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Design of a Human-in-the-Loop Centered AI-Based Clinical Decision Support System for Professional Care Planning

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Abstract. In the healthcare sector in particular, the shortage of skilled workers is a major problem that will become even more acute in the future as a result of demographic change. One way to counteract this trend is to use intelligent systems to reduce the workload of healthcare professionals. AI-based clinical decision support systems (AICDSS) have already proven their worth in this area, while simultaneously improving medical care. More recently, AICDSS have also been characterized by their ability to leverage the increasing availability of clinical data to assist healthcare professionals and patients in a variety of situations based on structured and unstructured data. However, the need to access large amounts of data while adhering to strict privacy regulations and the dependence on user adoption have highlighted the need to further adapt the implementation of AICDSS to integrate with existing healthcare routines. A subproject of the ViKI pro research project investigates how AICDSS can be successfully integrated into professional care planning practice using a user-centered design thinking approach. This paper presents the design of the ViKI pro AICDSS and the challenges related to privacy, user acceptance, and the data base. It also describes the development of an AI-based cloud technology for data processing and exchange using federated learning, and the development of an explicable AI algorithm for recommending care interventions. The core of the AICDSS is a human-in-the-loop system for data validation, in which the output of the AI model is continuously verified by skilled personnel to ensure continuous improvement in accuracy and transparent interaction between AI and humans.

Keywords. AI-based clinical decision support system, AICDSS, Human-in-the-Loop, HITL, Hybrid Human-Artificial Intelligence, federated learning, professional care planning, ViKI pro+

1. Introduction

Germany is one of several countries facing a nursing shortage. In the period 2018-2030 alone, the EU-27 will need additional 11 million health and long-term care (LTC) workers to satisfy the rising demand in the health and LTC sectors [1]. According to the Institute of the German Economy, there could be a shortage of around 307,000 nursing staff in inpatient care by 2035, resulting in a total supply gap of 500,000 specialists [2].

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In the context of the shortage of skilled workers, the nursing shortage in Germany is becoming increasingly serious, resulting in a lack of sufficient personnel, capacity, and resources to meet the growing demand for nursing services. Demographic change is also one of the biggest challenges facing Germany's care sector. The population is aging and the number of people in need of care is increasing while the number of people who can care for them is decreasing. The Federal Statistical Office predicts that around 4.53 million people in Germany will need long-term care in 2060 [2].

The consequences are long waiting lists, overcrowded care facilities, high staff turnover and inadequate care for those affected. The nursing shortage also results in overworked and stressed nursing staff, which can further impair the quality of care. According to the Covid Home Study, three-quarters of nurses show signs of work-related burnout [3]. The nursing shortage is a complex problem that is the result of several factors, including funding issues, skill shortages, and a lack of incentives to enter the nursing profession. This poses diverse challenges for the nursing system to ensure that there are enough qualified staff and sufficient capacity to meet the growing demand. Possible solutions include improving working conditions and pay for care workers, promoting education and training opportunities, and creating incentives for people to choose care careers. Digitalization also has the potential to address several challenges in the healthcare sector. But in practice, most digital solutions do not reach professional care because they are developed outside of the profession. In addition, the needs and services in nursing are very diverse, due to the nature of nursing as a "relationship and touch profession"[4]. This makes standardization difficult [5].

Artificial intelligence (AI) can help address the challenges facing the health sector. A subset of AI is machine learning (ML), whose algorithms recognize patterns and regularities in data sets and derive solutions from them. In particular, AI-based clinical decision support systems (AICDSS) can help improve medical and nursing care by analyzing existing patient data and deriving insights for diagnosis or treatment. However, AICDSS systems have hardly been used in practice and are still waiting for widespread implementation [6], [7]. For successful implementation, studies mainly mention user acceptance [8] and whether an AICDSS system is perceived as beneficial [9], [10].

This paper presents the design of the AI-based clinical decision support system of ViKI pro[2]. The ViKI pro project is a collaboration between experts in nursing science, nursing practice, technology, and industry to develop a digital application for care planning. This application will enable nursing staff to record individual care needs and plan appropriate interventions based on digitized expert knowledge. The recording of care interventions in the web application serves as a basis for gaining experience that can be used in similar planning situations in the future. The digital support of care processes aims to improve the quality of inpatient care while conserving limited resources (see [11] for details).

