User-Oriented Requirements for AI-Based Clinical Decision Support Systems in Sepsis: Study Protocol for a Mixed Methods Study

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Submitted to: JMIR Research Protocols
on: May 29, 2024

Table of Contents

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Abstract

Background: Artificial intelligence (AI)-based clinical decision support systems (CDSS) have been developed for several diseases. However, despite the potential to improve the quality of care and thereby positively impact patient-relevant outcomes, the majority of AI-based CDSS have not been adopted in standard care. Possible reasons for this include barriers in the implementation and a non-user-oriented development approach, resulting in reduced user acceptance.

Objective: This study has two research objectives. Firstly, problems and corresponding solutions that hinder or support the development and implementation of AI-based CDSS are identified. Secondly, this study aims to increase user acceptance by creating a user-oriented requirement profile, using the example of sepsis.

Methods: The study is based on a mixed methods approach combining (i) a scoping review, (ii) focus groups with physicians and professional caregivers and (iii) semi-structured interviews with relevant stakeholders. The research modules mentioned provide the basis for the development of a (iv) survey, including a discrete choice experiment (DCE) with physicians. The survey is followed by the development of a requirement profile for AI-based CDSS and the derivation of policy recommendations for action, which are evaluated in a (v) expert roundtable discussion.

Results: This study provides an overview of the barriers and corresponding solutions related to the development and implementation of AI-based CDSS. Using sepsis as an example, a user-oriented requirement profile for AI-based CDSS is developed.

Conclusions: The results of the study represent the first attempt to create a comprehensive user-oriented requirement profile for the development of sepsis-specific AI-based CDSS. In addition, general recommendations are derived, in order to reduce barriers in the development and implementation of AI-based CDSS.

(JMIR Preprints 29/05/2024:62704)
DOI: https://doi.org/10.2196/preprints.62704

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Background: Artificial intelligence (AI)-based clinical decision support systems (CDSS) have been developed for several diseases. However, despite the potential to improve the quality of care and thereby positively impact patient-relevant outcomes, the majority of AI-based CDSS have not been adopted in standard care. Possible reasons for this include barriers in the implementation and a non-user-oriented development approach, resulting in reduced user acceptance.

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Results: This study provides an overview of the barriers and corresponding solutions related to the development and implementation of AI-based CDSS. Using sepsis as an example, a user-oriented requirement profile for AI-based CDSS is developed.

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Background

The first clinical decision support systems (CDSS) date back to the 1970s. Early systems, such as MYCIN, a programme designed to advise on the choice of therapy selection for patients with infections [1], were rule-based expert systems. Nowadays, a wide variety of CDSS exist. These can be categorised as either knowledge-based or non-knowledge based systems.

Knowledge-based systems operate on logical decision rules (IF <condition> THEN <action>). The system retrieves data and transforms it into an output following distinct rules. A further segmentation can be made into Bayesian networks, causal-probabilistic networks and rule-based systems: The latter are usually based on medical guidelines [2].

Non-knowledge based CDSS require a clinical data source and generate recommendations using artificial intelligence (AI) including machine learning or statistical pattern recognition [3-4]. The potential of AI models to sustainably improve patient care is estimated to be enormous for almost all aspects of the clinical decision-making process (prevention, diagnostics, therapy) [5]. Based on big data analytics, AI-based CDSS offer the ability to pool, link and combine data, that would be impossible for humans to interpret due to its complexity. In this way, these applications can improve medical outcomes by optimising care [6].

While AI is established in some disciplines, such as radiology (e.g. automated image recognition), the transfer of AI-based CDSS into clinical use is lagging behind. Due to the inhomogeneity of different disease patterns, AI-based CDSS are often developed specifically for a target disease or a selected group of disease patterns, such as sepsis [7-8].

Sepsis is a life-threatening organ dysfunction caused by a dysregulated immune response to infection. It is a leading cause of mortality, with 49 million cases and 11 million deaths each year [9]. So far, only symptomatic therapies are available, which attempt to replace the function of the failed organ systems. Treatment of the dysregulated immune response as a cause of sepsis has not been successful in large trials and subsequently has therefore not found its way into clinical practice or sepsis guidelines.

