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REVIEW PAPER

Clinical Decision Support Systems at the Intersection of Technology and Ethics: A Critical Analysis of the Ethical Guidelines Issued by the German Medical Association

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Abstract

The statement "Decision Support in Medical Practice through Artificial Intelligence," (German: "Entscheidungsunterstützung ärztlicher Tätigkeit durch Künstliche Intelligenz") by the Central Ethics Commission at the German Medical Association critically evaluates the implementation of Clinical Decision Support Systems (CDSS) from medical, ethical, and legal standpoints. While the statement highlights numerous advantages and challenges inherent in the use of AI in healthcare, it remains vague, particularly concerning the assignment of accountability, the delineation of professional responsibility, and the technical feasibility of integrating these systems in real-world clinical workflows. In the present paper, we scrutinize the statement from both philosophical and technical angles, offering concrete proposals aimed at clarifying the ethical ambiguities while also addressing the technological constraints that currently impede widespread adoption. By doing so, we aim to critically evaluate the governmental document against practical realities and bridge the gap between theoretical possibilities and practical applicability, thereby fostering a more nuanced and responsible use of AI in contemporary medical practice.

Keywords CDSS · AI · Augmented intelligence · Center for responsible AI technologies

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1 Introduction

On 23 June 2021, the Central Ethics Commission of the German Medical Association (ZEKO) adopted the comprehensive position paper "Decision Support in Medical Practice through Artificial Intelligence," (German: *"Entscheidungsunterstützung ärztlicher Tätigkeit durch Künstliche Intelligenz*") (Zentrale Ethikkommission, 2021) in which it examines the use of Clinical Decision Support Systems (CDSS) in medical practice from a medical, ethical, and legal perspective. Numerous potentials as well as risks associated with the use of AI were identified. On a positive note, the position paper addresses the issue of discrimination through AI, and even though this is only mentioned in a footnote, it acknowledges biases and discrimination present in the medical sector more broadly. Furthermore, ZEKO thoroughly addresses questions of autonomy. It is particularly commendable that different levels of responsibility are mentioned, which is a crucial step towards addressing the complex issue of guilt and responsibility (including questions of liability) in connection with the use of AI. However, there is room for improvement in the allocation of responsibilities and the adjustment of duties. Moreover, the position paper lacks detailed consideration of the technical feasibility of AI implementation. Additionally, the paper predominantly takes an individual-ethical perspective on the use of AI systems in medicine, while social-ethical aspects receive less attention.

For these reasons, in this paper we examine ZEKO's position from both a philosophical and technical perspective. We begin with an in-depth exploration of the issue of responsibility, followed by a critical analysis of the attribution of autonomy, with the aim of addressing the gaps in the position paper.

Beyond this, we will evaluate the technical feasibility of AI in healthcare and its implications for further reflection, which we will illustrate by examining the underlying technologies. Following an overview, we will focus on the challenge of *explainability* in model-based decisions and explore current solution approaches from a technical perspective as a particularly crucial aspect for improving patient care. Next, we will analyze the importance of *collaboration* between machine learning specialists and medical professionals. Lastly, we will discuss the necessity of imparting adequate *digital competencies* to healthcare professionals.

2 Concept of Responsibility

The generalized use of the term "manufacturer" in the ZEKO position paper brings the issue of responsibility into sharper focus. At the *Center (anonymized)*, the concept of multi-actor responsibility, as discussed by the German Ethics Council (German Ethics Council, 2017), is further developed and examined in this paper in relation to the example of CDSS. The idea of multi-actor responsibility aims to capture both the multitude and the diversity of the various actors involved. This allows us to incorporate the different levels of responsibility identified by ZEKO (micro, meso, and macro levels), while also providing the precision that is required on this subject.

Based on ZEKO's position paper, we have identified and outlined the following areas of responsibility (Zentrale Ethikkommission, 2021, pp. 5–6):

Overview of the identified and unidentified responsibilities in the ZEKO position paper

Actors	Responsible for…	
Physicians	•Own digital competencies for using CDSS. •Own awareness of issues related to the use of CDSS. •Plausibility checks of the automated decision recommendations of CDSS. •The entire diagnostic and therapeutic decision-making process.	1. Micro Level
Institutional provider	•Examination of which CDSS should be implemented in one's own facility. •Preparation of staff for the use of CDSS through appropriate training programs.	2. Meso Level
?	•Maintenance and protection of the systems. •Inspection, certification, and auditing measures to ensure that data use is lawful, fair, secure, transparent, and accountable. •Intensive research on explainability, traceability, and non-discrimination.	
Legislator	•Examination of the legal framework for so-called "intelligent medical devices" to determine whether it accommodates the dynamic technological developments in this area.	3. Macro Level
Medical professional societies and guideline developers	•Consider CDSS in guidelines.	
?	•Enhanced provision of digital competencies in initial training, further education, and continuing education.	

