Challenges and Facilitation Approaches for the Participatory Design of AI-based clinical decision support systems - Protocol for a scoping review

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Challenges and Facilitation Approaches for the Participatory Design of AI-based clinical decision support systems - Protocol for a scoping review

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Abstract

Background: In the last few years, there has been an increasing interest in the development of artificial intelligence (AI)-based clinical decision support systems. However, there are barriers to the successful implementation of such systems in practice, including the lack of acceptance of these systems. Participatory approaches aim to involve future users to design applications such as clinical decision support systems (CDSS) more acceptable, feasible and fundamentally more relevant for practice. The development of technologies based on artificial intelligence, however, challenges the process of user involvement and related methods.

Objective: The aim of this review is to summarize and present the main approaches, methods, practices and specific challenges for participatory research and development of AI-based decision support systems involving clinicians.

Methods: This scoping review will follow the Joanna Briggs Institute (JBI) approach to scoping reviews. The search for eligible studies was conducted in the databases MEDLINE via PubMed; ACM Digital Library; Cumulative Index to Nursing and Allied Health (CINAHL); and PsycInfo. The following search filters, adapted to each database, were used: Period 01.01.2012-31.10.2023, English and German studies only, abstract available. The scoping review will include studies that involve the development, piloting, implementation and evaluation of AI-based clinical decision support systems (CDSS) (hybrid and data-driven AI approaches). Clinical staff must be involved in a participatory manner. Data retrieval will be accompanied by a manual gray literature search. Potential publications will then be exported into a reference management software, and duplicates will be removed. Afterwards, the obtained set of papers will be transferred into a systematic review management tool. All publications will be screened, extracted, and analyzed: title and abstract screening will be carried out by 2 independent reviewers. Disagreements will be resolved by involving a third reviewer. Data will be extracted using a data extraction tool prepared for the study.

Results: This scoping review protocol has been registered on March 11th, 2023 at the Open Science Framework. The full-text screening had already started at that time. Analysis and manuscript preparation are planned from March 2024 to June 2024 and the manuscript should be submitted no later than October 2024 at the latest.

Conclusions: This review will describe the current state of knowledge on participatory development of AI-based decision support systems. The aim is to identify knowledge gaps and provide research impetus. It also aims to provide relevant information for policy makers and practitioners.

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Conclusions:

This review will describe the current state of knowledge on participatory development of AI-based decision support systems. The aim is to identify knowledge gaps and provide research impetus. It also aims to provide relevant information for policy makers and practitioners.

Keywords:
Artificial intelligence; AI; Participation; participatory design; Co-Creation; Clinical decision support system (CDSS); decision support; Challenges; Clinical staff; Scoping Review

Introduction

Background

Clinical decision support systems (CDSS) play an important role in healthcare by providing evidence-based guidance and recommendations to clinical staff. Typical use cases include medication management, disease diagnosis and management, treatment planning, risk assessment, and workflow optimization. The use of these systems aims to increase the accuracy and effectiveness of clinical staff [1,2].

The increasing digital transformation of healthcare means that more and more healthcare data is available in digital form, which means that artificial intelligence (AI) applications are also becoming more relevant in this area. More and more artificial intelligence applications are being developed in healthcare. In clinical practice, AI has a wide range of potential applications, including disease diagnosis, treatment selection, and patient monitoring [3]. AI-based clinical decision support (CDSS) is essential in this context.

Although studies have shown that CDSS can reduce medical errors and improve outcomes, they have also shown that CDSS are not being used to their full potential [4–10]. It can be assumed that the challenges of non-AI-based CDSS also apply to AI-based CDSS. Further challenges arise with respect to AI-based CDSS: [11] point out in a viewpoint that the use of deep learning and other analytic methods brings additional challenges. These methods generate insights in ways that are not directly traceable, meaning that clinical staff cannot apply the same validation as with traditional clinical decision support tools. As a result of this lack of transparency, trust in the AI system may decrease [11,12].

Another challenge is integration into workflows [13,14]. When developing AI-based technologies for clinical use, it is crucial to consider existing workflows in both the design and development phases. This will ensure that the technology can be used effectively and make a positive contribution to patient care. Consideration of workflows and the needs of clinical staff will ensure the successful integration of AI technologies into everyday clinical practice. Poor integration processes can have a negative impact on uptake and adoption, as illustrated by a case study on the implementation of a clinical decision support system [14]. For successful integration, it is essential that clinical staff develop the skills to interpret the results appropriately. This "black box" nature of AI described by [11] and the lack of transparency of the basis for decision making can make practical implementation difficult and may also be a factor in low user adoption [11,15].

