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Responsibility and decision-making authority in using clinical decision support systems: an empirical-ethical exploration of German prospective professionals' preferences and concerns

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► Additional supplemental material is published online only. To view, please visit the journal online (http://dx.doi.org/10.1136/jme-2022-108814).

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Received 25 November 2022
Accepted 11 March 2023
Published Online First 22 May 2023

Check for updates

To cite: Funer F, Liedtke W, Tinnemeyer S, *et al*. *J Med Ethics* 2024;**50**:6–11

ABSTRACT

Machine learning-driven clinical decision support systems (ML-CDSSs) seem impressively promising for future routine and emergency care. However, reflection on their clinical implementation reveals a wide array of ethical challenges. The preferences, concerns and expectations of professional stakeholders remain largely unexplored. Empirical research, however, may help to clarify the conceptual debate and its aspects in terms of their relevance for clinical practice. This study explores, from an ethical point of view, future healthcare professionals' attitudes to potential changes of responsibility and decision-making authority when using ML-CDSS. Twenty-seven semistructured interviews were conducted with German medical students and nursing trainees. The data were analysed based on qualitative content analysis according to Kuckartz. Interviewees' reflections are presented under three themes the interviewees describe as closely related: (self-)attribution of responsibility, decision-making authority and need of (professional) experience. The results illustrate the conceptual interconnectedness of professional responsibility and its structural and epistemic preconditions to be able to fulfil clinicians' responsibility in a meaningful manner. The study also sheds light on the four relata of responsibility understood as a relational concept. The article closes with concrete suggestions for the ethically sound clinical implementation of ML-CDSS.

BACKGROUND

Facing complex decision-making situations is an integral part of healthcare's daily practice. Clinical decision support systems (CDSSs) have been supposed to enhance and accelerate professional decision-making over the last 30 years.[1] Given the plethora of patient data provided by electronic health records, machine learning-driven CDSSs (ML-CDSSs) seem particularly promising for future routine and emergency care. So far, ML-CDSSs have been successful mainly in the field of (imaging) diagnostics, but their use in prediction, prognostics and therapy also offers many opportunities. In response to the recent progress, ethical debates on the requirements for the clinical implementation of ML-CDSS have been unleashed, mainly about topics such as patient safety, privacy, data ownership, opacity/transparency/explainability, biases, trustworthiness, validity and reliability.[2–5]

Many of these important ethical aspects culminate in theoretical and practical questions about responsibility and its allocation when such technologies are used.[6–13] Often, in line with the designation as a support system, the importance that such systems should assist professionals in their decision-making has been highlighted. The ML-CDSSs pursue the goal of supporting professionals in their decision-making by making medical recommendations[14–16] and covering their existing information needs as human experts,[12 17 18] 'for example, by providing evidence that would have otherwise not been available within a reasonable time frame'.[19] Even if ML-CDSSs seem particularly suitable for this goal in view of the increasing technical capacities and the professional's epistemic dependency, the question arises whether and to what extent it is realiter still the professional who is responsible for the decision-making.

Responsibility is considered to be a relational concept in ethics. There is an ongoing discussion on the exact number of relata constituting this relationship.[13 20–24] While older contributions to the discussion of ethics of responsibility predominantly refer to the subject and object of responsibility and suffer from a lack of precision regarding the role of the normative standard[25] newer concepts expand the structure of the relation of responsibility in order to mirroring a holistic view and to clarify the normative implications.[20 23] But, according to a broad consensus, at least four relata are essential: subject of responsibility(A), object of responsibility(B), addressees of responsibility(C) and normative standards(D).[7 26] Thus, the relationship of responsibility can be expressed as:

A is responsible to C for B because of D.

While the subject and the addressee of responsibility can be either a person or institution, the object is an action and/or its consequences. The normative basis for attribution of responsibility, the normative standard, is a set of explicit (eg, legal) or implicit rules. Based on this relational concept, responsibility can be adopted in at least two directions: first, retrospectively, after harm has been caused; who is responsible, who should be held accountable and who is liable for the harm caused? With significant changes in the doctor–patient relationship since the 1970s one can detect a general move from a paternalistic understanding of the subject of responsibility to the concept of shared decision-making which implies a co-responsibility of doctors and patients; as well as a co-responsibility to developers and manufacturers.[27] This perspective is important not to simply assign blame, but to trace causes and prevent future reoccurrences more effectively.[7 28] Second, prospectively, insofar as moral requirements must be formulated and justified to prevent harm from the outset.[9] How, for example, should a healthcare worker act if (s)he does not agree with the ML-CDSS recommendation? Such specific decision-making situations (sometimes called 'peer disagreement'[10 18 29])[i], in which the professional's clinical judgement differs from the recommendation of the ML-CDSS and these judgements are incompatible due to their epistemic characteristics (ie, opacity), seem to be particularly problematic regarding the attribution and assumption of responsibility.[10 12 18 27 29] In these instances, it can be necessary to train professionals' suitable competencies 'as a safeguard to decrease the risk of harm in cases of cognitive misalignment between the physicians and the AI [=artificial intelligence] system—when an AI output cannot be confirmed (verified or falsified)'.[9]

Despite the extensive theoretical literature on ML-CDSS, responsibility and decision-making, to the best of our knowledge, little evidence currently exists on professionals' attitudes regarding these topics.[30] Empirical research mostly examines factors related to doctors' acceptance of ML-CDSSs and its promotion,[31 32] whereas aspects of moral responsibility or decision-making play only a minor role.

Therefore, responsibility and its attribution in the overall context of ML-CDSS merits more explicit research and analysis. Given the range of the existing theoretical debates, the inquiry of clinical stakeholders' views and their underlying reasoning may address important aspects of professional practice and adjust them regarding their theoretical relevance for clinical decision-making. This study explores the opinions, preferences and concerns of future healthcare professionals about potential changes of responsibility allocation and decision-making authority when using ML-CDSS from an ethical point of view. Based on our information, this study is the first to collect professionals' attitudes while confronting them with different case vignettes of ML-CDSS, thereby, enabling comparisons between different types of decision support. We consider different healthcare fields (surgery, nephrology, long-term care) and different degrees of decision support (alert, information, concrete recommendation for action). Furthermore, the study addresses future physicians and future nurses, which allows a closer look at the interprofessional similarities and differences. In this respect, our study represents an important enrichment of the theoretical discussion on responsibility and situations of disagreement that has taken place up to this point.

METHODS

We conducted a qualitative interview study to investigate how medical students and nursing trainees expect and assess responsibility and decision-making authority in their future clinical practice when using ML-CDSS. We used semistructured interviews with 15 medical students and 12 nursing trainees of a German maximum-care hospital. For more information on the personal characteristics of the interviewer as well as the coders (credentials, occupation, gender, experience), see online supplemental 1.