2. Clinical Decision Support Systems

The recent prominence of artificial intelligence and machine learning, combined with the increasing amount of clinical data available, for example through the development of electronic health records (EHRs), has led to increased interest in AI applications in

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healthcare [12]–[14]. AI is said to have the potential to help address challenges in healthcare [15]. Wolf et al. even see the potential for AI to have a significant impact on the entire healthcare industry [16]. Singh et al. envision a paradigm shift in how health diagnoses and treatment recommendations are communicated to patients [17]. In addition, AI can help expand access to quality healthcare while reducing system costs [18]. The applications of AI are diverse and have already proven beneficial in several healthcare settings [12]. For example, AI can be used in patient monitoring, health interventions, and healthcare administration [19]–[22]. Another important area of application is the use of computerized clinical decision support systems. CDSS are computer-based tools designed to assist healthcare professionals in their decision-making processes, intending to improve patient outcomes [7]. CDSS support healthcare professionals through various functions, including diagnostic support, treatment planning, disease management, image interpretation, and prescription and medication monitoring [7], [14]. Wyatt and Spiegelhalter define CDSS as active knowledge systems that use two or more sets of patient data to generate case-specific advice [23]. CDSS can use expertise and/or models learned from data using statistics and ML [14]. Initially, CDSS were expected to replace the decisions of doctors and health professionals. However, a more recent view is that CDSS are purely supportive, generating knowledge by processing large amounts of information and making it available to professionals. By combining the expertise of health professionals with the CDSS, it is hoped to achieve better outcomes than either the professionals or the CDSS alone [14]. Typically, a modern CDSS provides recommendations to health professionals, and health professionals are expected to make their own decisions and override CDSS recommendations that they consider inappropriate [14].

3. AI Acceptance in Healthcare

Despite the great potential of AI, its impact on healthcare has been limited [18]. AICDSS systems have also not been widely used in practice and are still awaiting widespread adoption [6], [7]. There are several reasons for this. On the one hand, systematic reviews suggest that the use of AICDSS reduces unwarranted variation in practice, improves the quality of health care, reduces waste in the health care system, and reduces the risk of overwork and burnout among clinicians [24]–[27]. On the other hand, an incorrect AICDSS or its inappropriate use can have significant negative consequences [14]. The PEAK project (Perspectives on the Use and Acceptance of Artificial Intelligence in Healthcare) aims to investigate the attitudes of medical professionals and patients towards the use of AI applications [28]. As part of the project, 12 doctors were asked what benefits they thought AI could have for medical care. The results were published by Holzner et al. [29] In the study, the benefits of AI were cited as reducing errors in care and thus increasing (patient) safety, reducing the workload of physicians by performing repetitive or simple tasks, optimizing processes, structuring data, or saving time. The respondents saw the strengths of AI primarily in the objectivity of the systems. Half of the medical professionals surveyed said that the responsibility for patients still lies with them, as AI is only used to support medical decisions. One respondent felt that the responsibility was increased, as medical professionals must take into account an external decision in addition to their assessment. When asked about the discrepancy between their medical judgment and that of the AI, two-thirds of health professionals saw this as an incentive to critically question their own decision and, if necessary, to seek a second opinion from a colleague [29]. Among the challenges of implementing AI in everyday medical practice, respondents cited the seamless integration of systems into existing settings. However, AICDSS should fit as well as possible into users' existing workflows, e.g., through integration with the electronic health record (EHR), to minimize user burden and increase access to recommendations [30]. The potential for manipulation or misuse of patient data has also been criticized [29]. A recent survey on AI in the United States shows that privacy is seen as the most important issue when it comes to this technology [31]. A lack of confidence in the security of data collection may reduce patient acceptance [17]. In addition, concerns have been raised about the susceptibility to an error in the development of AI systems due to the database, as well as the need for systems to be explainable and transparent [29]. This lack of transparency in decisions is particularly relevant for deep learning approaches. With the advent of deep learning, AICDSS are reaching the level of human performance in a variety of tasks, particularly image analysis, but often act as 'black boxes' where the rationale for the recommendation cannot be understood. Other authors have also identified regulatory constraints, ethical considerations, lack of transparency, and lack of enabling conditions as barriers to successful implementation [17], [32], [33]. Participants in the PEAK study also cited lack of clinical experience, patient awareness and interaction, and human instinct as weaknesses of AI [29]. Concerning AICDSS, several reasons for low use and/or effectiveness have been identified [34]. Various studies have identified lack of ease of use, lack of integration with host systems, lack of time to make recommendations, and alert fatigue, for example when used in the emergency department, as reasons for low use of AICDSS [6], [25], [35].

