Investigation of Current Translation Challenges and Barriers to the Use of Artificial Intelligence in the German Healthcare System

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Abstract

It has been suggested that Artificial Intelligence (AI) could be the key to solving some of the biggest challenges (cost saving, care quality improvement, and personal load reduction) facing healthcare today. Although there is a growing trend in research, only a few of these research projects have reached the stage of medical approval. This raises the question of what hurdles and challenges impede the effective translation of AI technologies into routine healthcare practice. Our paper aims to investigate the current translation challenges and barriers to using AI in healthcare, specifically focusing on the European Union, particularly Germany. During our research process, with the help of a workshop and interviews with domain experts, we identified challenges and barriers and will provide a comprehensive overview of the hurdles hindering AI adoption in multifaceted healthcare.

Keywords: Artificial Intelligence, Machine Learning, Barriers, Challenges, Germany.

1. Introduction

Artificial Intelligence (AI) and Machine Learning (ML) are seen as vital solutions to address the healthcare challenges of cost reduction, quality improvement, and workload reduction (Bajwa et al. (2021)). Even after more than ten years of substantial attention, the utilisation and integration of AI into clinical practice remain constrained, with numerous AI healthcare products still in the stages of design and development (Bajwa et al. (2021)). This persistence of early-stage development implies the presence of considerable translation barriers.

The pace of digitalisation in Germany's healthcare sector remains lethargic. According to a study conducted by the Bertelsmann Foundation using the Digital Health Index, Germany currently ranks second-to-last among 17 predominantly European nations (Bratan, 2022). One illustrative example of this slow progress is the adoption of the electronic patient record (ePA), which has yet to see regular practical utilisation (Stachwitz and Debatin, 2023). While significant strides have been made in the previous legislative period through the introduction of legal frameworks, there remains ample room for enhancement today.

The current political resolve in Germany has paved the way for the foundation of a regulatory sandbox in Baden-Württemberg, referred to as ROUTINE[1], with the goal of facilitating the integration of digital health applications and AI into the healthcare system. This initiative primarily centers on addressing and overcoming translation barriers, nurturing technical expertise, and harnessing real health data to drive progress.

To establish the groundwork for the regulatory sandbox, we conducted a targeted assessment of the translation challenges linked to AI-based medical product development, with a particular focus on Germany and, to some extent, Europe. This survey centers the attention on the following research question: *What impediments and difficulties hinder the efficient integration of AI technologies into the German healthcare system?* In pursuit of answers to these research question, we initiated the current study and enlisted domain experts to discern the barriers to the

[1] https://sozialministerium.baden-wuerttemberg.de/de/service/presse/pressemitteilung/pid/kuenstliche-intelligenz-reallabor-geht-an-den-start?highlight=ROUTINE

URI: https://hdl.handle.net/10125/106816
978-0-9981331-7-1

implementation of AI in clinical settings.

The present paper is structured as follows. In Section 2, the current literature regarding AI translation hurdles will be evaluated. Our procedure, which involved a workshop and interviews with domain experts, is described in Section 3. Then, we will classify the identified translation barriers into clusters in Section 4, and we will discuss our results in Section 5.

2. Theoretical Foundation

Translation encompasses the journey from initial research and conceptualisation to the creation of a finalised product ready for routine care. This process involves various stages, including the development of initial prototypes for feasibility assessment, the design of demonstrators for validation, evidence generation, and the attainment of approval and certification. To delineate these stages, various frameworks can be employed. Figure 1 illustrates the individual stages of the Digital Health Milestone Framework developed by the European Institute of Innovation and Technology (EIT) (2023). This framework builds upon the established methodology of Technology Readiness Levels (TRLs), which has been adapted to accommodate the distinct challenges encountered in the realm of healthcare innovation (European Institute of Innovation and Technology (EIT), 2023). The Technology Readiness Level concept was initially formulated by NASA during the 1970s. It provides a standardised way to assess and communicate the readiness of technology across various domains, helping stakeholders make informed decisions about the development, investment, and deployment of new technologies (NASA, 2018).

