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# Innovation through interoperable, linked health data and collaboration in science

An overwhelming amount of medical data is generated every day. Whether it's from blood pressure measurements, X-rays, and electrocardiogram (ECG) examinations in doctors' offices and hospitals, or genetic analysis in research institutions. The potential that Big Data in the healthcare sector holds for medical care and thus for patients is enormous.

With the help of artificial intelligence (AI), it is possible, for example, to discover patterns in data that are not recognizable to the human brain. Programs trained on this can suggest evidence-based diagnoses and therapies, resulting in faster, more personalized, and more effective treatment for patients. This results in a reduction of unnecessary treatments and examinations, which relieves medical staff and patients alike. It also saves resources that can be used more efficiently elsewhere.[1]

However, data from research and care are recorded differently in each laboratory and hospital. They are formatted, formulated, and stored in a different manner, are subject to different software systems or, in some cases, even exist only in paper form. Yet, data are indispensable for translational medicine, the transfer of research and development processes into medical application.[2]

To exploit the enormous potential of medical data, they must be made usable, i.e., prepared and laid out in such a way that they can be used and transmitted for treatment, research, diagnostic and other purposes.[3]

## Health data - Interoperability for better health care

The need to communicate medical data within an institution has existed since the first electronic patient records of the 1960s, which were mainframe-based. Today, there is an increasing demand for solutions able to communicate data across institutions, sectors, and states. In addition, the increased use of digital health applications (DiGA) requires support for mobile and cloud-based applications.[4]

Wearables and health apps, for example, are used by about thirty percent of the German population and provide valuable data and information on the health status of their users.[5] To ensure that existing data can also be used in diagnosis, treatment and research, interoperability must be guaranteed above all. The word, which comes from Latin, refers to "the ability of specific communication and collaboration between systems. Interoperability is a functional property of a system or program. The system's interfaces are open so that collaboration with other programs or systems is possible."[6]

In the field of health research and care, organiza-

tions such as Health Level 7 (HL7) or DICOM are concerned with the interoperability of these data for health care and health research.[7]

In Germany, HL7 is a registered association that was founded in Berlin in 1993 and aims to enable "more efficient communication and FAIR (= findability, accessibility, interoperability, reusability) data use, which improves diagnostics, therapy, and patient safety". Its 300 members include the National Agency for Digital Medicine (gematik), the National Association of Statutory Health Insurance Physicians (KBV), the Federal Institute for Drugs and Medical Devices (BfArM), and the Robert Koch Institute (RKI).[8]

Over the years, HL7 has developed several healthcare data exchange standards, including HL7 version 2 and the current "gold standard" FHIR (Fast Healthcare Interoperability Resources). Although they were developed by the same organization and share some common goals and functions, they are different standards.
Both enable interoperability of disparate systems within healthcare. These include Hospital Information Systems (HIS), Laboratory Information Management Systems (LIMS), Practice Management Systems (PVS), and Medical Billing and Electronic Health Record (ePA) systems. FHIR combines the advantages of previous standards with current web standards as known from Google, Twitter, and Facebook (e.g., XML, JSON, HTTPS, OAuth). FHIR's design is easy for software developers to learn and puts a focus on widely applied use cases. Data can always be exchanged and represented in human-readable form, even if any machine-readable interoperability fails. In addition, FHIR is based on an open-source license.[9]

"By using uniform languages such as FHIR, SNOMED and LOINC, the data can be interpreted unambiguously and can even be merged internationally and used for research purposes,"[10] says Prof. Dr. Sylvia Thun, Director of the Core Unit eHealth and Interoperability at the Berlin Institute of Health at Charité (BIH). A flagship for this is the Standard Dataset for COVID-19 patients, the "German Corona Consensus Dataset" (GECCO), which gives the scientific community a common language and working basis.

GECCO was used, among other things, in the Corona-Warning-App and was created by Professor Sylvia Thun and her team. It considers elements specified by the World Health Organization (WHO), such as the "International Statistical Classification of Diseases and Related Health Problems" (ICD).
Thus, the dataset can be used in Germany and internationally, as in the European ORCHESTRA project, where data from all over the world were merged and harmonized to answer questions about indications, side effects and drug interactions very precisely.[11]


Standard Datasets of this type can and should be created for any medical condition and have the potential to revolutionize medical care. As GECCO demonstrates, they enable scientists from around the world to collaborate on research into diseases, which consequently has a huge impact on their treatability.