4. Concept of the Decision Support System for Professional Care Planning

The sub-project is implemented by applying the requirements and steps of the professional care process and systematically combining them with the AI technology of ViKI pro (Figure 1). At the same time, an iterative development process and a participatory approach will be followed. A hybrid AI system, made available to the care facilities through federated learning (FL), analyses the expertise and the case database. Based on the results of the analysis, the system evaluates the relevance of possible care measures and makes relevant recommendations for decision support in the exemplary application areas of mobility and pain. Feedback from carers on the effectiveness of the care interventions implemented forms another basis of the case database that is part of the ViKI pro sub-project. After review and approval, the information is fed back into the case database.

4.1. Gathering the User-Centered Requirements

A design thinking approach is used to implement the human-in-the-loop-centered AICDSS for professional care planning. Design thinking refers to an iterative creative process aimed at understanding and solving complex problems from the perspective of the user and fostering innovation [36]. It focuses on identifying needs, generating ideas, and creating prototypes. Design thinking is a human-centered approach to the design process that aims to increase user adoption. By empathizing with the user, understanding their needs, and involving them in the process, the design team can create solutions that are tailored to the specific context and preferences of the user. To this end, the project will conduct guideline-based expert interviews with care professionals and use qualitative content analysis to capture their needs to design the target system. The focus will be on the conceptual design of the components to generate concrete added value for care professionals and to increase user acceptance through early involvement.

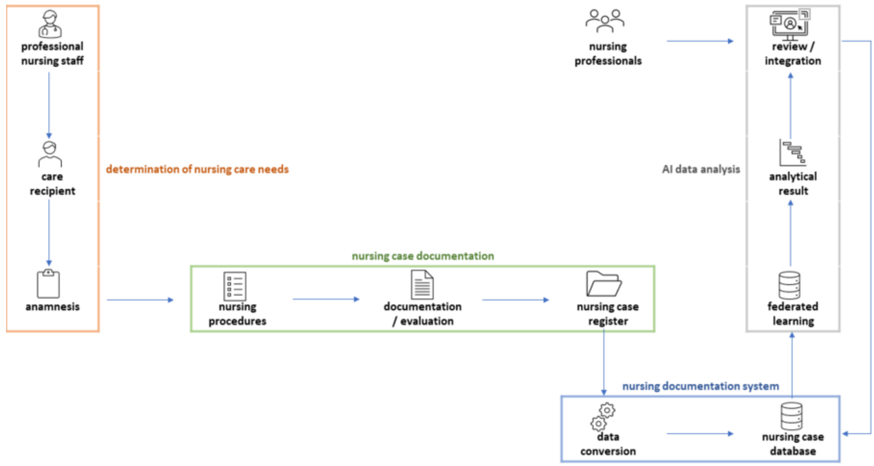

Figure 1. Schematic representation of the concept of the AI-based clinical decision support system for professional care planning for a patient in need of care in a nursing facility. In the project, the application will be tested on care recipients from