Innovators and Developers encounter throughout this transformative journey challenges and hurdles, which we explore as translation barriers within this paper. A substantial amount of literature explores the obstacles to and enablers of integrating AI in healthcare (Chomutare et al., 2022). A predominant emphasis in academic publications lies on specific branches of medicine, such as gastroenterology, intensive care units (ICUs) (D'Hondt et al., 2022), and radiology (Strohm et al., 2020), with a keen consideration of their distinctive characteristics. Another thematic approach examines the problem from a regulatory perspective (McKee and Wouters, 2022). Furthermore, an examination from the perspective of the algorithms used (D'Hondt et al., 2022) or the user (GP, nurses, patients, etc.) (Boillat et al., 2022) can be found in the literature. Identified Barriers are often either data-, methodological-, technological-, regulatory- and policy-related, or human factor-related (e.g., Tachkov et al. (2022), Aung et al. (2021)).

Nevertheless, Chomutare et al. (2022) claim that most of the knowledge we have about these obstacles and facilitators originates from anecdotal evidence, narrative commentaries, and reviews, primarily lacking empirical validation or a robust theoretical foundation. According to them, this has resulted in a gap and biases in the report of Barriers to AI implementation in healthcare.

Consequently, we have chosen a practice-based approach in this paper to identify the challenges that arise in the translation journey with a specific focus on Germany, as we have the unique opportunity to access a wide network of contacts to all stakeholders involved in the translation journey through ROUTINE.

3. Methodology

We applied a two-part qualitative research method to investigate current translation challenges and barriers to AI in healthcare.

First, we conducted an online workshop with the 15 domain experts of the ROUTINE sandbox (see W1-W15 in Table 1.), representing stakeholders from different areas of healthcare along the technology journey (e.g., academia, MedTech companies with AI innovations, medical service providers, health insurances, interest representatives, policymakers and regulators). As part of the workshop, the experts were divided into four smaller subgroups in which potential legal, technical, economic, and structural barriers and challenges were identified and recorded on a virtual whiteboard. Subsequently, the results of the subgroups were presented and clustered in the overall group.

In order to achieve a broader coverage of the topic area by the stakeholder groups, further domain experts were acquired for semi-structured interviews based on their field of activity as well as their experience with the topic area. We conducted 19 semi-structured interviews from March to April 2023 with these domain experts (see I1-I19 in Table 1). Transcripts were taken from these online interviews. The core theses of the interviews and the workshop were subsequently summarized by the authors in a pairwise review process and then enriched with examples, consequences, background, and possible solutions. The examples and included evaluations (i.e., 'is difficult') were taken from the descriptions of the interviews. The most important examples were selected in each case. Thereby, the thematic analysis by Braun and Clarke (2006) was used to evaluate and cluster the summarized texts, which includes the following six phases: 1) familiarising yourself with your data;

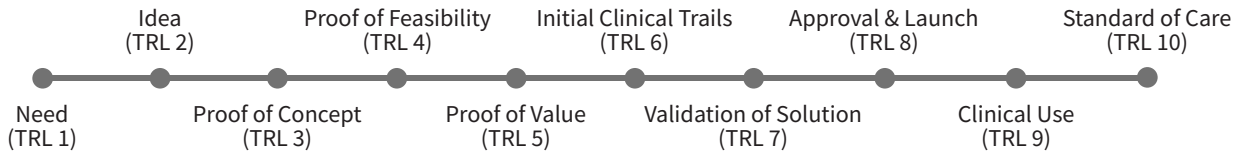

Figure 1. Innovation Maturity Levels to assess Digital Health Innovations. This scale is based on the Technology Readiness Level (TRL). (European Institute of Innovation and Technology (EIT), 2023)

2) generating initial codes; 3) searching for themes; 4) reviewing themes; 5) defining and naming themes; 6) producing the report.

4. Translation Challenges and Barriers

In the interviews, 52 translation barriers were identified, which were arranged thematically in 13 clusters. The list of the individual barriers, their description, and cluster affiliation is shown in Figure 2. All Interviews are indicated by '#I'. The 'reference' indicates the respective stakeholder so that the perspective can be assessed. All statements from the workshop are marked with a '#W'. These cannot be assigned to an individual stakeholder but to the workshop participants as a whole.

The 'Medical Device Regulation (MDR)' cluster groups together all the problems associated with this regulation. The inherent complexity of MDR, difficulties with timely standard evolution, and the lack of a clearly defined overarching goal all highlight the significant impact of regulatory complexities on the successful translation of AI technologies in healthcare systems.

This is followed by the cluster 'Regulation and Policy in general'. Here, the conflict between, on the one hand, the protection of patients and, on the other hand, invention becomes apparent. The various laws and regulations do not align with each other. The objective of legislation and regulation does not appear risk-based to the interviewees.

