the Digital Act, the **electronic patient record (ePA) is to be introduced for all statutorily insured persons by the end of 2024**, with an opt-out option. At the same time, the **e-prescription is to become the mandatory standard in pharmaceutical care from January 1, 2024,** and its use is to be simplified. The e-prescription can then be redeemed using both the health card and the e-prescrip-

tion app or an ePA app. It is also possible to redeem by paper printout. An automated digital medication overview in the ePA, closely linked to the e-prescription, is intended to prevent unwanted drug interactions.

In addition, the **Gesellschaft für Telematik (gematik GmbH) is to be further developed into a digital agency wholly owned by the federal government** and its ability to act strengthened. Furthermore, it is planned to enable assisted telemedicine in pharmacies or health kiosks, which will lead to noticeable added value, especially in underserved regions. **Structured treatment programs (disease management programs - DMPs) are to be supplemented by more digitized programs**.

Also, an **interdisciplinary committee** consisting of representatives of the Federal Commissioner for Data Protection and Freedom of Information (BfDI), the Federal Office for Information Security (BSI), medicine and ethics will **advise the Digital Agency on its decisions and make recommendations on issues of data protection, data security, data use and user-friendliness**. This committee replaces the previous agreement process with BSI and BfDI.[5]

The Health Data Use Act (GDNG)

The Health Data Use Act (GDNG) requires that a **central data access and coordination point be established** to facilitate access to research data from a variety of sources, such as data from registries and health insurance data.

The **event-related linking of different data sources is to be made possible via research indicators, starting here with data from the Health Data Hub (FDZ) and the national cancer registries**. The regulation on lead data protection supervision for cross-state research projects will be further developed and expanded to include all health data in a clearer form.
The **Health Data Hub (FDZ) at the Federal Institute for Drugs and Medical Devices (BfArM) is to be further developed** in order to also be able to process requests for data access from the researching industry. The purpose of use, not the sender, is to be the decisive factor in approving requests.

The **release of data from the electronic patient record (ePA) is to be developed into an opt-out**. Pseudonymized ePA data will thus be usable for research purposes via the FDZ in the future, provided that insured persons do not object to this. A **data cockpit will be established in the ePA** for simple and user-friendly objection.[6]

Cooperation with Israel in the field of research and health

According to the Israel Survey 2023 published by ELNET, **European parliamentarians are calling for closer cooperation with Israel in the area of research and health**.[7] In order to implement this and understand the current status quo in terms of health data use in Israel, the following section will look at Israel's legislation in general, with a focus on the newly published draft Medical Information Portability Law.

Access to medical data in Israel and the legal aspects

Guest article by Adv. Tamar Tavory, Special Counsel, Arnon, Tadmor-Levy

In the era of digital health data, the possibility to access and share medical data is crucial for patients, health care providers, and for medical research and innovation in healthcare.

Israeli Healthcare System – Background

According to the National Health Insurance Law, **every Israeli resident is entitled to membership in one of the four Israeli HMOs** and to receive, without charge, healthcare services included in the national "health basket", which is updated yearly. Most Israelis are also registered in supplementary health plans provided by the HMOs under MOH supervision, and some are insured, as well, by private insurance policies. Many hospitals in Israel are

owned by the Israeli government; some hospitals are owned by Clalit, the largest HMO; other hospitals are owned by Assuta, a subsidiary of Maccabi, a large HMO; and some hospitals and medical centers are privately owned. **Israel's hospitals and HMOs initiate and encourage innovation, in part by leveraging their access to high-quality digital medical data**.

Medical Data – Israeli Legislation

The **patient's right to privacy is a constitutional right according to the Basic Law**: Human Dignity and Liberty, and the right to privacy in medical data is protected by the Privacy Protection Law and the Patient's Rights Act. Subject to certain exceptions, **medical data may be used only for the purpose for which they are provided by the data subject**. **Additional uses, including secondary use of medical data, are generally subject to data subject consent**. In addition, **secondary use of medical data, cloud computing of medical data and the transfer of data in remote patient monitoring devices are regulated in MOH procedures** which outline the requirements for access to medical data and for processing it. The Privacy regulations provide guidance as to security data measurements required for collecting and storing medical data and particular requirements when exporting data abroad. Due to the **"adequacy decision" of the European Commission, personal data from the EU can be transferred to Israel without any need for additional measures**. Special legal protection may apply to certain categories of data, such as biometric data, genetic data and psychiatric data.