Data collection

A convenience sampling was used for data collection. Interview partners were included if they belonged to the groups of interest (medical students: fourth/fifth year of study; nursing trainees: second/third year of training), were ≥18 years old and had sufficient knowledge of German. There was no relationship established between the participants and the interviewer prior to the commencement of the study. Participants were informed in advance about the topic 'Digital Decision Support Systems and Digitisation in Medicine' before the interviews were conducted. There was no relationship established between interviewer and participants; only information about the interviewer's current affiliation and educational background was provided to the participants. All interviews were conducted via video calls between June and October 2021. Participants were generally at home and alone during the interview. They received a common expense allowance for participation. None of the participants dropped out after study enrolment.

The interviewer used a semistructured interview guide including case vignettes (see online supplemental 2). In the case of medical students, the guide included two case vignettes with ML-CDSSs to support doctors (intra-abdominal surgical navigation and the prognosis and therapy planning of chronic kidney diseases), and in the case of nursing trainees, one case vignette of a CDSS to support the monitoring of home-ventilated patients. The ML-CDSSs were selected regarding their diversity in terms of the clinical application field (surgery, nephrology, long-term care) and their degree of support (guidance for incision lines; information, prognosis estimation and therapy planning; alarm and intervention recommendation). A broad concept of responsibility was chosen due to the exploratory objective. The case vignettes were uniformly accompanied by non-theory-based questions about prospective and retrospective dimensions of responsibility. Audiorecordings and field notes were made to document the interviews. Data collection was terminated when informational saturation was reached, that is, when additional interviews did not provide any additional information about the research question.

Data analysis

Interviews were anonymised and transcribed ad verbatim. Transcripts were not sent to the participants for review. Data analysis relied on qualitative content analysis according to Kuckartz,[33] which is a multistage procedure combining inductive category building along data and theoretically derived categories. The coding system was developed collaboratively, starting from specific passages in the data to identify recurring themes and concepts. Topics typical for the research question were drawn from the literature and their occurrence in the data was investigated. We clarified coding rules for the initial coding categories and identified exemplary passages (see online supplemental 1). The coding system was constantly revised and expanded. After the coding system remained the same and the redundancy of findings did not contribute anything substantially new, we assumed theoretical saturation. The software MAXQDA (2020) was used to support the data analysis. Any ambiguities and potential disagreements were discussed critically between the first and last author and decided by consensus.

The focus during data analysis was directed at specific topics, such as the research question of the present article. All codes related were selected from the coding system. Finally, in an iterative process, types and subtypes were identified, suitable example codes were selected, translated from German and included in the article. The presentation of methods and results was guided

[i]'Peer disagreement' is used in literature to express that one expert opinion (the professional's) stands parallel to another expert opinion (that of the CDSS) and has equal epistemological weight.

Table 1 Sociodemographic data of interviewees

	Medical students	Nursing trainees
No	15	12
Average age (range, median)	25.5 years (23–36, 29.5)	25 years (20–50, 35)
Gender (self-reported)	8 ♀/7 ♂	10 ♀/2 ♂

by the Consolidated Criteria for Reporting Qualitative Research (COREQ).[34]

RESULTS

The interviews lasted an average of 51:26 min (with a range from 29:44 to 75:37 min) and the interviewees had the following sociodemographic characteristics (table 1).

In line with the interview guide, the ML-CDSSs were introduced to the interviewees, and they were confronted with two clinical scenarios: first, harm caused due to an erroneous ML-CDSS recommendation, and second, an ML-CDSS recommendation differing from their own professional judgement. Thus, they were asked about responsibility—retrospectively and prospectively—in a situation of (potentially) harmful treatment. The respondents' answers regarding these scenarios can be grouped into three strongly interrelated categories: (self-)attribution of responsibility, decision-making authority and need of (professional) experience.

(Self-)attribution of responsibility

The causation of errors and the assignment of responsibility for those errors is described as significant. This is seen as particularly difficult when ML-CDSSs are used: 'this question of when a mistake happens, who's to blame, the nurse, the person who made the robot [=CDSS], or the hospital, so that's, I think, one of the biggest complications I could imagine right now' (TI-6)[ii]. Since the error's originator is often not clearly known, interviewees hold that responsibility would lie with several entities and cite this 'shared responsibility' (SI-15) or 'joint failure' (SI-6).

Interviewees generally mention the following subjects of responsibility: developers/providers, regulatory control instances, healthcare institutions/supervisors and clinical professionals. Consensus exists that ML-CDSS could not bear responsibility. Instead, interviewees are concerned that colleagues could invoke ML-CDSS as an excuse and 'shift responsibility to the system' (SI-15).

Developers and providers were seen to be responsible for reliable functioning and would, therefore, be accountable in situations where the cause of the damage is 'faulty programming' (TI-10) or 'faulty prognosis based on a faulty weighting of statistics' (SI-8). Regulatory instances and purchasing institutions, such as hospitals or nursing services, are seen as additional assurances of reliability. However, the institutional responsibility depends significantly on the concrete use directive: exemplarily, if employees are required to use ML-CDSS or the latter are used for dealing with staff shortages, respondents determine more that the institution bears a greater responsibility. Some interviewees even recognise the risk of 'coercion': 'If I am now forced to use this support system and I actually don't feel safe with it […], then perhaps the hospital management with its guidelines would somehow also be responsible in a broader sense' (SI-2).

Respondents emphasise a professional's 'final responsibility' for decisions. One student underlines the merely supporting character of ML-CDSS: '[It] is supposed to support you in making your decisions, but ultimately you are the person who bears the risk of what decision you make' (SI-2), and 'it's my free decision whether I make the cut or not. It's not like it's forcing me to do it' (SI-2). More closely, final responsibility is characterised as the ability to critically scrutinise recommendations before action: 'And this is now a support, a tool, and I have to check and evaluate or question this tool again and again' (SI-8). The consolidation and interpretation is seen as integral part of a doctors' task: 'I think it always needs the one person who can somehow connect everything together a little bit and who then also takes responsibility for interpreting something out of it' (SI-9). Nursing trainees describe the final responsibility comparably but with a stronger reference to the caring relationship and the well-being of their patients: 'Yes, it's always still the nurse, because a device like that is all well and good, but patient observation and such is still the main task, so it's still my responsibility whether the person survives or not or whatever happens to them' (TI-1).

Although the participants see themselves as professionally responsible for treatment decisions, some problematise—in view of the complexity of ML-CDSS—that they could be no longer in a position to fulfil it: 'but if I have so much data that I can no longer keep track of it myself as a doctor, then I can also no longer actually control this algorithm' (SI-8).

Decision-making authority and coping strategies

When interviewees were asked how they would deal with a situation in which the recommendation of the ML-DCSS differs (significantly) from their own judgement, different rationales emerged.

