Aus dem Institut für Medizinische Informatik
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DISSERTATION

Implementierung von digitalen Gesundheitstechnologien in der Intensivmedizin: Eine Mixed-Methods-Studie mit Entwicklung eines Implementierungsframeworks
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Implementing Digital Health Technologies in Intensive Care: A Mixed Methods Study with Development of an Implementation Framework

zur Erlangung des akademischen Grades
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List of Abbreviations

AI	Artificial intelligence
CDSS	Clinical decision support systems
CFIR	Consolidated Framework of Implementation Research
CME	Continuing medical education
ERIC	Expert Recommendations for Implementing Change
etCO2	End-tidal carbon dioxide
EWS	Early warning score
ICU	Intensive care unit
IMCU	Intermediate care unit
PACU	Post anesthesia care unit
PhD	Doctor of Philosophy
PR	Pulse rate
RR	Respiratory rate
SOP	Standard operating procedure
SpO2	Peripheral capillary oxygen saturation
SWOT-analysis	Strengths-weaknesses-opportunities-threats-analysis

Zusammenfassung

Hintergrund: Neue digitale Gesundheitstechnologien könnten patientenbezogene Outcomes verbessern und die Arbeitsbelastung des Personals reduzieren. Ihre Einführung in die klinische Routinepraxis auf Intensivstationen verläuft jedoch schleppend. Im Kontext der Implementierung eines neuen Patientenmonitoringsystems auf einer Intensivstation untersuchten wir Erwartungen des Personals an die Monitoring-Technologie, validierten sie und entwickelten ein Implementierungsframework für digitale Gesundheitstechnologien auf Intensivstationen.

Methoden: Wir verfolgten einen explorativen Mixed-Methods Forschungsansatz. Die Datenerhebung umfasste semistrukturierte Interviews, Feldbeobachtungen und Fokusgruppen, die induktiv und deduktiv analysiert wurden, sowie einen Onlinefragebogen, der deskriptiv ausgewertet wurde. Das Implementierungsframework wurde induktiv und deduktiv aus der Datengrundlage heraus sowie aufbauend auf evidenzbasierten Rahmenwerken entwickelt.

Ergebnisse: Das Personal wünschte sich für ein zukünftiges Patientenmonitoring drahtlose Sensoren, höhere Benutzerfreundlichkeit und ein optimiertes Alarmmanagement. Sie bewerteten viele falsch-positive Alarme problematisch und forderten mehr Training mit neuen Geräten. Auch in der Validierungsstudie wurden zu viele falsch-positive Alarme (n=60, 70% wählten "stimme voll zu" oder "stimme zu") und zu viele Sensorkabel (n=66, 77%) bemängelt. Das Personal befürwortete den Einsatz von Patientenfernüberwachung um früher alarmiert zu werden (n=55, 65%), und von durch Künstliche Intelligenz gestützte Entscheidungshilfesystemen für die Früherkennung von Komplikationen (n=67, 79%). Für eine höhere Nutzung solcher Systeme seien Interoperabilität (n=79, 93%), Benutzerfreundlichkeit (n=78, 93%) und mehr Schulungen (n=75, 90%) sinnvoll. Zur Verbesserung der Implementierung sollten qualitativ hochwertige und regelmäßige Mitarbeiterschulungen, ein klares Leitungsengagement für das Projekt und Feedbackmöglichkeiten vorhanden sein. Das Implementierungsframework für digitale Gesundheitstechnologien auf Intensivstationen enthält Strategien, die vor, während und im allgemeinen Kontext der Implementierung angewandt werden können, wobei die Benutzerfreundlichkeit und Anpassungsfähigkeit der Intervention, die Einbeziehung des Personals, die Kommunikation und die Evaluierungsstrategien im Mittelpunkt stehen.

Schlussfolgerungen: Die Implementierung digitaler Gesundheitstechnologien in spezialisierten Settings wie Intensivstationen muss sorgfältig geplant werden. Im Fokus steht die Einschätzung der Anpassungsfähigkeit der Technologie, die mit nutzerzentrierten Methoden verbessert werden sollte, u.a. durch die Einbeziehung des interdisziplinären Personals und eine klare Kommunikation des Projekts. Zudem sollten Anforderungen für die Implementierung kontinuierlich neu eingeschätzt werden. Das Framework kann Verantwortlichen in der Implementierungspraxis als Leitfaden dienen.

Abstract

Background: In the context of the digital transformation of healthcare, technologies such as tablet-based remote patient monitoring systems promise to improve patient-related outcomes and reduce workload of healthcare staff. However, the introduction of novel digital technologies into routine clinical practice, e.g. in intensive care units (ICUs), is still lagging behind. In the context of implementing a remote patient monitoring system, we aimed to explore expectations of ICU staff regarding patient monitoring, validate them, and develop an implementation framework for digital health technologies in the ICU.

Methods: We followed an exploratory research approach using mixed methods. The data collection included semi-structured interviews, field visits and focus groups; and an online cross-sectional survey to validate the insights gained. We derived the implementation framework applying inductive and deductive analysis. The deduction was oriented towards the categories of the Consolidated Framework for Implementation Research and the Expert Recommendations for Implementing Change.

Results: Staff expectations regarding novel patient monitoring solutions included introducing wireless sensors, enhanced usability and optimized alarm management. Many false positive alarms due to poor alarm hygiene were considered problematic, more training with new devices was demanded. In the validation study, staff members stated that high rates of false-positive alarms (n=60, 70% chose “Strongly agree” or “Agree”) and too many sensor cables (n=66, 77%) would disturb patient care. They supported using remote patient monitoring for earlier alerts (n=55, 65%) and artificial-intelligence-powered clinical decision support systems for early detection of complications (n=67, 79%). To promote usage of such systems, respondents suggested more interoperability (n=79, 93%), high usability (n=78, 93%) and more training with technologies (n=75, 90%). High quality and regular staff training, clear leadership commitment and feedback opportunities for staff should be installed for improved implementation. The presented framework compiles strategies to apply before, during and in the general context of the implementation, focussing on usability and adaptability of the intervention, staff involvement, communication, and evaluation strategies.

Conclusions: The implementation of digital health technology in specialized settings like the ICU requires a high level of staff resources and commitment. It is important to test the

adaptability of the technology and improve it with a user-centered approach in design and implementation. The implementation involves interdisciplinary staff engagement, clear communication of the project, and continuous assessment of implementation requirements and conditions should be continuously reassessed. The presented framework may guide implementation leaders towards sustainable and user-centered introduction of digital health technology in the ICU.

1 Introduction

Despite the potential to improve outcomes, efficiency, and costs, the digital transformation of healthcare is lagging far behind compared to other sectors (Thiel et al. 2018; World Health Organization 2019). In the intensive care unit (ICU), staff is used to working with a multitude of electronic devices such as hospital information systems, organ replacement devices and, on a daily basis, the patient monitoring system. However, most of the technologies in use were invented in the 1970s and have not been substantially updated since then (Gardner et al. 2014). With today's developments in Artificial Intelligence (AI) research and computer science, a data-rich environment like the ICU seems predestined for the application of AI algorithms analyzing monitoring data in real time to predict complications or wireless remote patient monitoring solutions that stay with the patient after discharge from the ICU. First applications in that regard are being tested already today (De Cannière et al. 2020; Hashimoto et al. 2020; Kilic 2020). However, these technologies have not found their way into clinical routine yet and are only implemented in context of research projects or in single hospital sites (Mirsadeghi et al. 2016; Nagaraj et al. 2017; Chee et al. 2021; Chen, Pu, and Wang 2021; De Corte, Van Hoecke, and De Waele 2022).

Implementation of digital health technologies is lagging due to reasons on many levels: On a macro (national) level, a lack of legislations, a complicated market access and (aggravating) finance models hinder digital health technology introduction (Thiel et al. 2018). On a meso- (healthcare provider-) level, missing interoperability and high implementation and maintenance costs are major barriers (Wachter 2016; Lennon et al. 2017). On the micro (hospital ward) level, we see that health professionals' adoption and usability of the technologies influence implementation negatively (von Dincklage et al. 2017; Marcial et al. 2019; García et al. 2020). Yet, a breakdown of the specific reasons and targeted solution strategies for the context of ICUs do not exist.

The Consolidated Framework of Implementation Research (CFIR) is a mean to assess the implementation of an intervention into healthcare settings (Damschroder et al. 2009) and consists of five domains: (1) Intervention characteristics, (2) Outer setting, (3) Inner setting, (4) Characteristics of individuals and (5) Process, whilst each domain contains several sub-domains. To improve implementation efforts, Powell et al. published the Expert Recommendations for Implementing Change (ERIC), a compilation of 73 strategies

that were selected through a modified Delphi process with a panel of 73 experts in implementation science (Powell et al. 2015). For implementation research and practice, the research group around Laura Damschroder and Byron J. Powell published a tool to match CFIR-domains with ERIC strategies, which provides a prioritization of ERIC strategies best addressing respective CFIR-based barriers to implementation (Waltz et al. 2019). Ultimately, guidelines and frameworks for implementation of interventions in healthcare settings do exist, however, we lack evidence and recommendations for the specific use case of implementing digital health technologies in an ICU setting.
We aimed to explore the implementation of digital health technologies with the example of a remote patient monitoring system in an intensive care setting.

Objectives:

1. As part of this, we assessed clinical requirements and barriers to the implementation of a remote patient monitoring system and explored concerns, and perceived challenges of ICU staff on patient monitoring as well as their suggestions for future technological improvements.
2. We aimed to validate the findings of objective 1 in a larger cohort, putting focus on aspects of patient monitoring potentially disturbing patient care, the use cases for AI in the ICU, and whether ICU staff is willing to improve their digital literacy or contribute to improvement of existing technologies.
3. Finally, we aimed to evaluate the implementation of a novel digital technology after the implementation trial and to develop an implementation framework for digital health technology in the ICU.

2 Methods

Study design and overview of methods used

We followed an exploratory mixed-methods research approach. The qualitative part included semi-structured interviews, field visits, and focus groups to explore the research field and develop hypotheses. An online cross-sectional survey was conducted to validate the hypotheses and insights gained through the preceding qualitative methods.
Methods described in this section were part of the publications:

Poncette A-S, Spies C, **Mosch L**, Schieler M, Weber-Carstens S, Krampe H, Balzer F. Clinical Requirements of Future Patient Monitoring in the Intensive Care Unit: Qualitative Study. JMIR Medical Informatics 2019 Apr 30;7(2):e13064. [doi: 10.2196/13064]

Poncette A-S, **Mosch L**, Spies C, Schmieding M, Schiefenhövel F, Krampe H, Balzer F. Improvements in Patient Monitoring in the Intensive Care Unit: Survey Study. J Med Internet Res 2020 Jun 19;22(6):e19091. [doi: 10.2196/19091]

Mosch LK, Poncette A-S, Spies C, Weber-Carstens S, Schieler M, Krampe H, Balzer F. Creation of an Evidence-Based Implementation Framework for Digital Health Technology in the Intensive Care Unit: Qualitative Study. JMIR Formative Research 2022 Apr 8;6(4):e22866. [doi: 10.2196/22866]

Addressing objective 1., we conducted a qualitative study based on semi-structured interviews that were analyzed using a grounded theory approach (Poncette, Spies, et al. 2019). In order to validate and specify identified problems with patient monitoring as well as barriers and facilitators for the implementation of digital tools and AI in the ICU (objective 2.), we conducted a cross-sectional survey study via an online questionnaire (Poncette, Mosch, et al. 2020a). Finally, we applied an abductive research approach, specifying and elaborating previously established theories and generating new additional hypotheses, resulting in an implementation framework for digital health technologies in the ICU (objective 3, (L. K. Mosch et al. 2022).

Ethics approval and consent to participate

The Ethics Committee of Charité-Universitätsmedizin Berlin, Germany, approved this study (EA1/031/18). Participation in the study was voluntary. Informed consent was obtained from the participants in written form for all sub-studies and was available at all times.

Setting and technical setup

The study was conducted in the context of the pilot implementation of the Virtual Patient Monitoring Platform Vital Sync 2.4 developed by Medtronic plc, Minneapolis, United States. This system was installed in the post anesthesia care unit (PACU), one of the four intensive care units of a large German university hospital that was the setting of this study. The PACU had a capacity of ten beds, five of which were equipped with the Vital Sync monitoring system from May 2018 until June 2019.

The monitoring system consisted of two sensors (pulse oximetry and capnography) connected by a cable link to a bedside module that displayed the measured parameters and transmitted the data to remote devices (central monitor at the nurse station and six tablet computers). It was installed as a secondary monitoring system, primarily using the Philips IntelliVue patient monitoring system at the time of the study (MX800 software version M.00.03; MMS X2 software version H.15.41-M.00.04).

The vital parameters measured by the system were peripheral capillary oxygen saturation (SpO2), pulse rate (PR), end-tidal carbon dioxide (etCO2), and respiratory rate (RR) at a frequency of 1 Hz. On the home screen, which provided an overview of all admitted patients, all values for the measured vital parameters were displayed numerically (see Figure 1). In the bedside tile view of each patient, SpO2 and etCO2 were also displayed graphically on the user interface.

Figure 1. Home screen view with patient tiles and measured vital signs of the patient monitoring platform VitalSync. SpO2=peripheral capillary oxygen saturation, PR=pulse rate, etCO2=end-tidal carbon dioxide, RR=respiratory rate. Taken from: (Medtronic 2017a; 2017b)

Over the course of one month (March 2018) prior to the use of the system, technical briefings, and training on the use of the device were provided to ICU staff (i.e., physicians, nurses, and respiratory therapists). In addition, two workshops were held for all ward staff to clarify questions and solve problems in the application. For the duration of the whole implementation process, technical support was provided as needed.

Research Team

Pursuing a largely qualitative research approach, we put focus on interdisciplinarity within the research team, guaranteeing a multitude of perspective on the research topic. The team consisted of a Dr. med. candidate (LM); a postdoctoral researcher with a background in anesthesiology, intensive care medicine, digital health and geriatrics (ASP); a professor for medical data science, who is a consultant anesthesiologist and a computer scientist (FB); a psychologist (HK); a senior Human Factors student with a background in engineering (LS); a professor of ergonomics with a PhD in Human Factors and Industrial and Organizational psychology (MF); two medical doctors with a background in data science (MSCHM), and anesthesiology (FS); the head nurse (MSCHI); the ICU senior consultant (SWC); and the department's head of staff (CS).

Data Collection and Analysis

1) Pre-implementation interview study: assessing clinical requirements for patient monitoring in the ICU

The methods described in this section were part of the following publication:

Poncette A-S, Spies C, **Mosch L**, Schieler M, Weber-Carstens S, Krampe H, Balzer F. Clinical Requirements of Future Patient Monitoring in the Intensive Care Unit: Qualitative Study. JMIR Medical Informatics 2019 Apr 30;7(2):e13064. [doi: https://doi.org/10.2196/13064]

The interview guide (see Appendix 1) was developed by the research team by consulting the existing literature and discussing the research question in interdisciplinary focus groups and narrowed it down to seven guiding questions. Two pilot interviews were conducted to test the question order and validity; however, this did not alter the interview guide. Prior to usage of the patient monitoring system (April and May 2018), LM and ASP conducted 15 semi-structured interviews with ICU staff (five physicians, six nurses, four respiratory therapists, 7/15 female, 8/15 male). Attention was paid to achieving an even distribution of occupations, ICU work experience, and gender when composing the sample. The median length of interviews was 13 minutes (range 8-26).

Interview transcripts were analyzed applying a Grounded Theory approach (Strauss and Corbin 1990), meaning line-by-line coding of all three different transcripts with subsequent categorization and classification in a code system. The code structure was elaborated, specified, and adjusted through the analysis of the resulting transcripts. Qualitative analysis was performed by AP and LM, who regularly discussed the code system until mutual agreement was achieved. Findings were obtained through summarization of the code system in text and consolidation of the core statements in a sunburst diagram (see Figure 4). Relevant and representative quotes were translated into English and added to the manuscript of the publication (Poncette, Spies, et al. 2019).

2) Validation survey study: improvements and requirements for patient monitoring in the ICU

The methods described in this section were part of the following publication:

Poncette A-S, **Mosch L**, Spies C, Schmieding M, Schiefenhövel F, Krampe H, Balzer F. Improvements in Patient Monitoring in the Intensive Care Unit: Survey Study. J Med Internet Res 2020 Jun 19;22(6):e19091. [doi: 10.2196/19091]

Between November and January 2019, a web-based 36-item-questionnaire (see Appendix 2) was administered to nursing and medical staff in the four ICUs (N=270; 177 nurses, 93 physicians). The survey items were generated through analyzing findings of the pre-implementation interview study (Poncette, Spies, et al. 2019) and consolidated in focus group discussions within the research team. Items were created using an ordinal response format with a 5-point Likert scale. Pilot testing and pretesting with intensive care nurses and physicians were conducted to filter out redundant items and improve clarity, item order, and overall usability of the questionnaire. Experienced intensivists assessed the content and clinical validity of the survey items and topics.

Data cleaning and analysis was undertaken with R (R Foundation for Statistical Computing,(Wickham and RStudio 2019; Lüdecke et al. 2020; R Core Team 2018). We calculated the medians and their 95% bootstrap confidence intervals for each survey item using a bootstrap resampling procedure. For the bootstrap sampling distribution, 15,000 bootstrap samples per item were created. An item median was considered statistically significant if the 95% bootstrap confidence interval of the median did not contain 3, indicating the response "undecided." To compare the distributions of item responses of physicians and nurses, chi-square tests were used. Here, a two-sided P value <.05 was considered statistically significant.

3) Developing an implementation framework for digital health technologies in the ICU

The methods described in this section (see Figure 2 for an overview) were part of the following publication:

Mosch LK, Poncette A-S, Spies C, Weber-Carstens S, Schieler M, Krampe H, Balzer F. Creation of an Evidence-Based Implementation Framework for Digital Health Technology in the Intensive Care Unit: Qualitative Study. JMIR Formative Research 2022 Apr 8;6(4):e22866. [doi: 10.2196/22866]

Data collected and/or analyzed with this approach for this third sub-study included (1) results from sub-studies 1 and 2, (2) seven interview transcripts, (3) seven online Likert-scale questionnaires, and (4) field observations and informal discussions among the research team (see Figure 2). The interview guide for semi-structured interviews was developed on the basis of findings from previous studies (Poncette, Meske, et al. 2019; Poncette, Spies, et al. 2019; Poncette, Mosch, et al. 2020b) and the categories of the CFIR (Damschroder et al. 2009) (see Appendix 3). We conducted pilot interviews with ICU physicians, which did not alter the interview guide. Seven semi-structured interviews with ICU staff (three physicians, three nurses, one respiratory therapist) took place between June and November 2019. We took care to ensure that all professional groups were represented and that preferably persons were interviewed, who had participated in the stage 1 interviews. The number of respondents was limited because they should have held key positions in the ICU (e.g., head nurse, senior physician, staff with high work hours in the respective ICU) supervised the implementation process, received feedback from other staff on working with the system and the implementation process. As part of the interview guide, participants answered a 47-item online questionnaire including a technology commitment scale (Neyer, Felber, and Gebhardt 2012)see Appendix 3). The items were created to make participants' opinions on the implementation process comparable and matchable with the CFIR categories, using a 5-point Likert-type scale as an ordinal response format (options: *not correct at all, not quite correct, partly correct, quite correct,* and *completely correct)*. We pilot tested the interview guide and questionnaire with two ICU physicians, discussing the clarity, relevance, and order of the items. This did not lead to any changes in the interview guide or the questionnaire. The study data were collected and managed using REDCap electronic data capture tools hosted at Charité – Universitätsmedizin Berlin (Harris et al. 2009; 2019).

The interviews were conducted in a quiet and neutral environment (clinicians' offices on hospital grounds) and took place outside of regular ward shifts. Recordings of the interviews were transcribed verbatim by LM and were reviewed by ASP. From May 2018 to March 2020, the research team met throughout the implementation process to discuss progress, preliminary findings, and research strategy. This helped to improve auditability and reflexivity as well as minimize bias as much as possible (Noble and Smith 2015). To gain a more comprehensive understanding of the clinical implementation process and staff interactions with the system, LM also conducted field observations in the form of observations during shifts, which added field notes and memos to the data analyzed for this study. A summary of the field research findings was published by Poncette *et al.* in 2019 (Poncette, Meske, et al. 2019).

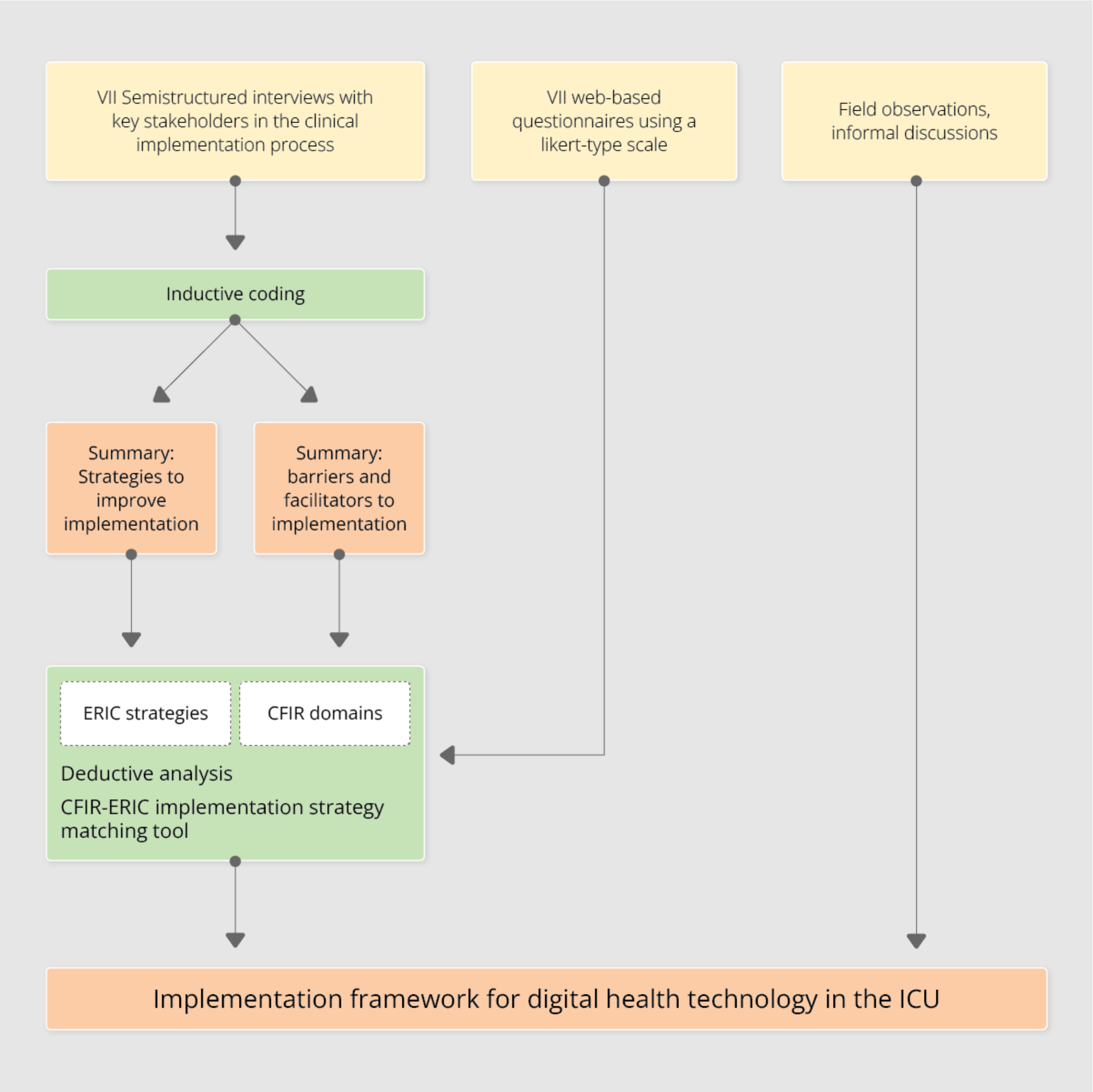

Figure 2. Overview of methods used for sub-study (3). ERIC=Expert Recommendations for Implementing Change, CFIR=Consolidated Framework of Implementation Research, ICU=Intensive care unit. Taken from: (L. K. Mosch et al. 2022)

To develop a framework of practical, evidence-based, yet specific recommendations for implementing new, digital technologies in the ICU, we chose the approach of systematic combining, as described by Dubois et al. (Dubois and Gadde 2002). In systematic combining, a case observation, empirical evidence, and an existing theory are assessed, aligned, guided, and directed toward a generalizable framework. It involves inductive and deductive methods of analysis and is characterized by the continuous matching of the four components (the case, the empirical world, the theory, and the framework) that leads to the ongoing specification and refinement of the framework.

As part of this, interview transcripts were analyzed inductively, using a thematic analysis (Boyatzis 1998; Fereday and Muir-Cochrane 2006). This resulted in summaries of (1) the evaluation of the implementation process and (2) strategies to improve implementation.

Those were subjects to the next, deductive step of the analysis, which connected the existing theory and evidence (CFIR and ERIC strategies) with the case observation (Damschroder et al. 2009; Powell et al. 2015). CFIR domains and ERIC strategies served as code system templates for the deductive part of thematic analysis, whereas summaries on strategies to improve implementation were analyzed with the ERIC strategies code system and summaries of barriers and facilitators to implementation were analyzed with the CFIR domains code system. All steps of inductive and deductive analysis were performed with MAXQDA 2020 qualitative data analysis software (VERBI Software 2022).

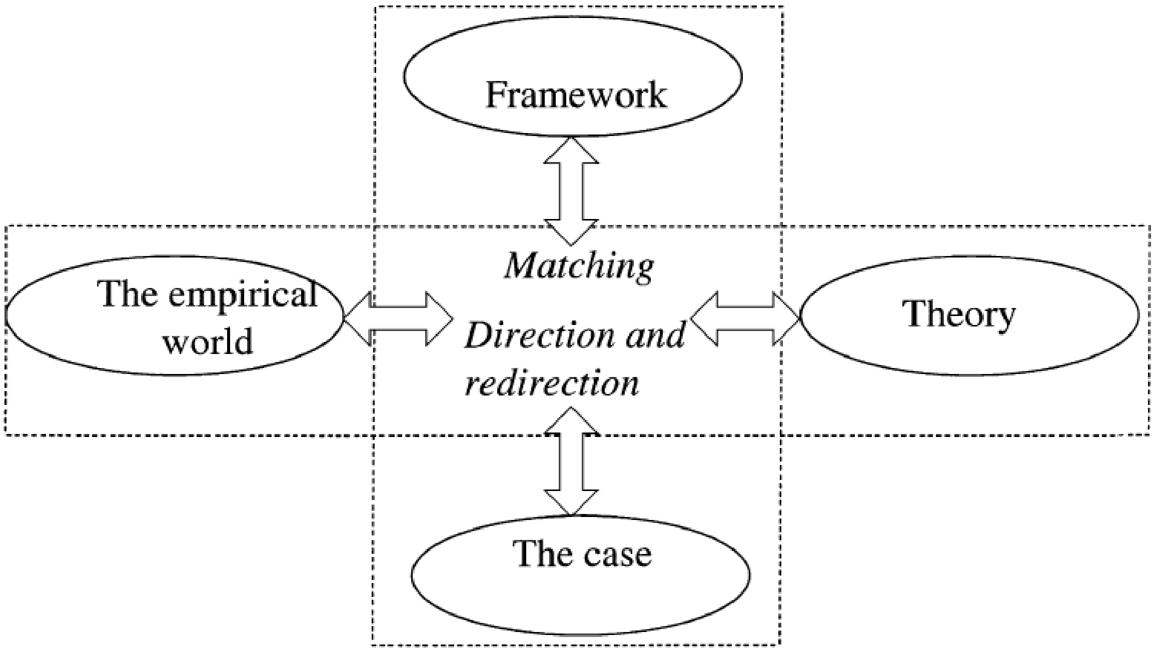

Figure 3. Systematic combining. Taken from: (Dubois and Gadde 2002)

Finally, the proposed implementation framework for digital health technology in the ICU was developed (3) based on the CFIR- and ERIC-guided analysis.

For prioritization of implementation strategies, we applied the CFIR-ERIC Implementation Strategy Matching Tool (“Strategy Design” 2016; Waltz et al. 2019), which maps strategies to CFIR domains, and took findings from field observations and informal research team discussions into account. Both ERIC-strategies that were congruent with staff suggestions from (2) and ERIC strategies that improved important CFIR-domains from (1) became part of the framework. Field observations and the research group's informal discussions helped prioritizing the findings and interview suggestions in the context of the implementation process. A temporal perspective was added, and recommendations were specified to the ICU environment (see Figure 13).

3. Results

1) Pre-implementation interview study: assessing clinical requirements for patient monitoring in the ICU

The results depicted in this paragraph, qualitatively screening requirements for patient monitoring in the ICU from the perspective of ICU staff, represent the findings of the following publication:

> Poncette A-S, Spies C, **Mosch L**, Schieler M, Weber-Carstens S, Krampe H, Balzer F. Clinical Requirements of Future Patient Monitoring in the Intensive Care Unit: Qualitative Study. JMIR Medical Informatics 2019 Apr 30;7(2):e13064. [doi: 10.2196/13064]

In evaluating the current monitoring system (see Figure 4, yellow), analysis of interviews with ICU staff revealed that usability factors such as intuitiveness and visualization were very relevant to staff in the context of daily use of the monitoring system in clinical routine. Trend analysis was rarely used, either by nurses, physicians, or respiratory therapists. Interviewees rated inadequate alarm management as well as the entanglement of monitoring cables as potential patient safety issues. The nurses and respiratory therapists interviewed confirmed routinely adjusting alarm thresholds according to patient condition, nonetheless situations in which multiple alarms are triggered at the same time would occur regularly and cause stress for both patients and staff. This was said to be caused by a high number of false alarms due to error-prone sensors, but also to patient-related factors (movement, arbitrary removal of monitoring parts) and to the lack of "alarm hygiene". i.e., regularly adjusting alarm thresholds, (de-)selecting parameters for alarms, resulting from low staffing levels and lack of time to set alarm thresholds.

For a future system (see Figure 4, green), again, the importance of high usability and intuitiveness was emphasized, which especially in emergency situations would ensure patient safety. Wireless, non-invasive, and interoperable monitoring sensors were desired; the use of mobile phones for remote patient monitoring and alarm management optimization were suggested; and clinical decision support systems (CDSS) based on artificial intelligence were considered useful.

Perceived barriers to implementation (see Figure 4, red) of novel technologies such as remote patient monitoring and AI-powered CDSS included lack of confidence in these technologies and fear of losing clinical skills if relying solely on the results of an AI system, for example. In addition, staff feared an even greater workload from setting up and running the technologies. Lack of awareness among critical care staff of available digital technologies and their potential benefits, as well as satisfaction with the current system, were also cited as potential barriers to implementation. More instructions and training with the new devices were demanded by staff.

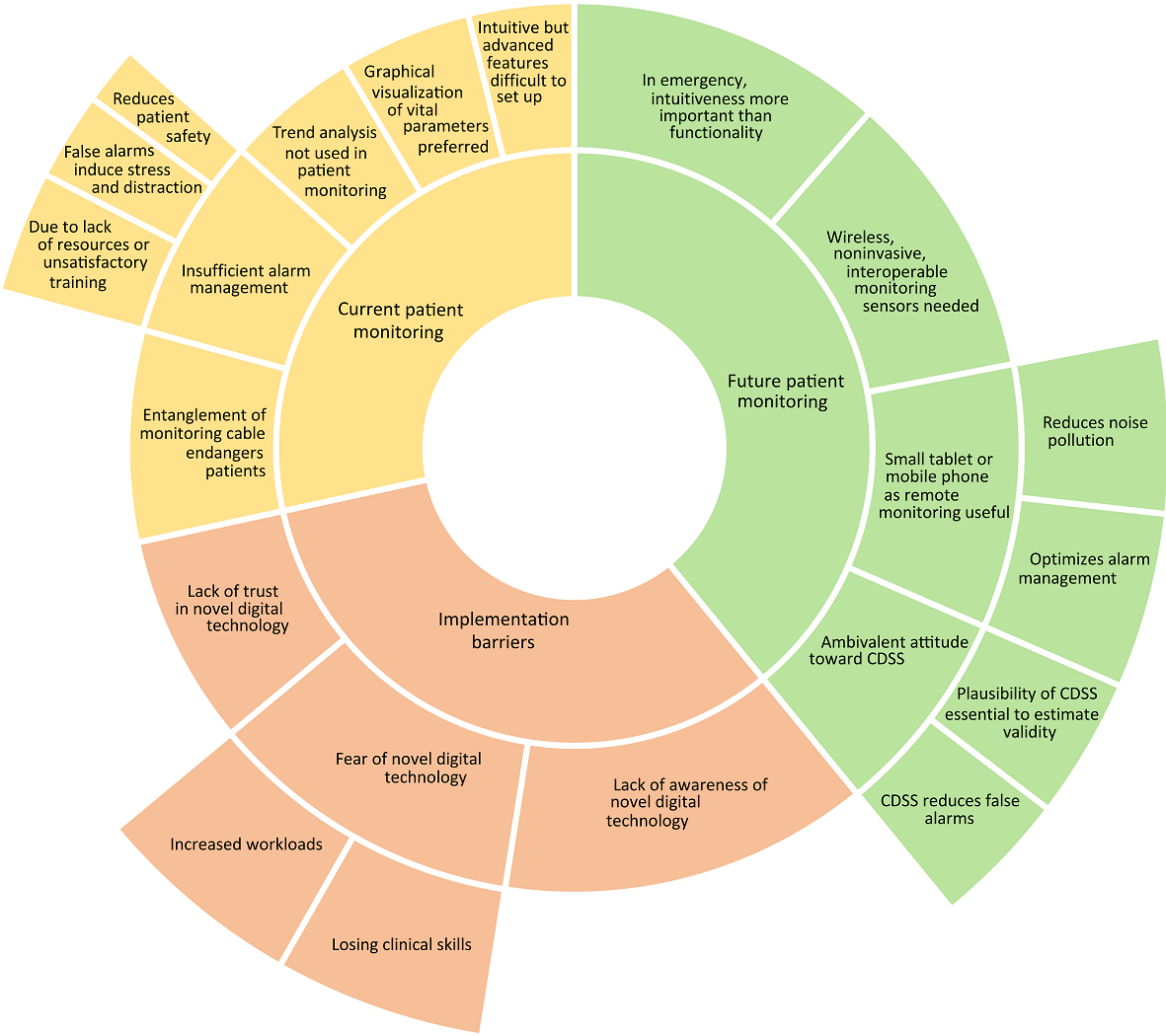

Figure 4. Perceptions of current (yellow) and future (green) patient monitoring in the intensive care unit and implementation barriers of novel monitoring solutions (red). CDSS = Clinical Decision Support System. Taken from: (Poncette, Spies, et al. 2019)

2) Validation survey study: improvements and requirements for patient monitoring in the ICU

The results described in this section were part of the following publication:

Poncette A-S, **Mosch L**, Spies C, Schmieding M, Schiefenhövel F, Krampe H, Balzer F. Improvements in Patient Monitoring in the Intensive Care Unit: Survey Study. J Med Internet Res 2020 Jun 19;22(6):e19091. [doi: 10.2196/19091]

In total, 86 of the 270 ICU physicians and nurses completed the survey questionnaire. The majority (n=66, 77% chose "Strongly agree" or "Agree") stated they felt confident using the patient monitoring equipment, but that high rates of false-positive alarms (n=60, 70% chose "Strongly agree" or "Agree") and the many sensor cables (n=66, 77% indicated "Strongly agree" or "Agree") interrupted patient care (see Figure 5).

