

Report "Communication & Trust"

More confidence in AI - from evidence to data use and trust

On October 19, 2022, the German Israeli Health Forum for Artificial Intelligence (GIHF-AI) held its Digital Health Roundtable on "Communication and Trust". High-level experts from the German¹ and Israeli² healthcare sectors exchanged ideas on the topic of "How to achieve greater confidence in AI – from evidence to data use and trust". The particular focus of the third GIHF-AI Roundtable was on the doctor-patient relationship, transparent communi-

cation, and evidence that promotes trust through the use of "Good Health Data". Accordingly, this report complements the GIHF-AI Policy Briefing "Trustworthy use of artificial intelligence in the healthcare sector" from October 14, 2022. The following is an initial summary of the recommendations for action developed, which are further explained in the subsequent text. The video recording of the roundtable can be found on the ELNET YouTube-Channel.

RECOMMENDATIONS FOR ACTION

■ **The proposal for a regulation laying down harmonised rules on Artificial Intelligence (EU AI ACT) of the European Commission should revise the definition of AI.** The current definition is still too broad. A differentiation between ML and AI as well as between weak and strong AI is also needed. In addition, the definition should subsequently be adopted by legislators at the federal and state levels. **A clear, unambiguous definition is required to gain trust in the use of AI in healthcare from physicians, patients, as well as policy makers and society.**

■ **Successful AI requires "Good Data" that follow the FAIR principle and are voluntarily made available for research** (for example, through an opt-out option in electronic health records). **This can minimize concerns related to potential data misuse.** The use of health data for AI use must not only be about "Big Data", i.e., the largest possible data sets. **The quality of the data, via the training of the AI, largely determines its susceptibility to faults.** Errors in turn reduce confidence in the functionality.

■ **The EU Commission's Proposal for a Regulation on the European Health Data Space (EHDS) should act as a regulatory framework for the use of health data.** A clear, regulatory framework for the privacy-compliant and ethical secondary use of health data, used across countries, would lead to **greater confidence in the use of health data for AI development.** It could also save researchers and industry from regulatory mistakes.

RECOMMENDATIONS FOR ACTION

- **Physicians should be closely involved in the development of AI**, since the doctor-patient relationship plays a supporting role with regard to the use of AI-based health applications by patients. The trust in AI use gained by doctors through the increased flow of information would thus be transferred to their patients.
- **A broad-based communication campaign that presents how AI is applied in the context of healthcare, in an understandable manner, should be launched.** It should showcase that AI can complement and enhance the treatment provided by healthcare professionals. This can simultaneously educate and build trust. For many people, it is very difficult to grasp how AI works. They fear, for instance, that AI will replace treatments by humans (doctors and patients).
- **Close exchange with countries like Israel, which already widely apply AI in healthcare, should be increased to build evidence-based trust.** AI-based treatments by physicians are already used extensively in Israel, which leads to low error rates in diagnoses, predictions of the effect of medications, the occurrence of certain symptoms, etc. by AI-based systems **in terms of causal inference.**

More trust in AI through clear definitions and unambiguous regulation

Although **artificial intelligence (AI)** is already used in many areas, it is **often met with great skepticism, especially in the medical context.** The reasons are obvious. AI requires a lot of health data for its training. However, these are very sensitive datasets and particularly worthy of protection. At the same time, in medicine, the high good of health is at stake, which is generally preferred to be entrusted to known physicians than to an AI. Due to its complexity, AI is also a black box for many people, and they have little idea what it is. In addition, there is the **fear that AI could replace doctors and nurses**, dehumanize medical care, or make diagnoses that are not checked by a human being and are therefore incorrect.

In order for stakeholders from the medical field, patients, science, politics, business, and society to place more trust in AI-based systems in medical care, **first and foremost a clear definition and classification of artificial intelligence in the medical context is required.** It should be emphasized, that in this context, we are talking about AI usage that supports doctors in making faster and better diagnoses, interpreting symptoms at an early stage, and

improving care through personalized medicine. It is therefore seen as **complementary to the role of physicians and nurses and does not replace them.**

A clear **demarcation of Machine Learning (ML) is just as important as the distinction between weak and strong artificial intelligence.** Neither is done in the current regulatory frameworks. A **clear definition would make it easier for policy makers to create a clear regulatory framework for the use of AI.** This, in turn, would make it easier for physicians to decide whether and how to use AI systems for diagnosis and treatment, and would give developers and the healthcare industry confidence that their applications meet the strict requirements for AI. This would benefit not only doctors, whose work would be made easier and more precise, but above all patients.