AI-based CDSS could be particularly useful in sepsis care due to the high heterogeneity and complexity of the disease [10]. Non-knowledge based respectively data-based CDSS are subject to a trade-off between model complexity and interpretability. As sepsis is an extremely complex condition, a majority of machine learning-based CDSS for this disease can be considered "black box" systems. Their treatment recommendations cannot or can only be interpreted by health care providers, with relatively high effort [11-12]. Health care providers may have to rely on these systems without understanding how the algorithms reach their conclusions, due to their black box nature. This lack of transparency can negatively impact the acceptability of such systems [13-15].

In addition to the black box nature of AI-based CDSS, there may be other possible reasons why such systems do not manage the transition into standard care, such as a non-user oriented development approach without or at least without sufficient consideration of the needs and preferences of future users [16-18], resulting in reduced user acceptance and implementation barriers (e.g. computer literacy of the future users, data availability or legal issues) [4].

These may be possible reasons why there is still no AI-based CDSS for sepsis in Germany that is included in the standard care of the statutory health insurance (SHI) system and is used nationwide. Currently, only few prototypes in the form of individual solutions are in use or under development (e.g. [19-20]). Also in other indications, despite a high frequency of development, only a marginal proportion of such systems successfully transition from the development phase into standard care.

Therefore, the study "User-Oriented Requirement Profile for AI-Based Clinical Decision Support Systems Using the Medical Example of Sepsis – KI@work", seeks to investigate AI-based CDSS in the above-mentioned disease context. In the framework of this study, it is assumed that there are two reasons for the lack of implementation:

1. There are administrative and organisational barriers (data availability, data collection,

knowledge gaps among potential users) as well as legal and institutional hurdles (implementation of European and national legal requirements, (medical) liability law, competent bodies) within the German healthcare system that make it difficult to transfer and integrate AI-based CDSS into the SHI system.

2. To ensure (sustainable) use and acceptance of AI-based CDSS, the system must have a high perceived benefit according to the Technology Acceptance Model [21]. In addition, future users should be involved in the development phase, as suggested by the Recursive Innovation Management Model [18]. Due to the strongly technology-driven development of AI-based CDSS, this is currently only done in a fragmentary manner, so that the requirements and preferences of users are only insufficiently taken into account within the framework of such systems.

The mixed methods study addresses both aspects, resulting in two equally important research objectives:

1. To identify and remove or overcome barriers by developing health policy recommendations for action to facilitate the transfer of AI-based CDSS across all indications in the German healthcare system in the future.
2. To develop a clinical requirement profile that can be incorporated into the initial development of CDSS or can be considered in the further development of existing systems. This should enable an increase in the usability and thus the acceptance of AI-based CDSS. The requirement profile is developed using the example of sepsis and is therefore indication-specific.

In order to achieve the objectives, three research questions and three sub-questions were determined:

a. What insights can be gained from AI-based CDSS that are already established in health care and which best practices can be derived?
   1.1. What is the data basis of these CDSS (input)?
   1.2. How are the decisions and recommendations of the CDSS presented to the health care providers (output)?
   1.3. How does the interaction between health care provider and CDSS take place (setting)?
2. What specific problems exist or are seen in the establishment of AI-based CDSS in patient care, with a particular focus on clinical sepsis care as well as on the German healthcare system?
3. What are the preferences of health care providers regarding the use and design of CDSS in the prevention, diagnosis and treatment of sepsis patients?

The study is conducted by the Institute for Health Care Management and Research at the University of Duisburg-Essen. Consortium partners are the Department of Anaesthesiology, Intensive Care Medicine and Pain Therapy at the University Hospital Knappschaftskrankenhaus Bochum, the Knappschaft Kliniken GmbH, the Department of Medical Informatics, Biometry and Epidemiology at the University of Bochum and the German Sepsis Society. The study is funded by the Innovation Fund of the German Joint National Committee (Funding Code: 01VSF22050).

Methods / Design

The study is based on a mixed methods approach which is separated in 3 work packages. Work package 1 combines a scoping review (1.1), focus groups with physicians and professional caregivers (1.2) and semi-structured interviews with relevant stakeholders of the German healthcare system (1.3). At the end of this work package, the interim results (problem, barriers and corresponding solutions) of the study are summarised and a set of criteria for AI-based CDSS is derived (1.4). Based on the results of the preceding work package, work package 2 includes the central element of the study: a survey of physicians, including a discrete choice experiment (DCE) (2). Work package 3 involves the development of a requirement profile for AI-based CDSS and the derivation of health policy recommendations for action (3.1), which are discussed in an expert roundtable discussion (3.2). The project concludes with a summary of the results in a white paper (3.3) (see Fig. 1).

