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GIHF AI

German Israeli Health Forum for Artificial Intelligence

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 location, 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).

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]

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.

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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