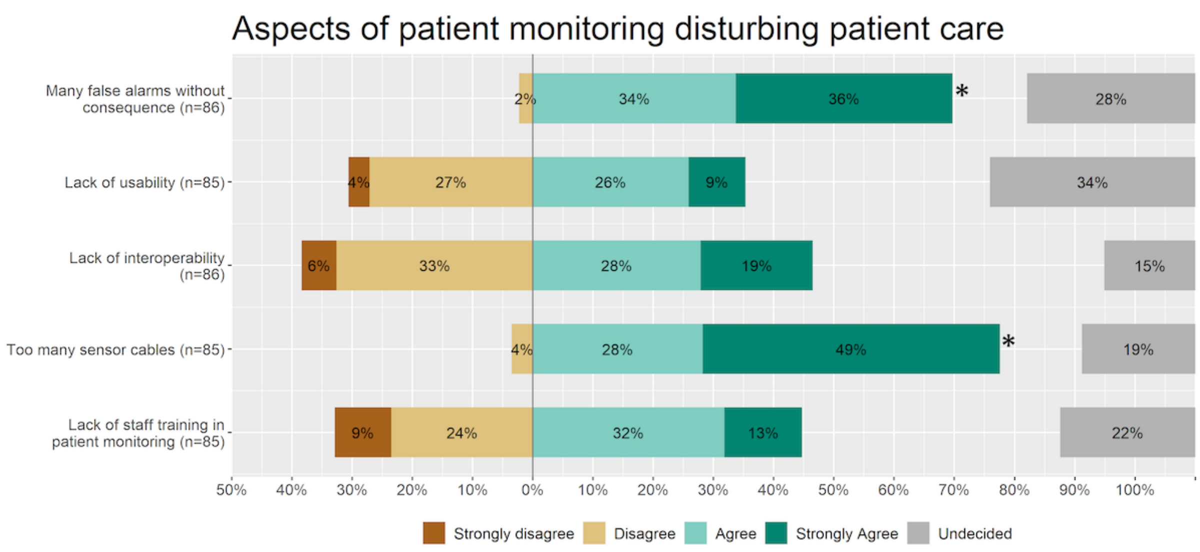

Figure 5. Distribution of survey responses regarding aspects of patient monitoring disturbing patient care. Statistical significance is indicated with an asterisk (*). Taken from: (Poncette, Mosch, et al. 2020a)

Regarding future improvements, the respondents asked for wireless sensors (n=80, 93% chose "Strongly agree" or "Agree"), to reduce false-positive alarms (n=80, 93% chose "Strongly agree" or "Agree") and supported hospital standard operating procedures (SOPs) for alarm management (n=53, 62% chose "Strongly agree" or "Agree", see Figure 6).

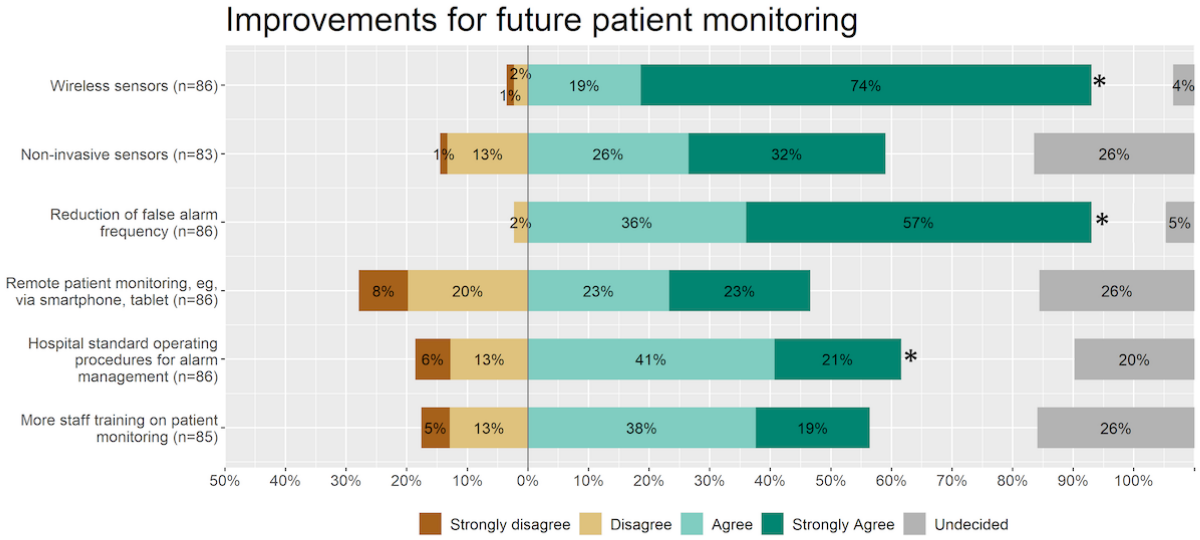

Figure 6. Distribution of survey responses regarding improvements for future patient monitoring. Statistical significance is indicated with an asterisk (*). Taken from: (Poncette, Mosch, et al. 2020a)

Most respondents indicated, remote patient monitoring would be useful for earlier alerting (n=55, 65% indicated “Strongly agree” or “Agree”) or when they were responsible for multiple wards (n=62, 74% chose “Strongly agree” or “Agree”, see Figure 7).

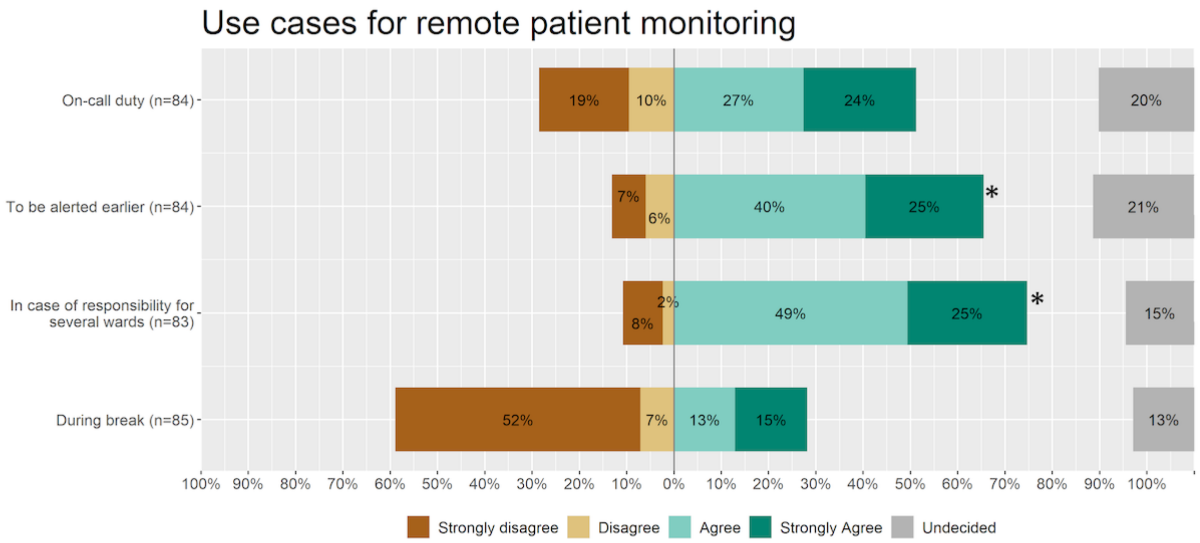

Figure 7. Distribution of survey responses regarding use cases for remote patient monitoring. Statistical significance is indicated with an asterisk (*). Taken from: (Poncette, Mosch, et al. 2020a)

Artificial intelligence used in CDSS for ICUs would be applicable for early detection of complications (n=67, 79% chose “Strongly agree” or “Agree”) and an increased risk of mortality (n=60, 71% indicated “Strongly agree” or “Agree”); in addition, the AI could propose guidelines for therapy and diagnostics (n=66, 78% chose “Strongly agree” or “Agree”; Figure 8).

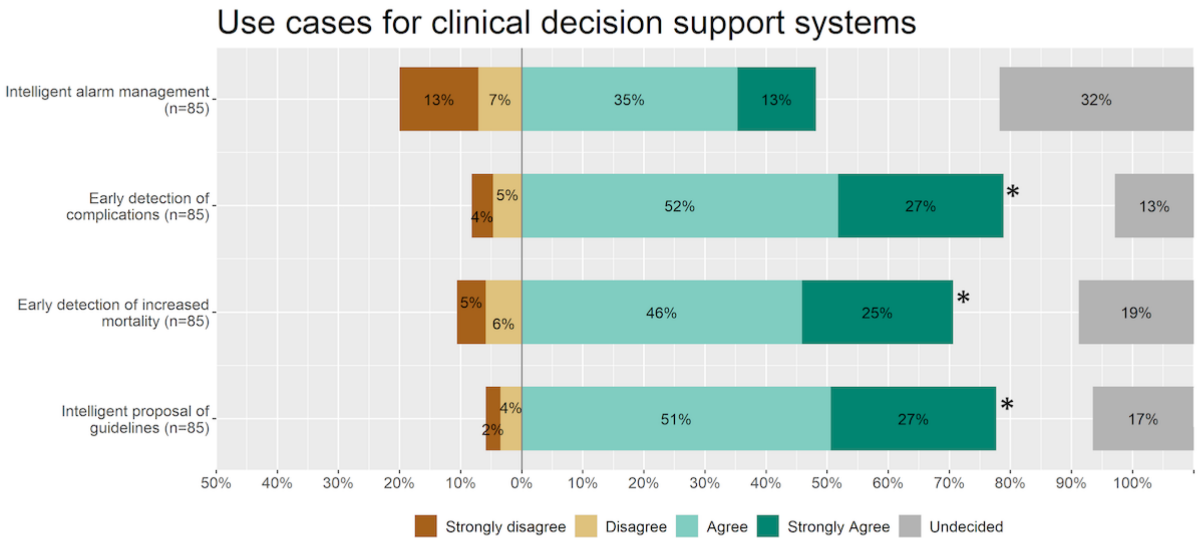

Figure 8. Distribution of survey responses regarding use cases for clinical decision support systems. Statistical significance is indicated with an asterisk (*). Taken from: (Poncette, Mosch, et al. 2020a)

Interoperability (n=79, 93% chose “Strongly agree” or “Agree”), usability (n=78, 93% indicated “Strongly agree” or “Agree”), high transparency (n=66, 78% indicated “Strongly agree” or “Agree”; Figure 9) and staff training (n=75, 90% chose “Strongly agree” or “Agree”) were essential to promote the use of AI.

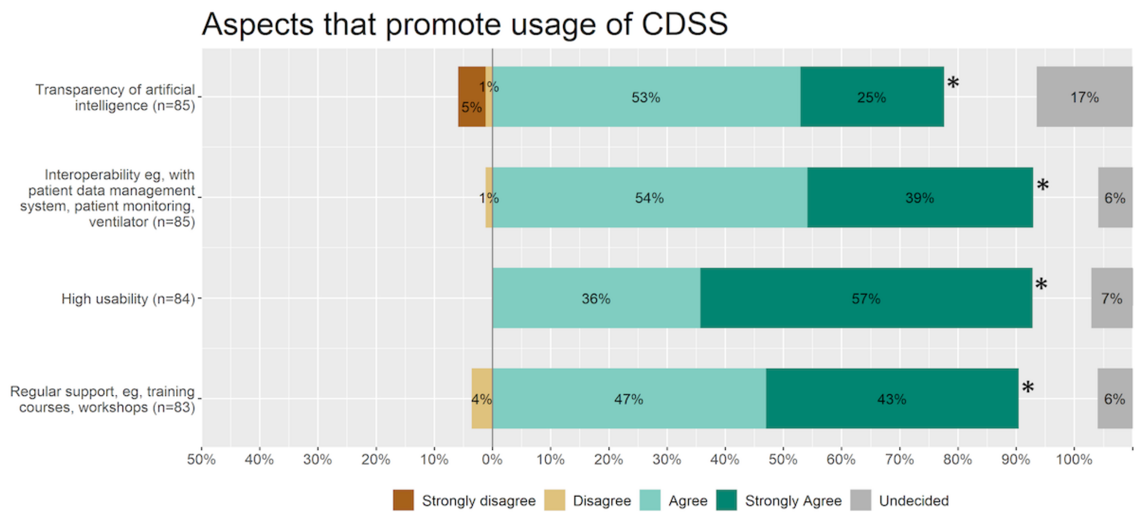

Figure 9. Distribution of survey responses regarding aspects that promote usage of clinical decision support systems. Statistical significance is indicated with an asterisk (*). CDSS=Clinical decision support system. Taken from: (Poncette, Mosch, et al. 2020a)

The majority wanted to learn more about new technologies (n=70, 81% chose "Strongly agree" or "Agree") for the ICU and required more time for learning (n=55, 65% indicated "Strongly agree" or "Agree"). The statement "I do not trust new digital technologies" was disagreed with or strongly disagreed with by 59 respondents (69%, see Figure 10).

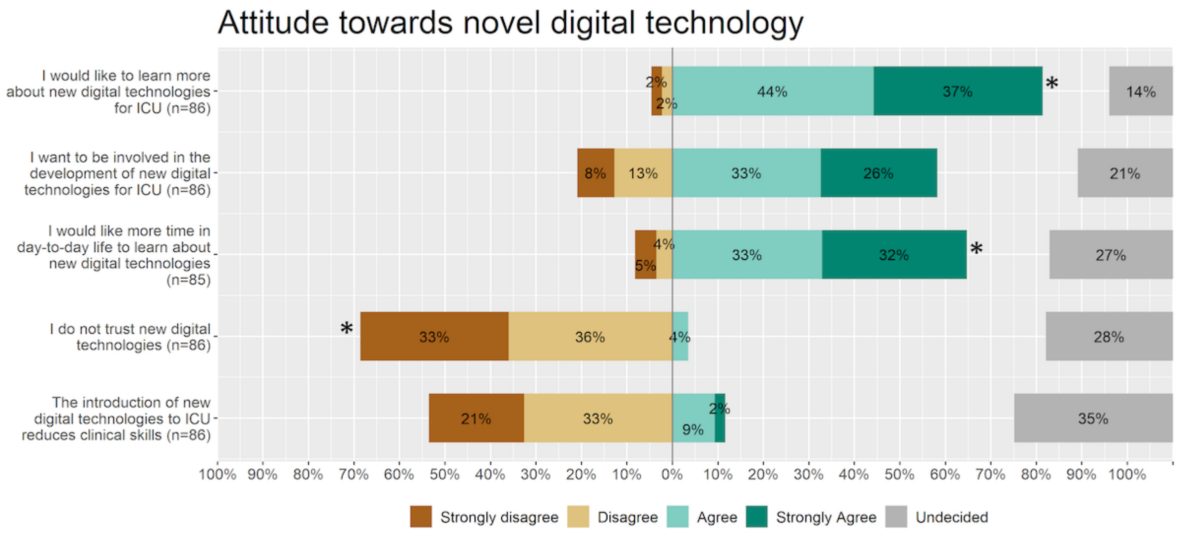

Figure 10. Distribution of survey responses regarding the attitude of staff towards novel digital technology in the intensive care unit. Statistical significance is indicated with an asterisk (*). Taken from: (Poncette, Mosch, et al. 2020a)

3) Implementation Framework

The results depicted in this paragraph were part of the following publication:

Mosch LK, Poncette A-S, Spies C, Weber-Carstens S, Schieler M, Krampe H, Balzer F. Creation of an Evidence-Based Implementation Framework for Digital Health Technology in the Intensive Care Unit: Qualitative Study. JMIR Formative Research 2022 Apr 8;6(4):e22866. [doi: 10.2196/22866]

The implementation of a remote patient monitoring was evaluated. We identified two major domains: (1) implementation process and (2) strategies to improve implementation. These qualitative findings resulted in the development of (3) a framework for implementation of digital health technology in the ICU.

Implementation Process

Figure 11 shows an overview of the findings regarding the implementation process evaluation according to the interviewed staff members.

Staff Involvement and Communication

The interviewed staff members stated, colleagues of all professions did not feel responsible for continuously applying the remote patient monitoring system (see Figure 11, red section). They lacked implementation leaders, regular staff training and motivation to connect patients to the device. Respondents reported that there was negative peer pressure not to use the monitoring system, which they associated with a lack of communication from opinion leaders about the intervention, along with nonpersistent engagement of leaders in the implementation process. The interviewees felt an unequal distribution of workload among the professions, with technical instructions and training being more targeted toward nurses. Physicians felt even less responsible for applying the system than nurses. Technical instructions were not given to all staff members on the ward, there was a need for more training with and information about the monitoring system. The intervention was perceived as imposed from outside the ICU, which was associated with the lack of information about the project aims and context.

Attitude of Staff

According to the interviewed stakeholders, the fear of losing break times, of an increase in workload and false alarms as well as the fear of reduced patient contact were present among staff members. In addition, colleagues would not apply the device on account of lacking the routine of using a portable device for patient monitoring. The interviewees claimed that the current monitoring system was sufficient, and they did not perceive a need for a change.

Additional Benefit

ICU staff did not find the monitoring system beneficial because the ICU was already covered with a monitoring system offering remote functions such as displaying parameters of critical patients on all bedside monitors in the case of an alarm. In addition, a high presence of nursing staff in the ICU would decrease the need for remote patient monitoring with a portable device and the frequent (re-)transfer of patients to and from the ICU (as a post-anesthesia care unit) resulted in an increased workload with setting up the system or disconnecting patients from the system. Finally, the interviewees claimed that when being away from the patient’s bedside, they could not perform the necessary immediate reaction to an alarm which would make remote monitoring less valuable.

Intervention Features

The monitoring system was not rated high in usability by staff members, a main point of criticism was the inconvenience of continuously carrying the device. Furthermore, the patient could not be monitored with the device during their transfer (e.g., to a radiological examination). The four vital parameters monitored by the system (PR, RR, SpO2, etCO2) were not perceived sufficient in the clinical routine to evaluate a patient's condition. The interviewees criticized the system's dependency on a stable wireless network connection as this would limit a flexible application.

Figure 11. Implementation process: 4 major categories were identified (inner ring), divided into themes (middle ring), and further specified (outer ring). ICU: Intensive care unit. Taken from: (L. K. Mosch et al. 2022)

Mapping of CFIR Domains

We assigned the findings regarding the implementation process from the interview transcripts (see Figure 11) and online Likert-scale questionnaires (see proof of primary data) to major domains of the CFIR (Damschroder et al. 2009), see Table 1 and Appendix 4).

Table 1. Mapped Consolidated Framework for Implementation Research domains and subdomains. Adapted from: (Mosch et al., 2022)

Mapped CFIR domains	Mapped CFIR subdomains
Intervention characteristics	Intervention source Evidence strength and quality Relative advantage Adaptability Trialability Complexity
Inner setting	Structural characteristics Networks and communication Implementation climate: tension for change, compatibility, relative priority, and learning climate Implementation readiness: leadership engagement and access to information
Individual characteristics	Knowledge and beliefs about the intervention Self-efficacy Individual stage of change
Process	Planning Engaging: opinion leaders and formally appointed implementation leaders Executing

Strategies to Improve Implementation

Figure 12 presents an overview of the findings regarding strategies to improve the implementation of digital health technologies according to the interviewed staff members.

Staff Involvement

For an improved implementation, the interviewed staff members highlighted that especially in the early implementation stages, continuous technical instructions, and staff training before and after shifts would be critical. Thereby, they considered a high quality as essential to prime the staff's opinion toward the intervention. In particular, project aims and context should be conveyed during staff trainings. Persistent leadership commitment and the designation of responsible staff members for the implementation project would be critical to highlight the priority of the project. In addition, the implementation culture and staff engagement would be improved through feedback discussions with staff and project leaders, while the communication should be encouraging and motivating.

Setting

Interviewees reported that, for improving implementation performance, the devices should be implemented in as many workplaces of the ICU staff as possible. ICUs with longer patient stays were preferred to reduce the workload for staff in setting up the system. A normal ward or an intermediate care unit (IMCU), where staff is scarcer and technology coverage lower, was deemed more convenient for a remote patient monitoring technology.

Intervention Features

The device to be implemented should be comprehensibly beneficial for both the patient and the workflow, interoperable with other technologies in the ICU, and preferably wireless. Interviewees highlighted the need for a high intuitiveness and a clear visualization, ultimately, a good usability. Statements large screen, but interviewees favored a device that fits into the pocket of a tunic.

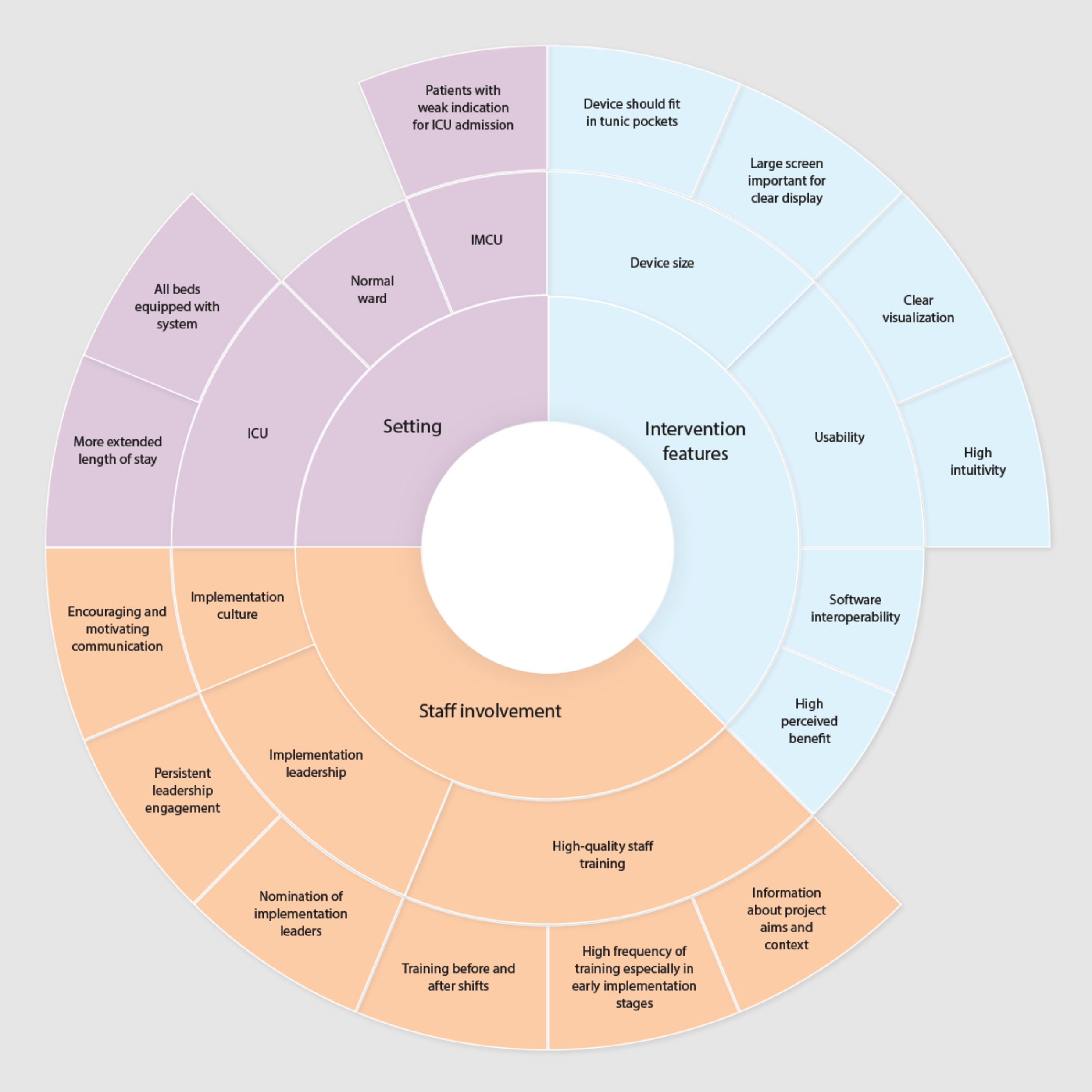

Figure 12. Perceived factors improving implementation: 3 categories were identified (inner ring), divided into subcategories (middle ring), and enriched with concrete suggestions (outer ring). ICU: intensive care unit; IMCU: intermediate care unit. Taken from: (L. K. Mosch et al. 2022)

Mapping of ERIC Strategies

The findings regarding improvement strategies from the interviews (see Figure X) and questionnaire responses were assigned to 19 of 73 (26%) strategies of the Expert Recommendations for Implementing Change (ERIC (Powell et al. 2015; Waltz et al. 2015)). The findings were mapped to 7/9 (78%) of the clusters of the ERIC framework (see Table 2 and Appendix 5).

Table 2. Mapped Expert Recommendations for Implementing Change clusters and strategies. Adapted from: (L. K. Mosch et al. 2022)

Mapped ERIC clusters	Mapped ERIC strategies
Use evaluative and iterative strategies	Purposely re-examine the implementation Develop a formal implementation blueprint Audit and provide feedback
Provide interactive assistance	Facilitation Provide clinical supervision
Adapt and tailor to context	Promote adaptability
Develop stakeholder interrelationships	Identify and prepare champions Organize clinician implementation team meetings Recruit, designate, and train for leadership Inform local opinion leaders Model and simulate change Involve executive boards
Train and educate stakeholders	Conduct ongoing training Make training dynamic Use train-the-trainer strategies Conduct educational meetings
Support clinicians	Facilitate relay of clinical data to providers Remind clinicians
Change infrastructure	Change physical structure and equipment Change service sites

Proposal for an Implementation Framework for Digital Health Technology in the ICU

The implementation framework (see Figure 13) includes 11 recommendations adapted from strategies of 4 clusters of the ERIC framework. It consists of 2 stages: “Before Implementation” and “During Implementation”. "Context" refers to strategies that can and should be applied or initiated at any point in the implementation process. We understand this to be a circular process, that is, re-assessment and feedback enable a revision of the implementation strategy, adapting it to changing conditions and ensuring a sustainable implementation process.

Before Implementation

A *local needs assessment* should be conducted at the implementation site involving ICU staff from all professional groups. To learn about potential barriers and facilitators for their project, implementation leaders should look for evidence on similar implementation efforts (*Visit other sites*). Simulating the implementation on a smaller scale (e.g., in an implementation unit), staff interviews and field observations can bring insight on the *adaptability* of the intervention. After these preparations, an *implementation blueprint* should be developed, including purpose, timeline, and outcome measures of the project. The blueprint should be accessible to all staff and easy to understand. To refine the implementation guide, conducting a strengths-weaknesses-opportunities-threats (SWOT) analysis, *assessing the ICUs readiness to change* and further specifying potential barriers and facilitators of implementation are important strategies. Also, staff members from all professional groups should be determined, forming the regularly meeting *clinician implementation team*, being responsible for the implementation project and supporting colleagues in applying the technology. Finally, local opinion leaders should be informed about the project and motivated staff should be selected as "champions" to promote the intervention.

During Implementation

During the implementation process, the strategies initiated before should enable a smooth implementation process. It should be supported by Facilitation, meaning to conduct regular training with the technology, to support communication among and across the professions regarding the intervention, and to continue informing staff about it. At the same time, implementation leaders should schedule feedback meetings with opinion leaders, the clinician implementation team and listen to feedback from staff members of all professional groups. Feedback given can directly improve facilitation (feedback loop, Figure 13), or even reveal a further need for innovation and initiate a new implementation project.

Context

At all times, implementation leaders should invest in building a network within their organizations but also outside (other intensive care departments, researchers in implementation science and intensive care, medical device industry, etc.). This may help to channel information, enables collaborative problem solving and induces innovation. Furthermore, an implementation advisor from outside the ICU might bring in a different perspective and expertise on the implementation strategy. Finally, the establishment of an implementation unit, gathering interprofessional experts for the local implementation characteristics and providing space and resources for simulating an implementation process is recommended (e.g., in university hospitals).

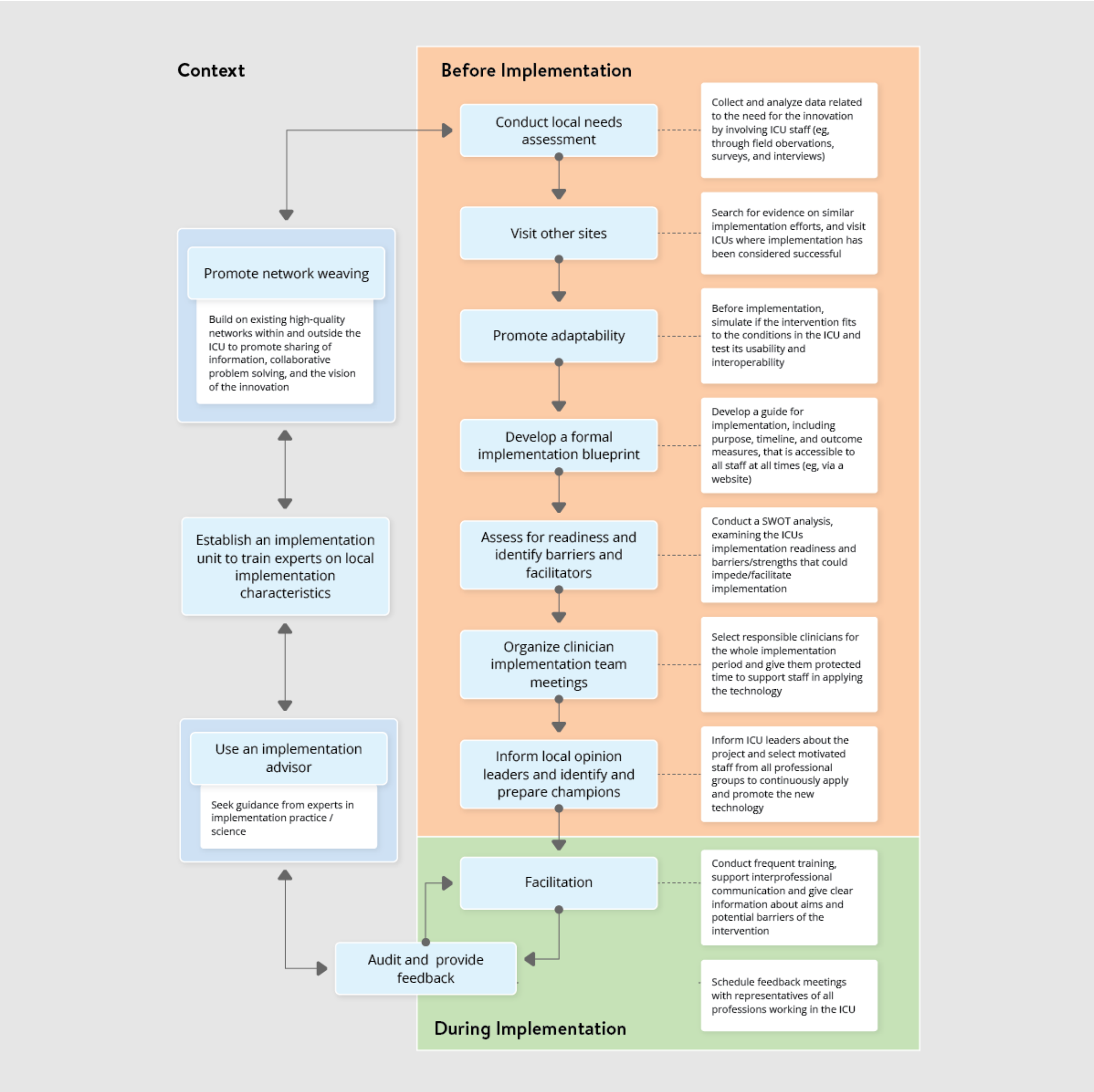

Figure 13. Evidence-based implementation framework for digital health technologies in the ICU. Strategies for improved implementation performance before (orange), during (green) and in the general context of the implementation project (white). CFIR: Consolidated Framework for Implementation Research; ERIC: Expert Recommendations for Implementing Change; ICU: intensive care unit; SWOT: strengths, weaknesses, opportunities, and threats. Taken from: (L. K. Mosch et al. 2022)

4. Discussion

4.1 Brief summary of the results

This dissertation, consisting of three sub-studies, analyzed the pilot-implementation of a digital health technology (the VitalSync^{TM} virtual patient monitoring platform, (Medtronic 2017b)) and the attitudes of ICU staff regarding patient monitoring and digital health technologies (e.g., remote patient monitoring or AI-based CDSS). Finally, we developed an evidence-based implementation framework for digital health technology in the ICU.

ICU staff perceived usability and clear visualization as essential features of a new technology to be implemented, i.e., a remote patient monitoring system. This finding from sub-study (1) was reproduced in the questionnaire-based validation study, where the majority agreed usability was essential for promoting usage of AI-based decision support tools. Yet, the post-implementation assessment showed that staff rated the system's usability as low.

In the pre-implementation phase, interviewees criticized many false-positive alarms resulting from poor alarm management, ultimately leading to an increased stress level of staff and patients. Accordingly, a majority of questionnaire respondents asked for a reduction of false positive alarms and the implementation of alarm–management SOPs.

The application of AI-based technologies in the ICU was considered useful by interviewed staff members in the pre-implementation study. In line with this, three quarters of questionnaire respondents agreed that AI-based CDSS were useful for predicting mortality (79%) and complications (71%).

Among the perceived barriers to implementation were staffs' lack of confidence and routine in competently using novel technology along with fears of a greater workload and losing clinical skills. These pre-implementation findings were reproduced post-implementation. Furthermore, interviewees claimed the staff would also fear a diminished personal contact with patients. The questionnaire study revealed that 29% of respondents were undecided about or agreed to the statement "I do not trust new digital technologies".

Consequently, in all three sub-studies, more training with and education about novel digital health technologies was requested by ICU staff. The post-implementation study revealed irregular training and instructions with the remote patient monitoring system failing to reach all staff members, hence impeding implementation. General paucity in information about the project and its aims led to a low engagement by staff with the project.

Prior to implementation, we already observed no pronounced readiness for change, which resulted from the lack of awareness of novel digital technology among staff, but also their satisfaction with the current patient monitoring system. After implementation, staff admitted that they preferred a different environment for implementing a remote patient monitoring system and did not see any additional benefit from the system being implemented.

To avoid cost-intensive and resource-draining, unsuccessful implementation efforts, we developed the evidence-based implementation framework for digital health technologies in the ICU depicted in Figure 13 (L. K. Mosch et al. 2022). The target audience are hospital managers in operational development or administration, chief medical officers and senior clinicians in the ICU, and implementation researchers. The strategies presented to improve implementation performance focus on improving four out of the five major domains of the CFIR (Damschroder et al. 2009): intervention characteristics (adaptability), inner setting (implementation climate, networks and communications), characteristics of individuals (knowledge and beliefs about the intervention) and process (planning, engaging, reflecting and evaluating). First, the adaptability of intervention to the setting can be tested through a local needs assessment, field observations and interviews with on-site staff, as well as visiting other implementation sites pursuing similar projects. Second, networks and communications and the implementation climate could be improved by forming a clinician implementation team, assessing the ICUs readiness to change, and informing every staff member (especially opinion leaders) about the implementation project through regular meetings, deliverables, and personal communication. Before implementation, the process is augmented through the development of a formal implementation blueprint. During implementation, the process can be driven by engaging and motivating facilitation and sustainably improved by a strong feedback culture. The installation of an implementation unit is recommended, e.g., in a university hospital. Here, implementation leaders can simulate their project in a protected environment considering local characteristics and/or consulting an (internal) implementation advisor.

4.2 Interpretation of the results and classification in the existing state of research

Usability and User-Centered Design

An important finding of this dissertation is the significance of the usability of digital health technologies for their adoption by clinicians and their successful clinical implementation as described before in the literature (Wade, Eliott, and Hiller 2014; Palacholla et al. 2019; Whitelaw, Pellegrini, and Van Spall 2020). Beyond this, poor usability of digital health technologies is endangering patient safety through provoking operational and technology-induced errors (Kushniruk et al. 2005; Guise, Anderson, and Wiig 2014; Turner, Kushniruk, and Nohr 2017; Howe et al. 2018). However, the usability of said technologies often is poor (Zapata et al. 2015; von Dincklage et al. 2017; Saeed, Manzoor, and Khosravi 2020). In a follow-up study to the work presented in this dissertation, we tested the usability of the remote patient monitoring device that was pilot-implemented as part of this dissertation (Poncette et al. 2022). This brought about 37 usability problems that we mapped, ranked, and finally targeted with a novel design solution, showing significantly improved usability. The plethora of usability problems could be avoided if health technologies applied user-centered design from the outset, i.e., if the end users of a technology were involved in its initial design and development (Middleton et al. 2013; Fidler et al. 2015; Wiggermann et al. 2019). An approach to prevent and target usability issues - something widely implemented in other sectors such as engineering and transport (Billings 1991; Greenstein 1995) - presents the implementation framework developed in this dissertation. It considers aspects of human-centered design, including the evaluation of health technology during its clinical implementation (Melles, Albayrak, and Goossens 2021). Strategies such as "Establish an implementation unit," "Organize clinician implementation team meetings," and "Audit and feedback" strengthen the end-user perspective and address human factors in implementation processes.

Need for Education and Training

Continuous patient monitoring devices are ubiquitous in modern ICUs. Although staff of all professions included in our studies reported to apply the system daily, only 77% agreed to feel confident using it. By itself, this suggests that ICU staff need more training on patient monitoring.

Consistent with other research, we demonstrated that a lack of trust in and knowledge of digital technologies in the ICU is a barrier to implementation (Ross et al. 2016; Kemp et al. 2021). Our study shows that staff would like to see more instruction on the devices. However, the education of all professional groups in the ICU in the field of digital medicine should also be improved in order to exploit the potential of digitalization in healthcare

(Topol 2019; Nagle, Kleib, and Furlong 2020). In a European-wide survey, medical students demanded more education on digital health and criticized the lack of such courses in medical curricula (Machleid et al. 2020). Efforts to introduce courses on digital health and artificial intelligence at German medical schools have since been made, but they are limited to individual universities and are mostly electives, i.e., not mandatory. (Poncette, Glauert, et al. 2020; Aulenkamp et al. 2021; L. Mosch et al. 2021). Even more urgent is the need for qualification with digital skills in the area of continuing medical education (CME) and specialty training - in Germany, for example, only 0.03% (30/87.136) certified CME-courses in the federal database of the German Medical Association had a relation with AI and there is no residency curriculum that includes learning objectives on this topic (L. Mosch et al. 2021).