Some point out a need for open-mindedness among human decision-makers, that ML-CDSS could perform some tasks better, and that proof of 'scientific quality criteria,' such as failure rates, would be crucial for risk assessment: 'If it has really been shown that my [decision] is usually worse than [that of] the AI, and, thus, I end up accepting fewer errors in exchange for preventing many errors on my part, then it was still the right decision to follow' (SI-6).

Contrarily, some call for human control to assume responsibility for decisions: 'to work with it, I would still like to have my complete background knowledge. I would still like to be able to control what I do and what the device tells me. So, I wouldn't want to just blindly rely on it' (SI-10). Others formulate the same fact as professionals urgently being the final bearer of decisions: 'The primary role of physicians will be not to let themselves get screwed, but to keep an eye on the fact that the final decision is made by people' (SI-11).

In order to explain the importance of taking the final decision, professionals state their necessary ability to justify themselves: 'We always have to justify ourselves for what we do. […] If I relied solely on the app without looking at the scientific basis for it, then it's my fault' (SI-13). No longer being able to decide about the correctness of an ML-CDSS recommendation is seen as a potential danger: 'That means that at some point, as a doctor who has an overview of this and can assess it again, I am in a certain way disengaged. And I just have to concentrate completely, just like the patient, on this app' (SI-8).

[ii]TI stands for interviews with nursing trainees; SI stands for interviews with medical students.

A dissenting ML-CDSS recommendation would compromise the professional's belief in her/his judgement: 'I think I would first check again all the data that I have entered. Then, of course, I would also question myself, that is, I would question myself on what basis do I come to the other conclusion. And there is, of course, again the question, how much experience do I have with the disease and with the course of the disease and on which data is the algorithm based' (SI-8). In order to resolve discrepant recommendations, joint deliberation could usually help, as it does with colleagues: 'Well, of course, I would prefer to ask […], so in the best case, the system could somehow explain to me how it came to this decision […], that I can just reassure myself' (SI-8).

However, if the ML-CDSS does not provide an explanation, different scoping strategies will be chosen. Some would prefer a consultation with (more experienced) colleagues or superiors: 'I would probably ask someone else again, because then it's basically opinion against opinion and then a third opinion is perhaps quite good to hear again' (SI-10). Given the undecidability about the 'correct' recommendation, other interviewees would communicate both versions to patients: 'Then I would, I think, openly explain the discrepancy to the patient. So, I would say, on the one hand, that's this algorithm, it comes to that result. But I personally, from my clinical experience, would see this rather positively' (SI-8).

Need for (professional) experience

Respondents initially underline ML-CDSS' potential to provide support to clinicians with less experience: 'I think the device is actually quite good if you haven't been qualified for a long time, so if you're sort of freshly qualified and you're coming to the ward' (TI-4). However, over-reliance on incorrect support is suspected especially for inexperienced professionals: 'So, if you're very inexperienced, you're more likely to stick to those kinds of systems than if you're more experienced' (SI-14). A differing ML-CDSS recommendation is compared with dealing with supervisors: 'but you don't necessarily contradict your boss, especially as a beginner. And so, then I could imagine it a bit similar with the device as well' (SI-15).

The bearing of responsibility for decision-making depends largely on sufficient (clinical) experience: 'The question is to what extent you can still decide for yourself if the robot [=CDSS] really, let's say, tells you how to cut. Would you have cut at this point, or would you have cut somewhere else? […] But that's probably where the experience that the surgeon has to bring plays a role again' (SI-7). Sufficient experience ensures that ML-CDSS recommendations could be critically scrutinised and evaluated: 'I think I would still need to have quite a lot of experience myself and know I'm about as good as this system. So, I think, if I start now as a physician, probably, I would think all the time like: 'Yeah, who's deciding?'' (SI-9). Consequently, the use of ML-CDSS is permissible only if the professionals could largely perform the decisions even without it: 'So I think, I personally, in my idea of a good education it is, I think, eminently important to gain experience and just to be able to do theoretically what the system supports even without the system' (SI-13).

Respondents conclude that standardised use of the ML-CDSS presented jeopardises both the acquisition and the maintenance of a required level of competence. Instead, there is the danger of a potential 'lack of experience' (SI-13) if the system does not function properly: 'Well, if, I don't know, it can still be that something, that it, that the system fails or something similar and then you stand in the operating room and think to yourself: 'Yeah, great. Now I don't have the support.' It can be anything, it's still technology that can fail and then if a surgeon is not trained to do it without that system, of course it's difficult' (SI-3). A nursing trainee said it similarly: 'If people only work with the device, they then get so used to it that they can no longer work stand-alone. That they suddenly stand there and no longer know what to do' (TI-4).

DISCUSSION

Respondents used 'responsibility' to describe theoretically distinctive objects, such as the positive assumption of individual moral accountability (including culpability) or legal liability. Nevertheless, when taking a relational perspective on responsibility,[13 23 24] the need of identifiable bearers of responsibility (subjects of responsibility) for clinical decision-making and its results (objects of responsibility) is consistently emphasised. Regarding clinical decision-making, respondents see it as their duty to justify—or at least to be able to justify—their clinical advice both to legal or institutional authorities and to their patients as moral authorities (addressees of responsibility). The normative standard was rarely made explicit. When this was done, interviewees mostly referred to presumptions about legal standards and to a moral obligation of justification towards patients and their autonomy.

The object of responsibility here includes even the delegation of decisions which are considered part of the physician's or nurse's role. The few studies already available indicate that physicians are willing to assign certain clinical activities to ML-CDSSs, while other tasks are considered 'as being central to who they are as physicians and as human beings'.[30] They emphasise that one of the high-valued core parts of their clinical role is a perceived 'final responsibility,' which means that they 'should always have a supervising role and, at least, every important decision should be made by (them)'.[30] To delegate responsibility within a cooperation—that is, 'share responsibility'[29]—then means handing over the supervising role for a definable task to a third party. Of course, concrete consideration should be given to what extent the decision-making is actually delegated.[19] However, there are preconditions for an assumption or assignment of responsibility.[23] For the results presented here, they can be divided into at least two requirements which are considered to be at risk when using ML-CDSSs.

First, the *structural freedom* or *institutional voluntariness*—as absence of institutional coercions—which would allow the use of ML-CDSS generally or the following of single ML-CDSS recommendations. In this sense, directives by institutional managements or superiors are seen as potential constraints to bearing responsibility. Additionally, more sublime types of coercion are seen as detrimental to responsibility, such as being pressured to use ML-CDSS in the face of human resource constraints or monetary profitability.