The **proposal for a regulation laying down harmonised rules on Artificial Intelligence (EU AI ACT) of the European Commission** can provide such a regulatory framework for a clear definition. However, the existing **AI definition there must be formulated much more narrowly** to leave less room for interpretation. The definition should then be adopted by governments at the federal and state level so that researchers, AI developers and the healthcare

industry in Germany, have a legal framework for trustworthy AI.

In addition, the **EU Commission's Proposal for a Regulation on the European Health Data Space (EHDS) can define the extent to which health data can be used for the development of AI.** As long as these regulatory frameworks do not exist, there is a risk that AI-based healthcare applications will not be approved in Germany and developers will look to other healthcare markets where there are clearer or fewer regulations. This means that the German healthcare system is missing out on great potential for improving diagnosis and treatment.

The doctor-patient relationship in the context of trust in AI

It is primarily physicians and patients who are expected to use or benefit from AI-based systems and applications. Nevertheless, **physicians are not involved strongly enough in the development yet, although their trust as main users is indispensable.** The same applies to the digitization of hospitals in general. For this reason, many healthcare facilities in this country appoint Chief Transformation Officers (CTO) who are responsible for the digital transformation of those facilities and act as facilitators. The resulting digitization, especially of healthcare data, lays the foundation for AI use.

In Israel, the largest hospitals have their own innovation hubs, where doctors, researchers, and startups work together on innovative solutions for better healthcare. The **strong involvement of physicians not only improves development, but also creates a great deal of trust.** The motto here is **"doctor-in-the-loop"**: the doctor is presented as an authority inside a loop, supplying an expert system with information about current patient data, treatment results, and possible additional (side) effects, returning treatment recommendations to the doctor himself.³

Patients generally have a high level of trust in their treating physicians.⁴ **By strengthening the medical profession's trust in AI-based applications, this**

can have a positive impact on patients' relationship with the use of AI in treatment. This includes a greater willingness to donate health data for research and development of AI-based applications. In addition to the doctor-patient relationship, patients themselves also play an important role in trusting AI use. Patient initiatives and petitions seeking increased data use and AI application, for instance in the oncology field, are evidence of this. **Patients' voices should be heard more,** as they are both data providers and beneficiaries.

Evidence and the use of "Good Data" builds trust

Trustworthy, data-driven predictions, as well as successful data-based treatments, build trust by **causally demonstrating the benefits of AI in medical treatment.** By using **"Good Data" according to the FAIR Data principles** that "data must be findable, accessible, interoperable, and reusable"⁵, trust is added to the use of sensitive health data. In addition, **to obtain "Good Data," national and international data exchange is critical.** This is because the more data that can be linked, the better the functioning of the AI system will be. At the same time, this has the advantage of avoiding bias (distortion of the result) due to one-sided data sets and making medicine more personalized.

In Israel, in the wake of the corona pandemic, an AI-based computational predictive medicine model was developed in cooperation with one of the largest hospitals to predict the deterioration of patients with Covid-19. Physicians were closely involved in the development and application in order to be able to explain and understand the predictions, so that they could be implemented in practice. In addition to the predictive capability, the model needed to be paired with actionable insights. The system was also monitored and controlled over time to ensure its reliability and compliance. Based on the **successful use of the model, trust was built, and skepticism was reduced.**

Another example of data-driven decisions about health management and treatment of patients from

Israel is the analysis of **causal relationships (causal inference) in health care. They allow estimation of causal effects when randomized controlled trials are not available. This allows decision-making processes to move from "best guess" to concrete answers based on data.**

Transparency and communication

In addition to a **trustworthy legal framework for the use of AI in healthcare and illustrative models of data-based diagnostic and treatment tools based on AI** that provide better understanding,

transparency and communication among the relevant stakeholders are needed above all. This refers to communication between AI developers and physicians, as well as in the context of the doctor-patient relationship. At the same time, **politics should be closely involved in the discourse** in order to be able to initiate regulations that promote innovation. An **evidence-based communication campaign** that educates society about the application of AI in healthcare and counters possible fears and skepticism with information is recommended, as is the **close involvement of patient representatives** in decision-making processes.⁶

Bibliography

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