The notion of the user’s acceptance of new technologies is derived from the Theory of Reasoned Action (TRA) [16]. According to various technology acceptance models (e.g. TAM, UTAUT) based on this theory, acceptance encompasses both the intention to use technology and its influence on actual use behaviour [4,17,18]. For researching clinicians' acceptance of CDSS these models serve as a foundation [19–22].

Acceptance of CDSSs is crucial for their successful use. Involving users at an early stage can improve the acceptance and use of information technology by taking into account their needs, preferences and experiences. This can help to optimise the user experience and increase the effectiveness of the technologies [15,17].

Involving future users is possible through participatory research approaches. Such approaches aim to plan and carry out research processes with people who investigate their social world and meaningful

actions as lifeworld-situated living and working practices that are to be improved by developing appropriate innovations [23]. In addition, a participatory approach may also help to avoid problems that arise when transferring the AI-based CDSS to new patient populations for instance due to overfitting of training data or lack of generalisability [24]. This problem can be counteracted by involving expert knowledge from practice, for instance by reviewing the operationalization of healthcare related concepts, feature selection, and data quality.

The stage of participation can be determined using the Wright et al. stage model [25]. This model consists of nine stages and is divided into four areas: 1. non-participation (stages 12), 2. pre-participation (stages 3-5), 3. participation (stages 6-8), and 4. beyond participation (stage 9). It is also used to determine the stage of participation in the studies reviewed. In order to be able to categorize the studies, particular attention should be paid to the methodological description of the studies. The second version of the GRIPP (Guidance for Reporting Involvement of Patients and Public), a tool to improve the reporting of patient and public involvement in research, shows in its fourth section of the long-form reporting checklist on the methodology of the work (design, people involved, stages of involvement, level or type of involvement) the relevant aspects for describing the involvement of groups of people [26]. The content can also be transferred to other stakeholder groups (not only patient and public involvement). An alternative to the Wright et al. stage model and GRIPP 2 could have been the participatory ergonomics framework, which focuses on the active involvement of participants, particularly workers, in ergonomic interventions to improve work conditions and processes [27]. However, the Wright model and GRIPP 2 were selected because of their established use in healthcare, their broad applicability, their transferability to different stakeholder groups and their alignment with the objectives of this review.

According to a recent review, clinical professionals (future users) are already involved in the development of AI-based CDSS, but only in about 30% of cases. The focus is on the creation of predictive CDSS specifications or the evaluation of system implementations. However, clinical experts are less likely to be involved in the development phases to check clinical validity, select model features, process data or act as a gold standard [28].

Nevertheless, the development of AI applications poses challenges to participatory methods: A precondition for carrying out participatory methods on the topic of AI is that the participants have a basic understanding of AI. Furthermore, implementing design ideas is difficult, as a realistic prototype is often hard to realize. In addition, evaluating the results is only possible to a limited extent. Much has to be done via simulations or imagination because it often requires a long testing period. Another difficulty is often the lack of comprehensibility of the AI decisions for the user [29].

Although clinical staff are already involved in the research and technology development process of AI-based CDSS, no overarching overview has been identified that summarizes and presents the main approaches, methods and practices for participatory research and technology development of AI-based CDSS for clinical staff. Hence, this gap of knowledge should be addressed by this scoping review.

A preliminary search of MEDLINE was conducted, and no current or ongoing systematic reviews or scoping reviews on the topic were identified.

Objectives and Research Questions

The objectives of the review are:

To provide an overview and systematization of participatory approaches of various disciplines for the

developing, piloting, implementing and evaluating AI-based information systems in a clinical setting.

The following research questions will be addressed:

1. Perspectives on the underlying clinical problem: Are the different perspectives on underlying clinical problems (eg, by nurses, doctors, and other health care workers) addressed by any particular CDSS included in the design of the CDSS?
2. Participation as a process: Which participatory approaches are used to develop, pilot, and evaluate AI-based CDSS in healthcare?
3. Participation in technical aspects of CDSS design: In which ways are participatory methods specifically supporting the development of AI components of CDSS and their performance?
4. Participation for ELSI: Which ethical, legal, and social implications (ELSI) have been identified in existing projects for participatory development, piloting, implementation and evaluation processes targeting clinical staff?