Second, the *epistemic freedom* or *level of information*, in which it is presupposed to have the necessary—mainly cognitive—competencies to make ML-CDSS advice seriously useful for the professional's decision-making. To make this possible, sufficient medical and technical background knowledge, practical experience in clinical decision-making without an ML-CDSS[14] and a comprehensible presentation of its outcomes are considered to be prerequisites. The alleged coping strategies if respondents do not (or no longer) see themselves in the epistemic position to reliably synthesise the ML-CDSS recommendation with their own judgement, that is, do not have the decision-making authority, are interesting. Professionals would seek advice from either colleagues or more experienced supervisors to ascertain 'shareable reasons' for weighing the ML-CDSS recommendation (as Kempt and Nagel suggested[29]). In this case, reasons for or against the final advice to the patient are deliberated between clinicians.[7 18 29] Alternatively, they would pass on the decision-making authority regarding the preferable advice to the patient (cf. the 'irresponsible outsourcing of responsibility' by Di Nucci[19]).

If professionals are structurally and epistemically able to act differently, they see themselves as responsible for their decision-making. Once one or both dimensions are restricted, the bearing of responsibility is assessed to be gradually reduced or even impossible.

The study results highlight the need of further balancing responsibility with other normative claims as well as the importance of preconditions. Insofar as the professionals continue to see themselves as integrated in a process of responsibility, this can lead to greater acceptance of normative regulations to meaningfully enable professionals to embrace responsibility as a bottom-up strategy with regard to shared responsibility. The study results are ambivalent insofar as the withdrawal or rejection of responsibility due to epistemic and/or structural limitations can also be observed. With regard to a normative solution, caution is required, not least in the interweaving with potential affected parties and their needs. Further investigations concerning the concrete epistemic and structural challenges are needed.

As a limitation of this study's results, it must be kept in mind that interviewees had little clinical experience. We also assume that especially those who were relatively more interested in questions of digitalisation of healthcare agreed to participate (selection bias) which might have had an influence on the answering behaviour.

CONCLUSIONS

Bearing responsibility for clinical decisions is linked to several requirements that were brought to the fore by our interview study. Particularly, structural opportunities for or against the use of ML-CDSS as well as a sufficient level of competency and clinical experience to meaningfully scrutinise ML-CDSS recommendations—that is, to have decision-making authority—were highlighted as necessary requirements. Even if the use of ML-CDSS may lead to shifts in roles and responsibilities,[6 35] legal and moral 'responsibility gaps'[12 36–38] should be prevented. As long as clinical professionals are assigned with the responsibility of being the final decision-maker, respectively, supervisor of ML-CDSS, they should also be given sufficient opportunities and qualifications to fulfil this responsibility. The ML-CDSS potentially offer numerous prospects to improve healthcare. However, the empirical findings illustrate that using ML-CDSS will require a consistent and transparent allocation of responsibility, not only for reasons of acceptance but also for the benefit of moral embedding.

Contributors SS, ADK, ST and HUZ conceptualised the study. ST and SS developed the interview guide; DS reviewed it. ST did the interviews with medical students and nursing trainees. WL and ML contributed to the conceptual background. FF performed the data analysis and interpretation and drafted the manuscript. WL, DS, ML and SS contributed to the data interpretation and discussion. All authors reviewed and approved the final version of this manuscript. FF is the guarantor for the overall content of the paper.

Funding This study was funded by Bundesministerium für Bildung und Forschung (ID 01GP1911A-D, ID 01ZX1912A).

Competing interests HUZ is the scientific coordinator of the junior consortium CKDNapp, which is developing a CDSS for practicing nephrologists which was used for this study. She had no involvement in developing the interview guide, conducting the interviews or analyzing the interviews.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants and this study was approved by the Research Ethics Committee of Hannover Medical School, Germany (Reg. No. 9805_BO_K_2021). All participants provided written informed consent to participate in this study. Participants gave informed consent to participate in the study before taking part.

Provenance and peer review Not commissioned; externally peer reviewed.

Data availability statement Data may be obtained from a third party and are not publicly available. The data are not publicly available as they might contain information that could compromise research participant privacy and consent.

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Supplement 1: Prospective nurse's interview guide and presentation of the used CDSS

Guiding question(s)	Aspects to be addressed/ concrete demands	Maintenance issues/ control issues
Topic complex I: Entry		
Dear Sir/Madam... Nice of you to take the time to talk to me today about digital decision support systems in healthcare. Thank you very much for your time. If you like, we can be on a first-name basis. Is that okay with you? Your participation in this interview is of course voluntary and you can withdraw your consent to participate in the study at any time without giving any reason. We will record the interview so that I can concentrate on it better, and an external transcription office will then transcribe it. The interview data will then be analyzed by our study team – of course, with strict confidentiality and non-disclosure. When we publish our results, there are only a few, short quotes (usually single sentences) in the publications. However, readers will never be able to attribute the quotes to a person (i.e., data are anonymous to readers). (Within the research team, attribution is possible using a pseudonymization list – as long as it exists). Are you okay with me recording our conversation from now on? *[If participant agrees, turning on the recorder – if not, taking notes.]* So, our conversation is now being recorded. We have already talked about the fact that your participation in this research project is, of course, voluntary. You can stop or interrupt the interview at any time. Feel free to go into as much detail as you see fit in the conversation; we have time. There are no wrong or right answers. We are interested in *your* experiences and assessments, which means that you are now the expert. You can be absolutely honest; we will not judge any answers. Do you have any questions about the interview process? Initial question: To what extent is the topic "digitization in medicine" an issue for you at all (studies, exchange with fellow students, etc.)?		

Supplement 1: Prospective nurse’s interview guide and presentation of the used CDSS

Topic complex II: Operating room of the future/surgery navigation		
[*Presentation of case vignette 1.*]		*Can be used for all topic complexes:*
Please describe your first thoughts about this system.	What do you spontaneously find good about using that system during surgery compared to surgery without the support of that system? And what do you spontaneously find less good or even bad about using this system?	Can you describe this in more detail? Why don’t you tell us a little bit more about it? Can you give an example of/for…?
To what extent would you like to use this system yourself in your daily work in the future?	What would be necessary for you to use this system yourself? (e.g., training, fitting into workflow, ...)	Would/Did that matter to you? What happened next?
Imagine that the system gives you an incision recommendation which you follow, but you hit a nerve tract, causing incontinence in the patient. Please describe your thoughts on this scenario!	Imagine that the patient now asks you what exactly happened and how it could have happened. What do you tell your patient? To what extent should your patient understand the system? To what extent should you inform your patients that they will be operated on using this system? Does your patient have to consent to the use of the system? To what extent would you feel responsible for the consequences of the surgery?	What do/did you think? Can you think of anything else to say about that? How did it actually come about that ...?