The **collection of data through medical research requires regulatory approval** in accordance with the Public Health Regulations (Medical Researches Involving Humans), and MOH procedures. Generally, the MOH's procedures adopt and follow international guidelines with respect to medical research. Secondary use of data could be approved by the Helsinki Committee (the IRB) for future research-use under certain conditions.

Who Owns the Medical Data?

This is a worthy question for which there is no unequivocal legal answer. **Israeli legislation refers to the patients' rights**, such as the right to privacy of one's medical data and the right to receive a copy of the data (The **Privacy Protection Law** and the **Patient's Rights Act**). The **digital medical data-base belongs to the medical institution**, which is also responsible, regulatory-wise, for protection of the stored data therein.

Medical Data Accessibility – Current Status

Currently there is **no overall – national regulatory – based solution for sharing medical data for primary use** – for the purpose of receiving or providing healthcare services. **Many HMOs and hospitals enable patient to access their medical data digitally**. In addition, the **MOH initiated a platform** which **enables the transfer of certain medical data between hospitals and HMOs for primary use**, i.e., the purpose of treatment. The medical data can be viewed by the receiving physician but cannot be stored. **Patients are not asked to provide prior consent** (**according to the Patients' Rights Act which allows the transfer of data between care providers for primary use**). This **platform is voluntary**, and not all hospitals and service providers have joined it.

Companies and researchers can only access medical institution's health data in a regulatory-approved medical research, and according to the protocol and the informed consent form (unless waived by the IRB), and **subject to the privacy legislation's limitations**. Future use of these data is also subject to the same regulatory conditions. Companies often collect data directly from users via applications and subject to their consent, usually manifested in privacy policy.

The Draft Medical Information Portability Law

Recently, the Ministry of Health published the draft Medical Information Portability Law ("Bill") and asked for comments by the public. The main purpose of the Bill is to enable patients to receive and share health information with healthcare providers digitally and in a unified format.

Under the Bill, hospitals, HMOs, clinics and providers will be obligated to accommodate patient requests to transfer medical data to authorized recipients ("Data Recipients"). To qualify as a Data Recipient under the Bill, the relevant entity will be required to obtain and maintain a license from a commissioner to be appointed by the Ministry of Health. The Bill **enables companies** – and not only medical institutions – **to act as data recipients** and receive health data, **subject to receiving a license from the commissioner and authorization by the patient**. Furthermore, the Bill sets data standardization requirements to enable sharing of medical data.

Health data may be used only for the provision of the health service appearing in the license, and such use is subject to patient consent. Health data may also be used for statistical purposes to improve health services on the condition that the products of such use do not contain identifiable personal data. **Use of health data for marketing and advertising purposes, including marketing medical services, is prohibited**.

Medical research will **continue to be conducted pursuant to existing laws and in accordance with Helsinki Committee requirements, patient consent requirements, and existing regulations**. Medical institutions may enable external researchers to access data within the institution's secured information platform even when such researchers do not hold a license.

Although the **Bill is an important step in establishing health data accessibility**, it raises several **challenges**: the **technological and administrative requirements are quite burdensome, especially considering small service providers – clinics, and startups**; There is **no legal arrangement for secondary use of data** other than in the framework of medical research, so that, secondary use for the purpose of improving an algorithm for future development may not be possible; the **requirement for obtaining government approval prior to engaging in certain change of control transactions** also raises difficulties. The **prohibition against receiving consideration in connection with data transfers also raised some objections**. As public comments are submitted and discussed, one can still expect some changes to be introduced in the Bill.[8]

Conclusion and Outlook

Both Germany and Israel are working at full speed on adapted legislation for the primary and secondary use of health data and maintain regular exchanges on this.

In addition to a large number of relevant stakeholders in the health and care system, **patients and industry are being involved in the process in order to design a binding framework that will benefit all stakeholders**. This development is worthy of support and has also been increasingly expressed during the GIHF-AI discussion rounds to date. **Especially also with regard to the use of health data for AI-based systems**, as AI relies on high-quality health data.