We note that ZEKO addresses the complex question of responsibility by identifying different levels of responsibility. However, when listing the responsibilities assigned by ZEKO, it becomes evident that not all responsibilities have been clarified (see question marks in the table), although they could be attributed to specific entities. For example, medical device manufacturers could take responsibility for the maintenance and protection of systems at the meso level. Medical facility operators should fundamentally only trust CE-certified devices that comply with the principles of "Conformité Européenne." Furthermore, approval must be obtained from designated bodies in accordance with the Medical Devices Act. To ensure intensive research on explainability, traceability, and non-discrimination, collaboration between medical device manufacturers and research institutions is essential. Regarding the enhanced dissemination of knowledge at the macro level, we particularly see applied research and continuing education providers as bearing responsibility. For the last two points mentioned, we will formulate specific proposals in this paper under Sect. 4.1 and 4.3.

Furthermore, we note that the technical perspective has not been considered. In the process of developing a CDSS, there are various actors who can be held responsible for different aspects, which are not adequately covered by the term "manufacturers" as used in the ZEKO position paper. For these reasons, we propose to first differentiate between various aspects of CDSS.

The aspects of a CDSS presented in Table 1 aim to provide an overview of all necessary stages in the lifecycle of the application, particularly those that should be considered and followed during development and auditing (Koshiyama et al., 2021, p. 3). These stages should not be understood as occurring in a strict, linear sequence;

Table 1 Aspects in the CDSS lifecycle

Aspects in the CDSS Lifecycle	Content
Data Collection and Preparation	•Possible *data sources* are identified. •Infrastructure for their collection is provided. •If access to a sufficient amount of data exists, a comprehensive *data analysis and validation* (quality assurance) should be conducted. •For a functional, transparent *machine learning dataset, annotations* must be made and necessary *metadata* included, if this has not yet been done, provided that such data is available or can be collected (this is also important for *bias detection*). •Information about the *label/feature distribution* of the dataset is necessary. Specifically in medicine, it is also essential to address questions regarding the correct *pseudonymization/anonymization* of sensitive patient data at an early stage.
Preprocessing of Data and Training of the Algorithm	•Technical *design decisions* must consider medical-specific *domain knowledge* to ensure that the model can be trained optimally for the respective application case. This includes, for example, questions regarding the appropriate preprocessing of data, the chosen model architecture, or cost function. Here, previously generated *information from data analysis* is helpful, as imbalanced datasets require a different approach than evenly distributed ones. •Insights from the *current state of research* should also be incorporated.
Evaluation and Explainability of the Algorithm	•It is also necessary to integrate *domain knowledge* here. Only by doing so can it be ensured that, for instance, *metrics are used correctly*, allowing statements about the *model's performance and robustness* to be properly understood. •In this sense, it is also important to integrate *explainability components*. •The measurability of the *clinical success of the application* must be considered/planned.
Development of the Application	•For the development of the software, into which the machine learning model is to be embedded before use, it is important to observe *current standards for medical devices*, specifically CDSS (MDR, IVDR). •It is also important to consider which features could be useful for optimal collaboration in terms of *user-friendliness* and *user experience*. Specifically concerning bias mitigation, it may be helpful to draw attention to features that are underrepresented in the training dataset, such as rarer skin types of patients.
Quality Control of the Application	•Before the CDSS can be brought to market, a successful *auditing process*, which should be considered from the beginning of planning, is necessary for it to be used as a *certified application*. How exactly this will look for AI-based medical devices is not yet precisely defined and is currently being discussed intensively in various committees and application domains. •In this context, *technical measures* to realize legislative requirements must be *standardized*, see, for example, *algorithm auditing* (Koshiyama et al., 2021).
Implementation and Use of the CDSS in Clinical Practice	•To ensure the correct use of the new technology in medical practice, *onboarding and feedback opportunities* for users, primarily physicians, must be provided. •This also aligns with the last process step: The improved decision support of the system builds upon previously made design decisions regarding necessary and useful features. •Furthermore, *maintenance* concepts are essential to iteratively measure the performance of the system in the real world.
New Data and Optimization of the Algorithm	•To further optimize the system, it is necessary to train new models with *new data* and *new insights from research*, which restarts the entire process but with the knowledge built up from previous iterations.