A significant problem cluster is the lack of standardisation. This cluster includes the lack of semantic and structural standardisation of the data as well as the lack of standardised interfaces and interoperability and standardisation in the storage of AI models.

The 'Digitisation and Digitalisation' cluster deals with the lack of digitisation and digitalisation, which is seen as the basis for AI applications.

Separately, the 'AI Competencies and Acceptance' cluster looks specifically at the lack of competencies and acceptance of medical staff with regard to AI.

Several clusters deal with data: 'Availability of data', 'Data Protection', and 'Access to data'. Since we focus on Germany in this paper, the hurdles raised are connected mainly to the GDPR. The regulation is interpreted differently in the individual member states within the European Union, in Germany it is rather strict. There are also complaints about the lack of a benefit-risk ratio in data protection. Data protection is complex, consumes many resources, and causes much uncertainty. The cluster 'Availability of data' summarises all barriers with missing or poor-quality data. There is a lack of incentives to provide data. The third data cluster deals with access to data. Even if the data were available in principle, accessing this data is described as laborious.

Various barriers are gathered beneath the 'Finance' cluster. One is the lack of transparency about future reimbursement in the health system. The other is financing during development. In particular, MDR-compliant development is cost-intensive and hardly affordable for SMEs.

Another cluster, 'Transfer of research,' summarises all the barriers to the transfer of research. The barriers deal with the structure of funding, the cost-intensive further development of prototypes, and the lack of transparency of the results. Whether AI is patentable at all is another open question.

Under 'Ethics proposal' are the two challenges that have arisen specifically concerning the ethics proposal. The scope and competence of the ethics committee are described as unclear.

Two hurdles raised address open liability issues, these are grouped under the 'Liability' cluster. The other barriers that could not be assigned to any other cluster are 'Miscellaneous'.

5. Discussion

This study provides an excellent starting point for an overview, without focusing on a specific algorithm or clinical area. It addresses the problems that most developers of AI applications experience in their everyday work. The empirical approach is the strength of this work. It allows us to identify similarities and differences in the results of theory-based approaches.

Medical Device Regulation (MDR)			
No.	**Reference**	**Name of barrier**	**Description**
1	#I4,#I5,#I8,#I9, #I11,#I2,#W	Complexity of the MDR	The lack of knowledge and the complexity of MDR makes it difficult for developers to bring new innovations to the market. Contradictory, incomprehensible, incomplete standards. In addition, it is very cost-intensive, in particular hardly bearable for SMEs, actually only bearable for large companies. Strong contradiction to other countries (e.g. FDA), where deregulation is more common.
2	#I5	Regulatory Science is missing	FDA has 250 Regulator Scientists, the EU has in the field of medical devices 0. But to understand regulatory systems, one would have to model them.
3	#I5	Aim of regulation remains unclear	By optimising patient safety, fewer products are put on the market.
4	#I5	Standardisation committees of MDR do not keep up with updating standards	Updating the standard every three years is not possible.

Regulation and Policy in general			
No.	**Reference**	**Name of barrier**	**Description**
5	#I5	Cross-domain legislation and regulation not aligned with each other	For example, MDR vs. AI Regulation vs. GDPR.
6	#I5	Legislation is currently not risk-based	Optimising patient safety prevents the development of new products. Examples of laws and regulations: AI regulation, GDPR, MDR.
7	#I3,#W	Private research is not considered in current political strategies	The digitisation strategy does not include all enablers (e.g. medtech companies) in the value chain for the use of health data. According to the German Patient Data Protection Act and the Data Transparency Regulation, no data access for private-sector research is foreseen.

Standardisation			
No.	**Reference**	**Name of barrier**	**Description**
8	#I1,#I2,#I3,#I7, #I9,#I15,#I16, #I17,#W	Lack of semantic and structural standardisation of the data	Data is often available in unstructured form (free texts, PDF documents) and in the heterogeneous format of the manufacturer's systems.
9	#I1,#I2,#I3,#I7, #I11,#I15,#I16, #I18, #W	Lack of standardised interfaces and interoperability	The majority of hospital information system providers provide no or heterogeneous interface definitions and documentation.
10	#W	Lack of standardisation in the storage of AI models	AI models from different frameworks (e.g. Scikit-Learn, Tensor Flow) are not portable.