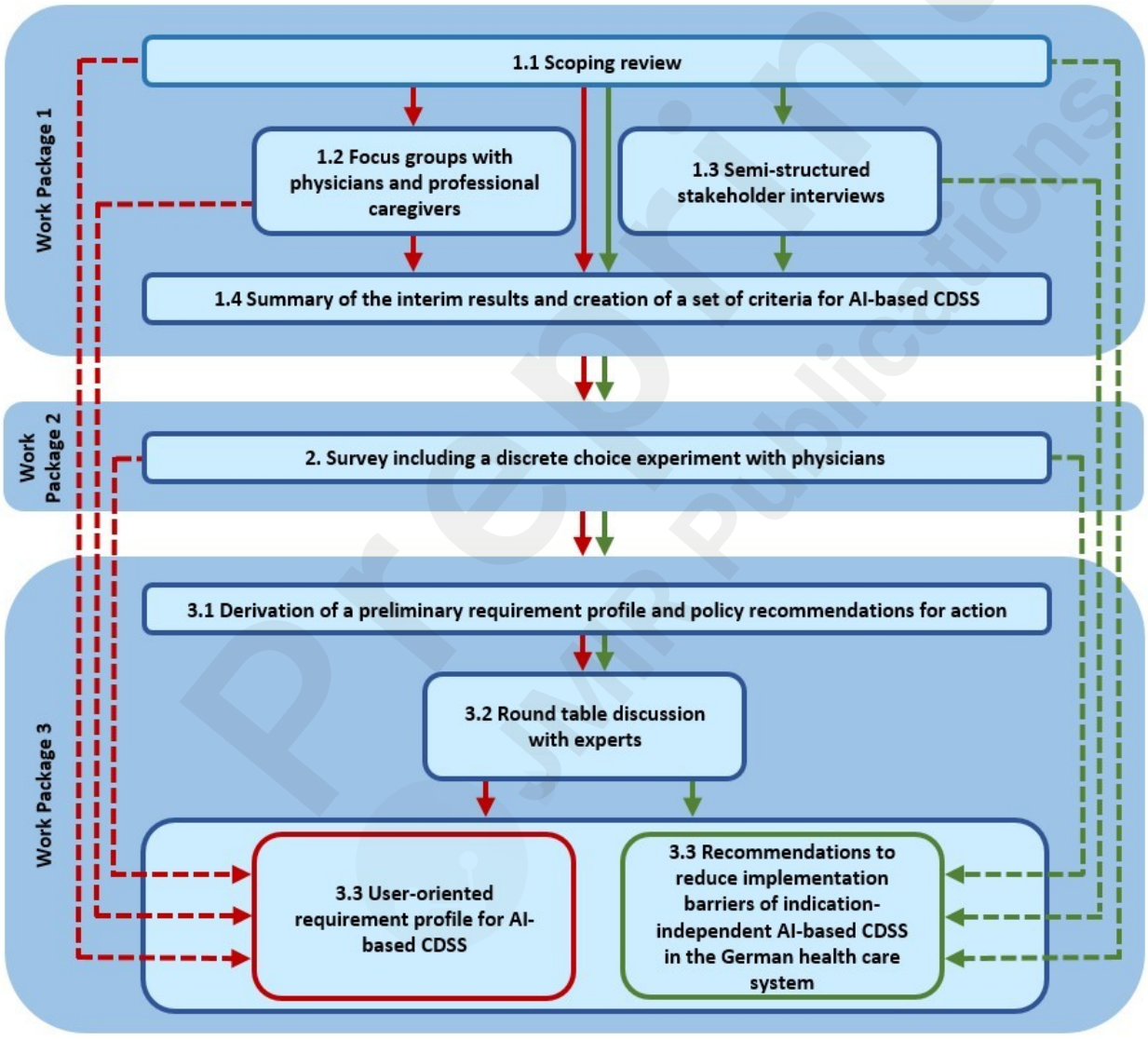

Fig. 1. Overview of the mixed method methodology (Source: own illustration). The results of work packages 1 and 2 are indirectly incorporated into module 3.3, as indicated by the dashed lines.

Work package 1

Work package 1 addresses both research objectives. It serves to identify problems and barriers regarding the transfer of AI-based CDSS into the SHI system (first research objective) and to create a preliminary set of criteria for AI-based CDSS in sepsis care (second research objective). Work package 1 is divided into 4 modules.