rather, the development of the software and the model can occur in parallel. However, certain sequences are mandatory: for instance, the data should be collected and correctly interpreted before model development, which requires comprehensive domain knowledge. Furthermore, the CDSS can only be brought to market after successful

auditing. At this point, only a fully trained and satisfactorily evaluated model that has been trained on a fixed dataset can be assessed. To clarify these iterative processes, including the concept of responsibility, it is beneficial to specify the relational aspects for a multi-faceted concept of responsibility (Heidbrink et al., 2017): Who is responsible for what under which criteria? (Coeckelbergh, 2020). In this context, we propose a process-oriented approach based on Table 1.

3 Focus on Autonomy

The ZEKO position paper exhibits an individual ethical focus, particularly on the topic of "autonomy" (Lob-Hüdepohl, 2020). In subsection 3.3, Autonomy (Zentrale Ethikkommission, 2021, p. 6), ZEKO addresses both physician and patient autonomy. Various risks are mentioned that accompany a decrease in personal assessments of decisions (or an increase in blind trust).

At this point, the role of understanding AI decision recommendations is not adequately addressed in the ZEKO paper. For instance, regarding physician autonomy, the possibility of an evaluation is mentioned; however, it remains questionable whether this autonomy could be weakened under standardized testing if physicians cannot understand or interpret the AI's decision recommendations. Similarly, in the section on "patient autonomy" in the ZEKO paper, it is stated that there can be benefits to patient autonomy if they "actively incorporate the results of CDSS into the decision-making process." Here, we also see potential benefits only if patients can understand and interpret the decision recommendations. What exactly must physicians and patients understand (and what should not be understood) about the decision recommendations of CDSS so that their autonomy is not compromised? We outline how a knowledge transfer adapted to this research could be realized in Chapter 4.3.

The ZEKO states: "Patients must be informed and give consent regarding whether and to what extent such systems should be integrated into the treatment process, as well as the opportunities and risks associated with their use." This point warrants further examination: Should physicians not only be trained to understand CDSS decisions/recommendations but also to explain them to patients and foster a basic understanding of the technology? This should also be considered in the context of the discussion on a (Threefold) Shared Decision, because: Who trains the patients? Furthermore, it remains unclear in which cases patients should be informed according to ZEKO and in which cases they should not. ZEKO states that this depends on whether the CDSS is an independent diagnostic and treatment method or merely provides support (Zentrale Ethikkommission, 2021, p. 8). Since Clinical Decision *Support* Systems should always be used solely for support, this explanation is not clear[1] and should be elaborated upon.

[1] The ZEKO is also not clear on this issue elsewhere: *"AI systems that replace medical decisions may therefore only be used with the explicit consent of patients after appropriate explanation."* Otherwise, the position paper conveys, and we also believe, that AI systems should in no case replace medical decisions but rather only support them in their decision-making process. The position paper should pursue a coherent view on the use of AI.

4 Requirements of ZEKO for the Integration and Development of CDSS

The ZEKO highlights the potential of AI-based CDSS in medicine (Zentrale Ethikkommission, 2021, p. 6) but emphasizes that their use should only be permitted if they can genuinely contribute to the improvement of patient care (Zentrale Ethikkommission, 2021, p. 4). It remains unclear how this effect is to be measured. One possibility would be to align with the requirements of the German Hospital Association, which defines structural, process, and outcome quality as focus areas of medical care (Deutsche Krankenhausgesellschaft, 2019, p. 8). The latter is the most meaningful for patient care, yet simultaneously the most difficult to measure (Deutsche Krankenhausgesellschaft, 2019, p. 12). Furthermore, it is emphasized that quality controls must be carried out by independent bodies (Deutsche Krankenhausgesellschaft, 2019, p. 26).