Other countries are further ahead in this regard: The Australian National Nursing and Midwifery Digital Health Capability Framework proves as an example of how digital competencies can be strengthened for healthcare workers in clinical practice (Woods et al. 2021). It complements the implementation framework developed in this dissertation in terms of characteristics of individuals (knowledge and beliefs about the intervention) by providing a guide for organizations to improve staff digital health maturity. Efforts to improve the digital literacy of healthcare professionals should occur at all levels of education (school, university, and professional development and training) and be offered to all professionals working together in an interdisciplinary setting, such as the ICU.

Remote Patient Monitoring Data for AI-based Early Warning Scores (EWS)

Our studies showed that ICU staff did not consider remote monitoring of patients *in an ICU* to be useful given the following circumstances: The added benefit was considered low, the ease-of-use poor, and staff feared an increased workload due to the frequency of setting up the system. However, application of remote monitoring was deemed beneficial in other settings such as the intermediate care unit where staff coverage is lower. There are approaches to continuous remote monitoring of patients in general wards. Studies suggest that it can increase patients' sense of safety and help detect deterioration in patients' health earlier (Downey et al. 2018; Weenk et al. 2019; 2020; Leenen et al. 2020). Larger cohort validation and implementation studies are needed to provide more accurate evidence.

Still, continuous patient monitoring has the potential to provide dense data for implementing EWS based on AI decision support, both in ICU and general ward settings. In our sub-study (1), ICU-staff admitted not to use trend analysis functions of the patient monitoring system routinely. This gap would likely benefit from utilising real-time EWS for the prediction of complications or mortality (Elvekjaer et al. 2020; Youssef Ali Amer et al. 2020). EWS based on spot monitoring data are already in use in some hospitals and have been shown to reduce length of stay and admission costs, as well as predict and reduce (in-hospital) mortality (Prytherch et al. 2010; Vincent et al. 2018; Escobar et al. 2020). With continuous monitoring, more accurate predictions and tailored alert strategies adapted to patients' individual baseline of vital signs could be realized (Keim-Malpass et al. 2020). Thus, remote monitoring of patients in general wards, supplemented by an automated early warning system based on predictive analytics, could reduce morbidity and mortality associated with hospitalizations and should be the subject of further research.

4.4 Strengths and weaknesses of the studys

The present work provides a thorough overview of the implementation of a digital health technology in intensive care settings, influencing factors and, subsequently an implementation framework for novel digital technologies in the ICU. The dissertation explored an implementation process close to the standard practice in healthcare settings (ICUs) in Germany, where implementation science is still an evolving discipline. Still, this dissertation is subject to limitations:

By the qualitative study design, the results of sub-study (1) cannot be considered representative, although some statements were quantitatively validated in the second sub-study. Conclusions regarding the benefit of remote patient monitoring technology for patient outcomes or the quality of care in the ICU cannot be drawn based on the findings of this dissertation.

Limitations of the questionnaire-based validation study (sub-study (2)) include the use of a non-validated questionnaire (based on the findings of sub-study (1)), a moderate response rate and the single-center character of the study. The fact that the survey was conducted online may have discouraged less tech-savvy employees from participating in the questionnaire.

The sub-study (3) is also subject to some aspects that limit its generalizability and transferability to other contexts - (which was desirable to a certain extent), as it was intended to highlight the specifics of implementing digital health technologies in intensive care settings. Still, interpretation of the findings should consider the local conditions, the small number of participants (naturally limited to the persons in leadership positions in the ICU) and the characteristics of the intervention (poor usability, low perceived benefit). To counteract these influencing factors, we drew on findings from the literature and supplemented the data base with in-depth field research and numerous discussions within the research group. Because the decision to implement the monitoring system was made prior to the start of the study, we were unable to evaluate the outer setting, gather insights to the technology development phase, nor could we undertake some of the recommended strategies before implementation (e.g., conducting a local needs assessment, visiting other sites, testing the adaptability of the intervention). Despite this, the unsuccessful implementation seems to have proven once again the importance of these implementation strategies. For the same reasons as mentioned above, it was not possible to follow a human-centered design approach in this specific context, involving the end users in the development of the technology and auditing their feedback during the implementation process. When interpreting the results, it is also important to keep in mind that the CFIR-ERIC matching tool needs further validation, which means that the ERIC strategies assigned to CFIR domains are not necessarily the best way to overcome barriers in that domain.

We aimed to mitigate this limitation through repeated and targeted discussions within the research team, extensive field research, and analysis of suggestions from staff. A limitation to the study's scope is that the ERIC strategies do not include changes in intervention characteristics, which would be essential when aiming to improve implementation performance in a user-centered design. ERIC only covers the last stages of implementation (planning and executing the implementation of the finalized intervention) but does not include the readaptation of the intervention as part of the development process. Moreover, the presented framework does not include a "post-implementation" stage. Thereby, we aimed to highlight the circular character of sustainable implementation – the intervention and setting should stay subject to continuous re-evaluation and potential re-implementation.

Especially in Germany, implementation research and -methods accompanying the introduction of technologies in healthcare settings is not widespread. We showcased how implementation research methods can help identify and close gaps in realizing the effectiveness and efficiency of digital health technologies in their use. The analysis of remote patient monitoring system implementation, highlighting local specifics, identifies important barriers and facilitators to technology adoption in intensive care. It could serve as a guide for clinicians and implementation leaders.

5. Conclusions

For this dissertation, we thoroughly analyzed the implementation of a remote patient monitoring system in an intensive care setting and derived a framework for guidance of implementation leaders. The mainly qualitative research approach brought about insights about staff perceptions of patient monitoring, AI in the ICU and their ideas for improvement of perceived problems with patient monitoring such as poor usability, high frequency of false positive alarms and high workload. Qualitative research in the field of digital health is especially important to explore the multitude of influencing factors to digital health adoption and -implementation; especially regarding the domain “individual characteristics”.

After studying an implementation project in the unique environment of the ICU, with its high technology density, stress levels, critically ill patients, and multidisciplinary team composition, we conclude that, especially in such an environment, the assessment and analysis of local specifics in advance of implementation is crucial, whether for operational or research purposes. In addition, we emphasize the importance of clear implementation leadership and a sound communication strategy for the project, its context, its goals, and its current status. The implementation framework can guide implementation leaders throughout the life of the project and should be subject to continuous reassessment, supported by feedback from "real-life implementers".

Lastly, we found that usability of a patient monitoring system is crucial for ICU staff. Therefore, user-centered design (and implementation practice) may not only improve performance of a product, but also enhance health professionals’ trust in and awareness of digital health technology. Clear ideas of how to improve existing monitoring technology in the ICU exist among staff members – e.g., wireless monitoring, CDSS based on AI and implementing hospital alarm SOPs. Thus, the goal should be to implement existing strategies to improve user-friendliness and reduce stress and workload when working with the monitoring system - rather than developing and implementing technologies past the end-users’ needs.

Appendix

Appendix 1: Interview guide for sub-study 1. Source: (Poncette, Spies, et al. 2019)

Leitfadengestütztes Interview – Vor Nutzung von Vital Sync

Haben Sie noch Fragen zum Hintergrund der Mitarbeiterbefragung?

[ICEBREAKER] Welche Rolle spielt das aktuelle Monitoringsystem für Sie generell?

[Status quo] Wie oft interagieren Sie mit dem Überwachungssystem in Ihrem Arbeitsalltag?
Was gefällt Ihnen an dem aktuellen Monitoring-System? Welche Funktionen nutzen Sie (z.B. Alarmgrenzen, Trendanalyse)? Was würden Sie an dem System ändern?

[Neues System] Wie sieht das Monitor-System der Zukunft für Sie aus? Welche Funktionen hat es?

[Visualisierung] Welche Rolle spielt die graphische Visualisierung (auch in Relation zur Zeit = Trend) der Parameter für Sie? Sollte die Visualisierung der Parameter und die Trendanalyse eine wichtigere Rolle bei der Übergabe spielen? (Tablet-PC einem Kollegen zeigen)

[Fern-Überwachung] Was halten Sie von Fern-Überwachung der ITS-Patienten? In welchen Situationen spielt die Fernüberwachung eine wesentliche Rolle in Ihrem Arbeitsalltag? (z.B. beim Schicht-Wechsel, Übergabe des Patienten, Abwesenheit vom Patienten)

[Clinical Decision Support (CDS)] Haben Sie schon mal was von CDS gehört? Wie würden Sie sich fühlen, wenn eine Software Empfehlungen zu Ihrer Therapie abgibt? Würden Sie diese in Ihre Therapieplanung miteinbeziehen?

[Usability] Welche Rolle spielt die Bedienbarkeit von Monitoringsystemen für Sie? Was ist für Sie wichtiger: Bedienbarkeit oder Anzahl der Funktionen? Denken Sie ein großes oder ein kleines Tablet wäre besser für Ihre Nutzungszwecke geeignet? Wäre ein Zugang über das Intranet des Krankenhauses von Nutzen? Sollte das Tablet einen Audio-Alarm haben?

[Personenbezogene Daten] Alter, Geschlecht, Qualifikation, ITS-Erfahrung in Jahren, Wie zufrieden sind Sie mit Ihrem Beruf (5 Sterne für *sehr zufrieden*)? Arbeiten Sie auch in anderen Bereichen? Wie IT-affin sind Sie (5 Sterne für *sehr IT*-affin)?

[Abschluss] Halten Sie die systematische Einführung von innovativen Patienten-Monitor-Systemen auf der ITS für sinnvoll? (5 Sterne für *sehr sinnvoll*)

Appendix 2: Online-Questionnaire. Source: (Poncette, Mosch, et al. 2020a)

Confidential

Patienten-Monitoring in der Intensivmedizin

Liebe Kolleginnen und Kollegen,

mit dieser Umfrage möchten wir einschätzen was Ihnen beim Patienten-Monitoring auf der Intensivstation (ITS) wichtig ist und was Sie sich von einem zukünftigen Patienten-Monitoring wünschen. Diese Substudie ist Teil der SARPI Studie "Staff Acceptance of Remote Patient Monitoring on ICU". Mit Ihren Umfrageergebnissen möchten wir die Patientensicherheit erhöhen und die Arbeitsbedingungen auf der Intensivstation verbessern.

Die Teilnahme dauert ca. 10 Minuten und ist anonym und freiwillig. Aus der Umfrage können keine arbeitsrechtlichen Konsequenzen abgeleitet werden und Sie können zu jedem Zeitpunkt abbrechen bzw. Fragen auslassen. Eine Leistungs- oder Verhaltenskontrolle erfolgt nicht. Alle für die Auswertung notwendigen Daten inklusive der personenbezogenen Daten (Alter, Beruf) werden in elektronischer Form auf dem KAI-Klinikserver hinterlegt und nach 10 Jahren vernichtet. Die Ethikkommission (EA1_031_18) und der Personalrat haben der Befragung zugestimmt.

Im Anschluss an diese Umfrage können Sie bei einem Gewinnspiel mitmachen, bei dem ein 50,- Euro Bahngutschein unter den Umfrage-TeilnehmerInnen verlost wird. Für Rückfragen stehen wir natürlich jederzeit zur Verfügung (E-Mail oder Tel. 631185).

Vielen Dank für Ihre Unterstützung!

AG Date Science in Perioperative Care

--

Prof. Dr. Dr. Felix Balzer (Studienleiter)

Dr. Akira-Sebastian Poncette (Studienkoordinator)

1)	Ich bin damit einverstanden, dass im Rahmen des oben genannten Forschungsvorhabens personenbezogene Daten von mir datenschutzgerecht gespeichert, analysiert und anonymisiert veröffentlicht werden.	☐ Einverstanden
2)	Arbeiten Sie derzeit regelmäßig im intensivmedizinischen Bereich (an mehr als 2 Tagen pro Monat)?	☐ Ja

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Diese Umfrage bezieht sich auf das aktuelle Patienten-Monitoring der Firma Philips der Intensivstationen der Klinik für Anästhesiologie m.S. operative Intensivmedizin CCM/CVK.

		Stimme gar nicht zu	Stimme nicht zu	Teils/Teils	Stimme zu	Stimme sehr zu
3)	Mit dem aktuellen Patienten-Monitoring bin ich zufrieden.	○	○	○	○	○
4)	Das aktuelle Patienten-Monitoring gewährleistet eine hohe Patientensicherheit.	○	○	○	○	○
5)	Ich fühle mich sicher im Umgang mit dem Patienten-Monitoring.	○	○	○	○	○

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Folgende Aspekte des Patienten-Monitorings stören die Patientenversorgung:

		Stimme gar nicht zu	Stimme nicht zu	Teils/Teils	Stimme zu	Stimme sehr zu
6)	Viele Falsch-Alarme, die keine Konsequenz haben (z.B. durch Messfehler, Artefakte, falsche Einstellung)	○	○	○	○	○
7)	Mangel an Benutzerfreundlichkeit	○	○	○	○	○
8)	Mangel an Vernetzung (z.B. mit Beatmungsgerät, COPRA)	○	○	○	○	○
9)	Zu viele Sensorenkabel (Kabelsalat bei Patienten-Transport)	○	○	○	○	○
10)	Fehlende Personal-Schulung in Patienten-Monitoring	○	○	○	○	○

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Das aktuelle Patienten-Monitoring auf der ITS sollte durch folgende Maßnahmen verbessert werden:

		Stimme gar nicht zu	Stimme nicht zu	Teils/Teils	Stimme zu	Stimme sehr zu
11)	Kabellose Sensoren	○	○	○	○	○
12)	Nicht-invasive Sensoren (z.B. für Hämoglobin)	○	○	○	○	○
13)	Reduktion der Falsch-Alarm Häufigkeit	○	○	○	○	○
14)	Patientenfernüberwachung z.B. über Smartphone, Tablet	○	○	○	○	○
15)	Klinikstandard für Alarm-Management	○	○	○	○	○
16)	Mehr Fortbildungen zu Patienten-Monitoring	○	○	○	○	○

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Alarm-Einstellungen des Patienten-Monitorings	nie	selten	gelegentlich	oft	immer
17) Bei Schichtübergabe übergebe ich die eingestellten Alarmgrenzen mündlich weiter.	○	○	○	○	○
18) Die Alarmeinstellungen (z.B. Alarmgrenzen) werden dokumentiert.	○	○	○	○	○
19) Ich verwende das voreingestellte Patienten-Monitoring Profil, ohne Grenzwerte zu verändern.	○	○	○	○	○
20) Bei Untersuchungen am Patienten setze ich die Alarme am Monitor auf "Pause".	○	○	○	○	○
21) Ich passe die Alarmeinstellungen patientenindividuell an.	○	○	○	○	○

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Alarme des Patienten-Monitorings	nie	selten	gelegentlich	oft	immer
22) Ich fühle mich überfordert von zu vielen Alarmen.	○	○	○	○	○
23) Es kommt vor, dass ein kritischer Alarm überhört und somit verpasst wird.	○	○	○	○	○
24) Alarme, die immer wieder angehen, ignoriere ich mit der Zeit.	○	○	○	○	○
25) In manchen Schichten gibt es so viel zu tun, dass ich nicht schnell genug auf Alarme reagieren kann.	○	○	○	○	○
26) Kritische Alarme werden schnell und deutlich wahrgenommen und führen zu sofortigem Handeln.	○	○	○	○	○

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Falsch-Alarme des Patienten-Monitorings (z.B. durch Messfehler, Artefakte, falsche Einstellung)

	Stimme gar nicht zu	Stimme nicht zu	Teils/Teils	Stimme zu	Stimme sehr zu
27) Falsch-Alarme erschweren die Versorgung von Patienten.	○	○	○	○	○
28) Falsch-Alarme reduzieren mein Vertrauen in die Alarme.	○	○	○	○	○

29) Wieviel Prozent aller Alarme sind Ihrer Meinung nach Falsch-Alarme (z.B. durch Messfehler, Artefakte, falsche Einstellung)?

0% 100%

(Place a mark on the scale above)

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Falsch-Alarme: Welcher Sensor bzw. welches Gerät generiert Ihrer Meinung nach generell die häufigsten Falsch-Alarme?

ABP=Arterieller Blutdruckmessung
NIBP=Nicht-invasive Blutdruckmessung
Temp.=Temperatur
Beatmung.=Beatmungsmaschine
SpO2=Pulsoxymetrie
EKG=Elektrokardiogramm

	ABP	NIBP	Temp.	Beatmung	SpO2	EKG
30) Am häufigsten	○	○	○	○	○	○
31) Am zweit-häufigsten	○	○	○	○	○	○
32) Am dritt-häufigsten	○	○	○	○	○	○

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Alle Alarme: Welcher Sensor bzw. welches Gerät generiert Ihrer Meinung nach generell die häufigsten Alarme (richtige und falsche Alarme)?

ABP=Arterieller Blutdruckmessung
NIBP=Nicht-invasive Blutdruckmessung
Temp.=Temperatur
Beatmung.=Beatmungsmaschine

	ABP	NIBP	Temp.	Beatmung	SpO2	EKG
33) Am häufigsten	○	○	○	○	○	○
34) Am zweit-häufigsten	○	○	○	○	○	○
35) Am dritt-häufigsten	○	○	○	○	○	○

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Für das Patienten-Monitoring der Zukunft wünsche ich mir zusätzlich folgende Geräte:

	Stimme gar nicht zu	Stimme nicht zu	Teils/Teils	Stimme zu	Stimme sehr zu
36) Smartphone	○	○	○	○	○
37) Großes Tablet	○	○	○	○	○
38) Kleines Tablet	○	○	○	○	○
39) Smartwatch	○	○	○	○	○
40) Allgegenwärtiges Zentralmonitoring z.B. durch Augmented Reality Brille (erweiterte Realität)	○	○	○	○	○

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In folgenden Situationen kann die Fern-Überwachung der Patienten mithilfe Smartphones oder Tablets nützlich sein:

	Stimme gar nicht zu	Stimme nicht zu	Teils/Teils	Stimme zu	Stimme sehr zu
41) Im Bereitschaftsdienst	○	○	○	○	○
42) Um schneller alarmiert zu werden	○	○	○	○	○
43) Bei Verantwortung für mehrere Stationen	○	○	○	○	○
44) In der Pause (z.B. beim Frühstücken)	○	○	○	○	○

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Was ist Ihre Einstellung zu neuen digitalen Technologien in der Intensivmedizin?

	Stimme gar nicht zu	Stimme nicht zu	Teils/Teils	Stimme zu	Stimme sehr zu
45) Ich möchte mehr über neue digitale Technologien für die ITS erfahren.	○	○	○	○	○
46) Ich möchte neue digitale Technologien für die ITS mitgestalten.	○	○	○	○	○
47) Ich hätte gerne mehr Zeit im Alltag um neue digitale Technologien kennen zu lernen.	○	○	○	○	○
48) Neuen digitalen Technologien traue ich nicht.	○	○	○	○	○
49) Die Einführung neuer digitaler Technologien auf die ITS verringert die klinischen Fähigkeiten.	○	○	○	○	○

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Folgende klinische Entscheidungshilfe-Systeme basierend auf Künstlicher Intelligenz würde ich in Zukunft gerne nutzen:

	Stimme gar nicht zu	Stimme nicht zu	Teils/Teils	Stimme zu	Stimme sehr zu
50) Intelligentes Alarm-Management (z.B. automatische Alarmgrenzen, Trendalarm)	○	○	○	○	○
51) Früherkennung von Komplikationen (z.B. Sepsis, akutes Nierenversagen)	○	○	○	○	○
52) Früherkennung erhöhter Mortalität	○	○	○	○	○
53) Intelligenter Vorschlag von Leitlinien (z.B. bei Antibiotika, Delir)	○	○	○	○	○

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Was würde Sie motivieren klinische Entscheidungshilfe-Systeme basierend auf Künstlicher Intelligenz regelmäßig auf der ITS zu nutzen?

	Stimme gar nicht zu	Stimme nicht zu	Teils/Teils	Stimme zu	Stimme sehr zu
54) Nachvollziehbarkeit der künstlichen Intelligenz	○	○	○	○	○
55) Vernetzung z.B. mit COPRA, Patienten-Monitoring, Beatmungsgerät	○	○	○	○	○
56) Hohe Benutzerfreundlichkeit	○	○	○	○	○
57) Regelmäßige Unterstützung z.B. Schulungen, Workshops	○	○	○	○	○

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Fragen zu Technik-Affinität.

	Stimme gar nicht zu	Stimme nicht zu	Teils/Teils	Stimme zu	Stimme sehr zu
58) Ich beschäftige mich gern genauer mit technischen Systemen.	○	○	○	○	○
59) Ich probiere gern die Funktionen neuer technischer Systeme aus.	○	○	○	○	○
60) Es genügt mir, dass ein technisches System funktioniert, mir ist es egal, wie oder warum.	○	○	○	○	○
61) Es genügt mir, die Grundfunktionen eines technischen Systems zu kennen.	○	○	○	○	○

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62) In welcher Berufsgruppe sind Sie derzeit tätig?

- ☐ Arzt/Ärztin in Weiterbildung
- ☐ Facharzt/-ärztin für Anästhesiologie
- ☐ Zusatzbezeichnung Intensivmedizin
- ☐ Zusatzbezeichnung Notfallmedizin
- ☐ Zusatzbezeichnung Schmerzmedizin
- ☐ Gesundheits- und Krankenpfleger/ -in
- ☐ Fachpflegekraft für Intensivpflege und Anästhesie
- ☐ Rettungssanitäter/in
- ☐ Atmungstherapeut/in

63) Geschlecht:

- ○ weiblich
- ○ männlich
- ○ divers
- ○ keine Angabe

64) Zu welcher Altersgruppe zählen Sie?

- ○ 18-24 Jahre
- ○ 25-34 Jahre
- ○ 35-44 Jahre
- ○ 45-54 Jahre
- ○ 55-64 Jahre
- ○ >65 Jahre

65) Sonstige Kommentare zur Umfrage

____

Appendix 3: Translated interview guide for sub-study 3. Source: (L. K. Mosch et al. 2022)

Remote patient monitoring system: CFIR - adapted questionnaire

Question	CFIR Category
Current patient monitoring in ICU	
1. I am satisfied with the current patient monitoring system. Likert scale 1= not correct at all - 5 = completely correct 2. In my opinion, there is a need to change or improve patient monitoring on the ward. Likert Scale 1= not correct at all - 5 = completely correct	Inner Setting - Implementation Climate: Tension for Change
3. What should be changed? Graphical representation Alarm Management Intuitive operation Less cables Interoperability with other devices (ventilator, PDMS, ...) Trend analyses Setting advanced functions Other proposed amendments: Likert Scale 1= not correct at all - 5 = completely correct	Inner Setting - Implementation Climate: Tension for Change
Remote patient monitoring e.g. via smartphones or tablets in the intensive care unit	
4. Remote monitoring of patients in the intensive care unit offers advantages. Likert Scale 1= not correct at all - 5 = completely correct	Inner Setting - Implementation Climate: Compatibility Intervention characteristics: relative advantage
5. I personally find the implementation of remote patient monitoring in intensive care important. Likert scale: 1= not correct at all - 5 = completely correct	Inner Setting - Implementation Climate: Relative Priority Individual Characteristics - knowledge and beliefs about the intervention
6. Why do you find the introduction of remote patient monitoring (not) important?	Inner setting - Implementation Climate: compatibility, relative priority Individual characteristics - knowledge and beliefs about the intervention
VitalSync remote patient monitoring system	

7. I find the use of the VitalSync System as a supplement to the current patient monitoring system useful. Likert scale: 1= not correct at all - 5 = completely correct	Intervention characteristics - relative advantage Individual characteristics - knowledge and beliefs about the intervention
8. The VitalSync system was of high benefit to my profession. Likert scale: 1= not correct at all - 5 = completely correct 9. Why (not)?	
10. Using VitalSync increases patient safety in the intensive care unit. Likert scale: 1= not correct at all - 5 = completely correct 11. Why (not)?	Outer setting: Patient needs and resources Individual characteristics - knowledge and beliefs about the intervention
12. In my opinion, the VitalSync System has been well integrated into the daily work on the ward. Likert scale: 1= not correct at all - 5 = completely correct 13. What do you think was the reason for that?	Intervention Characteristics: Complexity, Adaptability Process: Executing
Design	
14. The design of the VitalSync System is intuitive. Likert scale: 1= not correct at all - 5 = completely correct 15. The design of the VitalSync System is attractive. Likert scale: 1= not correct at all - 5 = completely correct 16. The design of the VitalSync System is clear. Likert scale: 1= not correct at all - 5 = completely correct	IC: Design Quality and Packaging
Communication of the project	
17. I feel well informed about the process of installing the VitalSync System on the PACU. Likert scale: 1= not correct at all - 5 = completely correct 18. The purpose and goals of the VitalSync project were clearly communicated by the project leaders. Likert scale: 1= not correct at all - 5 = completely correct 19. What would you have wished for in terms of communication by the project managers?	Inner Setting: Networks and communication, Intervention source, Implementation Climate: Goals and feedback, Learning climate Process: Planning, Engaging
20. Please evaluate how far the following factors contribute to the successful implementation of technologies like VitalSync from your perspective. Likert scale: 1= not correct at all - 5 = completely correct a. High intuitiveness b. Great additional benefit c. Low personnel turnover (constant personnel pool, little leasing) d. Low patient turnover on the ward (longer stays) e. Reduced workload f. a lot of technical instructions on the system	Intervention characteristics: Relative advantage, adaptability, evidence strength and quality Inner setting: structural characteristics

g. All patient beds in the ward equipped with the system (extensive availability) h. Higher number of available parameters in monitoring 21. Other factors that contribute significantly to a successful implementation of the system:	
Teamwork on the ward	
22. I feel well integrated into the interprofessional team in the intensive care unit. Likert scale: 1= not correct at all - 5 = completely correct 23. The team spirit within the team on the ward is good. Likert scale: 1= not correct at all - 5 = completely correct 24. The atmosphere within the team had a great influence on the introduction of the VitalSync System on the ward. Likert scale: 1= not correct at all - 5 = completely correct 25. Please give reasons for your decision.	Inner Setting: Networks and communication Process: Enganging, Executing
Hierarchical structures on the ward	
26. Hierarchies, both within and between professions (e.g. within the nursing team / between nurses and doctors) play a major role. Likert scale: 1= not correct at all - 5 = completely correct 27. Hierarchical structures on the ward had a great influence on the introduction of the VitalSync System. Likert scale: 1= not correct at all - 5 = completely correct 28. Please give reasons for your decision.	Inner setting Networks and communications Process: Executing
Adaptation to new situations	
29. In general, I am able to adapt well to new situations and challenges. Likert scale: 1= not correct at all - 5 = completely correct	CI: Self efficacy
30. Technology acceptance Neyer et al.	Individual Characteristics: self efficacy
Demographic data	
31. Qualification a. Physician in postgraduate specialization b. Specialist in anaesthesiology c. Additional qualification in intensive care medicine d. Additional qualification in emergency medicine e. Additional qualification in pain medicine f. Nurse g. Specialist nurse for intensive care and anaesthesia	

h. Paramedic i. Respiratory therapist 32. How old are you? a. 18-24 years b. 25-34 years c. 35-44 years d. 45-54 years e. 55-64 years f. >65 years	
33. Gender a. female b. male c. other d. not specified 34. I am satisfied with my job. Likert scale: 1= not correct at all - 5 = completely correct	CI: individual stage of change

Technical readiness according to Ney et al.

Appendix 4: Mapping of CFIR domains to summaries of codes concerning the implementation performances. Source: (L. K. Mosch et al. 2022)

CFIR Construct	Summary segment and questionnaire responses
Intervention characteristics	
Intervention source	There was a feeling among the staff that the remote patient monitoring system was being imposed from above without having an influence on being part of the implementation.
Evidence strength and quality	The installed beta version of the system only offered a limited number of vital parameters that could be monitored.
Relative advantage	The system was introduced to the ICU as a supplementary monitoring system, which was why the staff did not perceive its additional value as high.
	The current monitoring system already offered remote monitoring functions such as flexibly, displaying parameters of different patients on a bedside monitor
	In an ICU, the reaction to an alarm has to be immediate due to the severe conditions of the admitted patients.
	Remotely monitoring patients while being on a different ward or in a different part of the hospital makes the quick reaction impossible and, thus, is without consequence.
	The available vital signs were not sufficient to evaluate the patient's condition satisfactorily.
	The majority stated that using the remote patient monitoring as a supplementary monitoring in the ICU was not useful (5 not correct at all or not quite correct), did not have a benefit for the respective pro-

	fessional group (5 not correct at all or not quite correct,) [...].
Trialability	The system was introduced to the ICU as a supplementary monitoring system, which was why the staff did not perceive its additional value as high.
Adaptability	The system was introduced to the ICU as a supplementary monitoring system, which was why the staff did not perceive its additional value as high.
	In an ICU, the reaction to an alarm has to be immediate due to the severe conditions of the admitted patients.
	Remotely monitoring patients while being on a different ward or in a different part of the hospital makes the quick reaction impossible and, thus, is without consequence.
	If physicians are registering a remote alarm while being occupied with tasks such as placing a central venous catheter or performing surgery, those alarms remain without consequence.
	In key situations such as transport of patients, using the system for monitoring was not possible due to a large module and several cables.
	The majority stated that [...] the remote patient monitoring as a supplementary monitoring in the ICU [...] was not well integrated into the clinical routine (5 not correct at all or not quite correct).
Complexity	The high patient turnover in a post-anesthesia care unit led to a higher workload for nursing staff while connecting and disconnecting the system for every new patient.
	The tablet was perceived by some interviewees as too large for using it in the daily work routine.

	A reason for not using the system was the inconvenience of carrying another device in already packed tunic pockets.
	A concern was that the device can get lost.
	Interviewees raised concerns about the system's dependency on a stable WiFi connection.
Inner setting	
Structural characteristics	Training did not reach all staff due to a complex shift system and a big pool of staff for two ICUs.
	The system was implemented only at five out of ten bedsides on one out of two ICUs.
	The high number of monitors in an ICU made an additional tablet not necessary, according to the interviewees.
	The perceived impact of the system was low because high staff presence in the ICU made the implementation of remote patient monitoring superfluous.
	The high patient turnover in a post-anesthesia care unit led to a higher workload for nursing staff while connecting and disconnecting the system for every new patient.
	Respondents claimed that in an ICU, the reaction to an alarm has to be immediate due to the severe conditions of the admitted patients. Remotely monitoring patients while being on a different ward or in a different part of the hospital makes the quick reaction impossible and, thus, is without consequence.
Networks and communications	There was a lack of persisting initiatives to engage staff in the implementation process such as regular staff training and information events.

	Communication of negative aspects of the intervention created a negative peer pressure to not use the system.
	Training did not reach all staff due to a complex shift system and a big pool of staff for two ICUs.
	The team spirit on the ICU was stated to be good by the majority (7 quite correct).
	The general atmosphere within the ICU team had a large impact on the implementation process according to the interviewees (5 quite correct).
	The majority stated that the aims and purpose of the remote patient monitoring implementation was clearly communicated (6 quite correct or completely correct).
Implementation climate - *Tension for change*	The system was introduced to the ICU as a supplementary monitoring system, which was why the staff did not perceive its additional value as high.
	The current monitoring system already offered remote monitoring functions, such as flexibly displaying parameters of different patients on a bedside monitor.
	ICU staff saw no additional benefit in using the system.
	Interviewees said to be satisfied with the current patient monitoring and do not see the need for change.
Implementation climate - *Compatibility*	Staff involvement was perceived to be more targeted towards nursing staff, although not being in charge of the implementation project.
Implementation climate - *Relative priority*	There was a lack of feeling of responsibility by staff members of all professions to continuously apply the system.

Implementation climate - *Learning climate*	On the one hand, a leading nurse or physician was not identified for the implementation process by the staff, on the other hand, interviewees reported a lack of persisting initiatives to engage staff in the implementation process such as regular training and information events.
	The high patient turnover in a post-anesthesia care unit led to a higher workload for nursing staff while connecting and disconnecting the system for every new patient.
Implementation readiness - *Leadership engagement*	A lack of leadership engagement was reported both in the nursing and the medical department.
	Staff could not identify a leading nurse or physician responsible for the implementation process.
Implementation readiness - *access to information and knowledge*	A lack of knowledge about the aims and context of the implementation project, and a lack of continuous staff training led to a negative feeling towards the intervention, and a lack of motivation to engage further with the system.
Individual characteristics	
Knowledge and beliefs about the intervention	Communication of negative aspects of the intervention created a negative peer pressure to not use the system.
	A lack of knowledge about the aims and context of the implementation project, and a lack of continuous staff training led to a negative feeling towards the intervention and a lack of motivation to engage further with the system.
	The staff was afraid of losing their break times when applying the remote patient monitoring system.
	Another fear was that the system creates an increased workload for staff (e.g., set-up, connection) rather than decreasing it.

	ICU staff claimed that remote monitoring would lead to less direct patient contact and thus threaten patient safety as the patient's clinical condition would not be evaluated adequately.
	The staff feared that additional (false) alarms would appear when applying the system, increasing the stress level and endangering patient safety.
Self-efficacy	Interviewees accomplished, on average, 47 points on a 12–60 point technology commitment scale, which shows high technology commitment.
	ICU staff did not use the system because they lacked the habit and routine to use remote patient monitoring technology.
Individual stage of change	ICU staff saw no additional benefit in using the system.
	Opinions were split if patient monitoring improvements are necessary (3 not correct at all or not quite correct, 4 quite correct or completely correct), if remote patient monitoring of patients in the ICU has advantages (1 not quite correct, 3 quite correct or completely correct), and if remote patient monitoring in the ICU is important (2 not quite correct, 1 completely correct).
	The majority of participants stated to be satisfied with the current patient monitoring (6 quite correct or completely correct).
Process	
Planning	There was a lack of knowledge among staff about the aims and context of the implementation project.
Engaging	Staff involvement was perceived to be more targeted towards nursing staff, although not being in charge of the implementation project.

	There was a lack of persisting initiatives to engage staff in the implementation process such as regular staff training and information events.
Engaging - *Opinion leaders* - *Peers*	Communication of negative aspects of the intervention created a negative peer pressure to not use the system.
Engaging - *Opinion leaders* - *Experts*	Physicians were perceived to be not as engaged with the system and to have received less training.
Engaging - *Formally appointed internal implementation leaders*	Staff could not identify a leading nurse or physician responsible for the implementation process.
Executing	The frequency of staff training was very high in the beginning but decreased over time. Staff said to have felt well informed about the project initially, however, the information flow decreased equally.

Appendix 5: ERIC strategies mapped to summaries of codes concerning staff suggestions for improving implementation performance. Source: (L. K. Mosch et al. 2022)

ERIC strategy	Summary segment and questionnaire responses
Use evaluative and iterative strategies	
Purposely re-examine the implementation	Feedback discussions with staff and project leaders during implementation would increase staff engagement.
Develop a formal implementation blueprint	Staff should be informed of the implementation project and its aims in order to increase motivation to apply the new technology.
Audit and provide feedback	Feedback discussions with staff and project leaders during implementation would increase staff engagement.
Provide interactive assistance	
Facilitation	During training, staff should be informed of the implementation project and its aims in order to increase motivation to apply the new technology.
	A well-functioning team with good team spirit was deemed beneficial for successful implementation.
Provide clinical supervision	Persistent leadership engagement and the nomination of specific responsible persons for the implementation process was important for successful implementation, especially in a busy environment such as the ICU.
Adapt and tailor to context	

Promote adaptability	During training, staff should be informed of the implementation project and its aims in order to increase motivation to apply the new technology.
	With regard to the Software of the monitoring technology, interoperability with other devices such as the respirator or the PDMS is important for a successful implementation of a remote patient monitoring system, especially regarding import and export of patient data and visualization of parameters on one screen.
	High intuitiveness is crucial for effective implementation.
	A large screen for clear visualization is demanded, on the other hand interviewees favored a device that fits into the pocket of a tunic, e.g. a smartphone.
	The intelligent grouping and display of monitoring parameters thematically by organ systems is advocated. Visualization of alarms should be clearer. Intelligent alarm management would be beneficial. Remote patient monitoring via smartphone could work well with vibration alarms.
	Availability of all standard vital sign parameters (7 quite correct or completely correct), high intuitiveness (6 quite correct or completely correct) and high additional benefit (6 quite correct or completely correct) of the intervention would facilitate implementation.
Develop stakeholder interrelationships	
Recruit, designate, and train for leadership	Persistent leadership engagement and the nomination of specific responsible persons for the implementation process was important for successful implementation, especially in a busy environment such as the ICU.
	Furthermore, communication of the project by team leaders and coordinators should be encouraging and motivating.