Europe currently has a unique opportunity to become a pioneer in trustworthy AI. In order not to miss this opportunity and play into the hands of states where health data is not handled as carefully as in Europe, it is important to design the regulatory framework with care. **Close integration of the GDNG and the EHDS is essential** to reduce legal uncertainties and difficulties in interpreting the regulations. At the same time, it is worth **taking a look at countries such as Israel, where digitized, innovative healthcare is part of everyday life** and similar legal frameworks apply as in Europe.[9]

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GIHF AI

German Israeli Health Forum for Artificial Intelligence

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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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GIHF AI
German Israeli Health Forum for Artificial Intelligence

12.12.2023

Policy Briefing "Digital Mental Health"

Mental Health in Times of War

This policy briefing from the German Israeli Health Forum for Artificial Intelligence (GIHF-AI) sheds light on the impact of the Hamas attack on October 7, 2023, and the subsequent war on the Israeli population. It highlights both the psychological effects and the enormous challenges for the Israeli healthcare system. Additionally, it examines Israel and Germany's healthcare systems in the mental health sector, focusing on Digital Mental Health and international cooperation possibilities.

In July 2022, the European Leadership Network (ELNET) organized a Mental Health Day in Tel Aviv through its innovation project GIHF-AI. The event took place as part of a Digital Health delegation trip organized by the German Israeli Network of Startups & Mittelstand (GINSUM). The theme was "Where global challenges for mental health meet innovative solutions in technology". It centered around Israeli Mental Wellness and Health Tech innovations used in treating Post-Traumatic Stress Disorders (PTSD)[1] According to the World Health Organization (WHO), **mental health** is defined as **"a state of mental well-being that enables people to cope with the stresses of life, realize their abilities, learn well and work well, and contribute to their community"**.[2] Mental health is also a **prerequisite for individuals to realize their intellectual and emotional potential** and find fulfillment in society, education, and work. Societally, mental health contributes to **economic prosperity, solidarity, and social justice**.

PTSD can arise **in response to overwhelming events** such as **severe accidents, violent crimes, disasters, or acts of war.** In Israel, many people have had direct and indirect experiences with war trauma, stemming from the Holocaust and the wars and terrorist attacks since its establishment in 1948. Studies suggest that the Israeli population has significant resilience[3], which refers to the ability to "develop successfully despite adverse life circumstances and critical life events due to the multitude of potentially traumatizing events".[4]

Mental Health in Israel since October 7

However, the situation in Israel concerning the mental health of the population has changed. **The unprecedented Hamas attack targeting Israel on October 7, 2023, and the subsequent war, have far-reaching psychological and psychiatric consequences for the Israeli population**.[5] Clinics in Israel have admitted numerous patients with **acute stress reactions and stress disorders** since the attack. It is expected that many people will suffer from PTSD as a result of this attack. Among them are not only those directly affected psychologically and physically but also their families and indirectly involved individuals, as the attack and its consequences have shaken the entire country.[6]

Even the **medical personnel have not been immune to the fears prevalent in the population during the conflict**. Many of them have family members in the military, both on active duty and in reserve. Many mourn family members or close friends who were killed or held captive in the Gaza Strip.[7] Shortly af-

ter the Hamas massacre, the Israeli crisis hotline for mental health, operated by the NATAL organization, experienced a drastic increase in calls from 25 to 100 calls per day to now 1,200 calls per day.[8]

Studies worldwide have shown that traumatic events like wars and armed conflicts can lead to a significant increase in post-traumatic stress and depression. A review published by the World Health Organization (WHO) in 2022 of 129 studies from 39 countries shows that **one in five people (22 percent) who have experienced a war or another conflict in the last 10 years suffers from mental illnesses**. These include **depression, anxiety, post-traumatic stress disorders, bipolar disorders**, and **schizophrenia**.[9]

A **concrete example is the impact of September 11 in the United States**: Among adults living in New York City and adjacent areas in New Jersey and southern Connecticut, **7.5 percent reported symptoms of post-traumatic stress disorder (PTSD), and nearly 10 percent reported symptoms of depression**. The rates of these symptoms were almost double the national baseline prevalence of 3.6 percent for PTSD and 4.9 percent for depression.[10] The scale and resulting physical and emotional effects of the attack on October 7 are considered by experts to be comparable to the collective trauma experienced by American society during September 11.[11]

Compared to events in Israel in **recent years, it is anticipated that the recent attack will have more substantial, long-term effects on people**. Reasons for this include the current situation not being resolved and thus characterized by a high degree of uncertainty and instability. It is still unclear how many people were killed and who is still alive, making it impossible to find closure and grieve. Studies have found that situations of unclear loss are associated with a higher degree of psychological distress and post-traumatic symptoms.[12]

Added to this is the extreme brutality of the attack, which indiscriminately targeted soldiers and civilians, including entire families, Holocaust survivors, infants, children, and elderly people. Moreover, Israel being a **small and closely-knit society** means that **almost all Israeli citizens are directly or indirectly confronted with loss, fear, and grief**. Hundreds of thousands of residents from southern and northern Israel were evacuated for security reasons or due to the destruction and burning of their homes. The loss of housing and the extended stay in emergency shelters result in financial losses and difficulties in returning to everyday life.