Module 1.1 – Scoping Review

The scoping review combines systematic and structured research. The focus of the scoping review lies on research questions 1 and 2, thus addressing both research objectives.

Scoping Review

The actual scoping review examines the currently available evidence on the patient-relevant benefit of AI-based CDSS in the field of sepsis. Furthermore, it aims to identify factors that pose barriers to the transition of CDSS into the healthcare system and to identify solutions that reduce or overcome these barriers. Methodically it is based on the Joanna Briggs Manual for Evidence Synthesis [22]. A further development of the foundational work of Arksey & O'Malley (2005) [23] and Levac, et al. (2010) [24]. The documentation of the scoping review is based on the PRISMA Extension for Scoping Reviews [25]. The search strategy is designed using the PCC (Population / Concept / Context) framework. The databases examined are Medline and Embase as well as ACM Digital Library and IEEE Xplore. This proceeding is to ensure that the interdisciplinary character of the study can be adequately investigated from both the medical and the informatics perspective.

Additional structured medical device database search

The structured search provides an overview of authorised AI-based CDSS already in use. In order to identify such systems, the European Commission's medical device database EUDAMED is analysed. The filters "system", "software" and "risk class (IIa, IIb, III)" are used. The structured search examines the data on which the decisions of the systems are based (input), how the results are presented (output), and how the CDSS are integrated into the clinical context (setting). Particular focus is placed on the search for best practice examples and the identification of clinical areas where the use of AI is already established. These examples are used to recognise aspects that increase the likelihood of such systems being implemented.

Module 1.2 – Focus groups with physicians and professional caregivers

The focus groups with physicians and professional caregivers build on the findings of the scoping review (module 1.1).

The findings of the focus groups contribute to the preparation of a standardised questionnaire for the survey in work package 2. Relevant aspects of input, output and setting in the context of AI-based CDSS in the field of sepsis diagnosis and therapy are collected and derived, thus addressing the second research objective.

Five focus groups are held, each with a maximum of 12 participants. The participants include physicians and professional caregivers who are familiar with the care and treatment of sepsis patients, as well as those who contribute to the prevention and diagnosis of sepsis. Three focus groups are conducted with physicians and two with caregivers. The discussions are based on a semi-structured guideline. The focus groups are led by a moderator team according to Krueger and Casey [26], recorded and transcribed. Based on this, a qualitative content analysis according to Kuckartz [27] is carried out using MAXQDA (VERBI).

Recruitment of participants is supported by the Department of Anaesthesiology, Intensive Care Medicine and Pain Therapy of the University Hospital Bochum Knappschaftsklinikum and the Knappschaft Kliniken GmbH. In addition, participants from other hospital providers were also invited in order to represent a broad and provider-independent perspective of physicians and professional caregivers.

Module 1.3 – Semi-structured stakeholder interviews

Semi-structured interviews with stakeholders from different domains of the German healthcare system are conducted to complement the results of the scoping review (module 1.1) with the perspectives of various stakeholders. The expert interviews are undertaken to identify problems and barriers related to the implementation of AI-based CDSS in standard care (first research objective). Experts in the field of medical device law, representatives of the SHI system, patient representatives,

physicians and professional caregivers, representatives of quality management, data protection and ethics, various research institutions as well as private developers are interviewed. The interviews are recorded, transcribed and subjected to a qualitative content analysis based on Kuckartz [27].

Module 1.4 – Summary of the interim results (problem, barriers and corresponding solutions) and creation of a set of criteria for AI-based CDSS

Based on the results of the first work package, a set of criteria for AI-based CDSS in sepsis care are developed in module 1.4 (second research objective), which is based on national and international evidence and qualitative survey methods. Furthermore, the identified problems and barriers as well as corresponding solutions are systematised and summarised (first research objective).

Work package 2

The central element of work package 2 is a cross-sectional survey to identify perceived problems and barriers to the integration and usage of AI-based CDSS (first research objective) and to ascertain physicians' preferences regarding the design of AI-based CDSS in sepsis care (second research objective). The results of work package 1 serve as basis for the development of the survey including the DCE.

The survey is divided into three parts: first, socio-demographic data and general attitudes towards AI applications are collected; the second part aims to identify potential barriers to the integration of AI-based CDSS into care; third, a DCE is conducted to determine preferences for the criteria in the preliminary AI requirement profile. In particular, preferences are sought regarding the preferred data base (input), the preferred information content (output) and the appropriate integration into the care process (setting).