Supplement 1: Prospective nurse's interview guide and presentation of the used CDSS

Imagine that the system recommends you a cutting line that you think is too risky. How do you behave in this situation?	To what extent would you hold others responsible? Do other persons/instances (e.g., developer, system, hospital) play a role? Under what conditions would you not follow the system's recommendation? What does it take for you to trust the system?	
Topic Complex III: Nephrologists Prognosis and Therapy Planning App		
[*Presentation of case vignette 2.*] Please describe your first thoughts about this app.	What do you spontaneously find good about using this app? And what do you not find so good or even bad?	
To what extent would you like to use this system yourself in your daily work in the future?	Are there any requirements?	
Imagine that the app predicts a very favorable progression of the disease for your patient. In reality, however, the disease progresses extremely poorly and your patient has to go on dialysis regularly just a few weeks after your conversation. What are your initial thoughts on this scenario?	The patient asks you how exactly this incorrect prediction of the progression of the disease could have come about. What do you answer your patient? To what extent should your patient understand the system? To what extent should you inform your patients that the app is affecting your recommendations? To what extent would you feel responsible for the incorrect prognosis?	

Supplement 1: Prospective nurse's interview guide and presentation of the used CDSS

Imagine that the nephrology app predicts that your patient's disease will progress much worse than you think. Why don't you describe how you would deal with this situation?	To what extent would you hold others responsible? To what extent do other instances/persons play a role? Which progress of the disease do you report to your patient? Should you tell your patient about both progressions of the disease? Imagine that the patient asks you which progression (s)he is more likely to get. What do you answer? What does it take for you to trust the system?	
Topic complex IV: Training		
What do you think you need to be able for working well with such systems as the ones presented? To what extent do you feel prepared to use such systems yourself?	To what extent do you think you should understand the system or the app? How did your studies contribute to your preparation? What do you like to see in your studies to improve your preparation? What would you like to see in your future postgraduate residency training? What do you think about acquiring the necessary competencies alongside your job?	

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	Is "learning by doing" enough for you or do you wish for further training? How has your private use of digital devices contributed to your preparation? (Do you perceive differences within your own generation?)	
Other		
For the development of clinical decision support systems we need data sets – e.g. patient data. To what extent do you see your future task in contributing to good data sets? Is there anything else you'd like to get off your chest that we haven't addressed yet?		
Socio-demographic Check-list		

1. Gender
   - ♀
   - ♂
   - other

2. May I ask your age?_____________

3. How long have you been studying human medicine? In which semester are you?_____________

4. Have you already completed other training/courses of study?
   - No
   - Yes: Which ones?_____________

5. Have you gained practical experience independently of your course of study?
   - No
   - Yes: In which area? _____________

Supplement 1: Prospective nurse's interview guide and presentation of the used CDSS

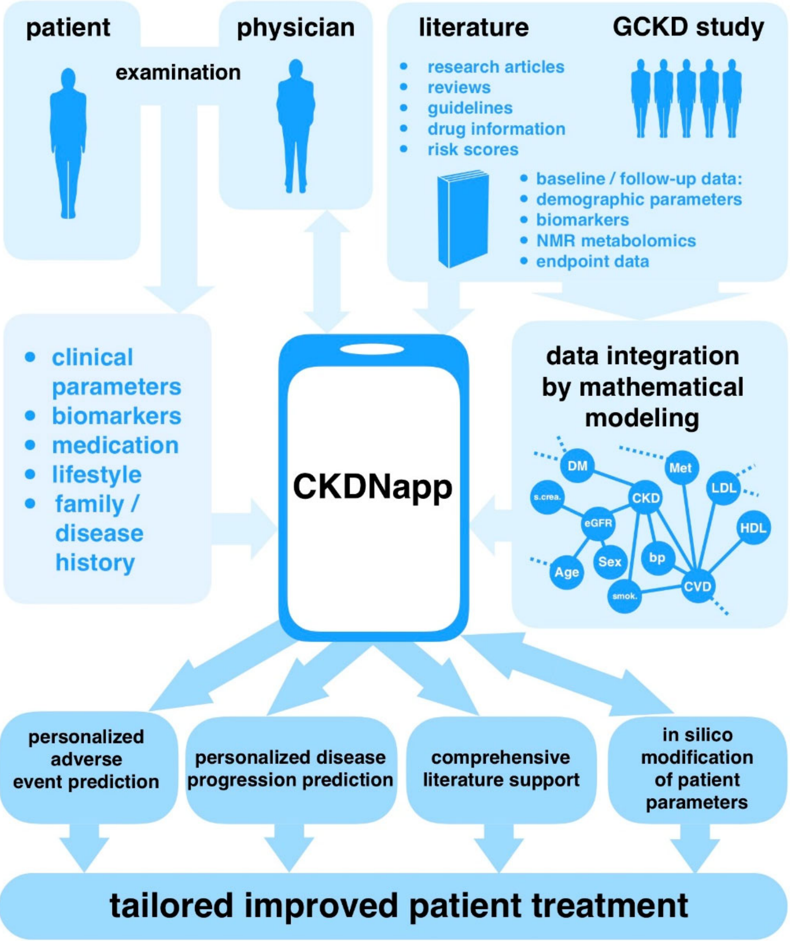
Presentation of "Operating room of the future" (computer-based + ML-supported assistance system, surgical navigation device)

- I would like to introduce you to a decision support system whose field of application is in surgery, I would be interested in your opinion about it.
- To illustrate, I'll show you a short video [play entire video]: https://www.youtube.com/watch?v=jJDANlCdMCg&t=155s
- I repeat and add: The decision support system is intended to assist the surgeon during surgery by indicating an optimal incision line (incision direction and risk structures that must not be violated).
- Objective: avoidance of patient harm, shortening of the operating room time
- Can be used when a rectal resection must be performed on a patient diagnosed with rectal cancer, can be performed laparoscopically (laparoscopy – reference to video).
- The Decision support system helps surgeons remove pathological tissue, preserve healthy tissue, not injure nerve pathways or major vessels during surgery by displaying the incision line + risk structures
- Thus, no functional restrictions such as incontinence or impotence as a result of the surgery in the patient (which are otherwise common in rectal surgery).
- Especially helpful in difficult surgical phases, e.g., in case of poor visibility due to adhesions, or for inexperienced surgeons
- Suggestions for incising are displayed to surgeons on a screen (as in the video), alternatively they can also work with digital glasses (system as a supplement to DaVinci)
- How is this assistance function created? (Function: show the best cut and certain risk structures that must not be violated).
    - AI (specifically: machine learning) is used to create the assistance function
    - Here, a system learns to perform these functions using examples from the past
    - What examples are used to learn here?
        - Surgical videos of the Da Vinci Surgical System
        - Individual images are isolated from these videos and then manually entered on them what you see there (e.g., where is the large intestine, where is the small intestine, where are nerves to be spared, where is the narrow area where cutting is allowed)
        - System is fed with these images and learns in this way "like a toddler" (e.g., what a large intestine looks like)
        - we cannot say what exactly the system has learned to distinguish the colon from the non-colon (we have only fed the system with pictures on which information is noted, like "this is the colon").
    - System learns in this way where risk structures are and how deep a surgeon may cut
    - During surgery, the system now receives live images of the patient's abdomen, plus preoperative images, and compares these with what it has learned in advance
    - It then shows the surgeon the optimal incision line or even the location of important nerves on the screen or data glasses – i.e., the system superimposes this information on the camera data of the abdomen of the patient lying on the operating table.