4.2. Data Structuring

Within the sub-project of ViKI pro, a data model is developed that forms the basis for converting the unstructured case documentation data into a structured case database. The data used for the analysis comes from the digital nursing documentation system and the case documentation of the practice partners. These documents have a high degree of personalization to identify the needs of the care recipients. As a result, the data base varies between facilities in terms of availability and data structure. In addition, case data is often recorded as free text. The challenge of unstructured data is mainly that different institutions record information in different ways [37]. The lack of structure arises from the fact that different terminology or abbreviations are used for the same topic, the texts contain spelling errors due to lack of time on the part of the nursing staff, or the text fields may contain different information. A central element of care process planning is the Structured Information Collection (SIS). The SIS takes place during an initial/admission interview between the person in need of care and the nurse. First, the treatment questionnaire, which consists of four sections, collects general information about the patient and the conditions of the interview, such as the time and type of interview. This is followed by a self-assessment by the person in need of care and a professional assessment by the carer, covering five areas: cognition and communication, mobility and exercise, disease-related demands and burdens, self-care, and life in social relationships. Finally, possible caregiving risks are derived from the information already collected. To make SIS data usable for the AICDSS, the free text data is processed using natural language processing (NLP) methods. In the first step, binary text classification is performed to classify SIS text modules as relevant/not relevant for the defined application areas. In the second step, attributes are defined based on the data model, which is extracted from the relevant text modules using named entity recognition (NER) and transferred to the case database. This is based on the open-source German Bert model, which has been trained specifically for German-language NLP tasks (see [38] for details).

4.3. Federated Learning

A major factor in the technical challenges is access to the data needed to respond to individual patients [39]. To generalize data without bias and to capture subtle relationships between disease patterns, socioeconomic and genetic factors, as well as complex and rare cases, it is crucial to train a model on as large and diverse a dataset as possible. The dataset should cover the entire population and not just common patient profiles [37], [40]. In practice, this is usually not possible because of data silos. Data silos occur when data is stored in different locations within an organization, or when only certain parts of an organization have access to this data [41]. There are many reasons for them. For example, they arise when data is collected in different institutions or organizational units and only the collecting unit has access to the data, usually for privacy reasons [37], [40]. Data silos are also created, particularly in the health sector, by sensitive data that can only be shared under strict conditions and is therefore stored in isolation. One of the greatest social, economic, and legal challenges in healthcare is privacy and accountability, especially when sensitive medical/clinical personal data is shared between institutions [37], [40]. Anonymization, access control, and secure transmission of health data are non-trivial and sometimes impossible tasks. Anonymized data from electronic health records may seem harmless, but even a few data elements can allow the re-identification of the patient [42]. Traditional AI-based approaches require open data exchange with clouds or data centers, making the information vulnerable to privacy attacks. Indeed, attackers may gain unauthorized access to AI training centers to retrieve data, or third parties such as cloud providers may be able to gain control of the data and alter data patterns without the consent of users [39]. In the case of personal data, therefore, high standards are set as to the circumstances and purposes for which data may be centrally aggregated and analyzed. Federated learning is a promising solution as it enables collaborative learning without centralizing data [40], thus overcoming a major privacy hurdle [37]. FL is a collaborative computing paradigm that allows several separate organizations to collaborate on scientific data projects without sharing sensitive information, such as patient records [39], [43], [44]. The basic idea of FL is to train the data collaboratively, where the model is brought to the data without the need to share the raw data itself [40]. Instead, the AI process takes place locally at each participating institution, and only the model properties (e.g., parameters, gradients) are transferred [40], allowing institutions to always maintain control and security over their data [37]. The goal is to provide better access to larger and more diverse datasets without violating privacy laws [44]. In the research project, a FL framework based on the existing Flower framework (see [45] for more details) will be built and piloted in two care facilities to provide access to the dataset while complying with privacy regulations.