These external bodies should specifically be responsible for measuring the quality of AI-based medical care and could, in turn, align with the requirements set forth by ZEKO, provided that these are technically feasible. The ZEKO position paper highlights that responsibility and accountability must not be delegated to the system (Zentrale Ethikkommission, 2021, p. 11). This means that in the event of a faulty treatment process, physicians must also be legally accountable for the use of CDSS, necessitating that they possess the necessary digital competencies, as well as all relevant information for the specific application case. Furthermore, software manufacturers should ensure that there are avenues for physician feedback. This encompasses not only the concrete implementation but also the development of a concept that integrates the experiences of physicians (and potentially patients) during the application of the system for its further development and monitoring, as well as informing the relevant authorities when necessary, as mandated by the Medical Devices Act.

These interactions are also mentioned by ZEKO and are intended to strengthen system trust by providing support to actors such as physicians and patients (Zentrale Ethikkommission, 2021, p. 5). To this end, ZEKO divides the concept of responsibility into three levels, as outlined in Chapter 2, with physicians situated at the micro level and thus not held accountable for every aspect of the use of CDSS (Zentrale Ethikkommission, 2021, p. 5). In various areas, such as the *explainability* of model-based decisions, *collaboration* between machine learning specialists and physicians, and the provision of sufficient *digital competencies* for medical professionals, the technical requirements for CDSS are now primarily addressed.

4.1 Explainability

Many CDSS are based on artificial neural networks, whose decision-making processes are not comprehensible to humans. This is due to the fact that the way such models are developed differs from how humans recognize images or interpret texts, for example: The decision-making process based on artificial neural networks involves optimizing millions of different parameters to perform optimally on a specific dataset. However, the opacity of artificial neural networks could have severe consequences in a safety-critical domain such as medicine. An artificial neural network is limited to

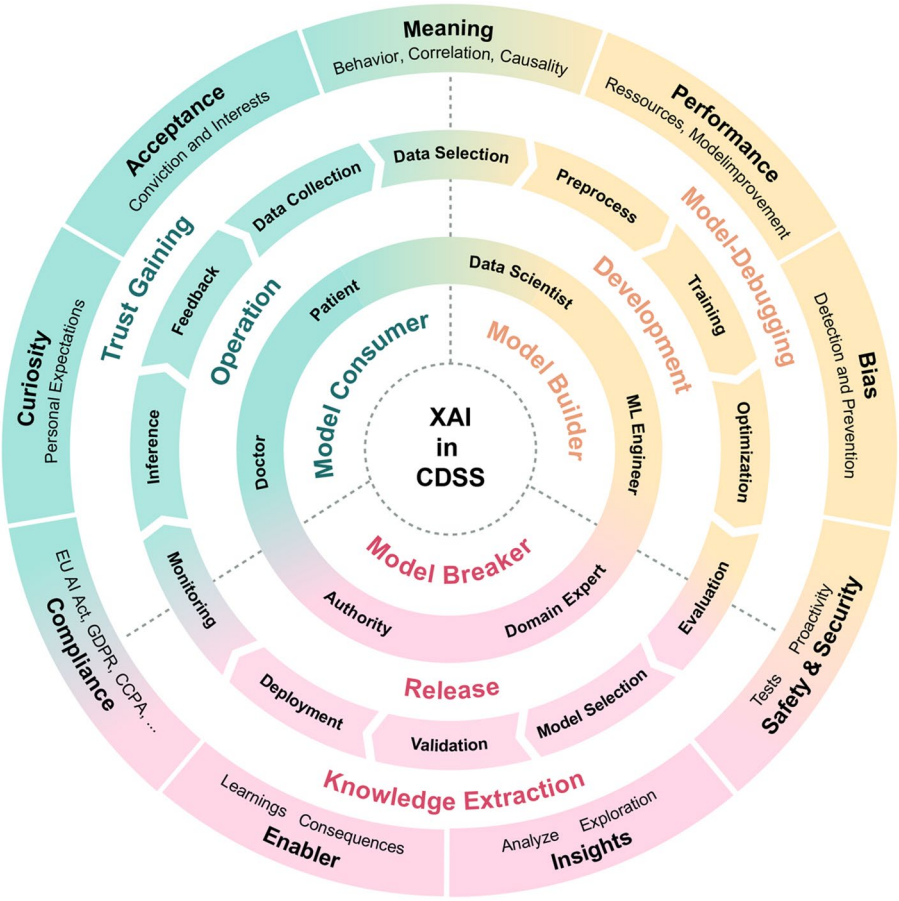

Fig. 1 Explainable AI in CDSS

the information from its training data, which may not accurately reflect the distribution of the population at a given time, such as the total population. This could result in the model learning a bias and treating or discriminating against different (societal) groups. If this behavior of the AI system remains unknown, patient welfare could be at risk—an outcome that can and must be mitigated to some extent.