Organize clinician implementation team meetings	Feedback discussions with staff and project leaders during implementation would increase staff engagement.
Model and simulate change	Staff should be informed of the implementation project and its aims in order to increase motivation to apply the new technology
Involve executive boards	Persistent leadership engagement and the nomination of specific responsible persons for the implementation process was important for successful implementation, especially in a busy environment such as the ICU.
Inform local opinion leaders	Persistent leadership engagement and the nomination of specific responsible persons for the implementation process was important for successful implementation, especially in a busy environment such as the ICU.
	Feedback discussions with staff and project leaders during implementation would increase staff engagement.
Identify and prepare champions	Persistent leadership engagement and the nomination of specific responsible persons for the implementation process was important for successful implementation, especially in a busy environment such as the ICU.
	Furthermore, communication of the project by team leaders and coordinators should be encouraging and motivating.
Train and educate stakeholders	
Conduct ongoing training	Furthermore, staff training should take place continuously before or after shifts and was particularly important in early implementation stages.
	High frequency of staff training would increase implementation success (5 quite correct or completely correct, 1 not quite correct).

Make training dynamic	The quality of the instructions was essential to positively influence the staff's opinion towards the implementation.
	Furthermore, communication of the project by team leaders and coordinators should be encouraging and motivating.
Conduct educational meetings	The personnel should be informed of the implementation project and its aims in order to increase motivation to apply the new technology.
Support clinicians	
Remind clinicians	Furthermore, staff training should take place continuously before or after shifts and was particularly important in early implementation stages. High frequency of staff training increased implementation success. During training, staff should be informed of the implementation project and its aims in order to increase motivation to apply the new technology. The quality of the instructions was essential to positively influence the staff's opinion towards the implementation. Feedback discussions with staff and project leaders during implementation would increase staff engagement.
Facilitate relay of clinical data to providers	During training, staff should be informed of the implementation project and its aims in order to increase motivation to apply the new technology. The quality of the instructions was essential to positively influence the staff's opinion towards the implementation. Feedback discussions with staff and project leaders during implementation would increase staff engagement.
Change infrastructure	
Change service sites	A normal ward or IMCU would be more suitable for a remote patient monitoring technology, as staff presence is lower and technical facilities are scarcer. Patients with a relatively weak indication for admission to the intensive care unit, such as postoperative monitoring in a patient with sleep apnea, could thus be admitted to normal ward or IMCU.

	Wards with low staff turnover (6 quite correct or completely correct) and low patient turnover (5 quite correct or completely correct) would be more suitable according to the majority.
Change physical structure and equipment	To increase implementation performance, all beds on the ward should be equipped with the respective technology, equally all staff members should have access to a portable monitoring device (tablet, smartphone).
	The majority stated ubiquitous availability of the technology (all beds equipped) would facilitate implementation (7 quite correct or completely correct).

Bibliography

Aulenkamp, Jana, Marie Mikuteit, Tobais Löffler, and Jeremy Schmidt. 2021. “Overview of Digital Health Teaching Courses in Medical Education in Germany in 2020.” *GMS Journal for Medical Education* 38 (4): Doc80. https://doi.org/10.3205/zma001476.

Billings, Charles E. 1991. *Human-Centered Aircraft Automation: A Concept and Guidelines*. Vol. 103885. National Aeronautics and Space Administration, Ames Research Center.

Boyatzis, Richard E. 1998. *Transforming Qualitative Information: Thematic Analysis and Code Development*. London and New Delhi: SAGE.

Chee, Marcel Lucas, Marcus Eng Hock Ong, Fahad Javaid Siddiqui, Zhongheng Zhang, Shir Lynn Lim, Andrew Fu Wah Ho, and Nan Liu. 2021. “Artificial Intelligence Applications for COVID-19 in Intensive Care and Emergency Settings: A Systematic Review.” *International Journal of Environmental Research and Public Health* 18 (9): 4749. https://doi.org/10.3390/ijerph18094749.

Chen, Junjun, Hong Pu, and Dianrong Wang. 2021. “Artificial Intelligence Analysis of EEG Amplitude in Intensive Heart Care.” *Journal of Healthcare Engineering* 2021 (July): 6284035. https://doi.org/10.1155/2021/6284035.

Damschroder, Laura J., David C. Aron, Rosalind E. Keith, Susan R. Kirsh, Jeffery A. Alexander, and Julie C. Lowery. 2009. “Fostering Implementation of Health Services Research Findings into Practice: A Consolidated Framework for Advancing Implementation Science.” *Implementation Science* 4 (1): 50. https://doi.org/10.1186/1748-5908-4-50.

De Cannière, Hélène, Federico Corradi, Christophe J. P. Smeets, Melanie Schoutteten, Carolina Varon, Chris Van Hoof, Sabine Van Huffel, Willemijn Groenendaal, and Pieter Vandervoort. 2020. “Wearable Monitoring and Interpretable Machine Learning Can Objectively Track Progression in Patients during Cardiac Rehabilitation.” *Sensors (Basel, Switzerland)* 20 (12): 3601. https://doi.org/10.3390/s20123601.

De Corte, Thomas, Sofie Van Hoecke, and Jan De Waele. 2022. “Artificial Intelligence in Infection Management in the ICU.” *Critical Care* 26 (March): 79. https://doi.org/10.1186/s13054-022-03916-2.

Dincklage, Falk von, Klaudiusz Suchodolski, Gregor Lichtner, Wolfgang Friesdorf, Beatrice Podtschaske, and Maximilian Ragaller. 2017. “Investigation of the Usability of Computerized Critical Care Information Systems in Germany.” *Journal of Intensive Care Medicine* 34 (3): 227–37. https://doi.org/10/f9tvbn.

Downey, Candice, Rebecca Randell, Julia Brown, and David G. Jayne. 2018. “Continuous Versus Intermittent Vital Signs Monitoring Using a Wearable, Wireless Patch in Patients Admitted to Surgical Wards: Pilot Cluster Randomized Controlled Trial.” *Journal of Medical Internet Research* 20 (12): e10802. https://doi.org/10.2196/10802.

Dubois, Anna, and Lars-Erik Gadde. 2002. “Systematic Combining: An Abductive Approach to Case Research.” *Journal of Business Research*, Markets as Networks, 55 (7): 553–60. https://doi.org/10/czsst3.

Elvekjaer, Mikkel, Eske K. Aasvang, Rasmus M. Olsen, Helge B. D. Sørensen, Celeste M. Porsbjerg, Jens-Ulrik Jensen, Camilla Haahr-Raunkjær, Christian S. Meyhoff, and for the WARD-Project Group. 2020. “Physiological Abnormalities in Patients

Admitted with Acute Exacerbation of COPD: An Observational Study with Continuous Monitoring.” *Journal of Clinical Monitoring and Computing* 34 (5): 1051–60. https://doi.org/10.1007/s10877-019-00415-8.

Escobar, Gabriel J., Vincent X. Liu, Alejandro Schuler, Brian Lawson, John D. Greene, and Patricia Kipnis. 2020. “Automated Identification of Adults at Risk for In-Hospital Clinical Deterioration.” *New England Journal of Medicine* 383 (20): 1951–60. https://doi.org/10.1056/NEJMsa2001090.

Fereday, Jennifer, and Eimear Muir-Cochrane. 2006. “Demonstrating Rigor Using Thematic Analysis: A Hybrid Approach of Inductive and Deductive Coding and Theme Development.” *International Journal of Qualitative Methods* 5 (1): 80–92. https://doi.org/10/gcdvss.

Fidler, Richard, Raymond Bond, Dewar Finlay, Daniel Guldenring, Anthony Gallagher, Michele Pelter, Barbara Drew, and Xiao Hu. 2015. “Human Factors Approach to Evaluate the User Interface of Physiologic Monitoring.” *Journal of Electrocardiology* 48 (6): 982–87. https://doi.org/10.1016/j.jelectrocard.2015.08.032.

García, Jorge Fernández, Solveigh Hieronimus, Angela Spatharou, Jan-Philipp Beck, and Jonathan Jenkins. 2020. “Transforming Healthcare with AI: The Impact on the Workforce and Organisations.” EIT Health and McKinsey & Company. https://eithealth.eu/wp-content/uploads/2020/03/EIT-Health-and-McKinsey_Transforming-Healthcare-with-AI.pdf.

Gardner, Reed M., Terry P. Clemmer, R. Scott Evans, and Roger G. Mark. 2014. “Patient Monitoring Systems.” In *Biomedical Informatics: Computer Applications in Health Care and Biomedicine*, edited by Edward H. Shortliffe and James J. Cimino, 561–91. London: Springer. https://doi.org/10.1007/978-1-4471-4474-8_19.

Greenstein, Joel S. 1995. “Introducing Human-Centered Design Early in the Engineering Curriculum.” *Proceedings of the Human Factors and Ergonomics Society Annual Meeting* 39 (6): 389–93. https://doi.org/10.1177/154193129503900603.

Guise, Veslemøy, Janet Anderson, and Siri Wiig. 2014. “Patient Safety Risks Associated with Telecare: A Systematic Review and Narrative Synthesis of the Literature.” *BMC Health Services Research* 14 (1): 588. https://doi.org/10.1186/s12913-014-0588-z.

Harris, Paul A., Robert Taylor, Brenda L. Minor, Veida Elliott, Michelle Fernandez, Lindsay O’Neal, Laura McLeod, et al. 2019. “The REDCap Consortium: Building an International Community of Software Platform Partners.” *Journal of Biomedical Informatics* 95 (July): 103208. https://doi.org/10.1016/j.jbi.2019.103208.

Harris, Paul A., Robert Taylor, Robert Thielke, Jonathon Payne, Nathaniel Gonzalez, and Jose G. Conde. 2009. “Research Electronic Data Capture (REDCap)—A Metadata-Driven Methodology and Workflow Process for Providing Translational Research Informatics Support.” *Journal of Biomedical Informatics* 42 (2): 377–81. https://doi.org/10.1016/j.jbi.2008.08.010.

Hashimoto, Daniel A., Elan Witkowski, Lei Gao, Ozanan Meireles, and Guy Rosman. 2020. “Artificial Intelligence in Anesthesiology: Current Techniques, Clinical Applications, and Limitations.” *Anesthesiology* 132 (2): 379–94. https://doi.org/10.1097/ALN.0000000000002960.

Howe, Jessica L., Katharine T. Adams, A. Zachary Hettinger, and Raj M. Ratwani. 2018. “Electronic Health Record Usability Issues and Potential Contribution to Patient Harm.” *JAMA* 319 (12): 1276–78. https://doi.org/10.1001/jama.2018.1171.

Keim-Malpass, Jessica, Matthew T. Clark, Douglas E. Lake, and J. Randall Moorman. 2020. “Towards Development of Alert Thresholds for Clinical Deterioration Using

Continuous Predictive Analytics Monitoring." *Journal of Clinical Monitoring and Computing* 34 (4): 797–804. https://doi.org/10.1007/s10877-019-00361-5.

Kemp, Emma, Joshua Trigg, Lisa Beatty, Chris Christensen, Haryana M. Dhillon, Anthony Maeder, Patricia A. H. Williams, and Bogda Koczwara. 2021. "Health Literacy, Digital Health Literacy and the Implementation of Digital Health Technologies in Cancer Care: The Need for a Strategic Approach." *Health Promotion Journal of Australia* 32 (S1): 104–14. https://doi.org/10.1002/hpja.387.

Kilic, Arman. 2020. "Artificial Intelligence and Machine Learning in Cardiovascular Health Care." *The Annals of Thoracic Surgery* 109 (5): 1323–29. https://doi.org/10.1016/j.athoracsur.2019.09.042.

Kushniruk, Andre W., Marc M. Triola, Elizabeth M. Borycki, Ben Stein, and Joseph L. Kannry. 2005. "Technology Induced Error and Usability: The Relationship between Usability Problems and Prescription Errors When Using a Handheld Application." *International Journal of Medical Informatics*, MedInfo 2004, 74 (7): 519–26. https://doi.org/10/btspc5.

Leenen, Jobbe PL, Crista Leerentveld, Joris D. van Dijk, Henderik L. van Westreenen, Lisette Schoonhoven, and Gijsbert A. Patijn. 2020. "Current Evidence for Continuous Vital Signs Monitoring by Wearable Wireless Devices in Hospitalized Adults: Systematic Review." *Journal of Medical Internet Research* 22 (6): e18636. https://doi.org/10.2196/18636.

Lennon, Marilyn R, Matt-Mouley Bouamrane, Alison M Devlin, Siobhan O'Connor, Catherine O'Donnell, Ula Chetty, Ruth Agbakoba, et al. 2017. "Readiness for Delivering Digital Health at Scale: Lessons From a Longitudinal Qualitative Evaluation of a National Digital Health Innovation Program in the United Kingdom." *Journal of Medical Internet Research* 19 (2). https://doi.org/10.2196/jmir.6900.

Lüdecke, Daniel, Alexander Bartel, Carsten Schwemmer, Chuck Powell, and Amir Djalovski. 2020. "SjPlot: Data Visualization for Statistics in Social Science." https://CRAN.R-project.org/package=sjPlot.

Machleid, Felix, Robert Kaczmarczyk, Doreen Johann, Justinas Balčiūnas, Beatriz Atienza-Carbonell, Finn von Maltzahn, and Lina Mosch. 2020. "Perceptions of Digital Health Education Among European Medical Students: Mixed Methods Survey." *Journal of Medical Internet Research* 22 (8): e19827. https://doi.org/10.2196/19827.

Marcial, Laura Haak, Douglas S. Johnston, Michael R. Shapiro, Sara R. Jacobs, Barry Blumenfeld, and Lucia Rojas Smith. 2019. "A Qualitative Framework-Based Evaluation of Radiology Clinical Decision Support Initiatives: Eliciting Key Factors to Physician Adoption in Implementation." *JAMIA Open* 2 (1): 187–96. https://doi.org/10/gg4krz.

Medtronic. 2017a. "QUICK GUIDE FOR CLINICIAN USERS: Vital Sync^{TM} Virtual Patient Monitoring Platform." https://www.medtronic.com/content/dam/covidien/library/us/en/product/health-informatics-and-monitoring/vital-sync-2-6-vpmp-user-quick-reference-guide.pdf.

———. 2017b. "Vital Sync^{TM} Virtual Patient Monitoring Platform: User Guide." https://www.medtronic.com/content/dam/covidien/library/us/en/product/health-informatics-and-monitoring/vital-sync-2-6-vpmp-user-guide.pdf.

Melles, Marijke, Armagan Albayrak, and Richard Goossens. 2021. "Innovating Health Care: Key Characteristics of Human-Centered Design." *International Journal for Quality in Health Care* 33 (Supplement_1): 37–44. https://doi.org/10/gh347n.

Middleton, B., M. Bloomrosen, M. A. Dente, B. Hashmat, R. Koppel, J. M. Overhage, T. H. Payne, S. T. Rosenbloom, C. Weaver, and J. Zhang. 2013. "Enhancing Patient

Safety and Quality of Care by Improving the Usability of Electronic Health Record Systems: Recommendations from AMIA." *Journal of the American Medical Informatics Association* 20 (e1): e2–8. https://doi.org/10.1136/amiajnl-2012-001458.

Mirsadeghi, M., H. Behnam, R. Shalbaf, and H. Jelveh Moghadam. 2016. "Characterizing Awake and Anesthetized States Using a Dimensionality Reduction Method." *Journal of Medical Systems* 40 (1): 13. https://doi.org/10.1007/s10916-015-0382-4.

Mosch, Lina, David Alexander Back, Felix Balzer, Mike Bernd, Jenny Brandt, Sebastian Erkens, Nicolas Frey, et al. 2021. "Lernangebote zu Künstlicher Intelligenz in der Medizin." Zenodo. https://doi.org/10.5281/ZENODO.5497668.

Mosch, Lina Katharina, Akira-Sebastian Poncette, Claudia Spies, Steffen Weber-Carstens, Monique Schieler, Henning Krampe, and Felix Balzer. 2022. "Creation of an Evidence-Based Implementation Framework for Digital Health Technology in the Intensive Care Unit: Qualitative Study." *JMIR Formative Research* 6 (4): e22866. https://doi.org/10.2196/22866.

Nagaraj, Sunil B., Siddharth Biswal, Emily J. Boyle, David W. Zhou, Lauren M. McClain, Ednan K. Bajwa, Sadeq A. Quraishi, et al. 2017. "Patient-Specific Classification of ICU Sedation Levels From Heart Rate Variability." *Critical Care Medicine* 45 (7): e683–90. https://doi.org/10.1097/CCM.0000000000002364.

Nagle, Lynn M, Manal Kleib, and Karen Furlong. 2020. "Digital Health in Canadian Schools of Nursing Part A: Nurse Educators' Perspectives," 19.

Neyer, Franz J., Juliane Felber, and Claudia Gebhardt. 2012. "Entwicklung und Validierung einer Kurzskala zur Erfassung von Technikbereitschaft." *Diagnostica* 58 (2): 87–99. https://doi.org/10.1026/0012-1924/a000067.

Noble, Helen, and Joanna Smith. 2015. "Issues of Validity and Reliability in Qualitative Research." *Evidence Based Nursing* 18 (2): 34–35. https://doi.org/10/gfvjff.

Palacholla, Ramya Sita, Nils Fischer, Amanda Coleman, Stephen Agboola, Katherine Kirley, Jennifer Felsted, Chelsea Katz, Stacy Lloyd, and Kamal Jethwani. 2019. "Provider- and Patient-Related Barriers to and Facilitators of Digital Health Technology Adoption for Hypertension Management: Scoping Review." *JMIR Cardio* 3 (1): e11951. https://doi.org/10.2196/11951.

Poncette, Akira-Sebastian, Daniel Leon Glauert, Lina Mosch, Katarina Braune, Felix Balzer, and David Alexander Back. 2020. "Undergraduate Medical Competencies in Digital Health and Curricular Module Development: Mixed Methods Study." *Journal of Medical Internet Research* 22 (10): e22161. https://doi.org/10.2196/22161.

Poncette, Akira-Sebastian, Christian Meske, Lina Mosch, and Felix Balzer. 2019. "How to Overcome Barriers for the Implementation of New Information Technologies in Intensive Care Medicine." In *Human Interface and the Management of Information. Information in Intelligent Systems*, edited by Sakae Yamamoto and Hirohiko Mori, 11570:534–46. Cham: Springer International Publishing. https://doi.org/10.1007/978-3-030-22649-7_43.

Poncette, Akira-Sebastian, Lina Katharina Mosch, Lars Stablo, Claudia Spies, Monique Schieler, Steffen Weber-Carstens, Markus A. Feufel, and Felix Balzer. 2022. "A Remote Patient-Monitoring System for Intensive Care Medicine: Mixed Methods Human-Centered Design and Usability Evaluation." *JMIR Human Factors* 9 (1): e30655. https://doi.org/10.2196/30655.

Poncette, Akira-Sebastian, Lina Mosch, Claudia Spies, Malte Schmieding, Fridtjof Schiefenhövel, Henning Krampe, and Felix Balzer. 2020a. "Improvements in Patient Monitoring in the Intensive Care Unit: Survey Study." *Journal of Medical Internet Research* 22 (6): e19091. https://doi.org/10/ggx2nm.

———. 2020b. “Improvements in Patient Monitoring in the Intensive Care Unit: Survey Study.” *Journal of Medical Internet Research* 22 (6): e19091. https://doi.org/10/ggx2nm.

Poncette, Akira-Sebastian, Claudia Spies, Lina Mosch, Monique Schieler, Steffen Weber-Carstens, Henning Krampe, and Felix Balzer. 2019. “Clinical Requirements of Future Patient Monitoring in the Intensive Care Unit: Qualitative Study.” *JMIR Medical Informatics* 7 (2): e13064. https://doi.org/10.2196/13064.

Powell, Byron J., Thomas J. Waltz, Matthew J. Chinman, Laura J. Damschroder, Jeffrey L. Smith, Monica M. Matthieu, Enola K. Proctor, and JoAnn E. Kirchner. 2015. “A Refined Compilation of Implementation Strategies: Results from the Expert Recommendations for Implementing Change (ERIC) Project.” *Implementation Science* 10 (1): 21. https://doi.org/10/f635v6.

Prytherch, David R., Gary B. Smith, Paul E. Schmidt, and Peter I. Featherstone. 2010. “ViEWS—Towards a National Early Warning Score for Detecting Adult Inpatient Deterioration.” *Resuscitation* 81 (8): 932–37. https://doi.org/10.1016/j.resuscitation.2010.04.014.

R Core Team. 2018. *R: A Language and Environment for Statistical Computing*. Vienna, Austria: R Foundation for Statistical Computing. https://www.R-project.org.

Ross, Jamie, Fiona Stevenson, Rosa Lau, and Elizabeth Murray. 2016. “Factors That Influence the Implementation of E-Health: A Systematic Review of Systematic Reviews (an Update).” *Implementation Science* 11 (1). https://doi.org/10.1186/s13012-016-0510-7.

Saeed, Nazish, Mirfa Manzoor, and Pouria Khosravi. 2020. “An Exploration of Usability Issues in Telecare Monitoring Systems and Possible Solutions: A Systematic Literature Review.” *Disability and Rehabilitation: Assistive Technology* 15 (3): 271–81. https://doi.org/10/gh8mfv.

“Strategy Design.” 2016. The Consolidated Framework for Implementation Research. October 25, 2016. https://cfirguide.org/choosing-strategies/.

Strauss, Anselm, and Juliet M. Corbin. 1990. *Basics of Qualitative Research: Grounded Theory Procedures and Techniques*. Basics of Qualitative Research: Grounded Theory Procedures and Techniques. Thousand Oaks, CA, US: Sage Publications, Inc.

Thiel, Rainer, Lucas Deimel, Daniel Schmidtmann, Klaus Piesche, Tobias Hüsing, Jonas Rennoch, Veli Stroetmann, and Karl Stroetmann. 2018. “#SmartHealthSystems - International Comparison of Digital Strategies.” Gütersloh, Germany: Bertelsmann Stiftung. https://www.bertelsmann-stiftung.de/fileadmin/files/Projekte/Der_digitale_Patient/VV_SHS-Studie_EN.pdf.

Topol, Eric. 2019. *Preparing the Healthcare Workforce to Deliver the Digital Future*. https://topol.hee.nhs.uk/wp-content/uploads/HEE-Topol-Review-2019.pdf.

Turner, P., A. Kushniruk, and C. Nohr. 2017. “Are We There Yet? Human Factors Knowledge and Health Information Technology – the Challenges of Implementation and Impact.” *Yearbook of Medical Informatics* 26 (1): 84–91. https://doi.org/10/gk987b.

VERBI Software. 2022. “MAXQDA 2022.” Berlin, Germany. maxqda.com.

Vincent, Jean-Louis, Sharon Einav, Rupert Pearse, Samir Jaber, Peter Kranke, Frank J. Overdyk, David K. Whitaker, Federico Gordo, Albert Dahan, and Andreas Hoeft. 2018. “Improving Detection of Patient Deterioration in the General Hospital Ward Environment.” *European Journal of Anaesthesiology* 35 (5): 325–33. https://doi.org/10.1097/EJA.0000000000000798.

Wachter, Robert M. 2016. "Making IT Work: Harnessing the Power of Health Information Technology to Improve Care in England." https://www.basw.co.uk/system/files/resources/basw_70727-3_0.pdf.

Wade, Victoria A., Jaklin A. Eliott, and Janet E. Hiller. 2014. "Clinician Acceptance Is the Key Factor for Sustainable Telehealth Services." *Qualitative Health Research* 24 (5): 682–94. https://doi.org/10.1177/1049732314528809.

Waltz, Thomas J., Byron J. Powell, María E. Fernández, Brenton Abadie, and Laura J. Damschroder. 2019. "Choosing Implementation Strategies to Address Contextual Barriers: Diversity in Recommendations and Future Directions." *Implementation Science: IS* 14 (1): 42. https://doi.org/10/gf4jq6.

Waltz, Thomas J., Byron J. Powell, Monica M. Matthieu, Laura J. Damschroder, Matthew J. Chinman, Jeffrey L. Smith, Enola K. Proctor, and JoAnn E. Kirchner. 2015. "Use of Concept Mapping to Characterize Relationships among Implementation Strategies and Assess Their Feasibility and Importance: Results from the Expert Recommendations for Implementing Change (ERIC) Study." *Implementation Science* 10 (1): 109. https://doi.org/10/f7k9xr.

Weenk, Mariska, Sebastian J. Bredie, Mats Koeneman, Gijs Hesselink, Harry van Goor, and Tom H. van de Belt. 2020. "Continuous Monitoring of Vital Signs in the General Ward Using Wearable Devices: Randomized Controlled Trial." *Journal of Medical Internet Research* 22 (6): e15471. https://doi.org/10.2196/15471.

Weenk, Mariska, Mats Koeneman, Tom H. van de Belt, Lucien J. L. P. G. Engelen, Harry van Goor, and Sebastian J. H. Bredie. 2019. "Wireless and Continuous Monitoring of Vital Signs in Patients at the General Ward." *Resuscitation* 136 (March): 47–53. https://doi.org/10.1016/j.resuscitation.2019.01.017.

Whitelaw, S, D Pellegrini, and H.G.C Van Spall. 2020. "Barriers to and Facilitators of the Uptake of Digital Health Technology in Cardiology: A Systematic Review." *European Heart Journal* 41 (Supplement_2): ehaa946.3500. https://doi.org/10.1093/ehjci/ehaa946.3500.

Wickham, Hadley, and RStudio. 2019. "Tidyverse: Easily Install and Load the 'Tidyverse.'" https://CRAN.R-project.org/package=tidyverse.

Wiggermann, Neal, Kelli Rempel, Robert Mark Zerhusen, Travis Pelo, and Nick Mann. 2019. "Human-Centered Design Process for a Hospital Bed: Promoting Patient Safety and Ease of Use." *Ergonomics in Design: The Quarterly of Human Factors Applications* 27 (2): 4–12. https://doi.org/10.1177/1064804618805570.

Woods, Leanna, Elizabeth Cummings, Naomi Dobroff, Shelley Nowlan, Helen Almond, Paula Procter, Angela Ryan, et al. 2021. "Intended Use of the National Nursing and Midwifery Digital Health Capability Framework." In *Studies in Health Technology and Informatics*, edited by Mark Merolli, Chris Bain, and Louise K. Schaper. IOS Press. https://doi.org/10.3233/SHTI210018.

World Health Organization. 2019. "WHO Guideline: Recommendations on Digital Interventions for Health System Strengthening."

Youssef Ali Amer, Ahmed, Femke Wouters, Julie Vranken, Dianne de Korte-de Boer, Valérie Smit-Fun, Patrick Duflot, Marie-Hélène Beaupain, et al. 2020. "Vital Signs Prediction and Early Warning Score Calculation Based on Continuous Monitoring of Hospitalised Patients Using Wearable Technology." *Sensors* 20 (22): 6593. https://doi.org/10.3390/s20226593.

Zapata, Belén Cruz, José Luis Fernández-Alemán, Ali Idri, and Ambrosio Toval. 2015. "Empirical Studies on Usability of MHealth Apps: A Systematic Literature Review." *Journal of Medical Systems* 39 (2). https://doi.org/10.1007/s10916-014-0182-2.

Eidesstattliche Versicherung

„Ich, Lina Katharina Mosch, versichere an Eides statt durch meine eigenhändige Unterschrift, dass ich die vorgelegte Dissertation mit dem Thema: „Implementierung von digitalen Gesundheitstechnologien in der Intensivmedizin: Eine Mixed-Methods-Studie mit Entwicklung eines Implementierungsframeworks“ / „Implementing Digital Health Technologies in Intensive Care: A Mixed Methods Study with Development of an Implementation Framework“ selbstständig und ohne nicht offengelegte Hilfe Dritter verfasst und keine anderen als die angegebenen Quellen und Hilfsmittel genutzt habe.
Alle Stellen, die wörtlich oder dem Sinne nach auf Publikationen oder Vorträgen anderer Autoren/innen beruhen, sind als solche in korrekter Zitierung kenntlich gemacht. Die Abschnitte zu Methodik (insbesondere praktische Arbeiten, Laborbestimmungen, statistische Aufarbeitung) und Resultaten (insbesondere Abbildungen, Graphiken und Tabellen) werden von mir verantwortet.

Ich versichere ferner, dass ich die in Zusammenarbeit mit anderen Personen generierten Daten, Datenauswertungen und Schlussfolgerungen korrekt gekennzeichnet und meinen eigenen Beitrag sowie die Beiträge anderer Personen korrekt kenntlich gemacht habe (siehe Anteilserklärung). Texte oder Textteile, die gemeinsam mit anderen erstellt oder verwendet wurden, habe ich korrekt kenntlich gemacht.

Meine Anteile an etwaigen Publikationen zu dieser Dissertation entsprechen denen, die in der untenstehenden gemeinsamen Erklärung mit dem/der Erstbetreuer/in, angegeben sind. Für sämtliche im Rahmen der Dissertation entstandenen Publikationen wurden die Richtlinien des ICMJE (International Committee of Medical Journal Editors; www.icmje.og) zur Autorenschaft eingehalten. Ich erkläre ferner, dass ich mich zur Einhaltung der Satzung der Charité – Universitätsmedizin Berlin zur Sicherung Guter Wissenschaftlicher Praxis verpflichte.

Weiterhin versichere ich, dass ich diese Dissertation weder in gleicher noch in ähnlicher Form bereits an einer anderen Fakultät eingereicht habe.

Die Bedeutung dieser eidesstattlichen Versicherung und die strafrechtlichen Folgen einer unwahren eidesstattlichen Versicherung (§§156, 161 des Strafgesetzbuches) sind mir bekannt und bewusst.“

Datum Unterschrift

Anteilserklärung an den erfolgten Publikationen

Lina Katharina Mosch (LM) hatte folgenden Anteil an den folgenden Publikationen:

Publikation 1: Poncette A, Spies C, Mosch L, Schieler M, Weber-Carstens S, Krampe H, Balzer F
Clinical Requirements of Future Patient Monitoring in the Intensive Care Unit: Qualitative Study
JMIR Med Inform 2019;7(2):e13064 doi: 10.2196/13064

Beitrag im Einzelnen (bitte ausführlich ausführen):

- Datenerhebung gemeinsam mit ASP:
  - LM entwarf den Interviewleitfaden gemeinsam mit ASP
  - LM überarbeitete den Interviewleitfaden gemeinsam mit ASP, LM führte selbstständig 13 Interviews durch
  - LM transkribierte selbstständig 15 Interviews.
- Datenanalyse gemeinsam mit ASP
  - LM codierte selbstständig 8 Interviews,
  - LM überarbeitete die Codierung von 7 Interviews durch ASP,
  - LM überarbeitete das Codesystem gemeinsam mit ASP, LM entwarf 7 Summaries und überarbeitete 8 Summaries entworfen durch ASP,
  - LM erstellte die Figure 4, die durch ASP überarbeitet wurde.
- Unterstützung von ASP bei der Manuskripterstellung
  - LM schrieb die Einleitung des Papers,
  - LM überarbeitete das Manuskript.

Publikation 2: Poncette A-S, Mosch L, Spies C, Schmieding M, Schiefenhövel F, Krampe H, Balzer F. Improvements in Patient Monitoring for the Intensive Care Unit: Survey Study. J Med Internet Res 2020 May 13; PMID:32459655.

Beitrag im Einzelnen (bitte ausführlich ausführen):

- Unterstützung von ASP bei der Datenerhebung, gemeinsam mit FS –
  - LM erstellte einen Entwurf für die Onlinesurvey
  - ASP, FS und LM erstellten die Onlinesurvey.
- Unterstützung von ASP bei der Manuskripterstellung, gemeinsam mit MS und FS
  - LM überarbeitete das Manuskript.

Publikation 3: Mosch LK, Poncette A-S, Spies C, Weber-Carstens S, Schieler M, Krampe H, Balzer F. Creation of an Evidence-Based Implementation Framework for Digital Health Technology in the Intensive Care Unit: Qualitative Study. JMIR Formative Research 2022 Apr 8;6(4):e22866. [doi: 10.2196/22866]

Beitrag im Einzelnen (bitte ausführlich ausführen):

- Konzeption der Studie zusammen mit ASP, CS und FB
  - LM erarbeitete die Fragestellung der Studie gemeinsam mit ASP.
  - LM konzipierte die Methodik, unterstützt durch ASP
  - LM entwarf den Interviewleitfaden und das Online Questionnaire.
- Selbstständige Datenerhebung und -analyse, Analyse unterstützt durch ASP
  - LM führte und transkribierte 7 Interviews,
  - LM führte Feldbeobachtungen durch,
  - LM führte die qualitative Analyse selbstständig durch (induktive Analyse der Interviews, deduktive Analyse mit ERIC-Framework, Anwendung des CFIR-ERIC Matching Tools), begleitet durch ASP (Qualitätssicherung für Qualitative Forschung durch 2. Forschenden

als Reviewer)
    - LM erstellte selbstständig die Abbildungen 1-4,
    - LM, ASP, HK und FB diskutierten die Ergebnisse gemeinsam, um die Reflektivität der Analyse zu erhöhen.
- Manuskripterstellung zusammen mit ASP
    - LM schrieb das Manuskript.

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Publikationen

Auszug aus der Journal Summary List

JMIR Medical Informatics:

Journal Data Filtered By: **Selected JCR Year: 2019** Selected Editions: SCIE,SSCI
Selected Categories: **"MEDICAL INFORMATICS"**
Selected Category Scheme: WoS
Gesamtanzahl: 27 Journale

Rank	Full Journal Title	Total Cites	Journal Impact Factor	Eigenfactor Score
1	IEEE Journal of Biomedical and Health Informatics	5,472	5.223	0.012910
2	JOURNAL OF MEDICAL INTERNET RESEARCH	16,349	5.034	0.029410
3	ARTIFICIAL INTELLIGENCE IN MEDICINE	2,953	4.383	0.003370
4	JMIR mHealth and uHealth	4,226	4.313	0.010020
5	JOURNAL OF THE AMERICAN MEDICAL INFORMATICS ASSOCIATION	9,959	4.112	0.017380
6	COMPUTER METHODS AND PROGRAMS IN BIOMEDICINE	8,014	3.632	0.011370
7	JMIR Serious Games	350	3.526	0.000660
7	JOURNAL OF BIOMEDICAL INFORMATICS	8,253	3.526	0.011190
9	Internet Interventions-The Application of Information Technology in Mental and Behavioural Health	996	3.513	0.002720
10	JOURNAL OF MEDICAL SYSTEMS	5,695	3.058	0.007050
11	INTERNATIONAL JOURNAL OF MEDICAL INFORMATICS	5,368	3.025	0.007110
12	Health Informatics Journal	981	2.932	0.001530
13	JMIR Medical Informatics	650	2.577	0.002340
14	BMC Medical Informatics and Decision Making	4,117	2.317	0.007370
15	MEDICAL DECISION MAKING	5,291	2.309	0.007670
16	STATISTICAL METHODS IN MEDICAL RESEARCH	4,647	2.291	0.011850

Publikation 1

JMIR MEDICAL INFORMATICS Poncette et al

Original Paper

Clinical Requirements of Future Patient Monitoring in the Intensive Care Unit: Qualitative Study

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Abstract

Background: In the intensive care unit (ICU), continuous patient monitoring is essential to detect critical changes in patients' health statuses and to guide therapy. The implementation of digital health technologies for patient monitoring may further improve patient safety. However, most monitoring devices today are still based on technologies from the 1970s.

Objective: The aim of this study was to evaluate statements by ICU staff on the current patient monitoring systems and their expectations for future technological developments in order to investigate clinical requirements and barriers to the implementation of future patient monitoring.

Methods: This prospective study was conducted at three intensive care units of a German university hospital. Guideline-based interviews with ICU staff—5 physicians, 6 nurses, and 4 respiratory therapists—were recorded, transcribed, and analyzed using the grounded theory approach.

Results: Evaluating the current monitoring system, ICU staff put high emphasis on usability factors such as intuitiveness and visualization. Trend analysis was rarely used; inadequate alarm management as well as the entanglement of monitoring cables were rated as potential patient safety issues. For a future system, the importance of high usability was again emphasized; wireless, noninvasive, and interoperable monitoring sensors were desired; mobile phones for remote patient monitoring and alarm management optimization were needed; and clinical decision support systems based on artificial intelligence were considered useful. Among perceived barriers to implementation of novel technology were lack of trust, fear of losing clinical skills, fear of increasing workload, and lack of awareness of available digital technologies.

Conclusions: This qualitative study on patient monitoring involves core statements from ICU staff. To promote a rapid and sustainable implementation of digital health solutions in the ICU, all health care stakeholders must focus more on user-derived findings. Results on alarm management or mobile devices may be used to prepare ICU staff to use novel technology, to reduce alarm fatigue, to improve medical device usability, and to advance interoperability standards in intensive care medicine. For digital transformation in health care, increasing the trust and awareness of ICU staff in digital health technology may be an essential prerequisite.