With the loss of family members, neighbors, and friends, many people have also lost their natural support systems, which are crucial for trauma coping.[13] Those who were held hostage for weeks must cope not only with processing the terrible experiences but also with the transition from isolation and helplessness to sensory overload and freedom, which can lead to strong stress reactions.[14] **A significant portion of the Israeli population will need professional psychosocial care now and in the future to process what they have experienced. Both the healthcare system and communities, social workers, and policymakers play a key role in creating the necessary conditions for this.**

The WHO Special Representative in Israel, Dr. Michel Thieren, has assessed healthcare measures at several points. He has visited hospitals, such as one in Ashkelon where many of the wounded are being treated, talked to the injured and displaced, visited destroyed and abandoned towns and villages, and observed the extremely challenging work of forensic experts to get an overview. He reported, among other things, that most victims did not speak about their own injuries but rather about what they experienced and the images of people dying before their eyes. Moreover, a significant amount of uncertainty is palpable. According to him, a great number of people urgently need psychological support, as mental health problems are rapidly spreading in the population. "Violence, deaths, injuries, displacement—all of this has significant long-term challenges that are difficult for healthcare systems to adequately address"[15], summarized Dr. Michel Thieren.

Israel's Psychosocial Healthcare

According to the National Health Insurance Law of 1994, the Israeli population is entitled to health-

care services through one of the four health service providers (HMOs): Clalit, Maccabi, Meuchedet, and Leumit, which simultaneously act as payers and providers. However, mental health care was the responsibility of the government until the mental health reform in June 2015. Since the reform, the sole responsibility for providing psychosocial services has been transferred from the Ministry of Health to the health service providers. The significance of this development lay in the merging of mental and physical health care, aiming not only to improve care but also to destigmatize mental illnesses. Since then, the HMOs have been responsible for providing psychosocial services, overseen by the Ministry of Health. **The importance of mental health due to the COVID-19 pandemic has also led to it being considered a critical aspect of healthcare, on par with physical health**.[16]

However, there is still a **need for improvement in healthcare**. There is a significant and growing gap between demographic groups in accessing psychosocial services. **Mental health issues are rapidly increasing across all age groups**, a trend observed globally. Particularly within the context of the COVID-19 pandemic, the worldwide prevalence of anxiety disorders and depression has increased by 25 percent, according to a report by the WHO.[17] **This trend is also evident in Germany**.[18] The psychiatric care in Israel is distributed among multiple service providers, including welfare and social services, leading to gaps in care and inconsistent data. **Regulations supporting psychosocial care in Israel lag behind compared to other sectors**.[19]

Additionally, integrating patient information from psychosocial treatment across all care settings presents a significant challenge. **There are evident gaps concerning various population groups, especially children and the Arab Israeli population**. Moreover, reimbursement pathways and financial incentive structures need updating to integrate solutions for mental health into the Israeli healthcare system. Finally, Israel, like many other countries, suffers from a significant shortage of mental health professionals across all care sectors. [20]

A positive note is the **significant interest among relevant stakeholders in Israel to improve mental health care at the national level**. This is attributed to the impact of the COVID-19 pandemic and recent traumatic events. This has led to multiple measures and was one of the driving forces behind the recent amendment of the Israeli Ministry of Health's data regulations in November 2023, allowing the inclusion of mental health data in the general patient records of HMOs. Hospitals, HMOs, and other relevant institutions are also working to support the population in coping with the situation, rapidly establishing new structures.[21]

Digital Mental Health in Israel

In addition to conventional methods such as psychotherapy and medication, experts affirm that internet-based applications help alleviate symptoms and reduce stress. The spectrum of deployment of Digital Mental Health or e-Mental Health applications ranges "from universal and targeted prevention for at-risk groups to psychotherapeutic internet interventions to bridge waiting times, as a complement to conventional methods, to relapse prevention after completing treatment". [22] They also offer the chance to address the increasing lack of therapy options and prevent relapses. **Technological solutions have the potential to create individualized solutions for patients that were hardly achievable with conventional approaches**.[23]