In this regard, it is necessary to take measures to make the decision-making processes of deep artificial neural networks and their limitations more understandable. This can be achieved, among other things, through the integration of explainability methods. Explainable AI is still a nascent field that has gained significant importance in recent years (Okolo et al., 2022, p. 1). Certification activities, for example, recognize explainability as a necessary aspect in the certification of products from high-risk domains (Soudain, 2024, p. 79).

To provide an overview of the topic, we utilize the compass illustrated in Fig. 1. Starting from the center of the circles (Explainable AI in CDSS), the various stakeholders (users, developers, and testers) of a CDSS are outlined, with their roles in

the innermost circle being indistinctly defined. The middle cycle depicts the phases of AI outlined in Table 1. Typically, a machine learning pipeline consists of several subprocesses, beginning with data collection. While these may vary according to the application case, they generally adhere to a technically necessary schema. In the outermost circle, the various objectives that can be set for explainable AI in CDSS are recorded. It is essential to understand that the involved stakeholders pursue different goals in the various phases of the CDSS lifecycle, leading to multiple requirements for explanations.

At the methodological level, a distinction is made between the two approaches. Inherently interpretable model types, such as linear regression models or decision trees, are considered understandable, allowing for explainability even before training (ante-hoc). In contrast, model types often referred to as black-box models lack information about their internal structure, with only the observable behavior of the models being known. Due to their high complexity, these models exceed human comprehension and are therefore regarded as difficult to interpret. The so-called post-hoc approach attempts to enhance interpretability by analyzing the model with specific techniques after training, for example, to identify relevant regions of an image or a time series that were important for the model. Various methods fall under this category, including prominent techniques such as Shapley Additive Explanations (SHAP), as well as several others that have been investigated in the context of AI-assisted medical diagnostics. These methods can assist physicians in better interpreting the outputs of the underlying models.

4.2 Domain Knowledge in the Development of AI Systems

Multidisciplinary teams are essential in the development and application of Clinical Decision Support Systems (CDSS) when it comes to incorporating domain knowledge into the development of the AI system. The inclusion of knowledge from a specific domain in the model development can facilitate human understanding of its decisions and thus achieve the desired transparency. This knowledge is provided by so-called domain experts.

The research field of *neuro-symbolic AI* offers a possible perspective for developing transparent systems, addressing the question of how domain knowledge in the form of symbolic expressions, such as mathematical formulas or logical connections, can be linked with artificial neural networks. This approach is grounded in the fact that symbolic expressions are causally understandable to humans and require little data. However, they are not suitable for complex questions, which is where deep artificial neural networks specialize (Susskind et al., 2021, p. 1).

The authors of *Expert Augmented Machine Learning* (EAML) describe a potential approach for the automated integration of medical domain knowledge in the form of rules. They have developed a platform that allows the application of learned and clinically validated rules for assessing hospital mortality in intensive care patients. This approach could also be applied to other use cases involving tabular data. Their results highlight many advantages of collaboration between medical and AI experts: On the one hand, the involvement of medical specialists in the development strengthens physicians' trust in the CDSS, as the learned rules have been previously validated

for clinical applicability, making the system's decisions comprehensible through the integration of domain knowledge into the model. On the other hand, this collaboration can identify errors in the dataset or learned biases and improve the generalizability of the models to new data, thereby making them more robust against changes in input data (Gennatas et al., 2019).

Furthermore, incorporating domain knowledge in the development of AI-based systems can enhance training efficiency through preprocessing that is aligned with the application domain. For instance, working with 3D lung CT scans requires a very different *preprocessing* approach than a model designed to classify ECG data.

Consequently, from a technical perspective, it is highly advantageous for medical domain experts to collaborate with data scientists and data engineers from the outset of a project, and if necessary, to work alongside patients as well. The specific composition of the respective teams depends on the problem to be solved and the corresponding phase of the application lifecycle (Verma et al., 2021, p. 2).[2]

The ZEKO mandates that the plausibility of results must always be evaluated from a medical perspective (Zentrale Ethikkommission, 2021, p. 5), a requirement that is also included in the current version of the Medical Device Regulation (MDR): mandatory clinical studies to measure the clinical success of applications. In addition to involving medical domain experts during the development phase, the ZEKO also calls for early reporting of any adverse developments based on feedback from experiences in the operational phase of the CDSS. Developers must implement this through feedback functions. Related processes are supported by appropriate quality metrics, which may lead to measures such as software updates or even recalls if necessary.