Methods

Design

We are going to conduct one scoping review. The PRISMA Extension for Scoping Reviews (PRISMA-ScR) is used as a basic tool [30] in combination with the Joanna Briggs Institute approach to scoping reviews. This approach ensures that the scoping review is transparent, reproducible, and methodologically sound [31].

Search Strategy and Terms

Information Sources

To identify relevant papers, we have chosen various databases that encompass publications from the fields of biomedical science and health science, computer science and information technology, psychology, and nursing and allied health. The following electronic databases will be included as information sources: MEDLINE via PubMed, ACM Digital Library, Cumulative Index to Nursing and Allied Health (CINAHL) and PsycInfo. Additionally, we will supplement this research with the snowball technique [32] and the screening of websites (eg, Google Scholar, DAHTA). These information sources were chosen since they encompass a wide range of research fields considered appropriate to address the objectives of this review. The databases provide the most comprehensive coverage of relevant studies examining the participatory design and development of AI-based technologies in healthcare, particularly CDSS.

Search Strategy

The above sources will be searched using combinations of relevant search terms we developed and tested for sensitivity before performing the scoping review. We used an iterative approach to develop the search strategy. First, we identified search terms used in previous studies and reviews related to participatory research and AI-based CDSS for clinical staff (particularly relevant: [33–37]. Then, we conducted an initial search in Medline (via PubMed) and CINAHL after analyzing text words (title and abstract) and indexed terms, as suggested by the Joanna Briggs Institute methodology for systematic scoping reviews [31,38]. Based on these results, we used the search terms in all databases. Afterward, we will check the references for all included contributions. If relevant, we will contact the authors. We will contact the authors if a publication is inaccessible or further information is required. Other reasons for contacting authors might include clarifying any ambiguous or unclear data presented in their publication, requesting additional data that may not have been included in the

original publication, or seeking permissions for using specific figures, tables, or other content.
Multimedia Appendix 1 demonstrates the search strategy for Medline (via PubMed). The research begins in 2012, the year in which the use of deep neural networks in image processing marked a breakthrough in the field of deep learning [39]. The terms will be adapted to the basic search particulars (eg, wildcards (*) and truncations) of each electronic database.

In order to describe the inclusion criteria precisely, we rely on the PCC scheme. PCC is an acronym for Population, Concept and Context [31,38]. **Table 1** shows the most important criteria according to the PCC scheme.

Table 1: PCC Criteria used in the scoping review

Population	clinical staff (medical doctors, nurses, …)
Concept	Participation/participatory design/Co-Creation/Co-Design
Context	Development, piloting, implementation and evaluation of AI-based CDSS (Hybrid and data-driven AI approaches)
Types of sources	Primary research - All study types (eg, qualitative, quantitative, mixed-methods) will be included. Systematic reviews and meta-analyses will be used for manual searches in the reference lists to identify further primary studies.

Papers that provide information on at least one research question should be included. More specific inclusion and exclusion criteria are provided below for each review.

Eligibility criteria

The inclusion and exclusion criteria that were applied to the studies are shown in **Table 2**.

Table 2: Inclusion and exclusion criteria applied in the scoping review“

Inclusion criteria	
Target group	Clinical staff
Involvement	Participation in the development, design, piloting and evaluation of AI-based information systems
Related Approaches	Other related approaches, research and design strategies or concepts often used interchangeably with participation and co-creation, such as co-design
Type of Research	Primary research using different methods (eg., qualitative, quantitative, mixed methods)
Language of Publications	English or German
Exclusion criteria	
Participation	No evidence of a participatory research element
Target group	No relation to clinical staff
Thematic Focus	Does not refer to AI-based CDSS

Study selection

The retrieved references will be checked for duplicates and transmitted to Covidence (Software for managing and streamlining reviews) [40] for the screening steps. We will use Zotero (free and open-source literature management programme) [41] as a bibliographic tool. Two independent reviewers (T.R. and P.G.) will screen all titles and abstracts separately for inclusion or exclusion. Disagreements will be solved by including a third reviewer. Afterward, the same procedure will be applied for the full-text screening, which is carried out by three independent reviewers (T.R. P.G. and C.H.). Reasons for excluding a study will be assessed in each of these steps. The results of the search and the study inclusion process will be reported in full in the final scoping review and presented in a Preferred Reporting Items for Systematic Reviews and Meta-analyses extension for scoping review (PRISMA-ScR) flow diagram [30].