This is particularly true in relation to rare diseases, for which one has very few data sets in a national context. Also, in the treatment of patient groups

that are underrepresented in clinical trials – such as women, since clinical trials are predominantly conducted on men – the resulting increase and diversification of research data can lead to significant advances in treatment.[12]

## German Israeli Science Cooperation: "The International Health-Tech Pilot Program"

Standard Datasets also have enormous added value for researchers in the context of international research projects. This is particularly true for Israel, which is one of the leading countries in digital health with over 700 digital health startups.
Around 85 percent of these young technology companies rely on artificial intelligence. As FHIR is increasingly becoming the leading standard in Israel as well, thanks to the efforts of the country's Ministry of Health and the Israeli HL7 community, comprehensive interoperability is guaranteed. That is especially important with regard to German Israeli scientific cooperation.[13]

One such initiative is the International Health-Tech Pilot Program, which emerged in 2019 from a cooperation agreement between Charité - Universitätsmedizin Berlin, the Berlin Institute of Health (BIH), and the Israel Innovation Authority. It aims to make medical innovations and new technologies available more quickly for global patient care through international collaboration. Selected startups receive financial support from the Israel Innovation Authority and the opportunity to test their medical innovations in studies at the Clinical Study Center of Charité and BIH in Berlin.[14]

In order for researchers to be able to cooperate even more closely in the national as well as international context and, above all, across institutions and borders, an efficient data infrastructure is needed above all in addition to data interoperability.
This also includes data platforms and research centers that meet national and international standards for data protection and data security as well as intellectual property rights, in addition to those within the institution.

## "Data for Health" and Germany's Data Infrastructure

The German Federal Ministry of Education and Research (BMBF), the German Federal Ministry of Health (BMG) and the German Federal Ministry for Economic Affairs and Energy (BMWi), now the German Federal Ministry for Economic Affairs and Climate Action (BMWK), have launched the "Data for Health" innovation initiative to establish such a data infrastructure in 2020.
This is intended to pave the way for the collection, archiving, and evaluation of digital health-related data in compliance with Germany's Patient Data Protection Act (PDSG). With the Medical Informatics Initiative, the BMBF is promoting the establishment of research data platforms as well as consortia that make data from research and patient care accessible to each other and open them up for medical research, as in the context of GECCO.[15]

The Research Data Center Health (FDZ) at the BfArM, which is currently being set up, will also make it possible to access the medical billing data of all people with statutory health insurance in Germany. From 2023, insured persons will also have the option of voluntarily making the data stored in the ePA available to research as part of a data donation. Since health data are subject to special protection in Germany and Europe, citizens should be able to decide for themselves whether personal health data are also made available for research.[16]

## TIMNA, EITAN and Medical Innovation Centers: Israel's advanced data infrastructure

In Israel, the Ministry of Health coordinates Big Data projects such as the "EITAN" data platform, which was created as part of some $270 million government initiative in 2018 to further promote digitization in healthcare. It complements the existing "OFEK" platform, which has been collecting data from the four health insurance companies (Kupot Holim), hospitals and healthcare organizations in Israel for more than 20 years. As in Germany, work is underway in Israel to guarantee the widespread

adoption of ICD-11, which comes into effect in 2022, and to ensure the uniform naming of diseases. In addition to EITAN, the Big Data research platform "TIMNA," the national project to promote data collection, storage, and analysis, promotes the creation of comprehensive analyses. According to Moshe Bar Siman Tov, former director general of the Israeli Ministry of Health, TIMNA "is a repository of anonymized data from various sources that serves as a basis for research and contains Big Data that enables scientists to gain insights and identify patterns that can later be used in decision support systems."[17]

In addition, the Israeli government supports healthcare organizations in establishing the technical infrastructure to promote digital health research and development with up to $2.5 million per institution, for example, to implement the FHIR standard. Innovation hubs, such as the I-Medata at Tel Aviv Sourasky Medical Center (Ichilov), which is directly connected to the hospital, also provide a comprehensive research ecosystem for data-based solutions to clinical issues.[18]

## Privacy Preserving Record Linkage (PPRL) and Federated Learning (FL)

Until the research data center in Germany is fully established, Open Data can be used to a sufficient extent, an EU-wide Health Data Space facilitates access to Big Health Data, and outstanding data protection and cybersecurity issues are resolved, other solutions for linking data are needed, such as Federated Learning (FL). AI calculations that are important for training the algorithm are performed directly on the end device. Only the results of the algorithm's calculations are transmitted and merged, so that sensitive data does not even have to be exchanged.[19]

Another possibility that is already finding application is the exchange of data via coded values. This process of linking records without disclosing sensitive or confidential information about the entities represented by those records is known as Privacy Preserving Record Linkage (PPRL). PPRL is used, for example, in technologies that are blockchain-based or use homomorphic encryption. Relevant data can be made available without identifying data. Using this method, data owners such as hospitals, research institutions, and laboratories can link their data and collaborate on joint research projects.[20]

## Conclusion and outlook

Since the "Act for Better Care through Digitization and Innovation" (Digitale-Versorgung-Gesetz; DVG) came into force in December 2019, German policymakers have spared little expense or effort in advancing digitization in the German healthcare system.[21]

Cross-ministerial initiatives such as "Data for Health," which have already led to improved data interoperability and linkage, are proof of this. However, it will be several years before patient data is digitized with the help of the ePA and available for research via the FDZ and Open Data platforms, for example. Neither scientists nor patients, who could benefit from more efficient therapies, have this time. Therefore, it is essential to enter international research collaborations with highly digitized countries such as Israel. Interoperable data and privacy-sensitive linking methods make it possible.

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