In terms of the traceability of the entire feedback process, concepts of traceability that have emerged in classical software development can also be applied in the implementation of CDSS. This is further enhanced by structured and sustainable development processes of the machine learning pipelines, where Machine Learning Operations (MLOps) include technical tools for version control of both program code and data (Stieler & Bauer, 2023).

4.3 Development of Digital Competencies

The intensive use of AI systems in medical practice requires the necessary expertise to comply with the ZEKO's demand for the conscious use of AI-based Clinical Decision Support Systems (CDSS) in the medical context (Zentrale Ethikkommission, 2021, p. 7). This underscores the need for efficient knowledge transfer among all involved stakeholders.

One approach to imparting knowledge about machine learning to physicians could involve categorizing them into different "learning groups" based on their interest in AI in medicine and their foundational knowledge necessary to utilize CDSS

[2] A possible, generalizable structuring of teams could be based on the framework described by the authors in Verma et al. (2021) for the development and implementation of ML-based solutions, specifically in the field of medicine. They exemplify the implementation of an intelligent early warning system for intensive care units. The entire process is divided into three phases, each with specifically defined objectives: exploration, solution design, and implementation and evaluation, with collaborative cooperation among various domain experts being an integral part of each phase (Verma et al., 2021, p. 3).

effectively. As a basis for this knowledge transfer, findings from specific research on the work of physicians in relation to CDSS could be utilized, such as in Henry et al. (2022). In this study, the integration of a real-time early warning system for patients with sepsis was examined to extract and analyze perceptions regarding the use of CDSS. The survey of physicians revealed that the *teaming perspective* was particularly decisive for the successful adoption of the technology. The system was perceived as a competent "second pair of eyes" (Henry et al., 2022, p. 2), assisting in organizational tasks such as prioritizing patient visits. Experience from trusted sources, such as colleagues, as well as personal experiences from interacting with the system, were identified as sources of trust. Notably, knowledge about the internal workings of the model was less critical, as physicians developed a mental model during their interactions with the CDSS regarding how its functionality should be evaluated (Henry et al., 2022, p. 2).

It would be beneficial to integrate fundamental knowledge of AI in medicine during medical education and then to deepen this knowledge iteratively in various forms, depending on the level of interest and professional activity. The second version of the NKLM (National Competency-Based Catalog of Learning Objectives for Medicine) includes digital competencies, and physicians are expected to specifically acquire this competence, "explain the opportunities and risks of digital offerings for health promotion and prevention" (NKLM, n.d., our translation). This includes knowledge of potential sources of error associated with the respective technology, which implies a fundamental technical understanding. However, digital competencies are currently limited in the curriculum and should be expanded to also include practical experiences in this field.

For instance, foundational knowledge for cardiologists interested in AI who wish to actively participate in system development could be based on works authored by a German physician (Haverkamp, Strodthoff, Israel, et al., 2022a, 2022b). The proposed concept for knowledge transfer begins with a basic introduction to *machine learning*-specific terminology relevant to the development of AI-based applications. General explanations, such as the distinctions between *machine learning, AI,* and *deep learning*, are supplemented with specific information from the ECG domain. The second part primarily addresses concrete use cases and outcomes of AI in cardiology. Following this structure, similar content could be developed for other areas of medicine as a guide for physicians with a deeper interest in the functioning of CDSS within their respective domains.

Another way to facilitate comprehensive knowledge transfer is through organizations like *The Clinical AI Interest Group*, which aims to create learning materials for "[…] AI-naïve clinicians and student healthcare professionals in the application of clinical AI" (see The Alan Turing Institute, 2024). In Germany, for example, the *KI-Campus*, in collaboration with the *State Medical Association of Baden-Württemberg*, offers free, certified online courses to "impart AI competencies in the medical field." These courses were developed through a collaboration between *Charité* and the *KI-Campus*, aiming for "further education in the medical sector" (see KI-Campus, n.d.). Furthermore, licensed physicians from various state medical associations have the opportunity to acquire the additional designation of "Medical Informatics" after two years of clinical practice (see Bayerische Landesärtzekammer, 2018).