4.4. Human-in-the-Loop

Acceptance and use of technologies by individuals are highlighted by Selder as the most important factors in health technology adoption [8]. However, Wang et al. found a lack of acceptance among healthcare professionals [33]. Cornelissen et al. conclude from their study that healthcare professionals will be more willing to use AI-enabled care pathways if they see the benefits and added value to the quality of care [15]. This assumption is also supported by other studies ([9], [10]), which show that the acceptance and use of an AICDSS by medical and healthcare professionals largely depends on how beneficial it is perceived to be. Identifying and addressing threats to professional identity at an early stage is another factor in increasing acceptance [15]. Studies show that the likelihood of beneficiary acceptance increases if the implementation of the AICDSS involves the end-users, rather than imposing the AICDSS on the end-users [10]. To address these challenges, a human-in-the-loop component is added to the decision support system. Human-in-the-loop machine learning is a set of strategies for combining human and machine intelligence in applications using AI. In the context of this project, the structured case database is used to derive care interventions for the application areas of mobility and pain, which are then proposed to the nursing staff for integration into the care plan for the person in need of care. The nurse can evaluate these in terms of expected effectiveness and necessity and then accept or reject a proposed intervention (Figure 2). The assessment of the care intervention is then fed back into the case database and serves as an improved data base for future training of the AI models. The integration of the human-in-the-loop component into the care management system of the care facilities is intended to generate added value for the care staff, as they can continue to work with their usual software, without any significant additional effort. By designing the system in such a way that nurses have to actively integrate the care measures into the care plan, the professional identity of the nurses should be strengthened, and it should be emphasized that the AI tool is only an assistance system and not a replacement for the nurse.

5. Outlook

AICDSS have shown great potential for improving healthcare and patient safety, as well as reducing unwarranted variation, resource use, and costs. AICDSS have recently been highlighted for their ability to leverage the increasing availability of clinical data to support healthcare professionals and patients in a variety of situations based on structured and unstructured data [14].

However, given the need to access large amounts of data under strict privacy regulations and the dependence on user acceptance, it has become clear that AICDSS implementation needs to be further adapted to fit into existing healthcare routines [16].

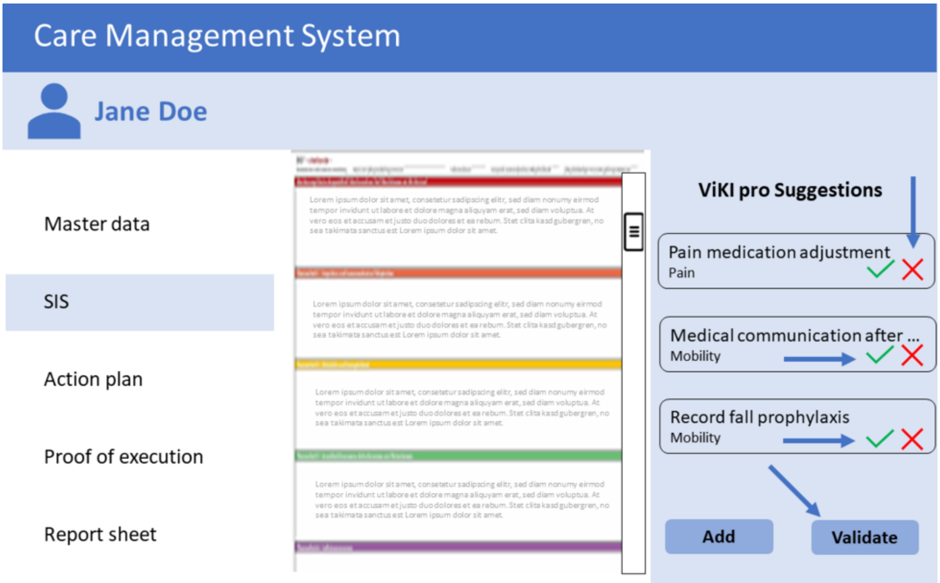

Figure 2. Schematic of the integration of the proposed nursing interventions into the graphical user interface of an example care management system, with a human-in-the-loop component for evaluating the results. Exemplary presentation of the proposed interventions: adjustment of pain medication (pain), medical communication after each fall event (mobility), and recording of fall prophylaxis and preparation of counseling sessions (mobility).

These challenges led to the need for an interactive, human-centered approach with a strong focus on privacy, which is incorporated in the Viki pro AICDSS design and will be realized within the following four work packages:

1. Gathering of acceptance requirements for the AICDSS by interviewing experts
2. Data structuring using NLP methods based on the German BERT model as a data basis for explainable AI algorithms for care planning interventions
3. Development of an AI-based cloud technology for data processing and data exchange using federated learning
4. Development of a human-in-the-loop demonstrator to verify the proposed care interventions of the AI model

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