doi:10.3233/SHTI240527

A Governance Framework for the Implementation and Operation of AI Applications in a University Hospital

Timo APFELBACHER[a,1], Sude Eda KOÇMAN[a], Hans-Ulrich PROKOSCH[a] and Jan CHRISTOPH[a,b]
[a] *Friedrich-Alexander-Universität Erlangen-Nürnberg, Institute for Medical Informatics, Biometrics and Epidemiology, Medical Informatics, Erlangen, Germany*
[b] *Junior Research Group (Bio-)medical Data Science, Faculty of Medicine, Martin-Luther-University Halle-Wittenberg, Halle, Germany*
ORCiD ID: Timo Apfelbacher https://orcid.org/0009-0003-0149-695X, Sude Eda Koçman https://orcid.org/0009-0009-2207-2172, Hans-Ulrich Prokosch https://orcid.org/0000-0001-6200-753X, Jan Christoph https://orcid.org/0000-0003-4369-3591

Abstract. Background: Artificial intelligence (AI) is becoming increasingly important in everyday life and medical care with a notable gap between AI development in medicine there and its practical implementation in university hospitals. Objective: The aim was to develop a governance framework to guide the procurement and implementation of AI applications in university hospitals. Methods: Seven role-play expert interviews were conducted with interviewees from two university hospitals, simulating realistic AI system implementation scenarios. Results: A detailed governance framework was developed, divided into the sections general considerations, system selection criteria, and implementation. Further, a condensed version of the checklist was also derived. Conclusion: Many aspects of AI applications in medical care, such as the establishment of an AI board, remain, along with numerous concerns about the technology. These findings provide valuable insights into the topic.

Keywords. Algorithms, Artificial Intelligence, Clinical, Software, Expert Systems, Governance, Machine Learning, Physicians, University Hospitals

1. Introduction

In the context of this work AI has been defined as *„the ability to process external data systematically and learn from it to achieve specific goals and tasks“* [1]. *“AI involves using machines to simulate human thinking processes and intelligent behaviors, such as thinking, learning, and reasoning, and aims to solve complex problems that can only be solved by experts.”* [2] This technology is gaining increasing significance, even though not all (dis)advantages are yet foreseeable. Sam Altman, CEO of OpenAI, is worried

[1] Corresponding Author: Timo Apfelbacher, Friedrich-Alexander-Universität Erlangen-Nürnberg, Institute for Medical Informatics, Biometrics and Epidemiology, Medical Informatics, Erlangen, Germany; E-Mail: timo.apfelbacher@fau.de.

about manipulated photos being used to influence election campaigns [3]. The use of AI in medical care is also growing rapidly [4]. This is inter alia shown by the rise of the annual AI/machine learning (ML)-based medical products approved by the FDA in the USA by five (2015) to 108 (2023). Meanwhile in Europa the numbers of CE-licensed AI/ML-based medical products rose from 13 (2015) to 100 (2019) [5] – even before the launch of ChatGPT. Nevertheless, in the hospital context, in contrast to other industries, it seems that AI systems are a sparsely used technology [6]. An attempt for explanation could be uncertainties. Who is liable for damage caused by an AI system and who makes the final therapeutic decision in cases of disagreement. In aviation, flight crews are now instructed to follow the instructions of the Traffic Alert and Collision Avoidance System when it issues an alert. [7] Both, aviation and medical care are high-risk areas where mistakes can cause immense damage. Other practices, such as working with checklists, have already been implemented in medical care. [8] Within the scope of this work the question: *Which aspects must be considered for the implementation of AI systems at the University Hospital Erlangen (UKER)?* was addressed and a governance framework was developed, which aims to provide a guidance for the implementation and operational use of AI systems in hospitals.

2. Methods

An explorative qualitative study design was chosen for this work. Stakeholders from different disciplines at UKER and the University Hospital Halle (Saale) participated in exploratory expert interviews using a semi-structured interview guide. Further, realistic application scenarios (use cases) were developed to introduce interviewees to the implementation an AI system in a clinical context. To increase engagement, the expert interviews were combined with a role-playing experiment, inspired by Sader [9]. Therefore, the experts were asked to assume specific roles and answer interview questions from that perspective.

In parallel with the progress of this work, a literature review was carried out using the PubMed platform and the Elicit search engine.