Digitisation and Digitalisation			
No.	**Reference**	**Name of barrier**	**Description**
11	#I17	Lack of use of existing systems	For example, the German Electronic Health Record (ePA) is not yet being used by all actors throughout the medical sector.
12	#I2,#I3,#I6,#I7, #I11,#I12,#I13, #I14,#I16,#I18, #I19	Lack of digitisation	Not all data is often available in digital form, but only in analogue format or is painstakingly digitised by hand. Digitisation as a basis for AI is missing.
13	#I2,#I3,#I6,#I7, #I9,#I11,#I12, #I13,#I14,#I15, #I16	Missing digitalisation skills	Digitalisation skills in society are lacking, especially in general practitioners and care workers.
14	#W	Supposed expertise in decision-making bodies	AI experts in decision-making committees in the German healthcare system are generally not implementation experts but policy-makers who have been involved in digitisation projects in an observational role at most.

AI Competences and Acceptance			
No.	**Reference**	**Name of barrier**	**Description**
15	#I8	Limited AI expertise among medical staff	Competence in the field of AI among medical staff is limited. However, it is unclear which competences medical staff actually need in the field of AI. Presumably, different application levels (doctor, MFA) need different competences.
16	#W	AI acceptance among medical staff	Fear among service providers of rationalisation. Nurses and doctors have limited exposure to and competence in AI. Acceptance in the medical profession is limited in principle. However, this is due to the general scarcity of resources for new IT projects, and rather less so for AI in particular.

Data Protection			
No.	**Reference**	**Name of barrier**	**Description**
17	#I2,#I3,#I9,#I12, #I15,#I19	Complex data privacy protection	Contracts for commissioned data processing between the partners involved must be legally drafted and reviewed by lawyers on both sides. For fear of mistakes, projects are rather not implemented.
18	#I5,#I8	The benefit-risk ratio in data protection is often lacking	The consequences of too strict data protection/non-use of data are not modelled.
19	#I3,#I5,#I8	Different interpretation of regulation in data protection	The same laws and regulations are interpreted differently in different countries within the EU.
20	#I2,#I4,#I6,#I15, #W	Lack of specification for implementation/ technical requirements with regard to data protection-compliant storage	For example, data protection-compliant storage (and processing) with cloud providers.
21	#I2,#I3,#I12, #I15,#I16,#W	Lack of technical requirements in terms of IT security and data protection	Ambiguities, e.g. regarding the scope for anonymisation or when to use annonymisation/pseudonymisation.
22	#I7,#I10,#W	Lack of use of broad consent in health care reality	Currently, broad consent is not yet comprehensively implemented in German practice. The implementation challenges are still too high at the moment.
23	#I15	Short deletion periods for current consents	In the MII Consent, the time limit for deleting the data is one year after the end of the project at the latest. After that, the data is no longer available and must be deleted.
24	#W	Uncertainties about the obligation to delete ML models	Ambiguity about deletion of the ML model when the deadlines for deletion of the data expire.
25	#I15,#W	Global differences in the legal framework complicate cooperation	Working with data in international teams (within and across EU countries) is complicated by different legal frameworks and their interpretations.
26	#W	Stiff data protection	Data protection concept must already be formulated before the project begins. Although specifications only emerge during the project (especially in agile projects).

Availability of data			
No.	**Reference**	**Name of barrier**	**Description**
27	#I2,#I4,#I17, #I18,#W	Missing data	Machine learning algorithms require representative sample data that map all relevant features for the classification goal. Longitudinal data are often not available, especially for rare diseases.
28	#I2,#I3,#I4,#I7, #I8,#I11,#I15, #I16,#W	Poor data quality	Existing data is often not sufficiently annotated. The annotation of the data depends on the findings of the treating physician. In addition, data are accounting data and not raw data.
29	#I1,#I2,#I4,#I9, #I7,#W	Lack of incentives to provide data	Data from publicly funded studies are often withheld by research institutions so that the findings can be obtained and published themselves. Data protection is used as an excuse not to share data.
30	#I2,#I4,#I14, #I15,#I16	Legal circumstances lead to a lack of data availability	Development with a clinic: Clinic has own older data, but as no consent of data, data cannot be shared.
31	#I3	Data producers are currently responsible for the high costs of collecting data.	Collection, quality assurance, pseudonymisation, aggregation of data cannot be done by individual researchers/data producers.
32	#I2,#I7, #I10,#W	Lack of knowledge about the added value of secondary use	Citizens do not consent because they do not understand the benefits of providing data.