Supplement 1: Prospective nurse's interview guide and presentation of the used CDSS

Presentation of the CKDNapp (Chronic Kidney Disease Nephrologist's App)

- I would like to introduce you to a Clinical Decision Support software that is provided for smartphones, tablets, PCs and can be used in the internet browser or as an app.
- This is another example of one of many decision support systems for doctors and I would be interested in your opinion on it.
- This decision support system is designed to assist nephrologists in the care of patients with chronic renal failure.
- It is well known that chronic renal failure is one of the most common causes of death and a very complex disease, the progression of the disease is very individual, there are many concomitant diseases.
    - Current condition and expected disease progress of a patient with chronic renal failure depends on numerous different parameters (e.g., demographic, disease history, lifestyle, and medication parameters).
    - Traditional and novel biomarkers can also provide information about future patient condition.
- In order to provide optimal care to patients with chronic kidney disease, physicians must collectively evaluate and integrate all of these disparate and complex data based on medical knowledge (only then can therapy be personalized)
- The system supports the physician in the complex process of data integration and thus in personalized treatment of patients.
- I would like to describe you the decision support system in more detail with help of this graph (see right).
    - The patient diagnosed with renal insufficiency consults a nephrologist.
    - Diagnosis by nephrologist: (S)he takes medical history and performs further examinations (e.g., urine examination, blood test).
    - The nephrologist then enters this extensive patient data into the software.
    - In addition: all available laboratory test results, if necessary,

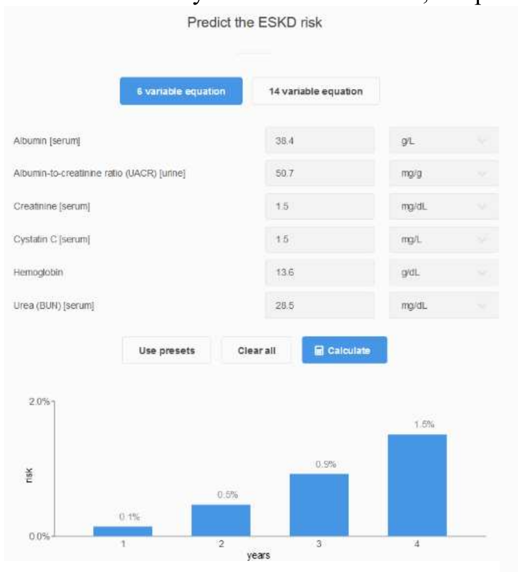


Graph 1: Schematic workflow of CKDNapp's development and application (cf. online: https://www.sys-med.de/de/juniorverbuende/ckdnapp/). Copyright: Michael Altenbuchinger and Helena U. Zacharias.

Supplement 1: Prospective nurse's interview guide and presentation of the used CDSS

from other specialists.

- CKDNapp uses these data to match them with results from digital databases (parameters of other patients) and digital libraries; here complex algorithms work in the background. The App is built on two pillars (see diagram):
  - First pillar: comprehensive mathematical diagnostic and prediction models (e.g., for personalized prediction of cardiovascular events, end-stage renal failure, or patient death)
    - These models are learned using data from the "German Chronic Kidney Disease" study, for example demographic, clinical data, biomarker data or metabolome data (i.e., the elaborate study of biochemical metabolites)
    - Integration of all these patient parameters is performed using the latest machine learning methods
    - (Focus on metabolism: Metabolites are intermediate/final products of the body's metabolism and are found in all body fluids/tissues. The kidney is one of the main regulators of metabolism. If kidney function is disturbed, metabolism becomes disordered and is then reflected in an altered composition of numerous metabolites in the blood/urine. Metabolites can serve as biomarkers for the patient's current physiological state, but also to predict future events).
    - The German Chronic Kidney Disease is one of the world's largest observational studies of kidney disease with over 5,000 patients followed for over 10 years.
    - The learned mathematical models are fed into the app in a fixed way (not the data from study).
  - Second pillar: Comprehensive collection from already identified risk predictors found in the scientific literature.
  - Based on these two pillars, software can enable various functions:
    - It provides personalized predictions for adverse medical events and disease progression (tells us probabilities for e.g., acute renal failure, cardiovascular or cerebrovascular events, death, complications such as gout flares) (currently we are talking about a 4-year period); CKDNapp also shows which predictors are behind this evaluation.
    - Extensive literature support (research articles, guidelines, drug information, established risk scores).
    - The software enables in-silico changes of patient parameters (virtually change patient parameters and simulate the resulting disease development: This means digital testing of lifestyle adaptations like weight loss or smoking cessation).
- I would like to demonstrate one more core element of the decision support system: A calculator to estimate individual risk of developing end-stage renal disease requiring dialysis or kidney transplantation within one, two, three or four years.
  (The interviewer opens the risk calculator [https://ckdn.app/tools/eskdcalc/], enters values [first using the default settings, then changing values – creatinine value first to 6 milligrams per deciliter, then to 13] and presents the results.



Graph 2: Exemplary CKDNapp's result (cf. Zacharias, H.U., et al.: A predictive model for progression of CKD to kidney failure based on routine laboratory tests. *American Journal of Kidney Diseases* 79,2 (2022): 217-230). https://ckdn.app/tools/eskdcalc/

Supplement 1: Prospective nurse's interview guide and presentation of the used CDSS

Guiding question(s)	Aspects to be addressed/ concrete demands	Maintenance issues/ control issues
Topic complex I: Entry		
Dear Sir/Madam... Nice of you to take the time to talk to me today about digitalization and digital decision support systems in healthcare. Thank you very much for your support of our research. If you like, we can be on a first-name basis. Is that okay with you? Your participation in this interview is of course voluntary and you can withdraw your consent to participate in the study at any time without giving any reason. We will record the interview so that I can concentrate on it better, and an external transcription office will then transcribe it. The interview data will then be analyzed by our study team – of course, with strict confidentiality and non-disclosure. When we publish our results, there are only a few, short quotes (usually single sentences) in the publications. However, readers will never be able to attribute the quotes to a person (i.e., data are anonymous to readers). (Within the research team, attribution is possible using a pseudonymization list – as long as it exists). Are you okay with me recording our conversation from now on? *[If participant agrees, turning on the recorder – if not, taking notes.]* So, our conversation is now being recorded. We have already talked about the fact that your participation in this research project is, of course, voluntary. You can stop or interrupt the interview at any time. Feel free to go into as much detail as you see fit in the conversation; we have time. There are no wrong or right answers. We are interested in *your* experiences and assessments, which means that you are now the expert. You can be absolutely honest; we will not judge any answers. Do you have any questions about the interview process?		