Trial Registration: ClinicalTrials.gov NCT03514173; https://clinicaltrials.gov/ct2/show/NCT03514173 (Archived by WebCite at http://www.webcitation.org/77T1HwOzk)

(JMIR Med Inform 2019;7(2):e13064) doi: 10.2196/13064

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KEYWORDS

patient monitoring; digital health; qualitative research; intensive care unit; intensive care medicine; multidisciplinary; user-centered design; design thinking; digital literacy; grounded theory

Introduction

Background

In decades to come, demographic developments and an increasing number of comorbidities will lead to an ever-rising number of chronically ill patients in need of intensive care treatment [1]. Moreover, health care institutions are highly challenged with rising workloads, due to a shortage of medical staff and an increasing financial burden [2]. Within this context, rapid and sustainable implementation of advanced digital technologies could mitigate this development.

Continuous monitoring of patients is one of the most essential components in intensive care medicine: first, to notice critical changes of patients' health statuses, and second, to guide daily intensive care therapy [3]. Its implementation led to significant improvements in patient safety in the intensive care unit (ICU) [4]. Notably, in comparison with other medical devices, patient monitoring is used by a multidisciplinary team of physicians, nurses, and respiratory therapists.

With advances in information and communication technologies (ICTs) and medical device technologies, new options for patient monitoring are being introduced that may potentially improve patient safety [5]. However, most of the monitoring devices used today, such as the electrocardiogram (ECG) or invasive blood pressure measurement, were already available in the 1970s, using alarm thresholds for single sensors [6,7]. Nowadays, technologies to remotely monitor patients are available, such as wireless monitoring sensors (eg, ECG, pulse oximetry [8,9], and hemoglobin [10]), noninvasive measurement of hemodynamic parameters (eg, blood pressure and cardiac output [11]), as well as mobile communication devices (eg, mobile phones and tablets) [12-14]. Furthermore, clinical decision support systems (CDSS) based on artificial intelligence can assist physicians by analyzing multiple parameters to detect early indications of sepsis, respiratory failure, or bleeding [15,16].

Despite these technological developments, the introduction of novel patient monitoring applications in the ICU remains a lagging process compared to other industry sectors [17,18]. The manifold reasons for this could be rooted in a mismatch of expectations and assumptions by clinical users and manufacturers about novel patient monitoring [19,20].

Aim

This qualitative study evaluated statements by ICU staff—physicians, nurses, and respiratory therapists—on current patient monitoring. This study also evaluated the staff's expectations for future technological developments to explore clinical requirements and barriers to the implementation of a novel monitoring system. We aimed to explore desires, concerns, and perceived challenges of ICU staff on patient monitoring that may stimulate rapid and sustainable technological adaption in the ICU.

Methods

Ethics Approval and Consent to Participate

Ethical approval for this study was provided by the ethics committee of the Charité—Universitätsmedizin Berlin, Germany (EA1/031/18). All participants gave their consent prior to the study.

Setting

This study was conducted at three ICUs of a German university hospital as a preliminary study of the implementation of the Vital Sync virtual patient monitoring platform 2.4, developed by Medtronic plc. This new system was installed in one of the three ICUs to monitor patients remotely and was utilized after completion of data collection for this study. In all three ICUs, the Philips IntelliVue patient monitoring system was installed at the time of the study (MX800 software version M.00.03; MMS X2 software version H.15.41-M.00.04). The COPRA 5 patient data management system (PDMS), developed by COPRA System GmbH, was used in all ICUs.

Research Team and Study Design

The research team consisted of a postdoctoral researcher with a background in anesthesiology, geriatrics, intensive care medicine, and digital health (ASP); a senior medical student with a strong affinity for digital health (LM); a professor for digital health, who is a consultant anesthesiologist and a computer scientist (FB); a psychologist (HK); a head nurse (MS); the ICU senior consultant (SWC); and the department's head of staff (CS). To maintain reflexivity, the research team challenged established assumptions in discussions and shared diaries throughout the study.

We chose an inductive, exploratory, qualitative research approach using semistructured interviews as described elsewhere [21-23]. The inductive approach allowed us to simultaneously collect and analyze data to see if any patterns emerged that would influence the study design.

Data Collection

Between April and May 2018, ASP and LM conducted face-to-face semistructured interviews with 5 physicians (4 women, 80%), 6 nurses (2 women, 33%), and 4 respiratory therapists (1 woman, 25%) from the ICU. The median of ICU experience was 4 years (range 2-15) for physicians, 6 years (range 1-14) for nurses, and 9 years (range 2-18) for respiratory therapists. Purposive sampling was employed to ensure an evenly distributed variety of professional staff.

The interview design was based on the research question and developed by the research team through consultation of further experts from intensive care medicine and psychology. Pilot interviews did not alter the questions. The developed questions were used as a guide for the interviews, giving the interviewers the freedom to change their weight or phrasing (see Textbox 1). Additionally, the order of the first three questions could be changed. The interviews were conducted during breaks between patient care in the ICU, were recorded and transcribed verbatim by the interviewers, and were reviewed by the researcher who had not done the transcription. Median interview length was 13 minutes (range 8-26).

Data Analysis

After the completion of five interviews, we began analyzing the data through an inductive approach by means of the grounded theory [24]. Codes that were generated through line-by-line coding of three particularly different interviews resulted in a category system (see Multimedia Appendix 1) that was adjusted and extended by analyzing further interview transcripts (see Multimedia Appendix 2). All coding was performed using the MaxQDA 2018 qualitative data analysis software. The first five interviews were coded twice by two independent researchers (ASP and LM). Inconsistencies between coders were discussed in meetings among the research team until a mutual agreement was achieved. All following transcripts were coded by one researcher and the codes validated by another researcher.

After completion of coding, the research team reviewed and summarized each core statement to extract themes that were relevant to the study objective. Throughout the process of data analysis, the weight and phrasing of all questions and the order of the first three questions asked during the interviews were adapted using a feedback loop as previously described [25] (see Figure 1). Data collection was finalized when no new codes were identifiable from new interviews [26]. Out of each category, representative statements were selected and translated into English.

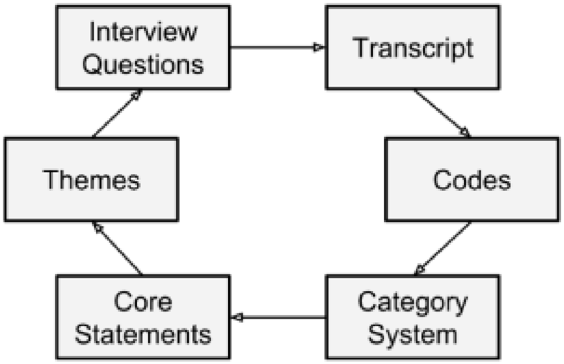
The datasets generated and analyzed during this study are not publicly available due to reasons of data privacy; however, they are available from the corresponding author (FB) upon reasonable request.

Textbox 1. Guide for intensive care staff interviews.

Interview questions:

- How often do you interact with the current patient monitoring system and which features do you use?
- Regarding the current patient monitoring system, is there anything that you find particularly useful? What suggestions for improvement do you have?
- Given endless financial and technical resources, what would your future patient monitoring system look like?
- Would you consider using a tablet for your clinical work regarding remote patient monitoring? In which situations would you use it?
- Would you consider using a clinical decision support system for your clinical routine?
- In your clinical workflow, is it important to have a graphical visualization of patients' vital parameters and their trends? Do you consider trend graphics of the patient monitoring system useful for shift handovers?
- What is more important to you: usability or number of features?

Figure 1. A feedback loop adapted the weight and order of the interview questions through parallel data collection and evaluation as previously described [25].

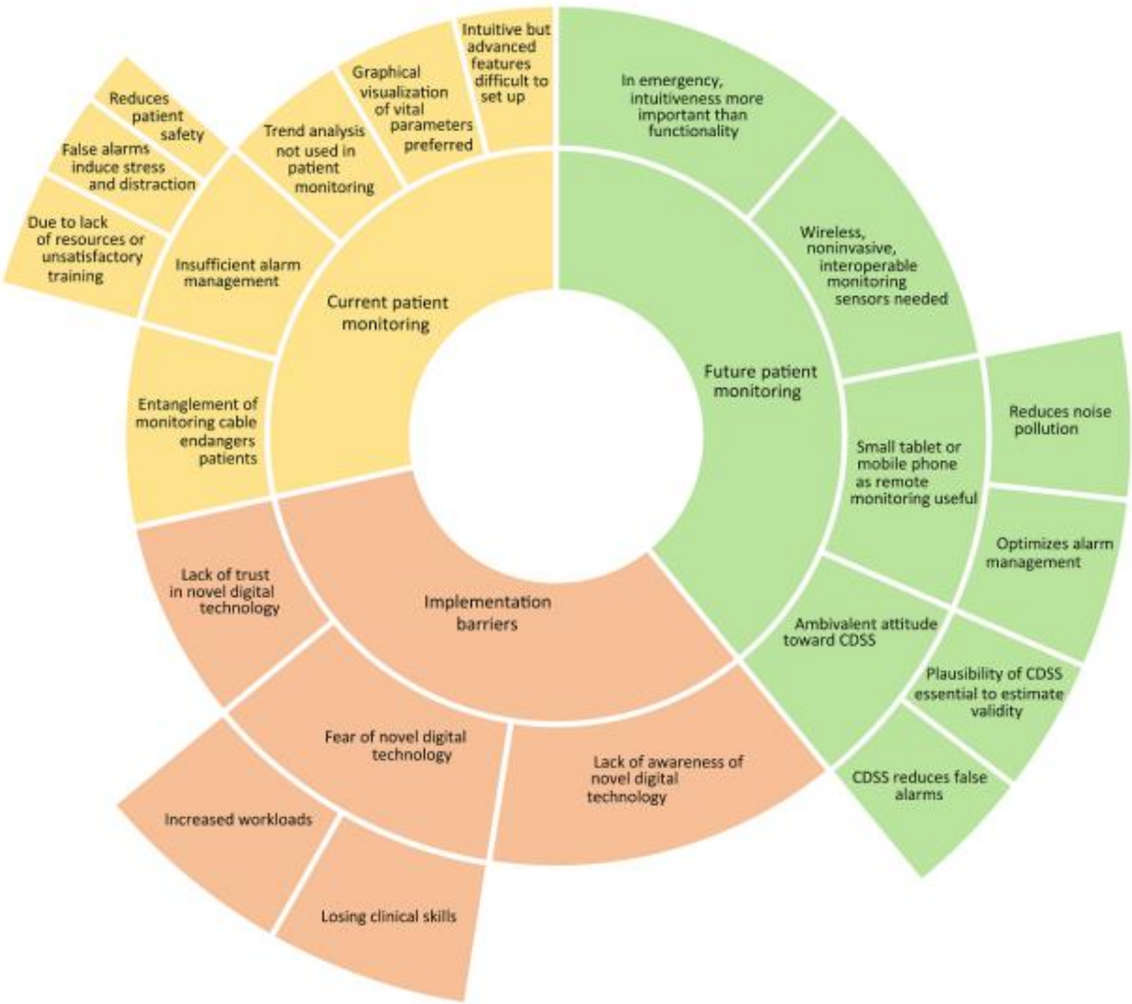


Results

Summary

This qualitative study was constructed based on 15 interviews with ICU staff regarding the complexity of patient monitoring in the ICU. According to our study objectives, resulting codes were classified into three main categories: (1) current patient monitoring, (2) future patient monitoring, and (3) barriers to implementation of novel patient monitoring. In the sunburst diagram (see Figure 2), the 12 most-relevant themes (middle ring) within the three categories (inner ring) are visualized and specified (outer ring).

Figure 2. Within three categories (inner ring), 12 themes (middle ring) were identified and specified (outer ring) to reflect the requirements of a novel patient monitoring technology from the view of intensive care staff. CDSS: clinical decision support system.



Most participants saw a need for improvement of patient monitoring in the ICU through novel technology, not only for enhanced efficiency in routine processes, but also to improve patient safety, quality of care, staff satisfaction, and quality of life for patients in the ICU as well as after discharge. Self-evaluation by participants regarding technological savviness using a Likert scale, with scores ranging from 1 (*no affinity for technology*) to 5 (*high affinity for technology*), resulted in the following median scores: physicians, 3.5 (range 2.0-5.0); nurses, 2.8 (range 1.5-4.0); and respiratory therapists, 3.8 (range 3.5-5.0).

Current Patient Monitoring

The interviewed ICU staff rated the software usability of the current patient monitoring as *good* with special emphasis on intuitiveness and uniformity. Standard features such as display of vital parameters and configuration of alarm thresholds were easy to use, however, advanced settings were considered difficult to set up without training.

> *It's sometimes very difficult to get all the parameters that I actually want on a monitor...Partly it's very complicated to be able to adjust the monitor quickly and effectively. So I often have the situation that I am called in by the nursing staff because they don't manage to display the parameters on the monitor that I would like to see. And then it costs me 20 minutes of work that is wasted during the day.* [Interview 13, physician]

For the visualization of single parameters, a graphical curve was stated to be essential for faster clinical interpretations and to ensure the validity of sensor measurements. All professional groups stated that they rarely use trend analysis on the patient monitoring device. Instead, the PDMS was used, as it provides other clinical data along with trends of vital parameters.

Concerning patient monitoring features used by ICU staff, alarm management was mentioned most frequently. Nurses and respiratory therapists would regularly adjust alarm thresholds to current patient conditions. However, alarm fatigue or "cry wolf" situations (ie, multiple alarms going off at the same time) were considered as a major deficit of the current system, leading to stress in patients and staff and, potentially, reduced patient safety. Reasons for this were stated as (1) technical: difficult to distinguish between false and critical alarm, and susceptibility to error of the ECG, peripheral capillary *oxygen* saturation (SpO_2), and end-tidal carbon dioxide ($etCO_2$) sensors; (2) patient related: interference of artefacts related to delirium (ie, movement), sepsis (ie, centralized circulation), or high perspiration; and (3) ICU staff related: inadequate alarm hygiene due to lack of staff training with patient monitoring and lack of staff resources.

> *Alarm management is rather a big problem in the intensive care unit; some people set the alarm limits very tightly, which often leads to false alarms. I think it's important to work on the alarm management within the team...especially at night, also the sound for the patients. When the patient is supposed to sleep and then the monitor beeps all the time...* [Interview p02, nurse]

> *Too little alarm hygiene is being done. This is not due to the laziness of the people, but simply due to the staff situation; there are too few nurses, too few doctors. Therefore, it just beeps very often. And the monitor can't distinguish; is this critical or not? It gets its limits set, and if you've had an alarm five times because the patient is moving, and therefore the heart rate is supposedly elevated, you won't look at it the sixth time, but maybe there is something else. Yes, that's a bit of a problem, because one or the other critical situation is only recognized very late.* [Interview 11, respiratory therapist]

Long distances and an angled architecture of the ICU along with missing additional patient monitoring displays at strategic positions (eg, corridor and doctor's office) were indicated to possibly lead to critical situations. Furthermore, all interviewees criticized the entanglement of cables, especially in situations such as bedding and transport, posing a major patient safety issue.

Future Patient Monitoring

Participants from all professional groups emphasized the importance of intuitiveness and usability of a future patient monitoring system, especially in an emergency, with options to add more advanced and individual settings.

> *So if you want to use something like that, it would be good to have more functions and individualize it...Because, I think to myself, it is precisely because of the fact that there are so many different professional groups on the move here, that a senior physician in the department may also have completely different things that he finds important than perhaps a respiratory therapist or another specialist.* [Interview 12, respiratory therapist]

> *It all has to be self-explanatory in my eyes because we have too many devices that are complicated, so it would be nice if it was very user-friendly.* [Interview 7, respiratory therapist]

Future conceptions were more accurate in measurements, while at the same time less invasive, wireless, and with better interoperability between medical devices; for example, access to PDMS through patient monitoring.

> *How do you imagine the monitoring system of the future?* [Interview 11, interviewer]

> *Capture more values with less effort. So less invasive and a little more accurate, yes.* [Interview 11, respiratory therapist]

> *In any case, a wireless transmission of the monitor would be great. Because this would of course have a clear advantage for the patient in terms of mobility.* [Interview 12, respiratory therapist]

Participants from all interviewed professional groups believed that using mobile communication technology, such as tablet computers or mobile phones, as remote patient monitoring devices could increase patient safety, reduce the length of stay in the ICU, and improve job satisfaction.

> *I absolutely believe it [remote patient monitoring] is a step in the right direction. It benefits the patients, after all. And in the best case, it makes the work easier.* [Interview p02, nurse]

A reduction of stress through remote patient monitoring, in both ICU staff and patients, was pointed out and justified by optimized alarm management (ie, the possibility to cancel false alarms from a mobile device and, thus, less noise pollution).

> *And if I also had the option of canceling [false] alarms while sitting at the PC without having to run to the central system, I think that would make life easier for me. And above all, it would protect the patient. You do not ignore false alarms, or other alarms, which you interpret as false alarms—which can be life-threatening—and that the patient is perhaps less stressed, if he does not hear these alarms constantly at his own bed...I think I'm also preventing delirium.* [Interview 13, physician]

To reduce distractions of doctors by false alarms, interviewees also proposed an alarm filtering system by the nursing staff and critical alarm transmission to the doctor's mobile device.

> *If you get distracted by other things again and again...I think you accomplish less in the time you have. And, therefore, related to your question, of course it is important that you get alerted, but in the end, I see the nursing staff as a certain filter.* [Interview 2, physician]

> *For [external staff and new staff members], I actually don't find that bad at all. That they can just say, "Ok, I press a button and know...when the alarm comes, that goes to the doctor..." And that this makes them more relaxed and they don't have to search for him.* [Interview 8, nurse]

A point of criticism of remote patient monitoring was the fear of less interprofessional communication and less patient contact when the physician is informed via a mobile device and the alarms are canceled remotely. To achieve better teamwork regarding alarm management, training in interprofessional communication was considered necessary.

> *I also find that a bit difficult, because then the communication just breaks down a bit. Because I like to go to the doc and say, "Hey, here, I noticed that, should I do something now?"* [Interview 8, nurse]

Staff expectations regarding the implementation of a CDSS, including artificial intelligence in monitoring, were ambivalent; however, an automatic adjustment of alarm thresholds through trend analysis and the CDSS was suggested. Critical attitudes resulted from lack of trust in the CDSS: the interviewees stressed plausibility to estimate the validity of CDSS recommendations in their clinical work routine.

> *And if I don't understand the physiology behind it, also in humans, and only stick to these theoretically calculated values there, then I think mistakes will occur...So a basic education in the basic understanding of physiology and also of technology, how these limits and parameters and recommendations arise, should be absolutely there.* [Interview 13, physician]

In terms of hardware design for remote patient monitoring, several interviewees of all professions agreed that a large tablet was applicable for stationary use because it would provide a better overview. However, most of the interviewed staff said they would prefer using a small device, even their own mobile phone, which would offer greater mobility since the pockets of the scrubs are too small for larger devices.

> *If I had to carry it [the tablet] with me all the time, then it would have to be the size of a scrubs pocket.* [Interview 3, nurse]

> *If it is stationary, then rather large [display] to provide a good overview.* [Interview 8, nurse]

Barriers to Implementation of Novel Patient Monitoring

We identified a lack of trust in technology as the greatest barrier to the implementation of novel patient monitoring devices in the ICU.

> *I think it's important to be at the patient's bedside, look at the patient, and not just rely on some kind of monitoring.* [Interview 10, physician]

ICU staff feared the implementation of new technology in the ICU that would increase workloads in a setting where time and resources are already scarce.

> *We have a lot of leasing staff [external staff], and we are a newly assembled team—I think it [new technology] would still be difficult to implement here at the moment.* [Interview p02, nurse]

They demanded more time for using advanced features and for training in new medical devices.

> *If I had more time, then I would like to have more functions [in patient monitoring] and we must be trained more intensively for using the new [medical] devices.* [Interview p02, nurse]

While satisfied with the current system, ICU staff reported that new technology seems very complex and they often did not foresee its benefit. By using new technology, they were afraid to lose their clinical skills and have less direct contact with the patient.

> *I think that we should use our brain, and that it makes sense to be able to rely on your own senses in case of a power failure, darkness, or whatever.* [Interview 10, physician]

> *Well, I think that the more you get taken off [by technology], the more you stop thinking. And then an ECG electrode falls off, and people think the patient is asystolic and start to resuscitate.* [Interview 4, nurse]

Additionally, lack of awareness and education of ICU staff about current technological developments was identified as a potential barrier to implementation.

Discussion

Principal Findings

This qualitative interview study provides valuable insights into the understanding of the complexity of patient monitoring in the ICU. For the ICU staff, the current patient monitoring system was intuitive to use for vital sign monitoring, but other features were difficult to set up due to lack of training and staff shortage. Further, ICU staff rated alarm fatigue and entanglement of cables as major threats to patient safety.

For future developments, a more interoperable, intuitive patient monitoring system was demanded with options to add advanced and individual features depending on the patients' or users' needs. Vital parameter measurements and alarms should be more specific, while being noninvasive and less obtrusive (eg, wireless). Interestingly, interviewees recognized mobile phones with a large screen as a potential remote patient monitoring device, which could reduce noise pollution, increase patient safety, and lead to enhanced job satisfaction. Additionally, a CDSS based on artificial intelligence could optimize alarm management if plausible for the ICU staff. For a more rapid introduction of novel patient monitoring solutions in the ICU, participants demanded more training in new medical devices.

As a major barrier to the implementation of novel patient monitoring, lack of both trust and awareness for novel, innovative technology was identified. Interviewees also admitted to being afraid to lose their clinical skills as a result of having less interprofessional communication and less contact with the patient due to novel patient monitoring technology.

False Alarms Endanger Patient Safety

Whereas alarm management is the main feature of patient monitoring used at the study sites, currently neither regular staff training nor a framework for alarm management is established. In the context where "cry wolf" situations with multiple alarms going off at the same time have become the standard environment in the ICU, this is an alarming insight [27]. Of all auditory alarms, up to 99% have been described to be false alarms that do not change patient treatment [28]. These false alarms are a product of a complex interplay between the patient's condition, the users' competence, and the technical features of the patient monitoring system. False alarms desensitize clinical staff to critical alarms (ie, alarm fatigue) and pose a major patient safety issue, leading to alarm-related patient deaths every year [29]. According to our study results, patient safety might also be compromised through the constant noise pollution that induces interruptions, stress, and concentration difficulties among the ICU staff.

Although several strategies have been developed to reduce false alarms in the ICU [12,28-31], implementation into a clinical routine is still lacking. Notably, the reduction of alarms due to alarm management strategies ranges from 24% to 88.5% per ICU, indicating the effectiveness of such strategies, including staff training for any ward that uses patient monitoring devices [32-34].

Interoperability and Usability of Devices in Intensive Care

Today, most acute care medical devices are not designed to interoperate [18]. Remarkably, our results indicate that requirements for future patient monitoring are steadily increasing to more than just monitoring the vital parameters. ICU staff demand a patient monitoring device to interoperate with other medical devices for detailed comparisons of vital parameters and trend analysis in the context of medication, ventilation, fluid balance, and more, as recently suggested by Flohr et al [35]. This could optimize workflow and reduce redundant documentation in the ICU.

In terms of usability, ICU staff expressed their demand for intuitive and reactive systems for clinical use. Although the implementation of electronic applications in health care dates back more than a decade, usability—referring to the efficient, effective, and safe use of technology—is still not fully optimized for clinical use [36,37]. In the ICU, digital applications should not induce stress. Instead, their use should focus the user for efficient, effective, and safe work. In usability research, various simple and low-cost methods are available that should be applied by anyone working in medical device development [38].

For both interoperability and usability, regular adaptation and application of medical device communication (ie, Institute of Electrical and Electronics Engineers [IEEE] 11073) and technical standards (ie, International Electrotechnical Commission [IEC] 60601) to current developments might minimize use-related hazards and risks to patients and ICU staff [39,40].

Mobile Phones in Intensive Care Routine

The use of tablet computers with access to electronic medical records or multiparameter monitoring has been perceived as beneficial in inpatient settings [35,41]. However, for ICU staff, large tablets were too bulky to carry around due to the small pockets of their scrubs; they instead preferred small tablets that are portable [42] or larger mobile phones for remote patient monitoring in the ICU. This finding may influence further device developments for the ICU and the operating room where scrubs are worn. Recently released foldable mobile phones could be an approach to combine the advantages of pocket-size and large-screen devices [43]. As industry stakeholders are already developing apps for mobile devices in the ICU, more interdisciplinary studies are necessary to obtain early feedback from clinicians, developers, and engineers [12,14].

In the move toward a widespread implementation of telemedicine and remote patient monitoring technology into various health care sectors including the ICU, the mobile phone or tablet computer could easily be deployed for these tasks. ICU staff claimed that the length of stay in the ICU could be reduced through the utilization of remote patient monitoring, which is in line with several recent studies on telemedicine [44,45].

Clinical Decision Support Systems for Alarm Management

Integration of novel medical devices and technological advances result in a steadily growing amount of data that are being analyzed by ICU staff daily, thus making automated systems based on artificial intelligence a necessity for the future. Although various research projects are focusing on CDSS in the ICU, translation into the clinical routine is lagging far behind [15,46-49].

In our study, participating staff stated that they would utilize a CDSS only if it was plausible and underlying algorithms were readily understandable. A physician also indicated that appropriate training for the application would be useful to avoid misuse. Taking into account that most CDSS are based on complex machine learning methods, explaining the underlying mechanism to intensivists might be challenging. However, participants expressed the necessity to optimize detection of false alarms with a CDSS. Thus, a self-learning alarm system via machine learning might be practicable for the near future [50].

Furthermore, according to interviewees, trend-based alarms might be a useful complement to the traditional threshold-based alarms; this is consistent with a publication by Charbonnier et al, who was able to reduce 33% of false alarms by using a trend-based alarm system in the ICU [51].

Building Trust in Information and Communication Technology

The most disruptive implementation of ICT in intensive care medicine in the recent past has been the introduction of tele-ICUs, which has been accompanied by several staff acceptance studies [21,52,53]. With the implementation of tele-ICU technology in existing ICUs, ICU staff are not only confronted with novel ICTs, but also with changes in clinical processes, such as teamwork, communication, and staff structure. This is due to the fact that therapy decisions are influenced by external experts, who might be unfamiliar to the ICU staff on site. In this constellation, trust has to be formed first toward the new ICT and in a second step toward the external experts [21]. With respect to our study, similar concerns were reported: after trust in ICTs are established, ICU staff must also get familiar with the CDSS, in contrast to the external (ie, human) experts. Notably, our results did not show any influence of prior experience with technology on the formation of trust [54].

We conclude that ICU staff are ready and willing to use more-advanced ICT devices in intensive care routine. Nevertheless, without adequate and regular training in novel technical and digital devices, even in alarm management, the full potential of digitization will not have been exhausted.

Digital Literacy

As suggested in recent publications, governments, health care institutions, and universities should include digital health care in the curriculum of high schools, as well as in medical and nursing schools, to ensure that future health care professionals acquire digital literacy [55,56]. Our finding of low tech-savviness among ICU staff indicates that regular staff training with novel medical devices, software, and mobile phone apps may be beneficial for successful implementation of future patient monitoring devices [20,57,58].

Innovation in health care derives from interdisciplinary teamwork with developers and medical engineers [59]. University hospitals, especially, should empower ICU staff to pursue academic research in the context of ICT implementation in the ICU.

Design Thinking in Health Care

In the context of digitization in health care, novel digital systems often fail after implementation as a result of a lack of user involvement [59]. The importance of validation of novel digital health solutions through early and continuous user involvement is often underestimated by the industry, hospitals, and governments [55]. Reasons for this include lack of financial resources, delays in time to market, or ignorance about how to validate a digital health product [59]. One way to mitigate this issue might be the design-thinking framework as a systematic process that prioritizes empathy for the users with the aim to develop a more comprehensive and effective solution [60]. In situations where the users cannot point out their needs, analyzing their behaviors through a more user-centered qualitative method such as design thinking can provide invaluable insights about their unmet desires [60].

Limitations

Through the use of a qualitative interview study design, we could identify several novel findings on the themes of patient monitoring from the perspective of ICU staff. However, as a descriptive approach, quantification of statements is not possible by design. When interpreting the results, it is crucial to take into account the small number of participants of a single hospital (ie, three ICUs) and possible biases due to the selection of participants. This makes the generalization to other hospital settings or countries difficult. A follow-up, quantitative, survey-based study with a larger cohort may be conducted on the basis of this study to further consolidate the results.

Moreover, it is not possible to draw conclusions about whether a novel patient monitoring system can improve patients' quality of life or quality of care in the ICU. Interdisciplinary investigations with patients, their relatives, health care providers, and technicians (ie, IT and engineering) might shed light on this question. Finally, a bias due to the implementation of the Vital Sync virtual patient monitoring platform cannot be excluded with certainty.

Conclusions

This qualitative study involves core statements by ICU staff in the analysis of current and novel patient monitoring applications in the ICU. In order to introduce more sustainable digital health solutions in the ICU, health care stakeholders might have to focus more on user-derived findings than top-down speculations. By valuing the opinions of health care providers, we may gain their trust to implement novel systems.

In particular, the results on alarm management and mobile devices in the ICU may be used (1) by health care organizations to prepare ICU staff for digital transformation, (2) by research institutes to reduce alarm fatigue, (3) by industry players to embrace medical device usability, and (4) by political stakeholders and decision makers to advance interoperability standards in intensive care medicine.

Our findings should motivate other researchers to conduct qualitative patient- and user-centered research in health care, especially before developing or implementing premature technological solutions.

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Conflicts of Interest

CS and FB report funding from Medtronic. The other authors do not declare a conflict of interest.

Authors' Contributions

CS had the idea for shared decision allocation and initiated the implementation of remote patient monitoring in the intensive care unit. The study was conceived by ASP, CS, and FB. ASP and LM conducted data acquisition and analyses, supported by MS and SWS, who provided perspectives from clinical routine and management. ASP wrote the manuscript with support from LM. HK contributed to the study's methodology and interpretation of results from a psychologist's point of view. FB supervised all parts of the study. All authors critically reviewed and approved the manuscript.

Multimedia Appendix 1

Category system that was constructed through line-by-line coding of the interview transcripts.

[PDF File (Adobe PDF File), 184KB-Multimedia Appendix 1]

Multimedia Appendix 2

Catalog with quotes from intensive care unit (ICU) staff regarding patient monitoring.

[PDF File (Adobe PDF File), 215KB-Multimedia Appendix 2]

References

1. Zimmerman JE, Kramer AA, Knaus WA. Changes in hospital mortality for United States intensive care unit admissions from 1988 to 2012. Crit Care 2013 Apr 27;17(2):R81 [FREE Full text] [doi: 10.1186/cc12695] [Medline: 23622086]
2. Gulland A. Shortage of health workers is set to double, says WHO. BMJ 2013 Nov 12;347:f6804. [doi: 10.1136/bmj.f6804] [Medline: 24222676]
3. Kipnis E, Ramsingh D, Bhargava M, Dincer E, Cannesson M, Broccard A, et al. Monitoring in the intensive care. Crit Care Res Pract 2012;2012:473507 [FREE Full text] [doi: 10.1155/2012/473507] [Medline: 22970356]
4. Moreno RP, Rhodes A, Donchin Y, European Society of Intensive Care. Patient safety in intensive care medicine: The Declaration of Vienna. Intensive Care Med 2009 Oct;35(10):1667-1672 [FREE Full text] [doi: 10.1007/s00134-009-1621-2] [Medline: 19697007]
5. Michard F. Hemodynamic monitoring in the era of digital health. Ann Intensive Care 2016 Dec;6(1):15 [FREE Full text] [doi: 10.1186/s13613-016-0119-7] [Medline: 26885656]
6. Drews FA. Patient monitors in critical care: Lessons for improvement. In: Henriksen K, Battles JB, Keyes MA, Grady ML, editors. Advances in Patient Safety: New Directions and Alternative Approaches. Volume 3: Performance and Tools. Rockville, MD: Agency for Healthcare Research and Quality; Aug 2008.
7. Thomas LJJ, Blaine GJ, Gerth VW, Hagen RW. Continuous Monitoring of Physiologic Variables with a Dedicated Minicomputer. Computer 1975 Jul;8(7):30-35 [FREE Full text] [doi: 10.1109/C-M.1975.219022]
8. Weller RS, Foard KL, Harwood TN. Evaluation of a wireless, portable, wearable multi-parameter vital signs monitor in hospitalized neurological and neurosurgical patients. J Clin Monit Comput 2018 Oct;32(5):945-951. [doi: 10.1007/s10877-017-0085-0] [Medline: 29214598]
9. Breteler MJM, Huizinga E, van Loon K, Leenen LPH, Dohmen DAJ, Kalkman CJ, et al. Reliability of wireless monitoring using a wearable patch sensor in high-risk surgical patients at a step-down unit in the Netherlands: A clinical validation study. BMJ Open 2018 Dec 27;8(2):e020162 [FREE Full text] [doi: 10.1136/bmjopen-2017-020162] [Medline: 29487076]
10. Baulig W, Seifert B, Spahn DR, Theusinger OM. Accuracy of non-invasive continuous total hemoglobin measurement by Pulse CO-Oximetry in severe traumatized and surgical bleeding patients. J Clin Monit Comput 2017 Feb;31(1):177-185. [doi: 10.1007/s10877-015-9816-2] [Medline: 26686689]
11. Balzer F, Habicher M, Sander M, Sterr J, Scholz S, Feldheiser A, et al. Comparison of the non-invasive Nexfin® monitor with conventional methods for the measurement of arterial blood pressure in moderate risk orthopaedic surgery patients. J Int Med Res 2016 Aug;44(4):832-843 [FREE Full text] [doi: 10.1177/0300060516635383] [Medline: 27142436]
12. Hoffmann R, Michaelsen J, Langenbrink L, Kastrati M, Piatkowski M, Hengemuhle G, et al. A novel ECG ward telemetry system with smartphone based alarm escalation. Int J Cardiovasc Res 2018;7(2):1-4. [doi: 10.4172/2324-8602.1000345]
13. Michard F, Pinsky MR, Vincent J. Intensive care medicine in 2050: NEWS for hemodynamic monitoring. Intensive Care Med 2017 Mar;43(3):440-442. [doi: 10.1007/s00134-016-4674-z] [Medline: 28124086]
14. Michard F, Barrachina B, Schoettker P. Is your smartphone the future of physiologic monitoring? Intensive Care Med 2018 Oct 19:1-3. [doi: 10.1007/s00134-018-5419-y] [Medline: 30341565]
15. Meyer A, Zverinski D, Pfahringer B, Kempfert J, Kuehne T, Sündermann SH, et al. Machine learning for real-time prediction of complications in critical care: A retrospective study. Lancet Respir Med 2018 Dec;6(12):905-914. [doi: 10.1016/S2213-2600(18)30300-X] [Medline: 30274956]
16. Komorowski M, Celi L, Badawi O, Gordon A, Faisal A. The artificial intelligence clinician learns optimal treatment strategies for sepsis in intensive care. Nat Med 2018 Nov;24(11):1716-1720. [doi: 10.1038/s41591-018-0213-5] [Medline: 30349085]
17. Hüsers J, Hübner U, Esdar M, Ammenwerth E, Hackl WO, Naumann L, et al. Innovative power of health care organisations affects IT adoption: A bi-national health IT benchmark comparing Austria and Germany. J Med Syst 2017 Feb;41(2):33. [doi: 10.1007/s10916-016-0671-6] [Medline: 28054195]