Access to data			
No.	**Reference**	**Name of barrier**	**Description**
33	#I4,#I8, #I10,#W	SMEs are often not given access to patient groups and research data for the evaluation of products.	No possibility for SMEs to get data for the development of products compared to large companies, which have their own data. The process of accessing and using data appears to be intransparent.
34	#I9	Lack of availability of legally and ethically correct collected data	Currently available data does not meet regulatory and ethical requirements for secondary use.
35	#I4	Duration of data access process not reflected enough in research projects	The duration of research projects is too short for real data access processes to be implemented.
36	#I6 #W	Lack of/Unspecific Legal Framework of Secondary Use of Data	To date, Art. 89 (1) of the GDPR has not been used to further process data for scientific research.

Finance			
No.	**Reference**	**Name of barrier**	**Description**
37	#I8	Traditional research funding does not include funds to accompany regulatory processes (MDR-compliant development)	High costs for accompanying regulatory processes (elicitation of requirements, risk management, technical documentation, usability studies / engineering, QM system, clinical trial (Art. 62 MDR) and evaluation, CE certification.
38	#I8	Lack of transparency in the assumption of costs by the statutory health care system	There is no transparent description of the criteria according to which the statutory health care system assumes costs for digital applications.
39	#I1,#I7 #11,#W	Financial resources for sustainable IT architectures are not provided	Staff capacity for sustainable IT architecture not given. IT is underfunded due to the lack of financial resources of a hospital. Medical providers are overburdened with the selection of providers for certain new technologies in order to implement legal requirements (e.g. for communication in medicine - KIM).
40	#I2	Studies on evidence of effectiveness for DiGA (and DiPA) are expensive	Studies on proof of effectiveness for Digital health application (DiGA) and Digital nursing application (DiPA) must be commissioned externally due to objectivity. This is very expensive.
41	#W	Lack of clarity about access to the primary healthcare market among AI developers	The path to marketing is sought via health insurance companies, which ultimately only refer to the DiGa process.

Transfer of research			
No.	**Reference**	**Name of barrier**	**Description**
42	#I1,#I9, #I2,#W	Lack of usability of research results	Many similar small projects, which lead to duplicate structures in administration, documentation etc., at the same time the small projects can only work to a limited extent because they lack the financial resources. Lack of clarity about the legal use of AI models generated on the basis of data in research.
43	#I9	Further development of the medical device is costly	Many AI start-ups are the extended arm of university research and not a company, lack of understanding that for the need for a clean business model. Lack of clarity about the exploitation goal of research results and lack of financial resources for exploitation and continuation during/after the research projects (research demonstrator vs. product).
44	#I1,#I2	Lack of transparency of research results	Results of research projects (e.g. code, publications) are not publicly accessible.
45	#W	Patentability of AI unclear	The question of whether developed AI models are patentable.

Ethics proposal			
No.	**Reference**	**Name of barrier**	**Description**
46	#I2,#W	Unclear responsibility of the Ethics Committee for non-clinically developed products	For a research project that does not involve a medical faculty, hospital or practising doctor, the responsibility of the ethics committee (university hospital or state medical association) is unclear.
47	#I2	Lack of clarity about the scope of the ethics application	The correct formulation of ethics motions for this is difficult for "non-ethicists" as the requirements and scope are unclear.

Liability			
No.	**Reference**	**Name of barrier**	**Description**
48	#I2,#I10	Lack of clarity about liability throughout the data use chain	In complex projects with several project partners, liability is not clearly defined.
49	#I7	Open liability issues	Analogous to autonomous driving, questions remain regarding liability for AI errors.

Miscellaneous			
No.	**Reference**	**Name of barrier**	**Description**
50	#I2,#I9,#I18, #W	Skills shortage	There is a lack of personnel with very specific qualifications (software engineers, lawyers specialising in medical devices, etc.). In research, payment is according to TV-ÖD or TV-L. Compared to the salaries to be expected in industry, this is not very attractive for these people. Moreover, the positions are often only temporary and/or part-time.
51	#I4	Computationally intensive models not feasible for SMEs	In Deep Learning the computing power will eventually reach its monetary limits. SMEs can't keep up with this. Only bigger companies can afford it.
52	#W	Versioning of data is time-consuming	It requires meticulous tracking, organization, and storage of multiple iterations or copies of data, which can become complex and labour-intensive.