Supplement 1: Medical student interview guide and presentation of the used CDSS

Topic complex II: Digitalization in healthcare and nursing		
Let's start in general and you simply report what comes to your mind: To what extent is the field of "digitalization in care" a topic for you at all? (*Focus on the use in patient care, if the interview partner does not come up with this on their own*.) What opportunities do you think digitalization will bring to care? (*If no examples are given by the interviewee, give three different examples: Nursing robot, bed exit system, hospital information system*.) What risks and fears do you think digitalization will bring to care? How will your profession change through the use of modern technologies?	How did you encounter the topic in the context of your training? In theory? In practice? Exchange with classmates/colleagues? Free time? Do the opportunities or the risks predominate for you? Are you more positive or negative minded about digitalization in care? What tasks that used to be the job of nurses can you think of that would be better handled with the help of modern technology?	*Can be used for all topic complexes:* Can you describe this in more detail? Why don't you tell us a little bit more about it? Can you give an example of/for…? Would/Did that matter to you? What happened next? What do/did you think? Can you think of anything else to say about that? How did it actually come about that ...?
Topic Complex III: DSS for home respiratory care (The "Safety Box")		
[*Presentation of the Safety Box (long-term use, emergency situation)*.] Please describe your first thoughts about this system.	What do you spontaneously find good about using this app? [*Hopes*] And what do you not find good or even bad about using this system?	

Supplement 1: Medical student interview guide and presentation of the used CDSS

	[*Concerns*]	
To what extent would you like to use this system yourself in your daily work in the future?	Are there any requirements?	
Imagine you are caring for three patients in a respiratory care residential group. Now that the safety box has been introduced, you are no longer responsible for three patients, but five. How comfortable would you feel with this situation?	All five safety boxes show no alarm signals. How reassured do you think you would be if you left the residential group?	
	To what extent should you inform your patients, if they are conscious, about the use of the safety box?	To what extent do patients need to understand the system?
	To what extent must the patient or the legal representative give his/her consent?	
	If something goes wrong, i.e., the safety box does not trigger an alarm even though the situation actually requires it – who do you think should bear the responsibility for the consequences?	To what extent do others bear responsibility/parts of responsibility? Does the developer or the system itself play a role?
Imagine that the safety box repeatedly sounds an alarm and prompts you to check the connection of the ventilation hose. However, you do not identify a disconnection of the ventilation hose or any other hazardous situation. What should you do?	In the end, do you rely more on your assessment or on the safety box?	
To what extent do you think the use of such a system will have an impact on the relationship between you as a nurse and the patient?		

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To what extent would it make a difference to you whether this system is used for the care of patients in respiratory care residential groups or for the care of patients in their own home environment? What impact do you think will the use of such a system in nursing have on the labor market?	Where would you rather use the system?	
Topic complex IV: Training		
What do you think a nurse needs to be able to do in order to work well with systems like the one presented? To what extent do you feel prepared to use such systems yourself?	To what extent do you think a nurse should understand the system? How did your training help to prepare you? What would you like to see in your training in terms of better preparation? What do you think about acquiring the necessary skills while working? Is “learning by doing” enough for you or do you wish for further training? How has your private use of digital devices contributed to your preparation?	
Other		
Is there anything else you’d like to get off your chest that we haven’t addressed yet?		
Socio-demographic Check-list		

Supplement 1: Medical student interview guide and presentation of the used CDSS

1. Gender
   - ♀
   - ♂
   - other
2. May I ask your age?____________
3. How long have you been in nursing training? ____________
4. Have you already completed other training/courses of study?
   - No
   - Yes: Which ones?____________
5. Have you gained practical experience independently of your training?
   - No
   - Yes: In which area? ____________

Presentation of the “Safety box” (not self-learning, purely rule-based)

- I would like to introduce you to a decision support system that can be used in home respiratory care.
- Objective: Care of ventilated patients – usually high-risk patients – even more safely in their home environment and to relieve nursing staff (or family caregivers).
- It’s used for tracheotomy patients, i.e., patients who are ventilated via an artificially created tracheal opening (with no to little self-breathing).
- The system recognizes medical emergencies in the home environment (e.g., disconnection of the ventilation tube), reacts to this with an alarm and with instructions for action for the nursing specialist (or for the caring relatives), in certain cases the home emergency call dispatcher is informed.
- The probability that patients suffer serious harm (e.g., hypoxia) decreases.
- With the help of this photo, I would like to give you a better understanding of the decision support system: [*Interviewer shows graph 1*.]
  - Photo was taken at a congress, normally the system has its place at the ventilated patient’s home or room.
  - We see a bed on which the patient is lying.

Graph 1: Photograph of the “Safety Box” setting.

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- Ventilation tubes are leading away from and towards the patient, connected to the ventilator on one side and to the tracheostoma (surgically created opening of the trachea) on the other side.
- To the left side of the bed you can see the ventilator, which can be used to make various settings (how much oxygen the patient receives, what intensity, etc.).
- In the top corner you see a small presence sensor (thermal imaging camera), which is mounted so that the patient and people in the immediate vicinity are detected.
- Above the ventilator you see a monitor on which you can read various parameters (e.g., heart rate, ventilation parameters, blood pressure) – I will show you exactly what you can read in a moment.
- The small white-green box between monitor and ventilator is the safety box, which receives all important metrics and information:
    - Metrics of the home ventilator: information about the settings of the ventilation parameters, the parameters currently present, information about the oxygen saturation, ventilation frequency.
    - Information of the motion sensor: number of persons present in the room and time information (how many persons were in the room how many minutes ago).
    - Information about which activities were last performed on the patient (nursing actions are not entered in safety box by nurse, safety box is not a documentation system; images from thermal imaging camera provide information about actions of persons present – images are stored for a defined period of time)
    - Blood pressure values via blood pressure monitor.
- Safety box evaluates all these data and gives a recommendation on possible courses of action based on algorithms (sequence of unambiguous instructions that enables computer to solve problem). [*Interviewer shows graph 2*.]
    - In an emergency situation a normal alarm tone of the safety box is heard, in addition the nurse receives instructions for action.
    - Such an instruction can be, for example, the request: "Please check the connection to the ventilation tube"; such emergency measures can be read on the monitor, but we also get verbal instructions via an audio track, these instructions give emergency measures (which should stabilize the condition of the patient, maintain the circulation, etc.).
    - Thus, there is no long search for causes of problems, the nurse is immediately shown what to do in this emergency situation.
    - In addition, you can see the following on the monitor in this emergency: [*Interviewer shows graph 3*.]
    - We can read that there is a life-threatening emergency.
    - Ventilation is not ensured because the tube system is leaking, oxygen saturation drops below the alarm limit (red lung), there is no person in the room (last one left the room 10 minutes ago), no information about the respiratory rate, battery charge of the ventilator 180

Graph 2: Diagram with instructions in case of emergency.