18. De Georgia MA, Kaffashi F, Jacono F, Loparo K. Information technology in critical care: Review of monitoring and data acquisition systems for patient care and research. ScientificWorldJournal 2015;2015:727694 [FREE Full text] [doi: 10.1155/2015/727694] [Medline: 25734185]
19. Heitmueller A, Bull A, Oh S. Looking in the wrong places: Why traditional solutions to the diffusion of innovation will not work. BMJ Innov 2016 Mar 25;2(2):41-47. [doi: 10.1136/bmjinnov-2015-000106]
20. Christodoulakis C, Asgarian A, Easterbrook S. Barriers to adoption of information technology in healthcare. In: Proceedings of the 27th Annual International Conference on Computer Science and Software Engineering (CASCON '17). Riverton, NJ: IBM Corp; 2017 Presented at: 27th Annual International Conference on Computer Science and Software Engineering (CASCON '17); November 6-8, 2017; Markham, ON p. 66-75 URL: http://dl.acm.org/citation.cfm?id=3172795.3172804
21. Moeckli J, Cram P, Cunningham C, Reisinger HS. Staff acceptance of a telemedicine intensive care unit program: A qualitative study. J Crit Care 2013 Dec;28(6):890-901. [doi: 10.1016/j.jcrc.2013.05.008] [Medline: 23906904]
22. Wilson ME, Rhudy LM, Ballinger BA, Tescher AN, Pickering BW, Gajic O. Factors that contribute to physician variability in decisions to limit life support in the ICU: A qualitative study. Intensive Care Med 2013 Jun;39(6):1009-1018. [doi: 10.1007/s00134-013-2896-x] [Medline: 23559079]
23. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: A synthesis of recommendations. Acad Med 2014 Sep;89(9):1245-1251 [FREE Full text] [doi: 10.1097/ACM.0000000000000388] [Medline: 24979285]
24. Strauss A, Corbin J. Basics of Qualitative Research: Grounded Theory Procedures and Techniques. 2nd edition. Thousand Oaks, CA: SAGE Publications; 1990.
25. Kean S, Salisbury L, Rattray J, Walsh T, Huby G, Ramsay P. 'Intensive care unit survivorship': A constructivist grounded theory of surviving critical illness. J Clin Nurs 2017 Oct;26(19-20):3111-3124. [doi: 10.1111/jocn.13659] [Medline: 27875013]
26. Malterud K, Siersma VD, Guassora AD. Sample size in qualitative interview studies: Guided by information power. Qual Health Res 2016 Nov;26(13):1753-1760. [doi: 10.1177/1049732315617444] [Medline: 26613970]
27. Donchin Y, Seagull F. The hostile environment of the intensive care unit. Curr Opin Crit Care 2002 Aug;8(4):316-320. [Medline: 12386492]
28. Paine C, Goel V, Ely E, Stave C, Stemler S, Zander M, et al. Systematic review of physiologic monitor alarm characteristics and pragmatic interventions to reduce alarm frequency. J Hosp Med 2016 Feb;11(2):136-144 [FREE Full text] [doi: 10.1002/jhm.2520] [Medline: 26663904]
29. Ruskin KJ, Hueske-Kraus D. Alarm fatigue: Impacts on patient safety. Curr Opin Anaesthesiol 2015 Dec;28(6):685-690. [doi: 10.1097/ACO.0000000000000260] [Medline: 26539788]
30. Sowan AK, Tarriela AF, Gomez TM, Reed CC, Rapp KM. Nurses' perceptions and practices toward clinical alarms in a transplant cardiac intensive care unit: Exploring key issues leading to alarm fatigue. JMIR Hum Factors 2015 Mar 16;2(1):e3 [FREE Full text] [doi: 10.2196/humanfactors.4196] [Medline: 27025940]
31. ClinicalTrials.gov. 2018 Apr 09. Outcomes and user acceptance of the IntelliVue alarm advisor software (Europe) URL: https://clinicaltrials.gov/ct2/show/NCT03182452 [accessed 2018-11-29] [WebCite Cache ID 74IIblp5w]
32. Turmell JW, Coke L, Catinella R, Hosford T, Majeski A. Alarm fatigue: Use of an evidence-based alarm management strategy. J Nurs Care Qual 2017;32(1):47-54. [doi: 10.1097/NCQ.0000000000000223] [Medline: 27500694]
33. Sendelbach S, Wahl S, Anthony A, Shotts P. Stop the noise: A quality improvement project to decrease electrocardiographic nuisance alarms. Crit Care Nurse 2015 Aug;35(4):15-22; quiz 1p following 22 [FREE Full text] [doi: 10.4037/ccn2015858] [Medline: 26232798]
34. Sowan AK, Gomez TM, Tarriela AF, Reed CC, Paper BM. Changes in default alarm settings and standard in-service are insufficient to improve alarm fatigue in an intensive care unit: A pilot project. JMIR Hum Factors 2016 Jan 11;3(1):e1 [FREE Full text] [doi: 10.2196/humanfactors.5098] [Medline: 27036170]
35. Flohr L, Beaudry S, Johnson KT, West N, Burns CM, Ansermino JM, et al. Clinician-driven design of VitalPAD: An intelligent monitoring and communication device to improve patient safety in the intensive care unit. IEEE J Transl Eng Health Med 2018;6:3000114 [FREE Full text] [doi: 10.1109/JTEHM.2018.2812162] [Medline: 29552425]
36. Fidler R, Bond R, Finlay D, Guldenring D, Gallagher A, Pelter M, et al. Human factors approach to evaluate the user interface of physiologic monitoring. J Electrocardiol 2015;48(6):982-987. [doi: 10.1016/j.jelectrocard.2015.08.032] [Medline: 26375330]
37. Ratwani RM, Hodgkins M, Bates DW. Improving electronic health record usability and safety requires transparency. JAMA 2018 Nov 29:1. [doi: 10.1001/jama.2018.14079] [Medline: 30489619]
38. Peischl B, Ferk M, Holzinger A. The fine art of user-centered software development. Softw Qual J 2014 May 27;23(3):509-536. [doi: 10.1007/s11219-014-9239-1]
39. International Organization for Standardization (ISO). 2015 Jan. IEC 60601-1-11:2015. Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment URL: https://www.iso.org/standard/65529.html [accessed 2019-02-26] [WebCite Cache ID 76TEr4I8Z]

40. International Organization for Standardization (ISO). 2018 Sep. ISO/IEEE 11073-20702:2018. Health informatics -- Point-of-care medical device communication -- Part 20702: Medical devices communication profile for web services URL: https://www.iso.org/standard/74703.html [accessed 2019-02-26] [WebCite Cache ID 76TFWoDks]
41. Duhm J, Fleischmann R, Schmidt S, Hupperts H, Brandt SA. Mobile electronic medical records promote workflow: Physicians' perspective from a survey. JMIR Mhealth Uhealth 2016 Jun 06;4(2):e70 [FREE Full text] [doi: 10.2196/mhealth.5464] [Medline: 27268720]
42. Mobasheri MH, King D, Judge S, Arshad F, Larsen M, Safarfashandi Z, et al. Communication aid requirements of intensive care unit patients with transient speech loss. Augment Altern Commun 2016 Dec;32(4):261-271. [doi: 10.1080/07434618.2016.1235610] [Medline: 27868434]
43. Dolcourt J. CNET. 2019 Mar 20. Galaxy Fold vs Mate X: Battle of the foldable phones URL: https://www.cnet.com/news/galaxy-fold-vs-huawei-mate-x-battle-of-the-foldable-phones-comparison-mwc/ [accessed 2019-02-26] [WebCite Cache ID 76TEaP34T]
44. Armaignac DL, Saxena A, Rubens M, Valle CA, Williams LS, Veledar E, et al. Impact of telemedicine on mortality, length of stay, and cost among patients in progressive care units: Experience from a large healthcare system. Crit Care Med 2018 May;46(5):728-735 [FREE Full text] [doi: 10.1097/CCM.0000000000002994] [Medline: 29384782]
45. Hawkins HA, Lilly CM, Kaster DA, Groves RH, Khurana H. ICU telemedicine comanagement methods and length of stay. Chest 2016 Aug;150(2):314-319. [doi: 10.1016/j.chest.2016.03.030] [Medline: 27048869]
46. Fritz BA, Chen Y, Murray-Torres TM, Gregory S, Ben Abdallah A, Kronzer A, et al. Using machine learning techniques to develop forecasting algorithms for postoperative complications: Protocol for a retrospective study. BMJ Open 2018 Dec 10;8(4):e020124 [FREE Full text] [doi: 10.1136/bmjopen-2017-020124] [Medline: 29643160]
47. Lee CK, Hofer I, Gabel E, Baldi P, Cannesson M. Development and validation of a deep neural network model for prediction of postoperative in-hospital mortality. Anesthesiology 2018 Oct;129(4):649-662. [doi: 10.1097/ALN.0000000000002186] [Medline: 29664888]
48. Nemati S, Holder A, Razmi F, Stanley MD, Clifford GD, Buchman TG. An interpretable machine learning model for accurate prediction of sepsis in the ICU. Crit Care Med 2018 Apr;46(4):547-553 [FREE Full text] [doi: 10.1097/CCM.0000000000002936] [Medline: 29286945]
49. Topol EJ. High-performance medicine: The convergence of human and artificial intelligence. Nat Med 2019 Jan;25(1):44-56. [doi: 10.1038/s41591-018-0300-7] [Medline: 30617339]
50. Eerikäinen LM, Vanschoren J, Rooijakkers MJ, Vullings R, Aarts RM. Reduction of false arrhythmia alarms using signal selection and machine learning. Physiol Meas 2016 Dec;37(8):1204-1216. [doi: 10.1088/0967-3334/37/8/1204] [Medline: 27454128]
51. Charbonnier S, Gentil S. A trend-based alarm system to improve patient monitoring in intensive care units. Control Eng Pract 2007 Sep;15(9):1039-1050. [doi: 10.1016/j.conengprac.2006.12.005]
52. Goedken CC, Moeckli J, Cram PM, Reisinger HS. Introduction of tele-ICU in rural hospitals: Changing organisational culture to harness benefits. Intensive Crit Care Nurs 2017 Jun;40:51-56. [doi: 10.1016/j.iccn.2016.10.001] [Medline: 28216177]
53. Larinkari S, Liisanantti JH, Ala-Lääkkölä T, Meriläinen M, Kyngäs H, Ala-Kokko T. Identification of tele-ICU system requirements using a content validity assessment. Int J Med Inform 2016 Feb;86:30-36. [doi: 10.1016/j.ijmedinf.2015.11.012] [Medline: 26725692]
54. Van Velsen L, Wildevuur S, Flierman I, Van Schooten B, Tabak M, Hermens H. Trust in telemedicine portals for rehabilitation care: An exploratory focus group study with patients and healthcare professionals. BMC Med Inform Decis Mak 2016 Jan 27;16:11 [FREE Full text] [doi: 10.1186/s12911-016-0250-2] [Medline: 26818611]
55. Lennon MR, Bouamrane M, Devlin AM, O'Connor S, O'Donnell C, Chetty U, et al. Readiness for delivering digital health at scale: Lessons from a longitudinal qualitative evaluation of a national digital health innovation program in the United Kingdom. J Med Internet Res 2017 Feb 16;19(2):e42 [FREE Full text] [doi: 10.2196/jmir.6900] [Medline: 28209558]
56. The Topol Review: Preparing the Healthcare Workforce to Deliver the Digital Future. Leeds, UK: Health Education England; 2019 Feb. URL: https://topol.hee.nhs.uk/wp-content/uploads/HEE-Topol-Review-2019.pdf [accessed 2019-02-26] [WebCite Cache ID 76THfTwlX]
57. Cresswell KM, Lee L, Mozaffar H, Williams R, Sheikh A, NIHR ePrescribing Programme Team. Sustained user engagement in health information technology: The long road from implementation to system optimization of computerized physician order entry and clinical decision support systems for prescribing in hospitals in England. Health Serv Res 2017 Dec;52(5):1928-1957 [FREE Full text] [doi: 10.1111/1475-6773.12581] [Medline: 27714800]
58. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: A consolidated framework for advancing implementation science. Implement Sci 2009 Aug 07;4:50 [FREE Full text] [doi: 10.1186/1748-5908-4-50] [Medline: 19664226]
59. Zajicek H, Meyers A. Digital health entrepreneurship. In: Rivas H, Wac K, editors. Digital Health: Scaling Healthcare to the World. Cham, Switzerland: Springer International Publishing; 2018:271-287.
60. Roberts JP, Fisher TR, Trowbridge MJ, Bent C. A design thinking framework for healthcare management and innovation. Healthc (Amst) 2016 Mar;4(1):11-14. [doi: 10.1016/j.hjdsi.2015.12.002] [Medline: 27001093]

Abbreviations

BioCog: Biomarker Development for Postoperative Cognitive Impairment in the Elderly
CDSS: clinical decision support system
DFG: Deutsche Forschungsgemeinschaft
DLR: Deutsches Zentrum für Luft- und Raumfahrt eV
ECG: electrocardiogram
etCO$_2$: end-tidal carbon dioxide
ICT: information and communication technology
ICU: intensive care unit
IEC: International Electrotechnical Commission
IEEE: Institute of Electrical and Electronics Engineers
PDMS: patient data management system
SpO$_2$: peripheral capillary oxygen saturation

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11	INTERNATIONAL JOURNAL OF MEDICAL INFORMATICS	4,765	2.731	0.006720

Publikation 2

JOURNAL OF MEDICAL INTERNET RESEARCH Poncette et al

Original Paper

Improvements in Patient Monitoring in the Intensive Care Unit: Survey Study

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Abstract

Background: Due to demographic change and, more recently, coronavirus disease (COVID-19), the importance of modern intensive care units (ICU) is becoming apparent. One of the key components of an ICU is the continuous monitoring of patients' vital parameters. However, existing advances in informatics, signal processing, or engineering that could alleviate the burden on ICUs have not yet been applied. This could be due to the lack of user involvement in research and development.

Objective: This study focused on the satisfaction of ICU staff with current patient monitoring and their suggestions for future improvements. We aimed to identify aspects of monitoring that interrupt patient care, display devices for remote monitoring, use cases for artificial intelligence (AI), and whether ICU staff members are willing to improve their digital literacy or contribute to the improvement of patient monitoring. We further aimed to identify differences in the responses of different professional groups.

Methods: This survey study was performed with ICU staff from 4 ICUs of a German university hospital between November 2019 and January 2020. We developed a web-based 36-item survey questionnaire, by analyzing a preceding qualitative interview study with ICU staff, about the clinical requirements of future patient monitoring. Statistical analyses of questionnaire results included median values with their bootstrapped 95% confidence intervals, and chi-square tests to compare the distributions of item responses of the professional groups.

Results: In total, 86 of the 270 ICU physicians and nurses completed the survey questionnaire. The majority stated they felt confident using the patient monitoring equipment, but that high rates of false-positive alarms and the many sensor cables interrupted patient care. Regarding future improvements, respondents asked for wireless sensors, a reduction in the number of false-positive alarms, and hospital standard operating procedures for alarm management. Responses to the display devices proposed for remote patient monitoring were divided. Most respondents indicated it would be useful for earlier alerting or when they were responsible for multiple wards. AI for ICUs would be useful for early detection of complications and an increased risk of mortality; in addition, the AI could propose guidelines for therapy and diagnostics. Transparency, interoperability, usability, and staff training were essential to promote the use of AI. The majority wanted to learn more about new technologies for the ICU and required more time for learning. Physicians had fewer reservations than nurses about AI-based intelligent alarm management and using mobile phones for remote monitoring.

Conclusions: This survey study of ICU staff revealed key improvements for patient monitoring in intensive care medicine. Hospital providers and medical device manufacturers should focus on reducing false alarms, implementing hospital alarm standard operating procedures, introducing wireless sensors, preparing for the use of AI, and enhancing the digital literacy of ICU staff. Our results may contribute to the user-centered transfer of digital technologies into practice to alleviate challenges in intensive care medicine.

Trial Registration: ClinicalTrials.gov NCT03514173; https://clinicaltrials.gov/ct2/show/NCT03514173

(J Med Internet Res 2020;22(6):e19091) doi: 10.2196/19091

KEYWORDS

digital health; patient monitoring; monitoring; intensive care medicine; intensive care unit; technological innovation; user-centered; usability; online survey; transdisciplinary; REDCap; email

Introduction

Background

In the near future, continuous monitoring of patients' vital signs will play an increasingly important role in alleviating the burden on the health care system caused by demographic change and, more recently, coronavirus disease (COVID-19) [1]. Both lead to an increased number of critically ill patients requiring intensive medical care, including mechanical ventilation and patient monitoring. However, existing advances in informatics, signal processing, or engineering have not yet been applied to patient monitoring [2], making it primarily an alarm system notifying health care providers whenever a patient's parameter deviates from preset values that are considered safe. To accelerate technology transfer into clinical routine, it may be beneficial to include users' pain points and suggestions for research and development.

Patient monitoring can be applied across almost all health sectors, which underlines its importance and the potential offered by digitalization. First, patients can monitor themselves preventively (eg, for atrial fibrillation), even with a consumer product such as the Apple Watch [3]. Second, remote monitoring of patients over long distances is a crucial component of telemedicine, which is becoming increasingly widespread in most areas of medicine [4]. Third, patient monitoring might soon be mandatory in general wards due to a shift in inpatient clientele toward the more critically ill [5,6]. Finally, patient monitoring produces high-frequency data that are a valid and essential source for clinical decision support systems (CDSS) based on artificial intelligence (AI), opening up many possibilities for precision medicine [7].

In the intensive care unit (ICU), as one of the most technologically enhanced medical areas, staff have used monitoring technologies over decades. In a previous qualitative study from our research group, ICU staff demanded wireless, noninvasive, and interoperable monitoring sensors and improved alarm management for a future patient monitoring system [8]. Mobile phones were desired as displays for remote patient monitoring, and CDSS based on AI was considered useful. To validate these inclinations in a larger cohort, we designed this survey study of ICU staff.

Aim

This survey study focuses on ICU staff members' satisfaction with the current patient monitoring system and their suggestions for future technological improvements. In particular, we aimed to identify the aspects of patient monitoring that disturb patient care, the display devices most appropriate for the ICU for remote patient monitoring on the hospital premises, the use cases for AI in the ICU, and whether ICU staff is willing to improve their digital literacy or contribute to product improvement. With regard to the multiprofessional structure of ICU teams, we further desired to uncover differences in perspectives between different health professions in the ICU.

Methods

Ethics Approval and Consent to Participate

The ethical approval for this study was granted by the Ethics Commission of the Charité – Universitätsmedizin Berlin (EA1/031/18). Participation in the survey was voluntary. Prior to the study, all participants provided their written consent.

Setting

This survey study was performed with ICU staff from 4 ICUs of a German university hospital, between November 2019 and January 2020 as a substudy for the implementation of the virtual patient monitoring platform Vital Sync 2.4 (Medtronic plc). This new system was implemented between May 2018 and June 2019 in one of the 4 ICUs as a secondary patient monitoring system to remotely monitor patients via tablet computers. As the primary patient monitoring system, the Philips IntelliVue patient monitoring system (Koninklijke Philips NV; MX800 software version M.00.03; MMS X2 software version H.15.41-M.00.04) was used in all 4 ICUs at the time of the study. COPRA 6 (COPRA System GmbH) was used as the patient data management system (PDMS).

Study Design

We chose a cross-sectional survey design, and developed a web-based questionnaire [9,10]. Survey item generation was initiated through the analysis of a preceding qualitative interview study with ICU staff about clinical requirements of future patient monitoring, and was saturated in focus group sessions within the research team [8]. Items were then grouped into topics, and 5 to 6 items per topic were anticipated. We chose a 5-point Likert-type scale as an ordinal response format, with the options "Strongly disagree" (score=1), "Disagree" (score=2), "Undecided" (score=3), "Agree" (score=4), and "Strongly agree" (score=5). In pretests with associated research colleagues, redundant items were eliminated without removing whole topics. Pilot testing was conducted face-to-face with experts from intensive care medicine, with a focus on the clarity, relevance, and arrangement of the items into topics as well as the usability of the web-based questionnaire. Experts also assessed content validity (ie, whether all aspects of the topic were accurately covered by the questionnaire) and clinical validity (ie, whether the questionnaire measured the intended research topic). The final questionnaire (Multimedia Appendix 1) contained 36 items grouped into 8 topics:

- ICU staff experience with the current patient monitoring system
- Aspects of patient monitoring that disturb patient care
- Improvements for future patient monitoring
- Suggestions for remote patient monitoring display devices
- Use cases for remote patient monitoring
- Use cases for CDSS based on AI
- Aspects that promote the usage of CDSS based on AI
- Attitude of ICU staff toward novel digital technology

Additionally, respondents indicated their age group, profession, and technical affinity. For the latter, we used the Affinity for Technology Interaction Short (ATI-S) scale [11] and reduced the options from a 6-point scale to a 5-point Likert-type scale due to usability issues. Other items in the questionnaire focused on alarm management, which was the subject of another study and is not reported here.

Data Collection

Data collection took place over a period of 2 months (November 2019 to January 2020) on an invitation basis. The sampling frame was defined as the 270 nurses and physicians working in the 4 ICUs the day before data collection began; in total, there were 177 nurses and 93 physicians. An email containing a detailed description of the study and the web address of the survey was sent to them. Study data were collected and managed using REDCap electronic data capture tools hosted at Charité – Universitätsmedizin Berlin [12,13].

To increase the survey response rate, participants were offered the opportunity to take part in a raffle to win a €50 (US $56.04) voucher for a train ticket after survey participation. Additionally, 2 reminder emails were sent to all participants 2 and 5 weeks after the initial email was sent. Finally, small handouts with a brief description of the study, the URL for the questionnaire, and a QR (quick response) code were given to ICU staff on site.

Data Analysis

We cleaned and analyzed the data with R (R Foundation for Statistical Computing) in combination with the packages tidyverse, psych, and sjPlots [14-17]. Inferential calculations were performed with the infer package [18]. For each of the 36 five-point items, we calculated the medians and their 95% bootstrap CIs by deploying a bootstrap resampling procedure as previously described [19,20]. For the bootstrap sampling distribution, we created 15,000 bootstrap samples per item. An item median was considered statistically significant when the 95% bootstrap confidence intervals of the median did not include 3, which indicates the response "Undecided." To compare the distributions of item responses of physicians and nurses, we used chi-square tests. Here, a two-tailed P value <.05 was considered statistically significant.

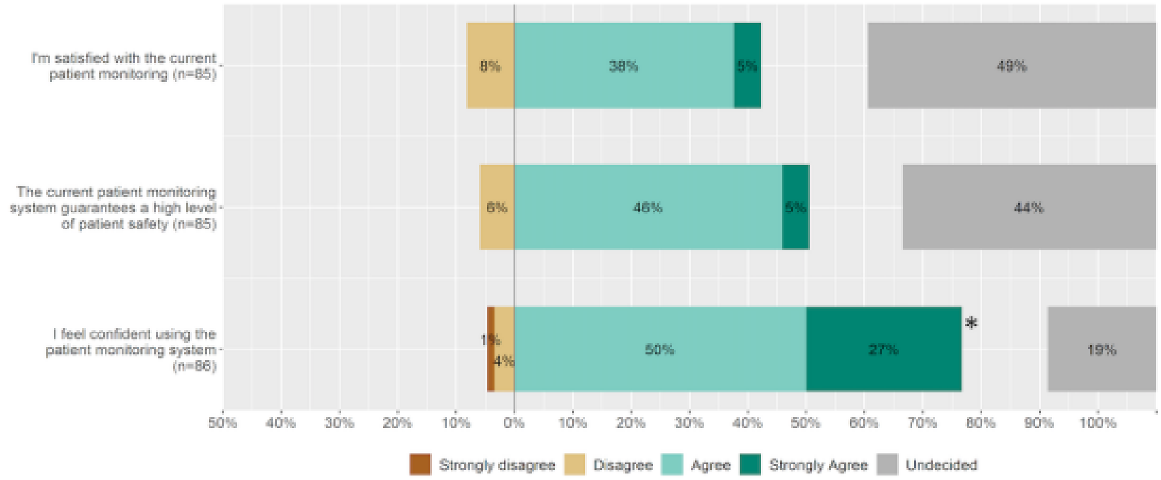
Results

Overview

This survey study is based on a questionnaire with 36 items regarding patient monitoring in the ICU, addressed to ICU staff. The actual response rate was 39.6% (107/270); however, only 86 responses from 62 nurses and 24 physicians were analyzable due to missing data. The ratio of male to female respondents was almost equal (42 men, 41 women, 3 not specified). The largest age categories were represented by participants aged 25 to 34 years (n=32, 37%) and those aged 35 to 44 years (n=28, 33%). Self-reported technical affinity (ATI-S) was rated with a mean of 3.4 (SD 0.88) and a median of 3.5 (range 2.9-4.1) on the 5-point Likert-type scale, with a Cronbach of 0.83 (95% CI 0.76-0.89).

The questionnaire results are presented as grouped Likert plots (Figures 1-8) [16], where one group represents one topic. An item median was considered statistically significant (items marked with an asterisk) when the 95% bootstrap CI of the median did not include 3, which indicates the response "Undecided" (Multimedia Appendix 2 shows item medians and bootstrap CIs). To improve readability, and in contrast to the questionnaire, the answer option "Undecided" is presented on the far right. Multimedia Appendix 3 contains the raw data, and Multimedia Appendix 4 shows the distribution of item responses of physicians and nurses.

Figure 1. ICU staff experience with current patient monitoring. An asterisk indicates statistical significance. ICU: intensive care unit.



Current Patient Monitoring

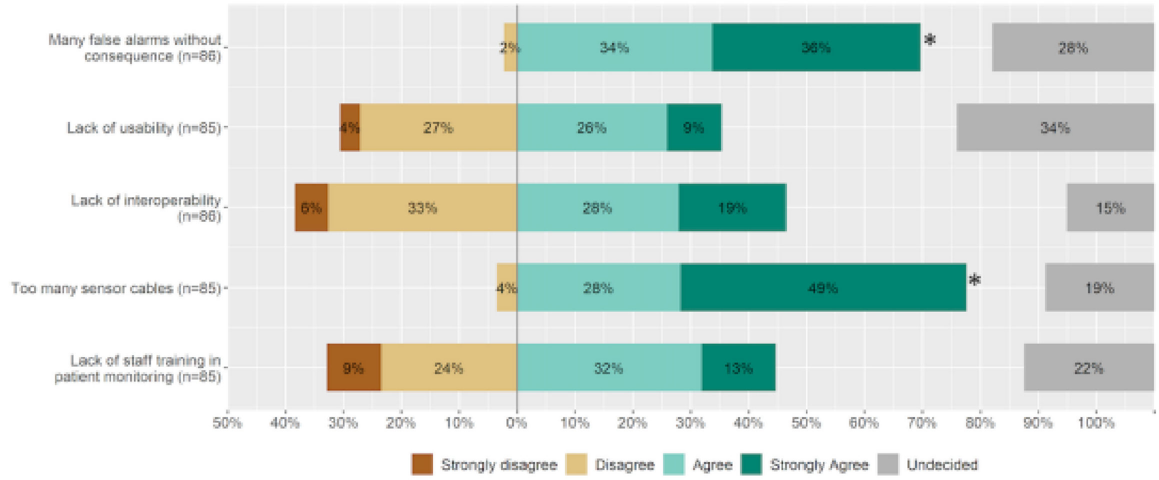
ICU Staff Experience

Most of the ICU staff who took part in the online survey were satisfied with the current patient monitoring system and felt that it ensured high patient safety, even though the median responses did not differ significantly from the option "Undecided" (Figure 1). The majority stated feeling confident in using the patient monitoring system (n=66, 77% chose "Strongly agree" or "Agree").

Aspects Disturbing Patient Care

The majority of respondents indicated that the patient monitoring system's high rate of false-positive alarms (n=60, 70% chose "Strongly agree" or "Agree") and high number of sensor cables (n=66, 77% indicated "Strongly agree" or "Agree") interrupted patient care. The opinions about detrimental effects elicited by a lack of interoperability, lack of staff training, and low usability of the patient monitoring system were split (Figure 2).

Figure 2. Aspects of patient monitoring disturbing patient care in the ICU. An asterisk indicates statistical significance. ICU: intensive care unit.

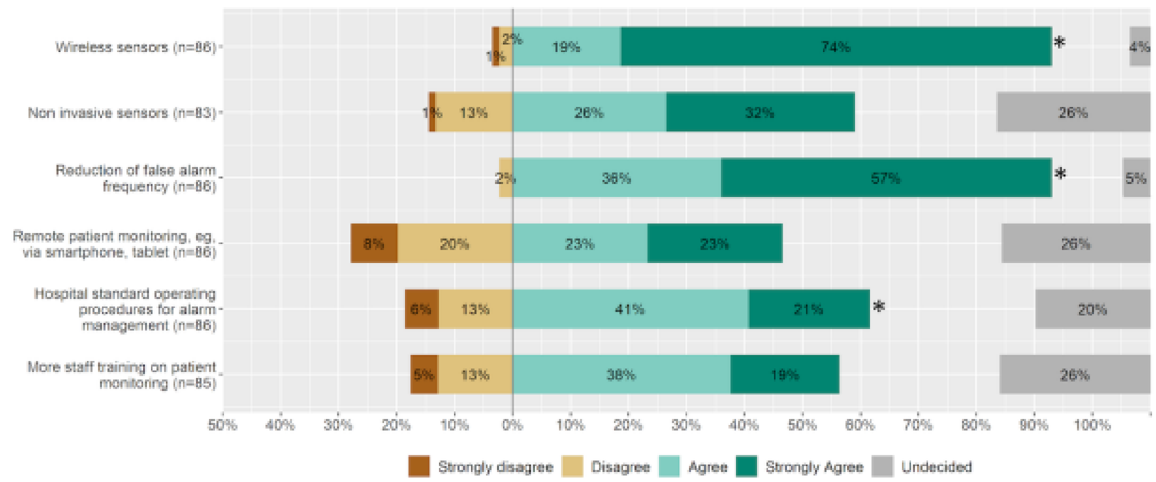


Suggestions for Future Patient Monitoring

Improvements for Future Patient Monitoring

For future patient monitoring, almost all of the ICU staff surveyed requested wireless sensors (n=80, 93% chose "Strongly agree" or "Agree") and a reduction in false-positive alarms (n=80, 93% chose "Strongly agree" or "Agree"). False-positive alarms may occur due to measurement errors, artifacts, or incorrect settings (Figure 3). Furthermore, respondents wanted a hospital standard operating procedure (SOP) for alarm management (n=53, 62% chose "Strongly agree" or "Agree"). The median responses for the items "Noninvasive sensors," "Remote patient monitoring," and "More staff training on patient monitoring" did not significantly differ from the option "Undecided."

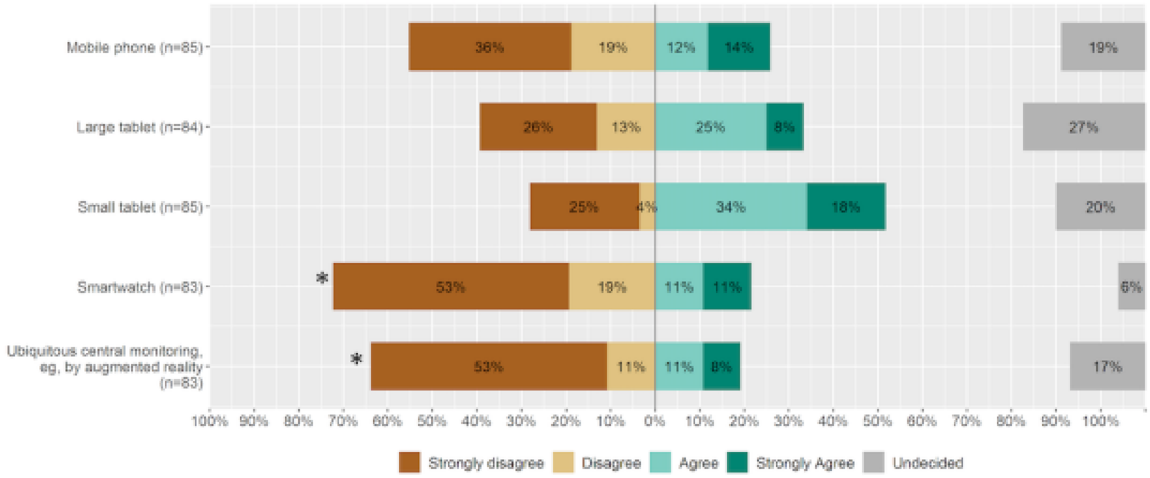
Figure 3. Improvements for future patient monitoring in the ICU. An asterisk indicates statistical significance. ICU: intensive care unit.



Display Devices and Use Cases for Remote Patient Monitoring

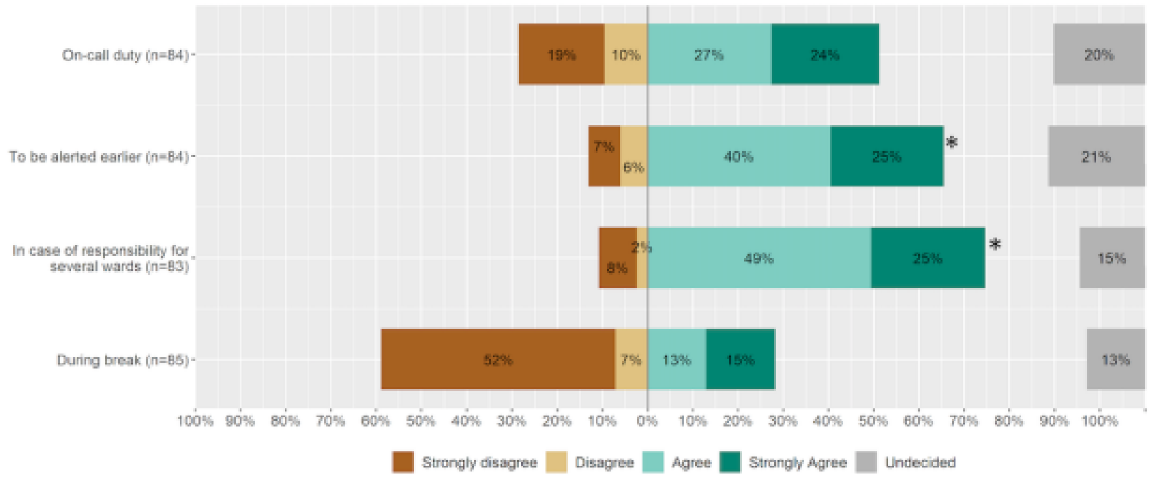
According to the survey results, none of the proposed display devices were desired by ICU staff (Figure 4). The use of smartwatches or augmented reality (AR) glasses in the ICU was rejected by 72% (n=60) and 64% (n=53) of respondents, respectively (those who chose "Strongly disagree" or "Disagree"). With regard to the use of mobile phones for remote patient monitoring, nurses strongly rejected it, while physicians had a neutral attitude toward it.

Figure 4. Suggestions for remote patient monitoring display devices in intensive care medicine for usage on hospital premises. An asterisk indicates statistical significance.



The majority of respondents would appreciate a remote patient monitoring system in an intensive care setting in case they wanted to be alerted earlier (n=55, 65% indicated "Strongly agree" or "Agree") or were responsible for multiple wards (n=62, 74% chose "Strongly agree" or "Agree"; Figure 5). Although not statistically significant, most respondents preferred a remote patient monitoring device for on-call duty, but did not find it useful while taking breaks.

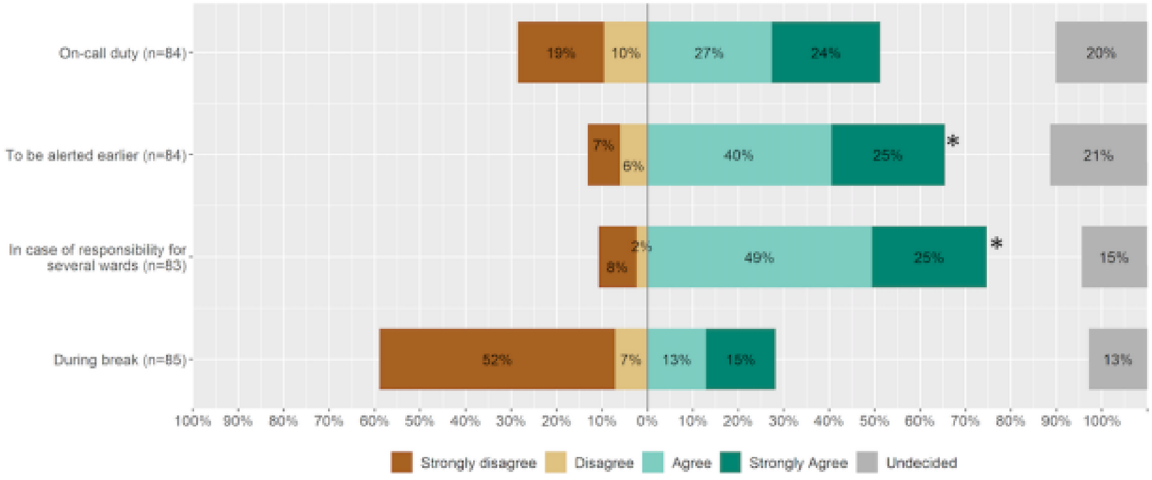
Figure 5. Use cases for remote patient monitoring on hospital premises for intensive care medicine. An asterisk indicates statistical significance.