Since 2011, 63 mental health startups have been founded in Israel, with a third of them inactive. Even before the COVID-19 pandemic, there was increased activity in mental health: between 2018 and 2020, 30 new startups were founded. Although the number of startups has decreased since then, the momentum with an average of five startups per year from 2021 to 2023 is still noticeable.[24]

Mental Health in Germany

Also in **Germany,** the **psychiatric support system faces the significant challenge of coping with the growing demand for assistance due to mental illnesses.** The German system encompasses **outpatient, day-care, inpatient, and supplementary services, involving various professionals and aim-**

ing to ensure high-quality care.[25] Germany's psychiatric policy is shaped by the Psychiatry Reform, the so-called **Psychiatry Enquete, of 1975**. The associated reform process towards community-based psychiatry focusing on social-psychiatric principles led to a significant improvement in care. Along with the **GKV Health Reform Act of 2000**, which also focused on reintegrating mentally ill people after hospital stays, it further **strengthened the role of social work** alongside the provision of psychosocial services by doctors and psychotherapists. The social work complements the range of services through coordination, counseling, support, accessing resources, as well as therapy.[26]

Demand for medical support due to mental health problems is increasing in Germany as well, while only a fraction of those affected actually receive professional support. **Although the utilization of medical help is growing, only about 20 percent of individuals with psychiatric diagnoses receive appropriate treatment**. Between 2019 and 2023, depressive symptoms increased multiple times in the population. Between 2021 and 2023, there was also an increased occurrence of anxiety symptoms. Furthermore, self-rated mental health deteriorated.[27]

The **significance of prevention and health promotion**, which also includes destigmatizing mental illnesses, is **steadily increasing**. Initiatives such as the *Aktionsbündnis Seelische Gesundheit* (Action Alliance for Mental Health) advocate for nationwide education and information on mental health and against the stigmatization of mental illnesses, welcomed by governmental bodies and practitioners. To obtain better data on the population's mental health, the German Federal Ministry of Health supported **extensive additional surveys on mental health as part of the Robert Koch Institute's study on the health of adults in Germany (DEGS)**. This also includes information on the use of facilities within the care system. The data from the survey phase is currently being evaluated.[28]

Aforementioned opportunities from innovative additions to care in the form of Digital Mental Health are also recognized and promoted in Germany. A task force established by the German Association for Psychiatry, Psychotherapy, and Psychosomatics (DGPPN) and the German Psychological Society (DGPs) has presented criteria that can help professionals and users select effective and recommended interventions.[29] Moreover, the **focus** of the **Digital Health Applications (DiGA) listed in the directory of the Federal Institute for Drugs and Medical Devices (BfArM) is on applications for treating people with mental illnesses**, supported by the E-Health Initiative of the Federal Ministry of Health (BMG). Additionally, the **Fraunhofer Institute for Open Communication Systems (Fraunhofer FOKUS) was tasked with creating a meta-catalog for criteria for evaluating health apps** (APPKRI criteria for health apps), incorporating the results of the DGPPN and other institutions.[30]

Conclusion and Outlook

Engagement in mental health needs to coincide not only with **destigmatization and health education** but also with **international and interdisciplinary collaboration**, especially an **increase in global investments and fostering innovation**. Moreover, enhanced cooperation between healthcare providers and policymakers is recommended to implement effective psychosocial programs and **facilitate access to Digital Mental Health**. In this context, an open dialogue regarding the added value of these digital applications, as experts may have varying assessments, is crucial. This could lead to acceptance challenges from the side of healthcare providers. Transparency, evidence, discourse, and the creation of a criteria catalog can persuade and optimize digital applications. Additionally, awareness of the benefits must be strengthened, and an innovation-promoting infrastructure needs to be established to offer more internet-based solutions. This is indispensable in times of increasing shortages of professionals and simultaneously rising demands.