It is likely that AI will someday become commonplace in medical practice. As a logical consequence of this assumption, physicians are explicitly encouraged by the ZEKO to engage with the new technology should it come to represent the status quo. According to the ZEKO, instances at the meso level, such as institutional stakeholders, are responsible for providing appropriate continuing education offerings. This raises the previously outlined application-oriented questions regarding how to meet the requirement for a conscious integration of AI: What content needs to be understood, and how should the imparting of the necessary knowledge be structured? How can CDSS be developed in such a way that their structure supports compliance with these requirements? What should an effective onboarding process look like? And what constitutes adequate support during the operational period? The ZEKO has not defined specific content regarding the methods of knowledge transfer or its limitations (Zentrale Ethikkommission, 2021, p. 5). Thus, it remains unclear how a good understanding and successful collaboration between humans and machines can be ensured.

There are various approaches to defining the scope of knowledge that physicians need to work effectively with intelligent software. Often, time constraints dictate medical and nursing routines, raising questions about how much time can be invested in learning AI-specific content. One way to counteract this restriction would be to develop systems that prioritize *usability, friendliness* and *user experience*, designing software to be as self-explanatory and intuitive as possible. Additionally, careful consideration should be given to which *features* are genuinely useful, as such time limitations may prevent users from exploring them at all (Henry et al., 2022, p. 3).

5 Summary and Outlook

In our contribution, we have provided an interdisciplinary examination of the ZEKO's statement. We have found that this statement primarily focuses on the aspect of responsibility. However, in the discussions regarding the allocation and localization of responsibility, we have noted a lack of specificity. We have addressed the existing gaps by integrating technical and ethical considerations and have proposed an extension of multi-actor responsibility, which accepts aspects of CDSS as a starting point for the allocation of relevant ethical concepts that can be meaningfully assigned to different stakeholders. In our further analysis of the individual ethical perspective of the ZEKO regarding autonomy, we identify a particular need for clarification on fundamental questions concerning what knowledge physicians and patients need to enhance (or at least not diminish) their autonomy. In the second part of our contribution, we have made specific implementation proposals regarding the ZEKO's recommendations from a technical perspective, addressing what we believe are particularly important points for improving patient care: the explainability of AI systems, the collaboration between physicians and developers, and the transfer of digital competencies to physicians.

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Declarations

Competing Interest The authors have no competing interests to declare that are relevant to the content of this article.

References

Bayerische Landesärtzekammer. (2018). *Medizinische Informatik*. February 13, 2023, from https://www.blaek.de/weiterbildung/qualifikationen-nach-der-weiterbildungsordnung/medizinische-informatik

Coeckelbergh, M. (2020). Artificial Intelligence, responsibility attribution, and a relational justification of explainability. *Science and Engineering Ethics*, *26*, 2051–2068. https://doi.org/10.1007/s11948-019-00146-8

Deutsche Krankenhausgesellschaft. (2019). *Qualität und Patientensicherheit*. Positionen der Deutschen. Krankenhausgesellschaft. Resource document. Retrieved December 8, 2022, from https://www.dkgev.de/fileadmin/default/Mediapool/2_Themen/2.6._Qualitaet_Hygiene_und_Sicherheit/DKG_Qualitaet-Sicherheit_Positionen.pdf

German Ethics Council. (2017). *Big Data und Gesundheit – Datensouveränität als informationelle Freiheitsgestaltung*. Retrieved October 1, 2024 from https://www.ethikrat.org/fileadmin/Publikationen/Stellungnahmen/deutsch/stellungnahme-big-data-und-gesundheit.pdf

Gennatas, E. D., Friedman, J. H., Ungar, L. H., Pirracchio, R., Eaton, E., Reichman, L. G., Interian, Y., Simone, C. B., Auerbach, A., Delgado, E., Van der Laan, M., Solberg, T. D., & Valdes, G. (2019). Expert-augmented machine learning. *Proceedings of the National Academy of Sciences of the United States of America.*, *117*(9), 4571–4577. https://doi.org/10.48550/arXiv.1903.09731

Haverkamp, W., Strodthoff, N., & Israel, C. (2022a). EKG-Diagnostik mithilfe künstlicher Intelligenz: Aktueller Stand und zukünftige Perspektiven – Teil 1. Grundlagen. *Herzschrittmachertherapie + Elektrophysiologie*, *33*, 232–240. https://doi.org/10.1007/s00399-022-00854-y

Haverkamp, W., Strodthoff, N., & Israel, C. (2022b). EKG-Diagnostik mithilfe künstlicher Intelligenz: Aktueller Stand und zukünftige Perspektiven – Teil 2. Aktuelle Studienlage und Ausblick. *Herzschrittmachertherapie + Elektrophysiologie*, *33*, 305–311. https://doi.org/10.1007/s00399-022-00855-x

Heidbrink, L., Sombetzki, J., & Langbehn, C. (2017). *Handbuch Verantwortung*. Springer.