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    minutes, heart rate and blood pressure are normal.
    - "Call triggered: Safety box automatic": Here you can set in advance who should be informed by a call in a triggering situation or in an emergency – you can set a direct connection to the home emergency call, to the caregiver, to the family member.
    - Examples of other possible dangerous situations and decisions for action that can be identified or specified by the system: 1.) "Please use suction because the ventilation hose is blocked", 2.) "Please check the cuff pressure", 3.) "Ventilation problem, please remove the machine and use a resuscitator bag", 4.) "Cardiovascular failure, please perform cardiac massage and place a board under the chest" (in some cases, very precise instructions for the procedure).
- When using the "Safety Box" nurses should reflect their action, not implement recommendations one to one.
- So far there is only a display on the ventilator that indicates, for example, increased ventilation pressure, but gives no indication of the cause. The "Safety Box" shows the nurses which pressure increase is due to which causes.
- Due to the high time requirement, respiratory care is shifting more and more to shared apartments, where there is no one-to-one care, i.e., there are even fewer nurses who can be reached at the same time.

Graph 3: Data in case of emergency.

Supplement 2: Coding tree and personal characteristics about interviewer and coder

Overarching categories	Coding rule	Number of codes assigned (percentage of total codes)
"Expectation of positive effects"	The category "Expectation of positive effects" is coded when statements are made about ... ... positive aspects (e.g., benefits, hopes, wishes) of digitization in general and ... positive aspects of the (presented) DSS in particular.	425 (11.7 %)
"Expectation of negative effects"	The "Expectation of negative effects" category is coded when statements are made about ... ... negative aspects (e.g., disadvantages, dangers, fears) of digitization in general and ... negative aspects of the (presented) DSS in particular.	301 (8.3 %)
"Reliability of the technology"	The category "Reliability of the technology" is coded when statements are made about... ... the correctness of the technical analyses, ... faulty analyses as well as the handling of them, ... the trust in technical systems or about aspects of a trustworthy technology (e.g. diversity/non-discrimination/fairness, robustness/security, cf. guidelines of the EU Commission).	329 (9.0 %)
"Traceability/Comprehensibility of decisions"	The category "Traceability/Comprehen-sibility" is coded when statements are made about... ... the weighting/importance of traceability in decisions in general, ... about the importance of traceability in decisions made by people (physicians/nurses), ... about the importance of traceability in decisions made on the basis of algorithmic analyses, ... about measures how traceability could be established (e.g., transparency, explicability of algorithmic results, explanations about medical treatments).	135 (3.7 %)
"Trust in human actors and institutions"	The category "Trust (in human actors and institutions)" is coded when statements are made about... ... the expectation that an event or action important to the speaker, which is in the context of digitized medicine/nursing (especially DSS use), will occur or be carried out in a way desired by the speaker but at the same time not controlled, … expectations of medical and nursing staff, themselves, and relevant institutions (e.g., facility providers, manufacturers, legislators), … someone else who has or should have such expectations (e.g., when medical students talk about their future patients).	139 (3.8 %)
"Trust in/reliance on technical systems"	The category "Trust in/reliance on technical systems" is coded when statements are made about… ... trust in/reliance on technical systems, ... the necessary preconditions for trust in/reliance on technical systems (if they do not directly concern "reliability" or "comprehensibility"), e.g., individual experience with the CDSS.	364 (10.0 %)

Supplement 2: Coding tree and personal characteristics about interviewer and coder

“Decision-making authority”	The category “Decision-making authority” is coded when statements are made about ... ... whether the recommendation of the DSS or the professional’s own judgment (especially in the case of disagreement) is given greater weight, ... how to proceed if the professional’s assessment differs from that of the DSS.	298 (8.2 %)
“Responsibility”	The category “Responsibility” is coded when statements are made about ... ... who (why) assumes or should assume responsibility for (the consequences of) (medical or nursing) actions influenced by a DSS.	352 (9.7 %)
“Competencies”	The category “Competencies” is coded when statements are made about ... ... Competencies required by medical or nursing staff for dealing with (the presented) DSS in particular, ... Competencies that medical or nursing staff acquire or should acquire for digitized medicine or digitized care, ... the understanding of the technologies that medical and nursing staff and patients (should) have, ... competencies that patients need in the context of digitized medicine or digitized care, ... competencies that patients need in the context of the DSS presented.	551 (15.1 %)
“Role setting”	The category “Role Setting” is coded when statements are made about ... ... the doctor-/nurse-patient relationship in the actual or imagined setting with and without modern technologies (incl. DSS), ... (possible) effects of the use of DSS on the doctor-/nurse-patient relationship, ... the (expectations of) roles of the human actors in the setting (doctors, nurses, patients, relatives, etc.), ... role changes of the human actors in the setting (doctors, nurses, patients, relatives, etc.).	160 (4.4 %)
“Patient education”	The category “Patient education” is coded when statements are made about ... ... whether and how patients should be informed in advance about the use of DSS, ... whether patients should consent to the use of DSS or whether they may refuse the use of DSS, ... what patients should be told in the event of harm in the context of the use of a DSS.	338 (9.3 %)
“Comparison between DSS and other systems/instruments”	The category “Comparison between DSS and other systems/instruments” is coded when statements are made... ... to what extent the presented DSS differs from other systems and instruments used in the medical or nursing context, ... to what extent one of the presented DSS differs from the other presented DSS.	81 (2.2 %)
“Other”	The category “Other” includes other aspects that are not included in the above categories, but which are related to the topic of DSS.	136 (3.7 %)

Supplement 2: Coding tree and personal characteristics about interviewer and coder

Personal characteristics about interviewer and coder (according to COREQ Statement)

	Interviewer (ST)	**Main Coder (FF; first author)**	**Co-Coder (SS; last author)**
Credentials	M. Ed.	M. D., M. A., Mag. theol.	M. D., Ph.D.
Occupation	research associate (Institute for Ethics, History and Philosophy of Medicine)	research associate (Institute for Ethics, History and Philosophy of Medicine)	professor, head of institute (Institute for Ethics, History and Philosophy of Medicine)
Gender	female	male	female
Experience and training	Bachelor's/Master's degree (German language and literature, Protestant theology, educational sciences; philosophy as extension subject); research experience in the field of applied ethics and qualitative social research/participation in various workshops.	University degrees in medicine, philosophy and catholic theology; research experiences in the field of medical ethics, especially digitization of medicine, patient will, and doctor-patient communication.	University degrees and doctoral degrees in medicine and philosophy; research experiences include empirical-ethical research, ethical issues at the end of life, professionalism and interprofessionalism in health care, and ethical issues of digitization in medicine.
Relationship to interviewees prior to study commencement	No	No	Not known (potentially some interviewees could have been listeners in university courses about "Medical Ethics")

Interviewees were informed about the topic "Digital Decision Support Systems and Digitization in Medicine" before the interviews were conducted. Only information about the interviewer's current affiliation and educational background was provided to the interviewees.