According to the recent WHO Mental Health Atlas, **governments worldwide spent an average of just over 2% of their health budgets on mental health in 2020**, and in many low-income countries, there was less than one mental health professional per

100,000 inhabitants. This does not align with the need. **Simultaneously, internet-based applications can improve treatment while relieving the financial and personnel burdens on the healthcare system**. If the innovative Startup Nation Israel collaborates with Germany and its firmly established and multimodal psychosocial care and research system, they can play a pioneering role in this field from which people worldwide can benefit.[31]

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GIHF AI

German Israeli Health Forum for Artificial Intelligence

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Report "Digital Mental Health"

Addressing Israel's Critical Mental Health Needs Post-October 7

Given the attack by Hamas on Israel on October 7, 2023, and the subsequent war, the European Leadership Network (ELNET) organized a GIHF-AI Digital Health Roundtable focusing on Digital Mental Health.
On December 13, experts from the German and Israeli healthcare sectors discussed the impact on the mental health situation of the Israeli population, presented research findings and practical examples in the field of Digital Mental Health, and explored how bilateral cooperation can support the Israeli health community in dealing with trauma as well as jointly enhance mental healthcare in Israel and Germany.

Prof. Dr. Ran Balicer, Chief Innovation Officer (CIO) at Clalit Health Services, described the impact of the October 7 events on Israel's mental health and highlighted challenges in the country's mental healthcare system. Best practices from Germany were presented by Prof. Dr. Maria Böttche, Chairwoman of the DeGPT, in the form of use cases of internet-based treatments, and Prof. Dr. Malek Bajbouj, Managing Senior Physician and Head of Center for Affective Neuroscience CBF at the Charité, who demonstrated international Digital Mental Health collaboration projects.

To enhance the understanding of dealing with mental health issues amongst children and adolescents and to highlight the importance of social work, Dr. Marianne Ledwon-Feuerstein, Chief Physician of the Department for Child and Adolescent Psychiatry at the Luisenklinik Bad Dürrheim, presented her practical experiences when dealing with young people suffering after traumatic events.

> *"The ultimate goal is to establish a more data-driven mental healthcare system, including AI-powered assessment tools."*
>
> Prof. Dr. Ran Balicer, Chief Innovation Officer (CIO), Clalit Health Services

Recommendations for Action

Integrated Mental Health System Redesign

Implement a comprehensive **redesign of the mental health system in Israel**, focusing on integrating risk stratification models to categorize and address varying mental health needs effectively. Establish a **tiered system of care to** accommodate different levels of mental health severity. Experiences may also be useful for Germany's mental health system.

Extension of Online Triage System

Extend and enhance the **implementation of online triage systems** to promptly identify and prioritize mental health care needs and reduce strains on hospitals. Develop **user-friendly interfaces** accessible to a broad demographic for efficient and immediate support.

Development of Digital Innovations

Encourage the continuous **development and adoption of digital tools** to modernize mental healthcare. This includes **AI-powered assessments**, secure **electronic health records**, and **evidence-based self-diagnosis and self-care tools** to ensure personalized and efficient care. Implement **DiGA-like structure in Israel** for more trust and secured reimbursement by HMOs.

Interdisciplinary Collaboration Training

Foster collaboration among mental health professionals, social workers, and medical practitioners also on an international level. Initiate **training programs** to equip professionals with skills needed for comprehensive and holistic care, promoting effective **collaboration across disciplines**.

Community-Based Mental Health Support Programs

Establish **community-oriented mental health support** programs to provide ongoing and timely assistance as well as preventive measures. Engage community leaders, educators, and local volunteers to **create supportive networks** for affected individuals.

Data-Driven Decision-Making and Evaluation

Emphasize data collection and evaluation to drive **evidence-based decision-making in mental healthcare**. Continuously assess the effectiveness of interventions and treatments, adjusting strategies based on **real-time data insights**.

Mental Health in Israel Post October 7

Prof. Ran Balicer began his keynote with words of gratitude for the solidarity that Germany has shown **in the aftermath of October 7** and gave an overview of the psychosocial situation in Israel since then. He highlighted the **unique aspects of the event**, such as the **high casualty rate, intense impact due to Israel's small size, the individualized brutality witnessed through shared videos, invasion of personal space, hostages including vulnerable groups, and ongoing rocket launches aimed at the entire country**. Prof. Balicer stressed that the **perceived risk was even higher than the actual risk**, using the framework of the Risk Perception Theory by Peter Sandman, which led to even greater strains on Israel's mental health status.