Inclusion criteria:

Inpatient physicians,

1. familiar with the medical care of adults **and**
2. with experience in intensive care medicine (e.g. specialists in anaesthesiology, specialists in surgery (general, visceral or orthopaedics and trauma surgery) and specialists in internal medicine).

Textbox 1. Criteria for physicians participating in the survey.

The weighting of the specialist groups participating in the survey is determined in the course of the study on the basis of the conditions in clinical care. If the results of the preliminary research in work package 1 indicate that the majority of the identified problems concerning the integration of AI-based CDSS cannot be influenced by physicians, there is the option of involving further stakeholders of the German healthcare system (for example representatives of caregiving, the Federal Ministry of Health, the Federal Institute for Drugs and Medical Devices (BfArM), producer of AI-based CDSS, SHI funds, patient representatives) in the survey.

Sample size of the survey of physicians

The sample size of the survey is not yet defined because it depends on the attributes queried in the DCE. The attributes are derived from the results of work package 1. Nevertheless, for orientation an initial sample size planning was done according to the heuristics developed by Johnson and Orme [28]. Therefore, assuming 12 choice decisions, 2 choice sets per task and a maximum of 3 levels, there must be 125 evaluable questionnaires. Since an additional evaluation according to subgroups (e.g. gender (m/f/d)[1], age , occupational group) is to be conducted, the necessary number increases to 125*8=1,000 completed questionnaires. Assuming an average response rate of 15%, at least 6,667 physicians must be contacted. Nine hundred members of the German Sepsis Society and 250 specialists from the Knappschaft Kliniken GmbH are included. The sample is supplemented by 5,517 randomly selected records of an address register according to the inclusion criteria (Textbox 1). In order to reach 'offliners', it is possible to take part in the survey both online and on paper. A pre-test is

[1] In accordance with Pöge, et al. (2022) [29] gender identity is used as a binary variable, so transgender and cisgender people are evaluated together. Gender diverse people are not reported separately in order to avoid identifiability due to the expected low number of cases, but are included in the overall category of all respondents.

carried out before the questionnaire is conveyed.

Work package 3

In work package 3, a white paper is developed. It includes (1) the final requirement profile for AI-based CDSS and (2) the determined health policy recommendations for action to reduce implementation barriers. Therefore, a preliminary requirement profile and health policy recommendations for action are developed (module 3.1), discussed with experts (module 3.2) and finally summarized in a white paper (module 3.3).

Module 3.1 – Derivation of a preliminary requirement profile and health policy recommendations for action

The preliminary requirement profile for AI-based CDSS in the treatment of sepsis is developed based on the results of module 1.4 (summary of interim results and creation of a set of criteria for AI-based CDSS) as well as the results of the survey from work package 2 (second research objective). Furthermore, the identified barriers to the implementation and integration of AI-based CDSS in the German SHI system are used to develop targeted strategies for the removal and reduction of implementation barriers and translated into health policy recommendations for action (first research objective).

Module 3.2: Expert roundtable discussion on the requirement profile and corresponding health policy recommendations for action

In module 3.2 an expert roundtable is held. Aim of the discussion is to evaluate and optimise the preliminary requirement profile for AI-based CDSS as well as the corresponding health policy recommendations for action. In order to gain a comprehensive perspective, different stakeholders involved in the development and provision of AI-based CDSS are invited. In the context of the requirement profile for AI-based CDSS for sepsis care, the expert roundtable discussion focusses on input (data basis), output (presentation of decisions/recommendations) and setting (context of interaction between AI-based CDSS and user). Besides technical requirements, the results can include further requirements such as organisational, procedural, legal or medical content.

The discussion is divided into four parts: after 1) introductory presentations, the 2) preliminary requirement profile for AI-based CDSS and 3) the health policy recommendations for action for the use of these systems in the German SHI system are presented. The workshop then provides an opportunity for 4) open discussion of the partial results of the requirement profile and the health policy recommendations. In addition, selected topics can be discussed in small groups with relevant experts, and the results of the discussions are presented in plenum to reach a consensus among the stakeholders on the main issues.

A maximum of 30 stakeholders are invited to the workshop. In addition, there are at least two moderators and a technical and organisational staff member from the Institute for Health Care Management and Research from the University of Duisburg-Essen, as well as representatives from the University Hospital Bochum Knappschaftsklinikum and the German Sepsis Society. Discussions are led by a team of facilitators using a prepared guideline. The results of the workshop are recorded, transcribed and subsequently analysed.