Data Extraction

A data charting form has been developed jointly by the authors to identify the variables to be extracted. The two reviewers will chart the data independently, discuss the results, and continually update the data charting form in an iterative process, with changes detailed in the scoping review. Any reviewer disagreements will be resolved by discussion or with an additional reviewer(s). Where appropriate, authors of papers will be contacted to request missing or additional data as required. A draft extraction form is provided (Multimedia Appendix 2). Data on the participation process is also extracted to assess the stage of participation.

Data Analysis and Presentation

Data Analysis and presentation will follow the recommendations of the JBI Scoping Review Methodology Group [42]. First, the extracted data will be presented in a logical and descriptive way (diagrams and tables), guided by the objectives and questions of the scoping review. Additional relevant data items may be identified during the data extraction process. If additional items are extracted that were not prespecified in the review protocol, this will be made clear in the final report together with a rationale as to why it occurred. The extracted data will be summarised in a narrative synthesis to bring together findings relating to challenges and facilitators for participatory design processes. Given the breadth of scoping review questions, the analysis will also use qualitative content analysis. In order to identify and structure relevant aspects on the research questions, the analysis will follow an inductive approach. Following an open-coding process, a coding framework will be developed and reviewed by all authors. This approach aims to provide insights into participatory design and research practice for AI-based CDSS and highlight areas for future research.”

Results

This review protocol was submitted to the Open Science Framework on March 11th, 2024. The full-text screening had already started at that time. Data collection and analysis as well as manuscript preparation are planned for the second and third quarter of 2024. The manuscript should be submitted towards the end of 2024.

Discussion

Principal Results

The main objective of this study is to identify, clarify and map key approaches, methods and procedures for participatory research and technology development of AI-based CDSS in the context of clinical staff. It will also analyze, synthesize and develop existing approaches, concepts and conceptualizations. The insights gained from this process will serve as a basis for designing, developing, and testing participatory processes specifically designed for clinical staff. Various stakeholders can use the results to design, develop and review participatory processes that address the development of an AI-based CDSS for clinical staff.

Limitations

Scoping reviews have limitations, particularly in that they focus on the collection and synthesis of data and do not assess the strength of evidence or the risk of bias in the research. Therefore, further research is needed to assess and analyze the quality of existing studies on the participatory development of AI-based decision support systems. It should be noted that only papers written in English or German were considered, which meant that potentially relevant studies in other languages could not be included. Furthermore, despite the comprehensive inclusion criteria, some relevant sources of information may not be included.

Conclusions

Up to now, no review of this scope and objective has been identified. Hence, this review will be the first to address this specific knowledge gap targeting clinical staff. Additionally, one aim of this review is to identify further research and knowledge gaps and to give hints where further reviews would be helpful.

Acknowledgements

The work on this review is part of the KIDELIR-Project (Hybrid AI delirium prediction system to reduce the burden on caregivers), funded by the Federal Ministry of Education and Research (BMBF) in Germany. The aim of the KIDELIR project is to develop hybrid AI models for predicting delirium in a hospital setting and supporting reflective care decisions with the close involvement of care professionals.

Data Availability

All data collected and analyzed during our scoping review will be available on the Open Science Framework repository and included as supplementary files with our scoping review publication.

Authors' Contributions

T.R. and P.G. conceptualised the study as a scoping review. C.K. and P.K. provided oversight for scoping review protocol development. T.R. drafted the protocol. P.G. C.K. and P.K. helped to review and edit the protocol. T.R., S.M. and P.G. drafted the search strategy and ran the search on electronic databases. All authors read and approved the final protocol. T.R. and P.G. carried out the title and abstract screening. Ambiguous cases were discussed and jointly decided with C.K. and P.K.. T.R., P.G., and C.H. conduct the fulltext screening.

Conflicts of Interest

The authors declare that there are no conflicts of interest.

Ethics

Formal ethical approval is not required, as primary data will not be collected in this study.