Furthermore, Balicer outlined the country's mental healthcare system as of today and future steps needed to improve it, stressing that October 7 hit the system quite hard. He described the **pre-existing challenges in Israel's mental health system**, following the **reform from 2015** which **moved responsibility for mental health to the HMOs**, with significant **underestimation of needs leading to high demand**

and low service yield. There were issues of **shortage of providers, long waiting times, lack of structure and monitoring, as well as one-size-fits-all approaches, ahead of the October 7 events**. The case of the 9/11 attack in the United States showed that 10 to 15 percent of people affected suffered from Post-Traumatic Stress Disorder (PTSD) and 7 percent from depression and anxiety. In the case of the recent attacks on Israel, not only the survivors of the attack but also first responders, people losing their homes, as well as the hostages returning to Israel, were expected to develop significant mental health issues. Existing **data shows that one can reduce the risk of detrimental impact by 30 percent when reacting immediately**. This can only be achieved with a functioning mental healthcare system. Therefore, in **response to the crisis**, there was a **mobilization of volunteers, additional manpower recruitment, pop-up clinics, and dedicated call centers to support the affected population**.

Looking forward, there's a plan to **redesign the mental health system** with a focus on **risk stratification**, implement an **online triage system** to stratify the care given according to the needs of people, create a new **tier of caregivers called *resilience supporters*** and **introduce digital innovations** to modernize and improve the system. Clalit is looking for ongoing innovations and collaborations globally to address these challenges, for example through a call for innovation open to continuous submissions. The ultimate goal is to **establish a more data- and evidence-driven mental healthcare system, including AI-powered assessment tools**, electronic health record **(EHR) case summarization, documentation of therapy sessions**, as well as **evidence-based self-diagnosis and self-care tools**.[1]

Digital Mental Health – Best Practices from Germany

Introducing best practices in mental health and Digital Mental Health, **Yael Ophir** outlined the discussion within HealthIL post-October 7. The approach of the **HealthIL community involved a focus on innovation and transformation in Israel's health system, mapping 45 technological solutions by engaging around 60 innovation managers**. Yael Ophir highlighted the significance of continuous learning and collaboration in healthcare beyond crises. She announced the upcoming HealthIL Week on February 5-8, inviting participation to discuss lessons learned and opportunities for collaboration in healthcare.[2]

Internet-Based Treatment Services for Trauma-Related Disorders in Different Populations

In her presentation, **Prof. Maria Böttche** provided insights into **internet-based treatments for PTSD**, particularly emphasizing the **efficacy of cognitive-behavioral therapy (CBT)** in internet-based interventions. She highlighted various forms of internet-based interventions, distinguishing between different approaches such as text-based communication, synchronous chats, and video-based interventions. Prof. Böttche elaborated on therapist-guided interventions that employ manuals, written communication, and secured platforms for an approximate 8-week treatment period. She discussed **two distinct internet interventions**, one **aiding war and torture victims in the MENA region in Arabic, called Ilajnafsy**, which was mainly used by highly educated younger female persons who are single or married, and living in a city. Another project Böttche introduced was the **9/11 First Responder project in collaboration with Mount Sinai Hospital in New York**, targeted especially at firefighters and police officers. Most of the participants were middle-aged, 50 percent male and 50 percent female. She highlighted the **effectiveness of these internet-based treatments in reducing PTSD symptoms across these diverse populations**. Böttche also acknowledged the **challenges** such as the **need for secure platforms, trained counselors, and financial resources** to ensure the success of internet-based treatments.

In the subsequent discussion, an inquiry about the effectiveness of internet-based treatments for different age groups took place. Maria Böttche responded that while their studies predominantly attracted a younger, more female audience, their **interventions were also effective for older individuals, even those above 70 years old. Dr. Lars Hunze**, Deputy Head of

the Unit at the German Federal Ministry of Health involved in advancing telemedicine and digital health applications, contributed by sharing insights from Germany. The data suggested that the **demographic for Digital Health Applications (DiGA) tends to encompass a middle range between 50 and 65**, but the success could vary depending on the application's design and usability. He discussed ongoing efforts in the German Parliament to approve legislation that will allow the integration of digital health technologies into care delivery, emphasizing the **importance of evidence-driven approaches and blended care models**. He also highlighted the interest in contributing expertise gained from previous experiences and expected advancements in the field once the legislation is approved.[3]

Digital Mental Health – Experiences from International Settings

In his impulse speech, **Prof. Malek Bajbouj** highlighted the **importance of learning from crises and using them as an opportunity for positive change and innovation in the healthcare system**. He emphasized the need for collaborative efforts and shared experiences from international projects that focused on mental health interventions, particularly in conflict settings. The ultimate goal was to achieve a **resilient health system** (definition according to the World Health Organization) that can **prevent, prepare for, detect, adapt to, respond to, and recover from public health threats**.