Figure 2. Translation challenges and barriers clustered.

Table 1. Categorization of the experts of the workshop and interviews.

Type of Stakeholder	Nr.	Role
Medtech Startup	W1	Software-Development Engineer
	W2	Chief Executive Officer (CEO)
	W3	Chief Executive Officer (CEO)
	I1	Chief Executive Officer (CEO)
	I2	Chief Executive Officer (CEO)
Small and medium-sized Medtech Company	I3	Chief Executive Officer (CEO)
Large Medtech Company	W4	Chief Medical Officer (CMO)
	W5	AI Expert
	I4	Head of R&D Medical Systems
Scientist	W6	PhD student (Digital Health and IT)
	W7	Digital Health Professor
	W8	Chemists
	W9	Head of IT Research in clinic
	W10	PhD student (Digital Health and IT)
	I5	Medical Informatics Professor and Regulatory Scientist
	I6	Chief Executive Officer (CEO)
	I7	eHealth Research Group Leader
Clinician	W11	Medical Specialist and Digital Medicine Expert
	I8	Psychologist
	I9	Dermatologist and Research Group Leader
	I10	Head of Health Data Research Group
	I11	Clinic Board
Care	W12	Head of Digitisation
	W13	Student (Health Assisting Engineering)
	I12	Business Development
	I13	Project Manager
Health insurance	I14	Federal State Manager
	I15	Digital Officer
	I16	Board of Directors
National Digital Health Agency	I17	IT-Architect
Associations of Statutory Health Insurance Physicians	I18	Head of the District Office
Consultant	W14	Digital Health Expert
	W15	Computer scientist
	I19	Digital Health Expert

As elaborated in many publications, the two major themes - data and regulations - can likewise be found. In the present work, the data cluster was divided into three categories: 'Data Protection', 'Availability of Data', and 'Access to Data'.

Since Artificial Intelligence insists on learning from data, data is indispensable. A lack of data and the poor quality of data undermine any attempt in the development of an AI application in advance. Unfortunately, there is hardly any incentive for hospitals or research institutions to provide data. There is neither a monetary incentive nor recognition in the scientific community for the collection and provision of data, including the necessary documentation and pre-processing. Far worse are some of the excesses described, where data collected with taxpayers' money is treated as a treasure trove of data and withheld in order to be analysed by the institutions themselves. These sharing requests are met with lengthy data protection agreements between the parties, which can drag on for 6-18 months. Therefore, work should be done to establish the value of collecting data in science and society.

In addition, numerous problems in dealing with the MDR were described. According to the interviews, many developers are so overwhelmed by the complexity that, in the final analysis, they are being advised against developing an medical device of class 2a and

higher. Due to the complexity, some interviewees expect developing a new product to take more than four years and a capital outlay of at least €20-50 million. This is impossible for small and medium-sized enterprises (SMEs) to cope with. In particular, the non-transparent requirements seem to be a problem.

While a lack of acceptance is described as a typical challenge in some publications (e.g., Tachkov et al., 2022), this challenge plays a rather subordinate role in the present empirical analysis. Some interview partners point out that the problem here is less due to AI than a lack of acceptance towards the digital in general. Therefore, when proposing solutions, it is essential first to determine precisely whether the problem is a lack of digitalisation or actually AI. Additionally, some interviewees were of the opinion that part of the lacking acceptance can be explained by the fact that products do not align with the market or user needs or are not matured.

Another explanation for the subordinate role of AI acceptance could be that most AI products developed are not yet permitted on the German market. With more approved AI-based medical products, the problem could then perhaps become more significant, although this would have to be verified.

One hurdle, which will presumably arise once more products have entered the market, is the still limited AI competencies among medical staff. The first step here would be to determine which group of employees (doctors, nurses, etc.) needs which knowledge and competencies in order to be able to act confidently and remain open to the adaptation of new technology.

6. Conclusion & Future Work

The survey has shown that the most critical points for action to reduce translation barriers are the legal regulation, and the individual clusters on data - 'Data Protection', 'Availability of Data' and 'Access to Data'. These are the points on which politics should focus.

In politics and legislation, there is currently a great effort to deal with the topic of AI, for example, in the EU AI Act, which is in the final phase of legislation. Due to these new developments, the barriers identified so far have to be rechecked for their validity.