CDSS

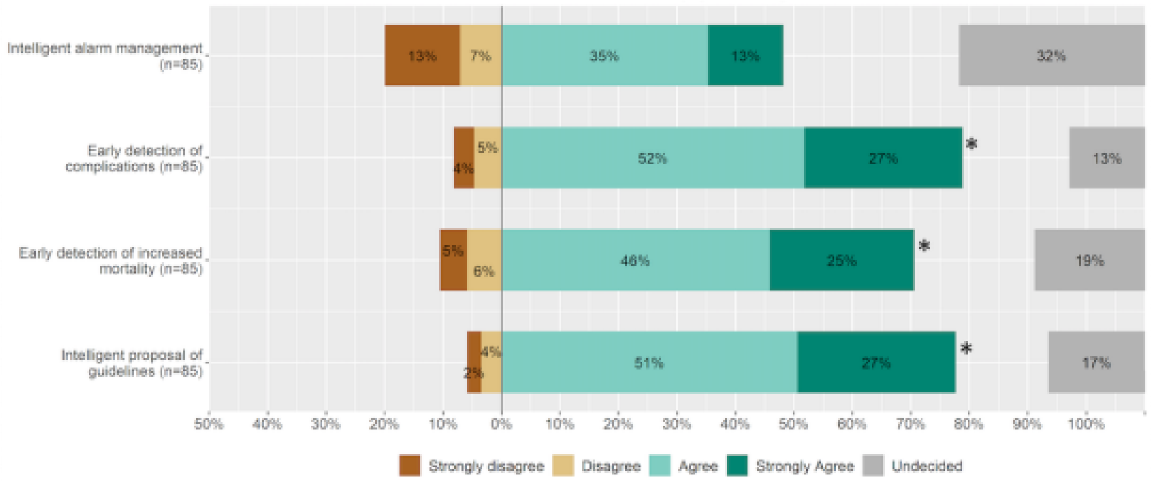
In the future, survey respondents would use a CDSS in the ICU that predicts complications (n=67, 79% chose "Strongly agree" or "Agree") or the risk of mortality of patients (n=60, 71% indicated "Strongly agree" or "Agree") as that intelligently proposes guidelines for therapy and diagnostics (n=66, 78% chose "Strongly agree" or "Agree"; Figure 6). Respondents were inclined to use it for alarm management. Physicians had fewer reservations in using a CDSS with intelligent alarm management than nurses.

Figure 6. Use cases for clinical decision support systems based on artificial intelligence in the ICU. An asterisk indicates statistical significance. ICU: intensive care unit.



Among the factors that users found essential for the use of CDSS, high interoperability (n=79, 93% chose "Strongly agree" or "Agree") and high usability (n=78, 93% indicated "Strongly agree" or "Agree") were deemed most essential. These were followed by the offer of regular staff training with the technology (n=75, 90% chose "Strongly agree" or "Agree") and high transparency of the system (n=66, 78% indicated "Strongly agree" or "Agree"; Figure 7). Most physicians and nurses agreed that regular support (eg, training and workshops) promotes the use of CDSS; more physicians chose "Strongly agree," while more nurses chose "Agree."

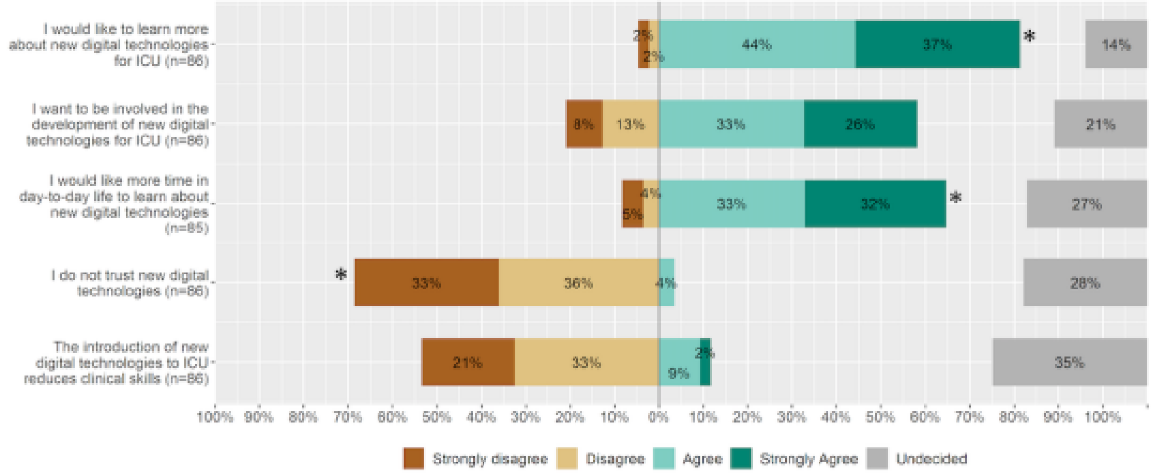
Figure 7. Aspects that promote the usage of clinical decision support systems based on artificial intelligence in the ICU. An asterisk indicates statistical significance. ICU: intensive care unit.



Attitude Toward Novel Technology

Overall, survey respondents were open-minded toward novel technology; among the respondents, 81% (n=70) wanted to know more and 65% (n=55) needed more time to learn about it ("Strongly agree" or "Agree"; Figure 8). The majority (n=59, 69%) disagreed or strongly disagreed on the item "I do not trust new digital technology." Although not statistically significant, 50 respondents (59%) wanted to be involved in the product development of novel digital technologies.

Figure 8. Attitude of ICU staff towards novel digital technology. An asterisk indicates statistical significance. ICU: intensive care unit.



Discussion

Principal Findings

This survey study of ICU staff provides a substantial understanding of the needs and expectations of patient monitoring systems in intensive care medicine from the user's perspective (Textbox 1). Although respondents were confident in using the current patient monitoring system, the high rate of false alarms and the numerous sensor cables were found to potentially interrupt patient care. ICU staff demanded wireless sensors, fewer false alarms, and a hospital SOP for alarm management. Notably, the median replies on display devices for remote patient monitoring did not differ significantly from the option "Undecided," except for the items "Smartwatch" and "Ubiquitous monitoring, eg, through AR," which were both declined. Remote patient monitoring was classified useful for earlier alerts or when responsible for several ICUs. Respondents would use a CDSS based on AI to predict complications, detect increased risk of mortality, and propose guidelines. High transparency, high interoperability, high usability, and regular staff training were all aspects that would promote its usage. Regarding digital literacy, ICU staff was eager to learn more about digital technology and spend more time with it.

Textbox 1. The five most anticipated improvements for patient monitoring by intensive care unit staff.

- Reduction of false alarms
- Implementation of hospital alarm standard operating procedures
- Introduction of wireless sensors
- Introduction of a clinical decision support system based on artificial intelligence
- Enhancement of staff members' digital literacy

Lessons Learned From Today's Patient Monitoring

Notably, we have not observed a proactive call to pioneer new technologies and integrate their respective digital gadgets (eg, smartwatch and AR) into clinical care. Rather, ICU staff looked forward to improvements in the functionality of existing technologies. In line with previous publications, respondents reported that the high rate of false alarms interrupted patient care and demanded a hospital SOP for alarm management [21]. In several studies, implementation of such an alarm management SOP reduced the alarm rate significantly [21,22]. Further temporal analysis of the alarm frequencies per sensor as previously described [23] may find causes for the high rate of false alarms.

It has been reported that cable entanglement is a problem in not only ICUs, but also other places where patients are monitored, such as in operating rooms [24]. Wireless sensors for monitoring vital signs have been tested and implemented several times on stepdown units [6,25]. In many cases, technical requirement analysis (eg, Bluetooth connectivity and interference with other medical devices) was conducted more than a decade ago [26,27]. However, implementation into intensive care routines is still in its infancy [28]. Reasons for this may be the costs associated with developing novel wireless sensors for a high-reliability environment such as the ICU, and technical challenges associated with the need to recharge sensors regularly. In the meantime, cord wraps may facilitate patient transfer with patient monitoring [29].

Remote Patient Monitoring in Intensive Care Medicine

Remote patient monitoring enables clinicians to collect health data via vital sign sensors from patients at location A and electronically transfer this information to location B, where specialists access the data and give health care providers at location A recommendations for managing their patients [4]. Although this is well established in the outpatient sector between the patient's home and the physician [30], the question remains whether this can be supportive to working conditions and patient care in the ICU without a telemedicine context.

Contrary to our preceding qualitative study results, opinions regarding the need for remote patient monitoring in the ICU were divided [8]. There are several industry providers that allow ICU patients to be monitored remotely from anywhere on the premises of the hospital [31-33]. However, scientific evidence of the utility of these devices (eg, for increasing patient safety) seems to be missing. For now, we can summarize that the advantages of on-premise remote patient monitoring for intensive care medicine have to be further quantified by measures such as the reduction of alarms, and improved patient outcomes such as a reduction in patient length of stay.

CDSS in Intensive Care Medicine

As the amount of data as well as the complexity of diseases and treatment of ICU patients are increasing, it seems reasonable to augment the abilities of ICU staff by implementing CDSS based on AI in the ICU. Our results indicate that most of the topics proposed (eg, prediction of mortality, prediction of complications, or proposal of guidelines) were seen as potential use cases for CDSS by ICU staff. For these and several other instances, algorithms already exist that could be adjusted for real-time data [34].

On the path toward implementing CDSS based on AI in intensive care medicine, several barriers have to be overcome [35]. With the introduction of the electronic health record and PDMS in the ICU, the first step has been taken to establish the technical infrastructure, but these systems need to be optimized in interoperability and data quality to act as the basis for complex machine learning processes. To utilize the power of AI as soon as possible, hospital providers should focus on developing data science departments, and introduce standards in implementing novel CDSS tools to rapidly address technical, legal, ethical, and privacy issues.

Transdisciplinary Research and Development

Clinical teams in ICUs are used to working closely together in multidisciplinary teams. This could be advantageous when adding further professions to the team for transdisciplinary research and the development of medical devices for intensive care medicine [36]. Our survey results show that ICU staff members are open to learning more about technology and are even willing to support product development in some cases. Thus, a clinical data scientist with formal medical training could be part of the ICU team as well as the product development team alongside engineers from a medical manufacturer [22,37]. This transdisciplinary approach should be piloted in further studies, to assess the effects on mutual exchange and innovation potential.

As much as the transdisciplinary approach is supported, blunt confidence in user feedback will mainly improve existing devices, as our study prominently indicates, which does not necessarily foster the discovery of disruptive technologies [38], such as avatar-based patient monitoring [39,40] or smart glasses [41]. More than cooperation, transdisciplinarity refers to the development of common theories, mutual observation, and search for challenges and needs [42]. Hackathons (weekend innovation events) are an excellent playground for transdisciplinary work, and participation should be encouraged and remunerated by medical manufacturers and hospital providers [43].

Limitations

With this survey study among ICU staff, we identified the most anticipated improvements for patient monitoring in the ICU from the user perspective. However, several limitations apply to this study. It is important to note that the developed questionnaire did not include questions of established reliability or validity; the data were collected at a single hospital in Germany; the number of participating physicians was small, making statements about group comparisons susceptible to coincidence; and the response rate was moderate. Due to the online collection of data, the participation of ICU staff with less technical affinity may have been reduced. Further studies including a sample size calculation and randomized sample collection would reduce the risk of bias.

Whether the findings (eg, introducing wireless patient monitoring sensors) actually lead to an improvement in working conditions and patients' quality of life or quality of care in the ICU can only be ascertained by further studies. Finally, a bias due to the deployment of the Vital Sync virtual patient monitoring platform in 1 of the 4 ICUs cannot be ruled out with certainty.

Conclusion

This survey study among ICU staff revealed anticipated key improvements for patient monitoring in intensive care medicine from the user perspective. We did not observe a proactive call to pioneer new technologies and integrate their respective digital gadgets (eg, smartwatch and AR) into clinical routine. Instead, ICU staff looked forward to improvements in the functionality of existing technologies. Particularly, hospital providers and medical device manufacturers should focus on reducing false alarms, implementing hospital alarm SOPs, introducing wireless sensors, preparing for CDSS based on AI, and enhancing the digital literacy of ICU staff. In the medium term, our results may contribute to the user-centered transfer of digital technologies into practice to alleviate challenges in intensive care medicine, such as those recently caused by COVID-19.

Acknowledgments

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Authors' Contributions

CS had the idea for shared decision allocation and initiated the implementation of remote patient monitoring in the intensive care unit. The study was conceived by ASP, CS, and FB. ASP conducted data acquisition, supported by LM and FS. ASP and MS analyzed the data, supported by HK, who provided expertise in statistics. ASP wrote the manuscript, supported by LM, MS, and FS. HK contributed to the study's design and interpretation of results from a psychologist's point of view. FB supervised all parts of the study. All authors critically reviewed and approved the manuscript.

Conflicts of Interest

CS and FB report funding from Medtronic. The other authors do not have conflicts to declare.

Multimedia Appendix 1

Final questionnaire.
[XLSX File (Microsoft Excel File), 55 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Survey item medians and bootstrap CIs.
[XLSX File (Microsoft Excel File), 11 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Survey raw data.
[XLSX File (Microsoft Excel File), 22 KB-Multimedia Appendix 3]

Multimedia Appendix 4

Distribution of item responses of physicians and nurses.
[PNG File , 3159 KB-Multimedia Appendix 4]

References

1. World Health Organization. URL: https://www.who.int/emergencies/diseases/novel-coronavirus-2019 [accessed 2020-06-05]
2. De Georgia M, Loparo K. Neurocritical Care Informatics: Translating Raw Data into Bedside Action Internet. Berlin, Heidelberg: Springer Berlin Heidelberg; 2020.
3. Perez MV, Mahaffey KW, Hedlin H, Rumsfeld JS, Garcia A, Ferris T, et al. Large-Scale Assessment of a Smartwatch to Identify Atrial Fibrillation. N Engl J Med 2019 Nov 14;381(20):1909-1917. [doi: 10.1056/nejmoa1901183]
4. Koenig M. Telemedicine in the ICU. Basel, Switzerland: Springer International Publishing; 2019.
5. Michard F, Bellomo R, Taenzer A. The rise of ward monitoring: opportunities and challenges for critical care specialists. Intensive Care Med 2019 May 27;45(5):671-673. [doi: 10.1007/s00134-018-5384-5] [Medline: 30259073]
6. Weenk M, Koeneman M, van de Belt TH, Engelen LJ, van Goor H, Bredie SJ. Wireless and continuous monitoring of vital signs in patients at the general ward. Resuscitation 2019 Mar;136:47-53. [doi: 10.1016/j.resuscitation.2019.01.017] [Medline: 30685546]
7. De Georgia MA, Kaffashi F, Jacono FJ, Loparo KA. Information technology in critical care: review of monitoring and data acquisition systems for patient care and research. The Scientific World Journal 2015;2015:727694-727699 [FREE Full text] [doi: 10.1155/2015/727694] [Medline: 25734185]
8. Poncette A, Spies C, Mosch L, Schieler M, Weber-Carstens S, Krampe H, et al. Clinical Requirements of Future Patient Monitoring in the Intensive Care Unit: Qualitative Study. JMIR Med Inform 2019 Apr 30;7(2):e13064 [FREE Full text] [doi: 10.2196/13064] [Medline: 31038467]
9. Burns KEA, Duffett M, Kho ME, Meade MO, Adhikari NKJ, Sinuff T, et al. A guide for the design and conduct of self-administered surveys of clinicians. CMAJ 2008 Jul 29;179(3):245-252 [FREE Full text] [doi: 10.1503/cmaj.080372] [Medline: 18663204]
10. Eysenbach G. Improving the quality of Web surveys: the Checklist for Reporting Results of Internet E-Surveys (CHERRIES). J Med Internet Res 2004 Sep 29;6(3):e34 [FREE Full text] [doi: 10.2196/jmir.6.3.e34] [Medline: 15471760]
11. Wessel D, Attig C, Franke T. ATI-S - An Ultra-Short Scale for Assessing Affinity for Technology Interaction in User Studies. 2019 Presented at: MuC'19: Proceedings of Mensch und Computer 2019; 2019; Hamburg, Germany. [doi: 10.1145/3340764.3340766]
12. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, REDCap Consortium. The REDCap consortium: Building an international community of software platform partners. J Biomed Inform 2019 Jul;95:103208. [doi: 10.1016/j.jbi.2019.103208] [Medline: 31078660]

13. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009 Apr;42(2):377-381 [FREE Full text] [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]
14. R Core Team. R Foundation for Statistical Computing. Vienna, Austria: A language and environment for statistical computing; 2018. URL: https://www.R-project.org/ [accessed 2020-06-05]
15. Wickham H. tidyverse: Easily Install and Load the Tidyverse. URL: https://CRAN.R-project.org/package=tidyverse [accessed 2020-03-09]
16. Lüdecke D, Bartel A, Schwemmer C, Powell C, Djalovski A. sjPlot: Data Visualization for Statistics in Social Science. URL: https://CRAN.R-project.org/package=sjPlot [accessed 2020-03-10]
17. Revelle W. 2020. psych: Procedures for Psychological, Psychometric, and Personality Research URL: https://CRAN.R-project.org/package=psych [accessed 2020-03-26]
18. Bray A, Ismay C, Chasnovski E, Baumer B, Cetinkaya-Rundel M, Laderas T, et al. infer: Tidy Statistical Inference Internet. 2019. URL: https://CRAN.R-project.org/package=infer [accessed 2020-03-10]
19. Duhm J, Fleischmann R, Schmidt S, Hupperts H, Brandt SA. Mobile Electronic Medical Records Promote Workflow: Physicians' Perspective From a Survey. JMIR mHealth uHealth 2016 Jun 06;4(2):e70 [FREE Full text] [doi: 10.2196/mhealth.5464] [Medline: 27268720]
20. Haukoos JS, Lewis RJ. Advanced statistics: bootstrapping confidence intervals for statistics with "difficult" distributions. Acad Emerg Med 2005 Apr 01;12(4):360-365 [FREE Full text] [doi: 10.1197/j.aem.2004.11.018] [Medline: 15805329]
21. Bach TA, Berglund L, Turk E. Managing alarm systems for quality and safety in the hospital setting. BMJ Open Qual 2018 Jul 25;7(3):e000202 [FREE Full text] [doi: 10.1136/bmjoq-2017-000202] [Medline: 30094341]
22. Pater CM, Sosa TK, Boyer J, Cable R, Egan M, Knilans TK, et al. Time series evaluation of improvement interventions to reduce alarm notifications in a paediatric hospital. BMJ Qual Saf 2020 Jan 20:2019. [doi: 10.1136/bmjqs-2019-010368] [Medline: 31959714]
23. Wilken M, Hüske-Kraus D, Röhrig R. Alarm Fatigue: Using Alarm Data from a Patient Data Monitoring System on an Intensive Care Unit to Improve the Alarm Management. Studies in Health Technology and Informatics 2019;273:281. [doi: 10.29007/5vpj]
24. Tscholl D, Handschin L, Rössler J, Weiss M, Spahn D, Nöthiger C. It's not you, it's the design - common problems with patient monitoring reported by anesthesiologists: a mixed qualitative and quantitative study. BMC Anesthesiology 2019;19(1):a. [doi: 10.21203/rs.2.238/v2]
25. Glasin J, Henricson J, Lindberg L, Wilhelms D. Wireless vitals-Proof of concept for wireless patient monitoring in an emergency department setting. J Biophotonics 2019 Apr 13;12(4):e201800275. [doi: 10.1002/jbio.201800275] [Medline: 30306737]
26. Wallin MKEB, Wajntraub S. Evaluation of Bluetooth as a replacement for cables in intensive care and surgery. Anesth Analg 2004 Mar;98(3):763-767. [doi: 10.1213/01.ane.0000097186.99167.ba] [Medline: 14980934]
27. Paksuniemi M, Sorvoja H, Alasaarela E, Myllyla R. Wireless sensor and data transmission needs and technologies for patient monitoring in the operating room and intensive care unit. 2005 Presented at: 27th Annual International Conference of the IEEE Engineering in Medicine and Biology Society; 2005; Shanghai, China p. 5182. [doi: 10.1109/iembs.2005.1615645]
28. Chung HU, Rwei AY, Hourlier-Fargette A, Xu S, Lee K, Dunne EC, et al. Skin-interfaced biosensors for advanced wireless physiological monitoring in neonatal and pediatric intensive-care units. Nat Med 2020 Mar 11;26(3):418-429. [doi: 10.1038/s41591-020-0792-9] [Medline: 32161411]
29. Lambert DH. Cord Wraps Facilitate Patient Transfer. Anesthesia & Analgesia 2016;123(1):257. [doi: 10.1213/ane.0000000000001376]
30. Koehler F, Koehler K, Deckwart O, Prescher S, Wegscheider K, Kirwan B, et al. Efficacy of telemedical interventional management in patients with heart failure (TIM-HF2): a randomised, controlled, parallel-group, unmasked trial. The Lancet 2018 Sep;392(10152):1047-1057. [doi: 10.1016/s0140-6736(18)31880-4]
31. Medtronic - Vital Sync Virtual Patient Monitoring Platform. URL: https://www.medtronic.com/covidien/en-us/products/health-informatics-and-monitoring/vital-sync-virtual-patient-monitoring-platform-2-6.html [accessed 2019-01-15]
32. Philips. IntelliVue Mobile Caregiver. URL: https://www.usa.philips.com/healthcare/product/HCNOCTN197/intellivue-mobile-caregiver-mobile-app-for-patient-monitoring-data [accessed 2020-03-17]
33. Draeger. Mobile Patient Watch. URL: https://www.draeger.com/en_sea/Hospital/Products/Medical-Systems-Solutions/Clinical-Applications/Mobile-Patient-Watch [accessed 2020-03-17]
34. Mlodzinski E, Stone DJ, Celi LA. Machine Learning for Pulmonary and Critical Care Medicine: A Narrative Review. Pulm Ther 2020 Jun 5;6(1):67-77 [FREE Full text] [doi: 10.1007/s41030-020-00110-z] [Medline: 32048244]
35. Komorowski M. Artificial intelligence in intensive care: are we there yet? Intensive Care Med 2019 Sep 24;45(9):1298-1300. [doi: 10.1007/s00134-019-05662-6] [Medline: 31236638]
36. Özcan E, Birdja D, Simonse L, Struijs A. Alarm in the ICU! Envisioning Patient MonitoringAlarm Management in Future Intensive Care Units. Basel, Switzerland: Springer International Publishing; 2019.

37. Hüske-Kraus D, Wilken M, Röhrig R. Measuring Alarm System Quality in Intensive Care Units. Zukunft der Pflege Tagungsband der 1. Clusterkonferenz 2018 2018:89-93. [doi: 10.29007/5vpj]
38. Cohen AB, Martin SS. Innovation without integration. NPJ Digit Med 2020 Feb 3;3(1):15 [FREE Full text] [doi: 10.1038/s41746-020-0220-z] [Medline: 32025575]
39. Garot O, Rössler J, Pfarr J, Ganter MT, Spahn DR, Nöthiger CB, et al. Avatar-based versus conventional vital sign display in a central monitor for monitoring multiple patients: a multicenter computer-based laboratory study. BMC Med Inform Decis Mak 2020 Feb 10;20(1):26 [FREE Full text] [doi: 10.1186/s12911-020-1032-4] [Medline: 32041584]
40. Tscholl DW, Rössler J, Handschin L, Seifert B, Spahn DR, Nöthiger CB. The Mechanisms Responsible for Improved Information Transfer in Avatar-Based Patient Monitoring: Multicenter Comparative Eye-Tracking Study. J Med Internet Res 2020 Mar 16;22(3):e15070 [FREE Full text] [doi: 10.2196/15070] [Medline: 32175913]
41. Romare C, Skär L. Smart Glasses for Caring Situations in Complex Care Environments: Scoping Review. JMIR mHealth uHealth 2020 Apr 20;8(4):e16055 [FREE Full text] [doi: 10.2196/16055] [Medline: 32310144]
42. Méndez F. Transdiscipline and research in health: science, society and decision making. Colomb Med (Cali) 2015 Sep 30;46(3):128-134 [FREE Full text] [Medline: 26600628]
43. Poncette A, Rojas P, Hofferbert J, Valera Sosa A, Balzer F, Braune K. Hackathons as Stepping Stones in Health Care Innovation: Case Study With Systematic Recommendations. J Med Internet Res 2020 Mar 24;22(3):e17004 [FREE Full text] [doi: 10.2196/17004] [Medline: 32207691]

Abbreviations

AI: artificial intelligence
AR: augmented reality
ATI: Affinity for Technological Interaction
CDSS: clinical decision support system
COVID-19: coronavirus disease
ICU: intensive care unit
PDMS: patient data management system
QR: quick response
SOP: standard operating procedure

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Original Paper

Creation of an Evidence-Based Implementation Framework for Digital Health Technology in the Intensive Care Unit: Qualitative Study

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Abstract

Background: Digital health technologies such as continuous remote monitoring and artificial intelligence–driven clinical decision support systems could improve clinical outcomes in intensive care medicine. However, comprehensive evidence and guidelines for the successful implementation of digital health technologies into specific clinical settings such as the intensive care unit (ICU) are scarce. We evaluated the implementation of a remote patient monitoring platform and derived a framework proposal for the implementation of digital health technology in an ICU.

Objective: This study aims to investigate barriers and facilitators to the implementation of a remote patient monitoring technology and to develop a proposal for an implementation framework for digital health technology in the ICU.

Methods: This study was conducted from May 2018 to March 2020 during the implementation of a tablet computer–based remote patient monitoring system. The system was installed in the ICU of a large German university hospital as a supplementary monitoring device. Following a hybrid qualitative approach with inductive and deductive elements, we used the Consolidated Framework for Implementation Research and the Expert Recommendations for Implementing Change to analyze the transcripts of 7 semistructured interviews with clinical ICU stakeholders and descriptive questionnaire data. The results of the qualitative analysis, together with the findings from informal meetings, field observations, and previous explorations, provided the basis for the derivation of the proposed framework.

Results: This study revealed an insufficient implementation process due to lack of staff engagement and few perceived benefits from the novel solution. Further implementation barriers were the high staff presence and monitoring coverage in the ICU. The implementation framework includes strategies to be applied before and during implementation, targeting the implementation setting by involving all ICU stakeholders, assessing the intervention's adaptability, facilitating the implementation process, and maintaining a vital feedback culture. Setting up a unit responsible for implementation, considering the guidance of an implementation advisor, and building on existing institutional capacities could improve the institutional context of implementation projects in the ICU.

Conclusions: Implementation of digital health in the ICU should involve a thorough preimplementation assessment of the ICU's need for innovation and its readiness to change, as well as an ongoing evaluation of the implementation conditions. Involvement of all stakeholders, transparent communication, and continuous feedback in an equal atmosphere are essential, but leadership roles must be clearly defined and competently filled. Our proposed framework may guide health care providers with concrete, evidence-based, and step-by-step recommendations for implementation practice, facilitating the introduction of digital health in intensive care.

Trial Registration: ClinicalTrials.gov NCT03514173; https://clinicaltrials.gov/ct2/show/NCT03514173

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KEYWORDS

digital health; patient monitoring; intensive care medicine; intensive care unit; technological innovation; user-centered; usability; implementation; implementation science; qualitative research; interview

Introduction

Background

In intensive care medicine, digital health technologies promise to improve outcomes by reducing the patients' length of stay or preventing complications [1-3]. Continuous remote monitoring allows early detection of deterioration in intensive care unit (ICU) patients and therefore rapid therapeutic intervention [4]. Algorithms used in clinical decision support systems and early warning scores can analyze the large amounts of data generated by ICU monitoring devices to decrease ICU mortality and the risk of complications such as prescription errors [5,6]. Despite the potential, the digital transformation of health care is lagging in numerous countries for reasons that can be ascribed at every level of the health care system. At the macro level, weak national internet infrastructures, high market fragmentation, and lack of legal frameworks, financing models, and interoperability play a significant role [7-9]. At the meso and micro levels, cumbersome operation, high costs, lack of interoperability, information governance uncertainty, and organizational resistance block digital health technology implementation [10-13].

Implementation science, as an increasingly evolving discipline, has brought about the publication of numerous guidelines and recommendations for the implementation of digital health technologies in health care settings by various institutions and researchers [9,14-17]. However, still scarce is the evidence regarding meso- and micro-level implementation and the guidelines for the successful integration of digital health technologies into specific clinical settings [16,18-20]. Successful and sustainable implementation in health care requires a holistic concept to be followed, applying meaningful strategies at all levels [21-23]. In particular, the implementation processes of digital health tools in German ICUs are poorly explored, apart from the concept *tele-ICU*, which involves augmenting local ICU capacity with external expertise through video consultation, remote monitoring, and web-based access to patient data management systems [1,24,25].

Five domains are essential for the implementation of digital health in various health care settings: (1) the individual digital health technology (eg, remote patient monitoring systems), (2) the outer setting (eg, external regulations, laws, and patient needs), (3) the inner setting (eg, the direct implementation environment, social factors, networks, and communication), (4) the individual health professionals, and (5) the implementation process [11]. These domains were first outlined in the Consolidated Framework for Implementation Research (CFIR), a well-proven tool to evaluate the implementation of an intervention into health care settings [12,13,26-29]. Targeting the improvement of implementation performance, the Expert Recommendations for Implementing Change (ERIC) provide a comprehensive compilation of strategies to boost implementation in clinical practice [30,31]. The CFIR domains and ERIC strategies are coherent and synergistic and provide meaningful guidance for implementation researchers and practitioners; however, they require more use cases and documentation of applications in a specific context and setting. In addition, the present literature on implementation strategies for digital health technologies in health care settings and particularly the ICU is extensive and unstructured, and the strategies reported are often poorly conceived [20,32,33].

It is unclear whether the aforementioned barriers and facilitators to digital health implementation can be transferred into the ICU context, given that it is a very specific setting: multiple professional groups work together, many different technologies are already in place, and staff stress levels are also high because of critically ill patients requiring acute treatment, high alarm frequency, and staffing and capacity constraints [34-36]. Concrete implementation strategies for digital health technologies in intensive care settings are still lacking.

Objectives

This study aims to (1) investigate barriers and facilitators to the implementation of a remote patient monitoring technology and (2) develop a proposal for an implementation framework for digital health technology in the ICU.

Methods

Overview

To assess the barriers and facilitators to implementing a remote patient monitoring system, we explored stakeholder perspectives using an abductive qualitative approach. This research design, combining inductive and deductive elements, included semistructured interviews with ICU leaders and key stakeholders in the implementation process, as well as field observations and regular feedback discussions within the research team. To develop the presented implementation framework for digital health technology in the ICU, we conducted a deductive analysis by matching the collected data to the CFIR and ERIC domains. Using the CFIR-ERIC mapping tool, we filtered out relevant strategies to improve implementation performance. In a final step, the strategies were ordered in a temporal sequence and visualized in a figure [37]. The Standards for Reporting Qualitative Research were consulted to report this research [38].

Ethics Approval and Consent to Participate

The ethical approval for this study was granted by the Ethics Commission of the Charité–Universitätsmedizin Berlin (EA1/031/18). Participation in the survey was voluntary. Before the study, all participants provided their consent.

Context and Technical Setup

We conducted this study with ICU staff from a German university hospital over the course of the implementation of the Virtual Patient Monitoring Platform Vital Sync (version 2.4; Medtronic plc). The device remotely monitored ICU patients from portable tablet computers at the hospital premises and was supplemental to the primary patient monitoring system, the IntelliVue patient monitoring system (MX800 software version M.00.03; MMS X2 software version H.15.41-M.00.04; Koninklijke Philips N.V.). The primary Philips IntelliVue monitoring system displayed the vital parameters on stationary touchscreen displays at the bedside and on a monitor at the central nurse station. COPRA (version 6; COPRA System GmbH) was used as the patient data management system (PDMS); however, no data transmission from the Vital Sync system to the primary monitoring system or PDMS occurred.

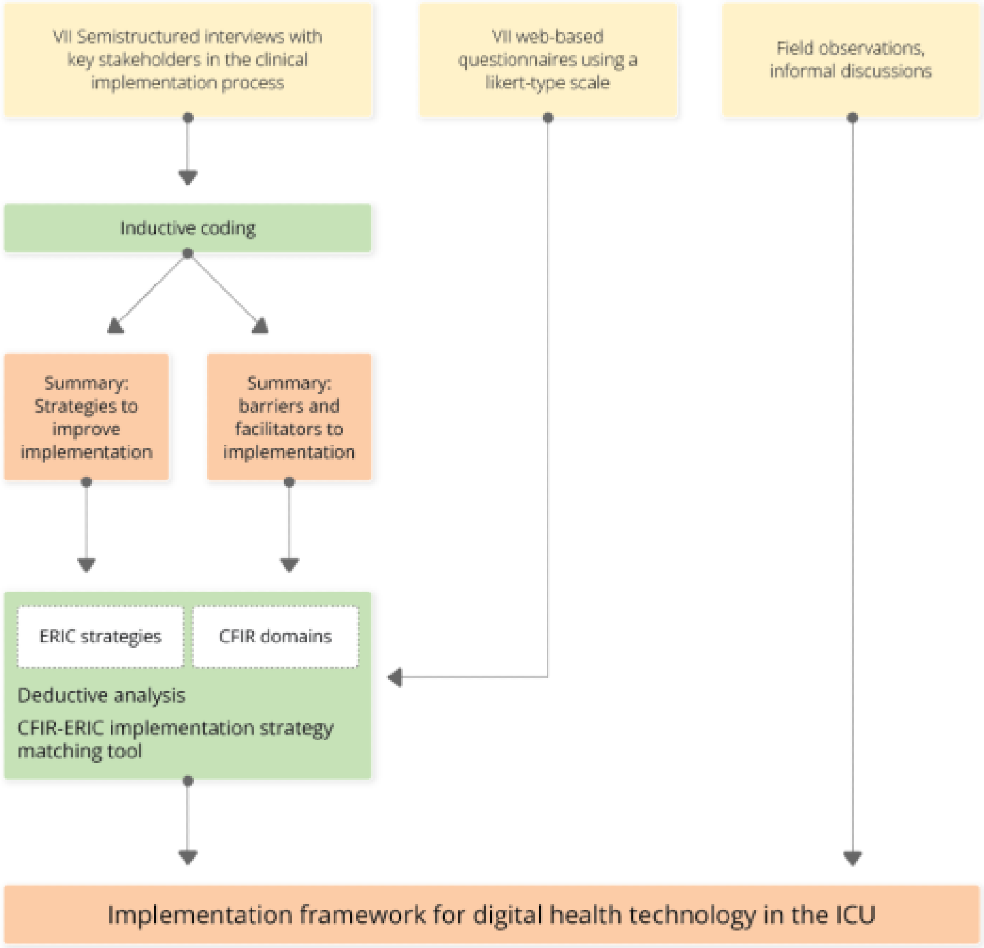
The remote monitoring system was installed between May 2018 and June 2019 in 50% (5/10) of the beds of the postanesthesia care unit, an ICU mainly for postoperative patients that need short-term intensive care treatment and monitoring. The system included 2 sensors (the pulse oximetry and the capnography) that registered peripheral capillary oxygen saturation, pulse rate, end-tidal carbon dioxide level, and respiratory rate at a frequency of 1 Hz. The vital parameters were displayed on a monitor at the central nurse station and were retrievable from 6 tablet computers (2 large 10.2“ iPad tablets [9th generation; Apple Inc], 2 iPad mini 4 tablets [Model A1550; Apple Inc], and 2 Surface Pro 4 laptops [Microsoft Corporation]). A 6-digit code protected the iPad access, and the data were accessible after logging into the Vital Sync website. A username and a password protected the access to the Microsoft Surfaces. Technical instructions of ICU staff (ie, physicians, nurses, and respiratory therapists) into the device were conducted over a period of 1 month. In addition, 2 workshops were conducted for hands-on training. Additional assistance was provided as needed. Further technical description and use of the software can be found elsewhere [39,40].

Study Design and Research Team

This qualitative exploratory implementation study is based on an abductive research approach, as described by Dubois and Gadde [41] and Zainal [42]. The abductive approach of systematic combining (containing inductive and deductive analysis methods) specifies existing theories, refining them according to the individual case and context. We considered this approach essential to derive practical recommendations for the implementation of new technology in the ICU. The transcripts of 7 semistructured interviews and web-based questionnaires with key stakeholders in the clinical implementation process, the results of field observations and informal discussions among the research group, and findings from previous explorations in the context of the implementation were analyzed and applied to the CFIR domains and ERIC strategies to develop the proposed implementation framework (Figure 1) [43].

The research team consisted of an MD candidate (LKM); a postdoctoral researcher with a background in anesthesiology, intensive care medicine, digital health, and geriatrics (ASP); a professor for digital health, who is a consultant anesthesiologist and a computer scientist (FB); a psychologist (HK); a head nurse (MS); an ICU senior consultant (SWC); and the department's head of staff (CS).

Figure 1. Overview of the data collection and analysis for the derivation of the proposed implementation framework for digital health technology in the ICU. CFIR: Consolidated Framework for Implementation Research; ERIC: Expert Recommendations for Implementing Change; ICU: intensive care unit.



Data Collection

Our data included interview transcripts and quantifiable results of a questionnaire with key stakeholders in the ICU, informal meetings and discussions among the research group, field observations, and the results of previous explorations [39,43]. The outer setting and manufacturer's perspective were not part of this study because we could not evaluate these domains with the data given.