Module 3.3: Finalisation of the requirement profile as well as the health policy recommendations for action and preparation of a white paper

Based on the results of the expert roundtable discussion (module 3.2), the requirement profile for AI-based CDSS is finalised using the example of sepsis care. This enables a user-oriented development of AI-based CDSS in this context. Wherever possible, generic aspects are elaborated and presented in order to include indication-independent and therefore generalisable information in the requirement profile.

In addition, the health policy recommendations for action are concretised. It is discussed how to reduce or overcome barriers to the implementation and establishment of AI-based CDSS in clinical care and finally, proposals for legal adaptations are derived.

The results of both project objectives, the requirement profile for an AI-based CDSS and the health

policy recommendations for action, are published in a white paper.

Discussion

AI-based CDSS are developed for various diseases. These systems possess the potential to enhance the quality of care and thereby positively impact patient-relevant outcomes (such as a reduction of sepsis-related mortality, a reduced average hospital length of stay or an earlier administration of antibiotics) [30]. Nonetheless, despite extensive development efforts, the majority of CDSS developed have not been adopted in standard care and do not make a significant contribution to improving care in their current form.

There may be two primary reasons for this. First, it is assumed that a technology push development is currently taking place, wherein AI-based CDSS are being developed without or only insufficiently considering the requirements and preferences of users [16]. In order to optimise user acceptance, innovations must provide a high perceived benefit [21]. According to the recursive innovation management model, this can be achieved by involving users in the developmental phase and considering their requirements and preferences for innovations [18]. Second, the implementation of such systems may face various barriers during the transition from the developmental phase to standard care, for instance operational problems or regulatory uncertainties [4]. These and other hindrances may have a negative effect on the successful integration of AI-based CDSS and need to be identified and addressed before AI-based CDSS can be sustainably integrated into care.

Based on these two hypotheses it is necessary to analyse potential barriers, as well as the requirements and preferences of health care providers for AI-based CDSS. The results are summarised in health policy recommendations for action to reduce barriers and a requirement profile for AI-based CDSS in order to develop user-oriented systems and thereby optimise user acceptance.

Since the requirements for AI-based CDSS vary depending on the indication, the requirement profile is developed using the specific example of sepsis. Sepsis is a suitable subject for investigation due to its heterogeneity and complex pathophysiological processes, which pose challenges for health care providers in terms of diagnosis and treatment [10]. In addition, the intensive medical treatment and the continuous monitoring of sepsis patients in the ICU generate a large amount of data suitable for use in AI-based analysis.

The requirement profile for sepsis-specific AI-based CDSS, which is developed based on requirements and preferences of health care providers, can help to ensure that future CDSS development is aligned with medical practice needs. Involving future users of such systems may counteract the current technology-push development and contribute to greater user acceptance. Following completion, the requirement profile is evaluated in terms of generalisability and transferability to other indications. In addition, indication-independent health policy recommendations for action are developed based on the identified inhibiting factors for the implementation of AI-based CDSS.

Conclusion

Based on the results of this study, developers are provided with guidelines for the development of new AI-based CDSS or the revision of existing systems in order to make their products more user-oriented. In addition, the study culminates in the development of health policy recommendations for action to reduce barriers to the implementation of AI-based CDSS. Ultimately, this enables AI-based CDSS to become a future standard in health care practice, providing benefits to patients.

Abbreviations

AI: Artificial Intelligence
CDSS: Clinical Decision Support System
DCE: Discrete Choice Experiment
EUDAMED: European Database on Medical Devices
SHI: Statutory Health Insurance
BfArM: Bundesinstitut für Arzneimittel und Medizinprodukte

Acknowledgments

This research is part part of a wider research project (Mixed Methods Study on Requirements for AI-Based Clinical Decision Support Systems Using the Medical Example of Sepsis (="KI@work")) funded by the German Federal Joint Committee (funding code: 01VSF22050 – KI@work). We acknowledge support by the Open Access Publication Fund of the University of Duisburg-Essen.

Conflicts of Interest

None declared.

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Supplementary Files

Figures

Overview of the mixed method methodology (Source: own illustration). The results of work packages 1 and 2 are indirectly incorporated into module 3.3, as indicated by the dashed lines.