In addition, the German healthcare system, with its care-oriented statutory financing as well as the specifically applicable national and EU legal framework conditions, are the focus of the considerations, making generalisation of the translation challenges to other industries and countries difficult.

The interviews conducted in this paper only represent a small sample. Therefore, in order to achieve an even more robust result, a more significant number of interviews should be conducted per stakeholder group.

This would be particularly relevant as surveys that do not focus on one stakeholder group, but look at the health system as a whole, are scarce. Since there are countless unconnected observations on translation barriers from many different directions with varying aspects, survey methods, and goals, a systematic literature review could provide an overview of the state of the art in AI translation barriers in the health sector and thus form the starting point for the development of countermeasures.

References

Aung, Y. Y. M., Wong, D. C. S., & Ting, D. S. W. (2021). The promise of artificial intelligence: A review of the opportunities and challenges of artificial intelligence in healthcare. *British Medical Bulletin*, *139*(1), 4–15. https://doi.org/10.1093/bmb/ldab016

Bajwa, J., Munir, U., Nori, A., & Williams, B. (2021). Artificial intelligence in healthcare: Transforming the practice of medicine. *Future Healthcare Journal*, *8*(2), e188–e194. https://doi.org/10.7861/fhj.2021-0095

Boillat, T., Nawaz, F. A., & Rivas, H. (2022). Readiness to Embrace Artificial Intelligence Among Medical Doctors and Students: Questionnaire-Based Study. *JMIR Medical Education*, *8*(2), e34973. https://doi.org/10.2196/34973

Bratan, T. (2022, December). *E-health in deutschland* (Nr. 12-2022). Fraunhofer ISI. https://publica-rest.fraunhofer.de/server/api/core/bitstreams/9b4bf68e-ea9e-4fcb-8958-c184015d23b1/content

Braun, V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, *3*(2), 77–101.

Chomutare, T., Tejedor, M., Svenning, T. O., Marco-Ruiz, L., Tayefi, M., Lind, K., Godtliebsen, F., Moen, A., Ismail, L., Makhlysheva, A., & Ngo, P. D. (2022). Artificial Intelligence Implementation in Healthcare: A Theory-Based Scoping Review of Barriers and Facilitators. *International Journal of Environmental Research and Public Health*, *19*(23), 16359. https://doi.org/10.3390/ijerph192316359

D'Hondt, E., Ashby, T. J., Chakroun, I., Koninckx, T., & Wuyts, R. (2022). Identifying and evaluating barriers for the implementation of

machine learning in the intensive care unit. *Communications Medicine*, *2*(1), 162. https://doi.org/10.1038/s43856-022-00225-1

European Institute of Innovation and Technology (EIT) (Ed.). (2023, May). Digital Health Milestone Framework. https://eithealth.eu/wp-content/uploads/2023/05/EIT-Health_DigitalHealth_Milestones-Framework_VF.pdf

McKee, M., & Wouters, O. J. (2022). The Challenges of Regulating Artificial Intelligence in Healthcare Comment on "Clinical Decision Support and New Regulatory Frameworks for Medical Devices: Are We Ready for It? - A Viewpoint Paper". *International Journal of Health Policy and Management*, 1. https://doi.org/10.34172/ijhpm.2022.7261

NASA. (2018). Technology Readiness Level Definitions. Retrieved September 3, 2023, from https://www.nasa.gov/directorates/heo/scan/engineering/technology/technology_readiness_level

Stachwitz, P., & Debatin, J. F. (2023). Digitalisierung im Gesundheitswesen: Heute und in Zukunft. *Bundesgesundheitsblatt - Gesundheitsforschung - Gesundheitsschutz*, *66*(2), 105–113. https://doi.org/10.1007/s00103-022-03642-8

Strohm, L., Hehakaya, C., Ranschaert, E. R., Boon, W. P. C., & Moors, E. H. M. (2020). Implementation of artificial intelligence (AI) applications in radiology: Hindering and facilitating factors. *European Radiology*, *30*(10), 5525–5532. https://doi.org/10.1007/s00330-020-06946-y

Tachkov, K., Zemplenyi, A., Kamusheva, M., Dimitrova, M., Siirtola, P., Pontén, J., Nemeth, B., Kalo, Z., & Petrova, G. (2022). Barriers to Use Artificial Intelligence Methodologies in Health Technology Assessment in Central and East European Countries. *Frontiers in Public Health*, *10*, 921226. https://doi.org/10.3389/fpubh.2022.921226