The use cases aimed to represent typical clinical scenarios at UKER, involving complex decision making rather than simple if-then decision trees. The final use case was as follows: *Radiation therapy (interview partner: head of radiation therapy): Hello …, a fellow student, who is a senior physician at another university hospital, informed me about a new AI system they are already utilizing. With the assistance of this AI system, radiation therapy can be more precisely tailored to individual patients, as it identifies pre-therapeutically radioresistant or radiosensitive tumor components. According to his accounts, the system has significantly improved treatment outcomes in managing cancer in their clinic. This could potentially elevate the standard of our patient care as well!* [10]

A semi-structured interview guide was developed for the expert interviews, following the recommendations of Helfferich [11]. A total of seven expert interviews were conducted, two of which were pre-tests. All interviews took place online via Zoom between May 10 and June 28, 2023. The interviewees had specialism in medication therapy safety, ethics, paediatrics, quality management, radiology, and radiotherapy. Years of experience were not asked. Four out of the seven experts held habilitation, indicating several years of professional experience. As only minor adjustments were necessary, the information obtained in the pre-tests was included in the overall analysis.

For the data analysis, the interviews were transcribed according to the transcription rules of Dresing & Pehl [12] with a few adaptions and with the help of the MAXQDA programme. The qualitative analysis of the collected data was carried out according to Kuckartz and Rädiker [13].

The governance framework emerged from the synthesis of the expert interviews and was contextualized within the scientific context.

3. Results

Before the implementation: An AI committee should be established, including experts in i. a. data protection, ethics, IT, chairman of the hospital board, medical informatics, and patient representative. This committee will provide advisory support, ensure close coordination between the departments involved, and have veto power to adjust or reject implementation of the AI application.

Further a designated representative from the department implementing the AI application should also be appointed. A holistic cost-benefit analysis is also required [14]. It is also crucial to adapt processes in the AI application deployment area to ensure seamless integration and optimal utilization of the AI potential.

The requirements for the system are that it must be CE certified, and its benefits must be scientifically proven. Furthermore, high-quality training, test, and validation datasets are crucial. To ensure this, information on this must be obtained from the manufacturer. In addition, data relevance to patient cohorts and adherence to ethical standards are essential, so explainable AI should be used. This is morally and ethically more justifiable and ensures that system suggestions are understandable. It is important that the AI application does not operate autonomously, but rather that a human makes the final decision, aiming for the best patient outcomes by combining human experience with system expertise. Safety is ensured through feedback loops, emergency numbers, and a designated contact person at the manufacturer´s side for emergencies. Physicians are primarily responsible for medical errors, but the manufacturer is liable for system-related problems. Clear agreements between the hospital and the manufacturer are necessary before implementing an AI system.

During the implementation: A multi-month test phase is essential, ideally running alongside day-to-day business and with patient awareness. Productivity may initially drop during the implementation until users become familiar with the AI system.

For high reliability, the AI system needs backup power, and strict security standards must protect patient health data.

Comprehensive training is essential, as there are varying levels of knowledge and experience with the AI application.

After the implementation: The application needs to be monitored and eventually adjustments to the patient cohort of the UKER may need to be made. These checks and adjustments should be carried out at regular intervals by independent audit organizations. The UKER should receive certificates from the audit organizations as confirmation.

4. Discussion

The diverse group of experts provided different disciplinary perspectives. Role-playing scenarios enlivened the interviews, although the consistency varied and sometimes resembled traditional expert interviews. The interviewees found the use cases easy to understand, which facilitated their immersion in the scenarios presented. Many aspects of the expert interviews were in line with the current literature, but some points provoked heated debate, notably the establishment of an AI board. While some experts saw this as potentially burdensome or redundant given the existing literature, examples if its effectiveness in implementing AI systems were demonstrated. The discussion remains heterogeneous, with no clear consensus. This governance framework serves as a guideline for the implementation of AI applications in university hospitals. The expert interviews and the literature review revealed that a governance framework is needed. [4,15–17] At the same time, it does not claim to be exhaustive especially in unresolved areas such as the legal situation. There are different concepts and approaches for the regulation of AI systems [16]. The expected AI legislation in the European Union is likely to contribute to this. Additional aspects may emerge over time as AI systems become part of everyday life. Furthermore, regular checks on the governance framework may be necessary to address changes in ethical, legal, and technical aspects.

5. Conclusions

The aim of this work was to develop a governance framework for the implementation of AI systems. The literature review combined with the expert interviews provided a comprehensive basis reflecting relevant aspects of clinical practice. Both sources indicated the need for stronger regulation, taking into account ethical, legal, and technical aspects, in order to fully realize the AI potential. The guideline serves as practical tool for university hospitals implementing AI systems in their clinical routine. The framework is dynamic and will need to be regularly reviewed and adapted and developed over time. Due to the small sample size, the generalization of the results is limited, suggesting the need for further research in this area of science.

Acknowledgement and Ethics

We thank all interviewees. OMI is funded by the Federal Ministry of Education and Research (BMBF) under the FKZ 01ZZ2315C. The present work was performed in fulfillment of the requirements for obtaining the degree "Dr. rer. biol. hum." from the Friedrich-Alexander-Universität Erlangen-Nürnberg. Ethical approval was not required.

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