Henry, K. E., Kornfield, R., Sridharan, A., Linton, R. C., Groh, C., Wang, T., Wu, A., Mutlu, B., & Saria, S. (2022). Human-machine teaming is key to AI adoption: Clinicians' experiences with a deployed machine learning system. *NPJ Digital Medicine*, *5*, 97. https://doi.org/10.1038/s41746-022-00597-7

KI-Campus (n.d.). *Erste zertifizierte Online-Kurse zu KI in der Medizin*. Retrieved December 9, 2022, from https://ki-campus.org/press/zertifizierte-medizin-kurse

Koshiyama, A., Kazim, E., Treleaven, P., Rai, P., Szpruch, L., Pavey, G., Ahamat, G., Leutner, F., Goebel, R., Knight, A., Adams, J., Hitrova, C., Barnett, J., Nachev, P., Barber, D., Chamorro-Premuzic, T., Klemmer, K., Gregorovic, M., Khan, S., & Lomas, E. (2021). Towards algorithm auditing: A survey on managing legal, ethical and technological risks of AI, ML and associated algorithms. *SSRN Online Publications*https://doi.org/10.2139/ssrn.3778998

Lob-Hüdepohl, A. (2020). Autonomisierung von Maschinen und die Autonomie des Menschen. Ethische Sortierungen In A. Manzeschke & W. Niederlag (Eds.), *Ethische Perspektiven auf biomedizinische Technologie* (Vol. Health Academy 3, pp. 23–32). De Gruyter.

NKLM. (n.d.). *Nationaler Kompetenzbasierter Lernzielkatalog Medizin*. Retrieved February 13, 2023, from https://nklm.de/zend/objective/list/lve/1845/objective/10006411

Okolo, C. T., Dell, N., & Vashistha, A. (2022). Making AI explainable in the global south: A systematic review. *Proceedings of the 5th ACM SIGCAS/SIGCHI Conference on Computing and Sustainable Societies* (COMPASS '22). Association for Computing Machinery. 439–452. https://doi.org/10.1145/3530190.3534802

Settles, B. (2010). *Active learning literature survey*. Retrieved October 1, 2024, from https://burrsettles.com/pub/settles.activelearning.pdf

Soudain, G. (2024). EASA Artificial Intelligence concept paper. First useable guidance for Level 1&2 machine learning applications. Issue 02. Retrieved October 1, 2024, from https://horizoneuropencpportal.eu/sites/default/files/2024-06/easa-concept-paper-guidance-for-level-1-and-2-machine-learning-applications-2024.pdf

Stieler, F., & Bauer, B. (2023). Git workflow for active learning: A development methodology proposal for data-centric AI projects. *Proceedings of the 18th International Conference on Evaluation of Novel Approaches to Software Engineering*.https://doi.org/10.5220/0011988400003464

Susskind, Z., Arden, B., John, L. K., Stockton, P., & John, E. B. (2021). Neuro-symbolic AI: An emerging class of AI workloads and their characterization. ArXiv, Abs/2109.06133. https://doi.org/10.48550/arXiv.2109.06133

The Alan Turing Institute. (2024). *Clinical AI*. Retrieved December 9, 2022, from https://www.turing.ac.uk/research/interest-groups/clinical-ai

Verma, A. A., Murray, J., Greiner, R., Cohen, J. P., Shojania, K. G., Ghassemi, M., Straus, S. E., Pou-Prom, C., & Mamdani, M. (2021). Implementing machine learning in medicine. *CMAJ: Canadian Medical Association Journal = Journal de l'Association Medicale Canadienne*, *193*(34), E1351–E1357. https://doi.org/10.1503/cmaj.202434

Zentrale Ethikkommission. (2021). Künstliche Intelligenz – Teil der ärztlichen Entscheidung. *Deutsches Ärzteblatt*, *118*(33–34). Retrieved October 1, 2024, from https://www.zentrale-ethikkommission.de/fileadmin/user_upload/_old-files/downloads/pdf-Ordner/Zeko/Kuenstliche_Intelligenz.pdf