He stressed several key points, such as the need for **co-design and co-production**, meaning developing interventions with **meaningful involvement and input from the beneficiaries** rather than just informing or tokenizing them. Prof. Bajbouj also stressed the importance of **implementing stratified and collaborative care models** instead of one-size-fits-all solutions. He also noted the **importance of evidence-based, data-driven practices and ongoing evaluation** of interventions to ensure their **effectiveness in the reduction of stress symptoms** as well as **cost-effectiveness**.

Prof. Bajbouj shared experiences from the **MEHIRA project in Germany, a stepped and collaborative care model supporting refugees and asylum seekers in Germany**. MEHIRA had a structured approach to **managing stress symptoms based on varying severity levels**. It involved watchful waiting for lower stress levels, non-expert interventions using smartphone-based platforms for mid-level cases, group therapies, and face-to-face psychological or psychiatric interventions for severe cases, showing both **great efficiency as well as cost-effectiveness**. Another use case mentioned was a **collaborative project in the wake of the war in Ukraine supporting 41.000 patients in 26 hospitals called Solomiya**. It included a Chatbot, an app, and a telemedical network. The chatbot is being already translated into Hebrew in the aftermath of October 7.[4]

Integration of Social Workers into Therapeutic Approaches for Mental Health

To add a further perspective to the discussion, Dr. Marianne Ledwon-Feuerstein shared insights into **social work collaborations within mental health care** while working with children and adolescents. She emphasized the **necessity of expert networks**, particularly when addressing severe disturbances and traumatic disorders. Drawing from experiences in Germany, she highlighted the **role of social workers in diverse settings**, including **schools** and **emergency welfare systems**, to aid traumatized individuals, such as children from war-torn regions. Dr. Ledwon-Feuerstein stressed the importance of **immediate support and basic care** before advanced psychotherapy to **prevent the development of PTSD**. She highlighted the collaboration between mental health professionals and social workers, emphasizing the **need for information flow while respecting patient privacy**. This integration allows for a holistic approach to addressing mental health challenges, bridging gaps between various touchpoints in the healthcare system.[5]

Discussion and Outlook

The subsequent discussion centered on the use of digital tools in mental health care within Israel's system and the question of **how to bridge the data**

flow gap between welfare and social services and the broader mental health care system. Also **in Germany**, the situation appears highly **fragmented**, when dealing with different institutions. An **integrated approach**, involving a combination of psychotherapists, psychiatrists, and social workers collaborating closely, is possible within organizations only. Regarding data protection, there are protocols in place where **patients grant permission for information sharing** among doctors within the center, ensuring a secure and regulated exchange of information. This **lack of integration poses challenges for comprehensive data management** and sharing, potentially impacting the effectiveness of healthcare services. **Israel and Germany could work on a solution together** since both countries face similar challenges regarding smooth data transfer.

Another question raised was aimed at understanding how hospitals could potentially transform or adapt their roles in situations like after October 7, suggesting a need for potential changes or new approaches within hospital-based mental health services. The answer was that hospitals needed to **transition from a primarily treatment-based role to one focused on prevention**, delegating tasks to social workers or counselors, thereby widening their scope to aid more people. **Hospitals** should only be **treating those in severe need** while **developing frameworks for broader interventions**, including preventive measures, such as a **triage system within hospitals** to identify and prioritize urgent cases among many seeking help. Much of the work done in hospitals for physical health could be effectively managed in general practices and further facilitated through digital tools, preventing over-medicalizing cases.

Furthermore, the difficulties in **sustaining patient engagement over time** were discussed, including the experiences of an Israeli digital solution focused on treating PTSD. More **guidance, human interaction, and continuous evaluation** would **improve patient compliance** and overall effectiveness. Health insurance companies **offering additional services like coaching or expert guidance** may be useful as well as **support by general practitioners**. In Germany, Digital Health Applications (DiGA) follow strong guidelines and are suitable for reimbursement. This may lead to **greater trust and transparency**. Especially in the field of mental health, Germany has been seeing rising numbers of DiGA prescriptions.
The Ministries of Health of Germany and Israel are already collaborating to **advance the use of DiGA-like structures in Israel's healthcare system**, potentially leveraging insights and experiences gained from German companies and their involvement. This development is an important step and may be extended for the sake of both countries. Finally, emphasis was placed on ongoing cooperation and the need for collaboration, along with suggestions to leverage global research for better integration of **advanced tools like AI into healthcare systems**.

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Health Forum for
Artificial Intelligence

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