Abbreviations

AI: artificial intelligence
CDSS: clinical decision support system
PRISMA-ScR: PRISMA Extension for Scoping Reviews

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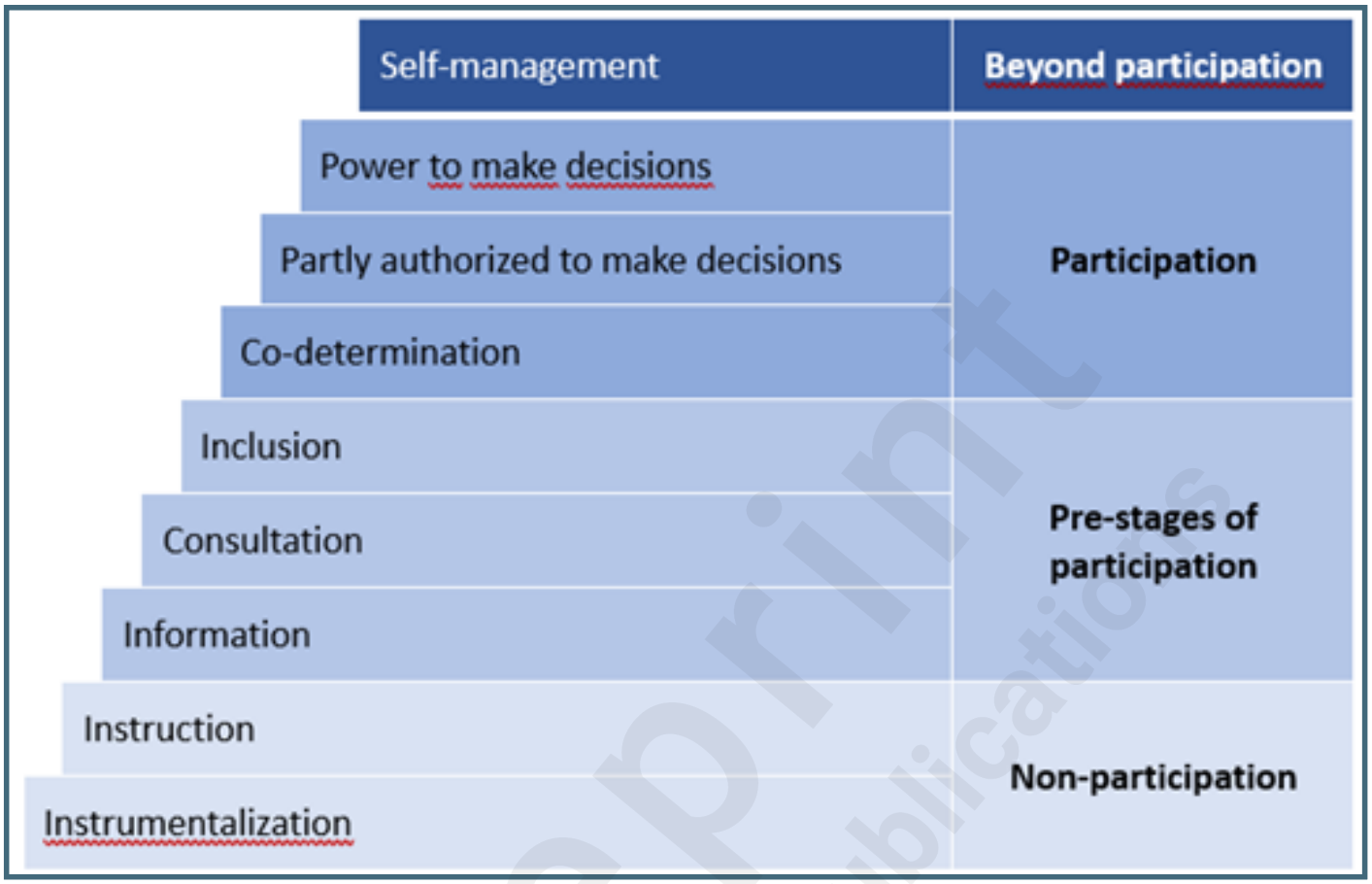
Supplementary Files

Figures

Stages of participation (Adapted from [21]).



Multimedia Appendixes

Search strategy.
URL: http://asset.jmir.pub/assets/5d932533a2549370345686e80cdff837.docx

Data extraction form.
URL: http://asset.jmir.pub/assets/754e7a7e936fefe7c7b980109dd8070b.docx

TOC/Feature image for homepages

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