From June to November 2019, we conducted 7 semistructured interviews with ICU staff members, including 3 physicians, 3 nurses, and 1 respiratory therapist. We used purposive sampling with the aim of including all stakeholders who were closely involved in the implementation process and in leading positions in the ICU and presenting all professional groups. The identified study participants were key stakeholders (eg, head nurse, senior physician, and staff member with high working time in respective ICU) of the ICU and had closely experienced remote patient monitoring implementation, overseeing the implementation process, receiving feedback regarding the system from other staff members, and using the system in their own clinical practice.

The interview guideline was deduced on the findings of a previous study from our research group [43] and was oriented toward the categories of the CFIR (Multimedia Appendix 1 [44]). Pilot interviews with associated intensive care physicians did not alter the questions. The interviews were performed either before or after patient care and were recorded and transcribed verbatim.

The semistructured interview guideline included web-based questionnaires containing 47 items and a technology commitment scale [44]. We conducted face-to-face pilot testing with ICU staff with a focus on clarity, relevance, and order of the items. We used a 5-point Likert-type scale as an ordinal response format, with the options *not correct at all*, *not quite correct*, *partly correct*, *quite correct*, and *completely correct*. The study data were collected and managed using Research

Electronic Data Capture (REDCap) tools hosted at Charité–Universitätsmedizin Berlin [45,46]. Data resulting from the questionnaire responses were collected in an overview table.

To gain auditability and enhance reflexivity in the research process, informal meetings and discussions among the research group and field observations occurred from the start of the implementation in May 2018 until March 2020. These methods helped gain a more objective perspective and minimize potential biases that naturally arise when using a qualitative research approach, as described by Noble and Smith [47]. Results of the field research were published by Poncette et al [39].

Data Analysis

For qualitative analysis, we applied a hybrid approach combining inductive and deductive coding elements, as described by Fereday and Muir-Cochrane [48].

First, the interview transcripts were analyzed using a thematic analysis approach, applying an inductive coding process, meaning that themes and codes were iteratively developed and applied to all transcripts [49]. The resulting content of the codes was summarized to obtain the main findings and serve as the basis for the deductive analysis, as described by Crabtree and Miller [50].

Second, for deductive analysis, we used as code system templates the CFIR domains and ERIC strategies, which were grouped into 9 clusters [30,31]. Summaries from the inductive analysis and the findings of the questionnaires were coded according to templates (Multimedia Appendices 2 and 3). That is, data from the web-based questionnaires were not analyzed with quantitative methods. Specifically, the CFIR template was used to analyze the summaries regarding implementation performance, whereas the ERIC strategies served as a template for analyzing the summaries of staff's suggestions on implementation process improvements. All coding was performed using the MaxQDA 2020 qualitative data analysis software [51].

Finally, the proposal for an implementing framework for digital health technology in the ICU was derived from the results of the CFIR- and ERIC-guided analyses. The CFIR-ERIC Implementation Strategy Matching Tool supported the prioritization of the derived recommendations [52]. Findings from the informal meetings, discussions, and field observations supported in situating the results and the interview suggestions in the context of implementation and in supplementing objective characteristics. We ordered the findings into a temporal perspective.

Results

Overview

Inductive analysis of the interview transcripts revealed the two major categories *perceived performance of the implementation* and *perceived factors improving implementation*, which contained 4 and 3 subtopics, respectively. According to the interviewed stakeholders, the remote patient monitoring system's implementation was insufficient owing to a lack of staff engagement in the process and little perceived benefit from the novel solution in its current version. Factors suggested improving implementation were targeting staff training, features of the technology itself, and implementation setting.

Deductive coding revealed four major CFIR domains: *intervention characteristics*, *inner setting*, *individual characteristics*, and *process*. Regarding perceived factors improving implementation, seven clusters of the ERIC framework were mapped: *use evaluative and iterative strategies*, *provide interactive assistance*, *adapt and tailor to context*, *develop stakeholder interrelationships*, *train and educate stakeholders*, *support clinicians*, and *change infrastructure*.

Implementation Process

Staff Involvement and Training

The interviewees identified staff involvement and training as being more targeted toward nursing staff, although they were not in charge of the implementation project. According to the interviewed stakeholders, staff members of all professional groups lacked a feeling of responsibility to continuously apply the remote patient monitoring system. In addition, the staff was unable to identify a leading member in charge of the implementation process and longed for more regular staff training and information sessions. Interviewees reported that opinion leaders' communication created a negative peer pressure not to use the system.

Interviewees said that they felt well informed about the project initially; however, the information flow decreased equally. Training did not reach all staff members because of a complex shift system and a big pool of staff for 2 ICUs, whereas the system was implemented only at 50% (5/10) of bedsides on 1 ICU. Staff perceived the system as an imposition from outside the ICU and felt that it did not have any influence on the implementation.

Additional Benefit

Staff did not perceive the system's added value as high for four reasons: First, the ICU already had a monitoring system offering remote functions (eg, displaying vital parameters of different patients on all bedside monitors), although it did not offer a portable monitoring device. However, according to interviewees, this made an additional system superfluous. Second, the high staff presence in the ICU decreased the need to remotely monitor patients. Third, high patient turnover in the ICU was associated with frequent connecting and disconnecting of patients to and from the system, resulting in an increased workload for nurses. Fourth, remotely monitoring patients while being on a different ward or performing a clinical intervention would make a necessary immediate reaction to an alarm impossible.

Intervention Features

Interviewees highlighted that the limited number of vital parameters monitored by the system was not sufficient to satisfactorily evaluate the patient's condition. Furthermore, the system's dependency on a stable wireless network connection raised concerns. Interviewees perceived the tablet as too large and inconvenient to use and carry in the tunic pockets. Finally, the device would not allow patients' monitoring during their transportation.

Attitude of Staff

Interviewees said that they were satisfied with the current monitoring system and did not see the need for a change. ICU staff did not use the system because they lacked the habit and routine of using a remote patient monitoring technology. They were afraid of losing break times when applying the system and of an increased workload (eg, system setup). They feared that reduced patient contact and false alarms might increase stress levels and endanger patient safety. Overall, the staff saw no additional benefit in the technology. Figure 2 presents an overview of the factors influencing the implementation process from the perspective of interviewed staff members.

Figure 2. Implementation performance: 4 major categories were identified (inner ring), divided into themes (middle ring), and further specified (outer ring). ICU: intensive care unit.

Mapping of CFIR Domains

The summaries of the staff interview transcripts and descriptive data from the questionnaire responses were coded and assigned to four major domains of the CFIR: intervention characteristics, inner setting, individual characteristics, and process (Textbox 1 and Multimedia Appendix 2 [44]).

Textbox 1. Mapped Consolidated Framework for Implementation Research domains and subdomains.

Intervention characteristics

- Intervention source
- Evidence strength and quality
- Relative advantage
- Adaptability
- Trialability
- Complexity

Inner setting

- Structural characteristics
- Networks and communication
- Implementation climate: tension for change, compatibility, relative priority, and learning climate
- Implementation readiness: leadership engagement and access to information

Individual characteristics

- Knowledge and beliefs about the intervention
- Self-efficacy
- Individual stage of change

Process

- Planning
- Engaging: opinion leaders and formally appointed implementation leaders
- Executing

Strategies to Improve Implementation

Staff Engagement and Communication

According to the interviewed stakeholders, persistent leadership engagement and nomination of specific responsible persons for the implementation process were essential, especially in a busy environment such as the ICU. Staff training should be conducted continuously and was particularly critical in the early implementation stages. The quality of instructions was considered essential to influence the staff's opinion toward the implementation. Feedback discussions with staff, project leaders, and a well-functioning team would increase staff engagement. Communication of the project should be encouraging and motivating.

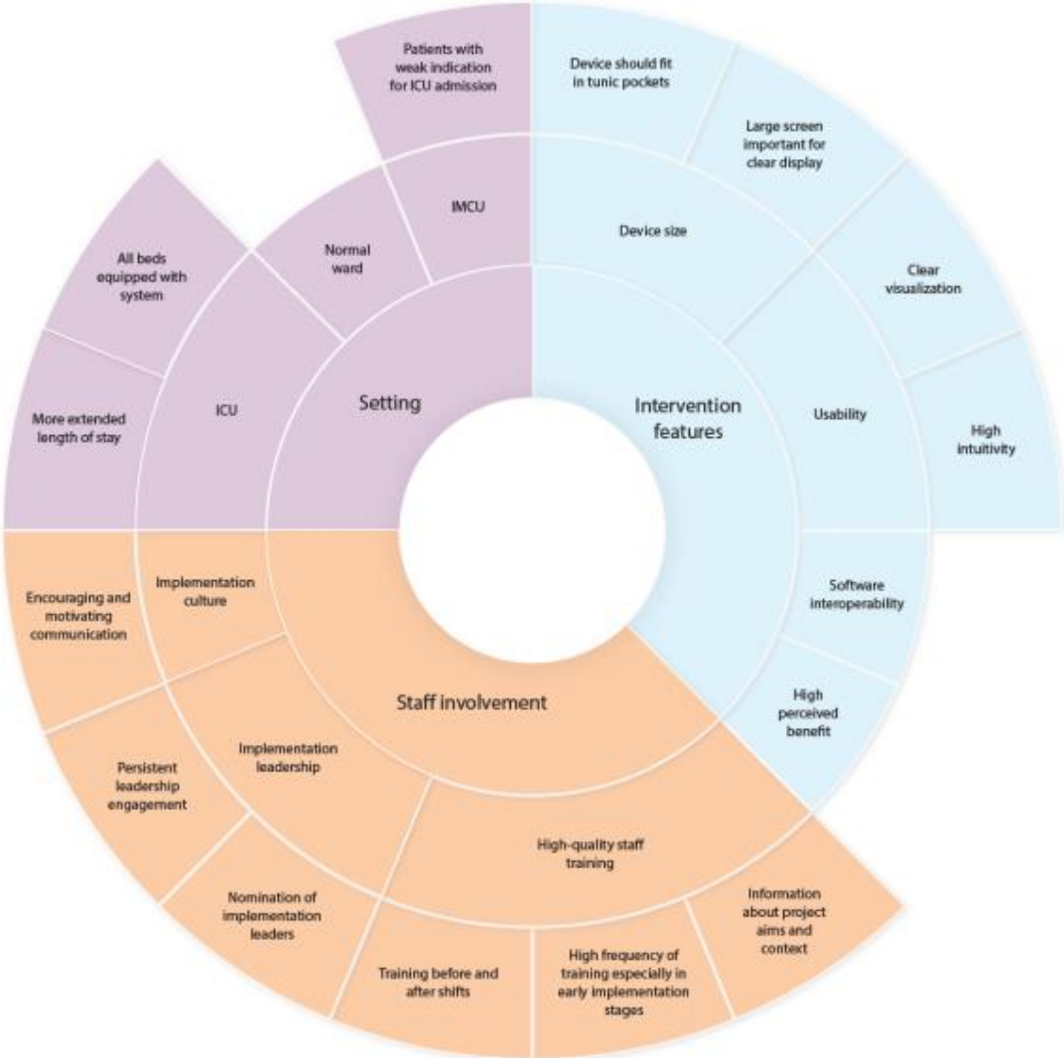
Setting

It was reported that equipping all beds in the ward with the technology and all staff members with portable monitoring devices would increase the implementation performance. A normal or intermediate care unit (IMCU) could be more suitable for a remote patient monitoring technology owing to a lower staff presence and scarcer technical facilities. Interviewees suggested that patients with a relatively weak indication for admission to the ICU could be admitted to a normal ward or IMCU and be monitored remotely. The implementation of technology concerning ICU patients would be more straightforward in a ward with more extended patient stays, as short stays imply more work to install the system.

Intervention Features

High intuitiveness would be crucial for effective implementation, as stated by the interviewees. A monitoring solution without cables would increase usability and perceived benefit. Opinions on the device size varied; a clear visualization needs a large screen, but interviewees favored a device that fits into the pocket of a tunic. Software interoperability with other devices (eg, the respirator or the PDMS) would be essential. Figure 3 presents an overview of the strategies to improve the implementation of digital health technologies according to the interviewed staff members.

Figure 3. Perceived factors improving implementation: 3 categories were identified (inner ring), divided into subcategories (middle ring), and enriched with concrete suggestions (outer ring). ICU: intensive care unit; IMCU: intermediate care unit.



Mapping of ERIC Strategies

Of the 73 ERIC strategies, 19 (26%) were mapped to the summary segments concerning staff suggestions for implementation and quantifiable questionnaire responses (Textbox 2 and Multimedia Appendix 3). The segments were assigned to 78% (7/9) of the clusters of the ERIC framework.

Textbox 2. Mapped Expert Recommendations for Implementing Change clusters and strategies.

Use evaluative and iterative strategies

- Purposely re-examine the implementation
- Develop a formal implementation blueprint
- Audit and provide feedback

Provide interactive assistance

- Facilitation
- Provide clinical supervision

Adapt and tailor to context

- Promote adaptability

Develop stakeholder interrelationships

- Identify and prepare champions
- Organize clinician implementation team meetings
- Recruit, designate, and train for leadership
- Inform local opinion leaders
- Model and simulate change
- Involve executive boards

Train and educate stakeholders

- Conduct ongoing training
- Make training dynamic
- Use train-the-trainer strategies
- Conduct educational meetings

Support clinicians

- Facilitate relay of clinical data to providers
- Remind clinicians

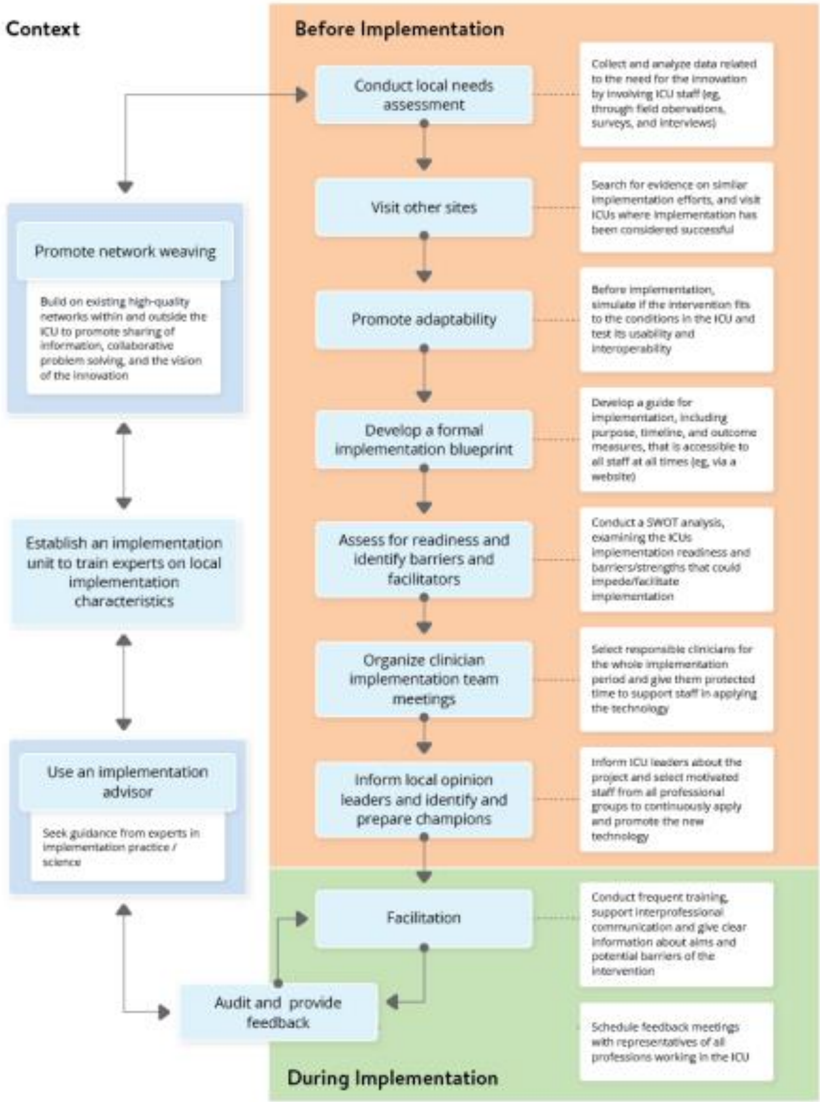
Change infrastructure

- Change physical structure and equipment
- Change service sites

Proposal for an Implementation Framework for Digital Health Technology in the ICU

The developed implementation framework includes 11 recommendations derived from ERIC strategies belonging to 4 clusters of the ERIC framework. A temporal perspective was added, and recommendations were specified to the ICU environment (Figure 4). Our recommendations are targeted toward hospital administrations, leading clinicians in the ICU, and implementation researchers—individuals responsible for the implementation process of new digital health technology in the ICU. Before implementation, 7 strategies, such as *conduct local needs assessment, visit other sites,* or *promote adaptability*, should be completed. During the implementation process, we recommend applying the ERIC strategies *facilitation* and *audit and provide feedback* continuously. The strategies *promote network weaving* and *use an implementation advisor* should optimize the implementation setting's context. Optimally, an implementation unit with experts for the local implementation characteristics should be established. Several factors influence the choice of the time to start the implementation process, and an implementation advisor should be consulted to adapt these factors to the context and local needs. Regular feedback by ICU staff regarding the implementation process, illustrated in Figure 4, through the feedback loop can lead to a further need for innovation and ideas to implement digital health technologies. The implementation is a circular process; therefore, we did not include an *after implementation* phase. Continuous re-evaluation triggers a new entry into the implementation strategy and thus leads to a sustainable implementation environment that is always adapted to new needs.

Figure 4. Strategies resulting from the CFIR-ERIC Implementation Strategy Matching Tool and the mapping of staff suggestions for improving implementation to the ERIC strategies before (orange) and during (green) implementation and in the general context of the implementation (yellow). CFIR: Consolidated Framework for Implementation Research; ERIC: Expert Recommendations for Implementing Change; ICU: intensive care unit; SWOT: strengths, weaknesses, opportunities, and threats [52].



Discussion

Principal Findings

Taking the example of a remote patient monitoring system, this study confirmed critical barriers to the implementation of new digital health technologies in the intensive care setting [11,13,53]. The proposed implementation framework for digital health technology in the ICU includes practical strategies to overcome these barriers while using facilitators from the ERIC clusters that can be applied before and during implementation and in the general context of an implementation.

Before implementation and in the general context, sharing use cases and building upon existing best practices are crucial strategies to adapt and choose the technology that best fits the local settings (ie, *visit other sites*, *promote network weaving*, and *use an implementation advisor*) [13,21]. Initiators of an implementation project should lay out its details, aim, and context before implementation (*develop a formal implementation blueprint)*. Transferable discoveries from these strategies and the strategies we propose to be applied before implementation (*promote adaptability*, *conduct local needs assessment*, *assess for readiness*, and *identify barriers and facilitators*) could be used to improve the adaptability and needs orientation of the intervention. Adaptability and user-centered design have been identified as key facilitators of digital health implementation in other settings [11,53,54]. To create the respective conditions, developers and providers of digital health technologies should actively participate in the implementation processes by taking advantage of the valuable feedback from clinical stakeholders and adapting their products in the spirit of user-centered design [55-57]. Therefore, our proposed implementation framework suggests several strategies to enhance the involvement of clinical stakeholders directly (*organize clinician implementation team meetings*, *inform local opinion leaders*, and *identify and prepare champions*), in line with the proposed strategies for other implementation settings [58,59].

During implementation, ensuring a transparent communication of the project's aim and context (*audit and provide feedback*) is as critical as an effective *facilitation* to improve staff involvement and to promote and sustain implementation.

Sustainable implementation practice means to include the aforementioned aims and strategies in the general context of implementation practice. We propose the strategies *use an implementation advisor* and *establish an implementation unit* to improve the implementation environment and the local conditions for a fast, efficient, and sustainable implementation of technology that focuses on the needs of users and patients and adds value. These processes should always be re-evaluated to readapt interventions following the changing needs [58,60,61].

Implementing Technology in the ICU

For decades, the ICU has been equipped with high technology to support staff with continuous monitoring of patients' vital signs, application of medication, documentation (eg, PDMS), or diagnostics (eg, ultrasound and bronchoscopy). However, the implementation of innovative technology in a demanding and hectic environment such as the ICU is a challenge [62]. This has been prominently shown by various projects, more recently, through the rise of telemedicine in the ICU [63], necessitating frameworks for the implementation of such endeavors.

Reported digital health implementation efforts in the ICU rarely involved the use of developed implementation frameworks [64]. This could be due to a lack of both implementation expert consultation and framework transferability into clinical routine. Current frameworks for the design and implementation of digital health technologies are based on best practices and, if evidence-based, need to be validated [30,65]. Our study provides an explicit approach to target implementation challenges and optimize innovation flows and adaptability in the complex environment of an ICU. Further optimization by saturating theories with practical experiences from clinical translation is crucial for the development of a scalable and agile framework for the implementation of digital health technology in the ICU.

Internet of Things, Interoperability, and Data Security

Especially in ICU settings, where various technical devices continuously generate data, the amount of data that can be analyzed and processed is growing rapidly [66-68]. With growing amounts of data to analyze and process, the adoption of the Internet of Things (IoT) in health care is a promising approach to alleviating issues such as high staff stress levels, alarm fatigue, and even medical errors [69,70]. ICUs, in particular, use many different end devices that could be integrated into a fog-, edge-, or cloud-based IoT network for fast and efficient data processing [71,72].

To enhance the capacities of cloud systems, interoperability has become increasingly important, especially in relation to IoT infrastructures [73,74]. Holistically implemented, interoperable technologies could alleviate the burden on staff by reducing documentation time, and easier data retrieval can facilitate therapy and diagnosis [75]. The lack of interoperability of the remote patient monitoring system may have presented a barrier to its implementation. Consistent with findings from other research [55,76], our results show that health care staff support the implementation of interoperable, intelligent monitoring interfaces.

When harnessing the potential of interoperable IoT networks and implementing them in health care settings, a secure and reliable IT infrastructure is required [77,78]. Cybersecurity in health care organizations should be fostered through the definition of cybersecurity duties, sufficient funding, and the application of state-of-the-art measures to reduce the risk of cyberattacks [79,80]. For instance, blockchain technology combined with IoT-enabled smart devices using interoperable fog/edge and cloud computing networks can enable secure, instantaneous data transmission and processing while reducing costs and network delays [70,71].

Implementation Units

With aforementioned promised benefits, health care providers will experience the need to implement new digital health technology into their infrastructures in the decades to come [63,81-83]. They have to be abreast of the latest digital health technologies to select the appropriate technology for the specific area of application and to plan and execute the implementation process, requiring an effective and efficient approach to implementation.

The question arises as to which staff position is responsible for overseeing, evaluating, and adapting recent evidence and strategies in implementation science to the local context. As suggested, internal and external implementation experts should be involved as early as possible [30]. With the introduction of a unit for implementation as a central starting point for any implementation project, resources for redundant project planning or ineffective implementation could be spared and invested elsewhere. The extent to which these units will be involved in the ICU design, for example, should be assessed individually. Beyond the consultation and proposal regarding innovations, such a unit could assess the usability of devices and the adaptability of the intervention before procurement [84] or foster exnovation and deimplementation of outdated or useless technology.

Implementation Frameworks

Implementation science is a young discipline that has developed over the last 2 to 3 decades [85]. Nonetheless, numerous implementation frameworks, either for specific health care settings or for general guidelines, have been published during this period [26,64,86-88]. Other implementation frameworks and strategies for health care are nonspecific in terms of either the intervention targeted [26,64], as they refer to evidence-based practices [89], or technology [90-92]. Looking at intensive care medicine, implementation frameworks are widely limited to the implementation of evidence-based practices [93,94]. Explicit guidelines for the implementation of novel digital health technologies in the special ICU environments are lacking.

The implementation framework at hand was developed through an interdisciplinary approach, is specific to the ICU setting, and considers relevant particularities in terms of digital health technology implementation.

Limitations

The research team was only able to obtain a limited view of the entire implementation project. The decision to implement the system was made before the study began, which prevented conducting front-end exploration of the implementation setting or evaluation of the external setting and vendor perspective. It was not possible to pursue a user-centered design and implementation in this specific context. However, our study provides valuable insights into the process of implementing digital health technology in the ICU and highlights important application strategies while planning an implementation project. In particular, we identified explicit pitfalls for implementation processes in the specific clinical environment of an ICU and solutions to overcome them.

The interpretation of the results should consider that the CFIR-ERIC mapping tool needs further validation and evidence. Thus, the mapping of strategies to the major barriers might not reflect the best strategy to tackle the respective barrier. We sought to overcome this limitation through profound discussions at meetings within the research team, extensive field research, and analysis of suggestions from staff to improve the implementation performance.

A limitation to the study's scope is that the ERIC strategies do not include changes in intervention characteristics, which would be essential when aiming to improve implementation performance in a user-centered design. ERIC only covers the last stages of implementation (planning and executing the implementation of the finalized intervention) but does not include the readaptation of the intervention as part of the development process.

Finally, the fact that every ICU has unique structural and sociotechnical features, as well as the number of interviewees, could limit the general validity of derived findings. As we investigated an explicit use case in an ICU, potential interviewees were limited because we identified and interviewed the key stakeholders throughout the study. This study depicts an implementation project in intensive care medicine that is close to the standard practice in Germany, where implementation science is still an evolving discipline. However, it is specific to the setting in which it was conducted (ICU, country, and health system), and translation of our findings to other contexts is limited and should be done with these specificities in mind. In terms of continuous reassessment, our proposed framework may need further validation and evaluation in ICU or IMCU settings to fully realize its potential for optimization of implementing digital technologies.

Conclusions

We propose an implementation framework for digital technology in the ICU, which entails practical and evidence-based strategies to improve the implementation process. The ICU provides an exceptional setting for the introduction of digital health technology: the stress level of staff is high, and the ICU team is composed of multiple different professions using the same technologies.

The proposed framework outlines strategies to be applied before and during implementation and in the general context of implementation. Before implementation, the need for innovation and potential interventions should be carefully assessed by involving all clinical stakeholders with clear implementation leadership. Interventions should be needs-oriented, user-centered, and adaptable to changing circumstances. During implementation, a clinical implementation team should ensure transparent, inclusive, and motivating staff communication regarding the project and continuous feedback through local opinion leaders and champions. To ensure efficient management of resources and time, we recommend optimizing the general context of implementation practice in the ICU and the health care institution by involving an implementation advisor, ideally in consultation with an implementation unit of the same institution. Our proposed framework should encourage health care institutions to implement modern digital technology in ICUs and facilitate clinicians and implementation advisors in the practical execution of implementation projects in ICU settings.

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Data Availability

The data sets generated and analyzed during this study are not publicly available because of data privacy; however, they are available from the corresponding author (FB) upon reasonable request.

Authors' Contributions

CS had the idea for shared decision allocation and initiated the implementation of remote patient monitoring in the intensive care unit. The study was conceived by ASP, CS, FB, and LKM. LKM conducted data acquisition and analysis, supported by ASP. LKM and ASP wrote the manuscript. HK contributed to the study's methodology and interpretation of results from a psychologist's point of view, and MS (nurses' perspective) and SWC (physicians' perspective) contributed the perspective of the intensive care unit where this study was conducted. FB supervised all parts of the study. All authors critically reviewed and approved the manuscript.

Conflicts of Interest

CS and FB report funding from Medtronic. FB also reports grants from German Federal Ministry of Education and Research, grants from German Federal Ministry of Health, grants from Berlin Institute of Health, personal fees from Elsevier Publishing, grants from Hans Böckler Foundation, other from Robert Koch Institute, grants from Einstein Foundation, and grants from Berlin University Alliance outside the submitted work.

Multimedia Appendix 1

Interview guideline.
[DOCX File , 22 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Mapping of Consolidated Framework for Implementation Research domains to summaries of codes concerning implementation performance.
[DOCX File , 27 KB-Multimedia Appendix 2]

Multimedia Appendix 3

Expert Recommendations for Implementing Change strategies mapped to summaries of codes concerning staff suggestions for improving implementation performance.
[DOCX File , 23 KB-Multimedia Appendix 3]

References

1. Kumar S, Merchant S, Reynolds R. Tele-ICU: efficacy and cost-effectiveness of remotely managing critical care. Perspect Health Inf Manag 2013;10(Spring):1f [FREE Full text] [Medline: 23805066]
2. Hawkins HA, Lilly CM, Kaster DA, Groves Jr RH, Khurana H. ICU telemedicine comanagement methods and length of stay. Chest 2016;150(2):314-319. [doi: 10.1016/j.chest.2016.03.030] [Medline: 27048869]
3. Meyer A, Zverinski D, Pfahringer B, Kempfert J, Kuehne T, Sündermann SH, et al. Machine learning for real-time prediction of complications in critical care: a retrospective study. Lancet Respir Med 2018;6(12):905-914. [doi: 10.1016/S2213-2600(18)30300-X] [Medline: 30274956]
4. Khanna AK, Hoppe P, Saugel B. Automated continuous noninvasive ward monitoring: future directions and challenges. Crit Care 2019;23(1):194 [FREE Full text] [doi: 10.1186/s13054-019-2485-7] [Medline: 31146792]
5. Escobar GJ, Liu VX, Schuler A, Lawson B, Greene JD, Kipnis P. Automated identification of adults at risk for in-hospital clinical deterioration. N Engl J Med 2020;383(20):1951-1960 [FREE Full text] [doi: 10.1056/NEJMsa2001090] [Medline: 33176085]
6. Prgomet M, Li L, Niazkhani Z, Georgiou A, Westbrook JI. Impact of commercial computerized provider order entry (CPOE) and clinical decision support systems (CDSSs) on medication errors, length of stay, and mortality in intensive care units: a systematic review and meta-analysis. J Am Med Inform Assoc 2017;24(2):413-422 [FREE Full text] [doi: 10.1093/jamia/ocw145] [Medline: 28395016]
7. Thiel R, Deimel L, Schmidtmann D, Piesche K, Hüsing T, Rennoch J, et al. #SmartHealthSystems - international comparison of digital strategies. Bertelsmann Stiftung. 2018. URL: https://www.bertelsmann-stiftung.de/fileadmin/files/Projekte/Der_digitale_Patient/VV_SHS-Studie_EN.pdf [accessed 2020-06-20]
8. Bughin J, Hazan E, Labaye E, Manyika J, Dahlström P, Ramaswamy S, et al. Digital Europe: realizing the continent's potential. McKinsey Global Institute. 2016. URL: https://www.mckinsey.com/business-functions/mckinsey-digital/our-insights/digital-europe-realizing-the-continents-potential [accessed 2019-01-25]
9. Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society. European Commission. 2018. URL: https://ec.europa.eu/newsroom/dae/document.cfm?doc_id=51628 [accessed 2019-06-22]

10. Wachter RM. Making IT Work: harnessing the power of health information technology to improve care in England. British Association Of Social Workers. 2016. URL: https://www.basw.co.uk/system/files/resources/basw_70727-3_0.pdf [accessed 2019-10-30]
11. Ross J, Stevenson F, Lau R, Murray E. Factors that influence the implementation of e-health: a systematic review of systematic reviews (an update). Implement Sci 2016;11(1):146 [FREE Full text] [doi: 10.1186/s13012-016-0510-7] [Medline: 27782832]
12. Marcial LH, Johnston DS, Shapiro MR, Jacobs SR, Blumenfeld B, Rojas Smith L. A qualitative framework-based evaluation of radiology clinical decision support initiatives: eliciting key factors to physician adoption in implementation. JAMIA Open 2019;2(1):187-196 [FREE Full text] [doi: 10.1093/jamiaopen/ooz002] [Medline: 31984353]
13. Lennon MR, Bouamrane MM, Devlin AM, O'Connor S, O'Donnell C, Chetty U, et al. Readiness for delivering digital health at scale: lessons from a longitudinal qualitative evaluation of a national digital health innovation program in the United Kingdom. J Med Internet Res 2017;19(2):e42 [FREE Full text] [doi: 10.2196/jmir.6900] [Medline: 28209558]
14. WHO guideline: recommendations on digital interventions for health system strengthening. World Health Organization. 2019. URL: https://www.who.int/reproductivehealth/publications/digital-interventions-health-system-strengthening/en/ [accessed 2019-11-30]
15. Expert Panel on effective ways of investing in Health. Assessing the impact of digital transformation of health services. Publications Office of the European Union. 2019. URL: https://ec.europa.eu/health/system/files/2019-11/022_digitaltransformation_en_0.pdf [accessed 2019-02-01]
16. World Health Organization, International Telecommunication Union. National eHealth strategy toolkit. World Health Organization. 2012. URL: https://www.who.int/publications/i/item/national-ehealth-strategy-toolkit [accessed 2019-11-30]
17. Balas EA, Chapman WW. Road map for diffusion of innovation in health care. Health Aff (Millwood) 2018;37(2):198-204. [doi: 10.1377/hlthaff.2017.1155] [Medline: 29401030]
18. Chambers DA, Glasgow RE, Stange KC. The dynamic sustainability framework: addressing the paradox of sustainment amid ongoing change. Implement Sci 2013;8:117 [FREE Full text] [doi: 10.1186/1748-5908-8-117] [Medline: 24088228]
19. Giger JT, Pope ND, Vogt HB, Gutierrez C, Newland LA, Lemke J, et al. Remote patient monitoring acceptance trends among older adults residing in a frontier state. Comput Hum Behav 2015;44:174-182. [doi: 10.1016/j.chb.2014.11.044]
20. Powell BJ, Fernandez ME, Williams NJ, Aarons GA, Beidas RS, Lewis CC, et al. Enhancing the impact of implementation strategies in healthcare: a research agenda. Front Public Health 2019;7:3 [FREE Full text] [doi: 10.3389/fpubh.2019.00003] [Medline: 30723713]
21. Aanestad M, Jensen TB. Building nation-wide information infrastructures in healthcare through modular implementation strategies. J Strateg Inf Syst 2011;20(2):161-176. [doi: 10.1016/j.jsis.2011.03.006]
22. van Dyk L. A review of telehealth service implementation frameworks. Int J Environ Res Public Health 2014;11(2):1279-1298 [FREE Full text] [doi: 10.3390/ijerph110201279] [Medline: 24464237]
23. Eom D, Lee H. A holistic approach to exploring the divided standards landscape in E-Health research. In: ITU Kaleidoscope: Challenges for a Data-Driven Society. 2017 Presented at: ITU K '17; November 27-29, 2017; Nanjing, China p. 1-7. [doi: 10.23919/itu-wt.2017.8246985]
24. Larinkari S, Liisanantti JH, Ala-Lääkkölä T, Meriläinen M, Kyngäs H, Ala-Kokko T. Identification of tele-ICU system requirements using a content validity assessment. Int J Med Inform 2016;86:30-36. [doi: 10.1016/j.ijmedinf.2015.11.012] [Medline: 26725692]
25. Moeckli J, Cram P, Cunningham C, Reisinger HS. Staff acceptance of a telemedicine intensive care unit program: a qualitative study. J Crit Care 2013;28(6):890-901. [doi: 10.1016/j.jcrc.2013.05.008] [Medline: 23906904]
26. Damschroder LJ, Aron DC, Keith RE, Kirsh SR, Alexander JA, Lowery JC. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci 2009;4:50 [FREE Full text] [doi: 10.1186/1748-5908-4-50] [Medline: 19664226]
27. Damschroder LJ, Lowery JC. Evaluation of a large-scale weight management program using the consolidated framework for implementation research (CFIR). Implement Sci 2013;8:51 [FREE Full text] [doi: 10.1186/1748-5908-8-51] [Medline: 23663819]
28. Gimbel S, Mwanza M, Nisingizwe MP, Michel C, Hirschhorn L, AHI PHIT Partnership Collaborative. Improving data quality across 3 sub-Saharan African countries using the Consolidated Framework for Implementation Research (CFIR): results from the African Health Initiative. BMC Health Serv Res 2017;17(Suppl 3):828 [FREE Full text] [doi: 10.1186/s12913-017-2660-y] [Medline: 29297401]
29. Abbott PA, Foster J, de Fatima Marin H, Dykes PC. Complexity and the science of implementation in health IT--knowledge gaps and future visions. Int J Med Inform 2014;83(7):e12-e22. [doi: 10.1016/j.ijmedinf.2013.10.009] [Medline: 24444700]
30. Powell BJ, Waltz TJ, Chinman MJ, Damschroder LJ, Smith JL, Matthieu MM, et al. A refined compilation of implementation strategies: results from the Expert Recommendations for Implementing Change (ERIC) project. Implement Sci 2015;10:21 [FREE Full text] [doi: 10.1186/s13012-015-0209-1] [Medline: 25889199]
31. Waltz TJ, Powell BJ, Matthieu MM, Damschroder LJ, Chinman MJ, Smith JL, et al. Use of concept mapping to characterize relationships among implementation strategies and assess their feasibility and importance: results from the Expert

Recommendations for Implementing Change (ERIC) study. Implement Sci 2015;10:109 [FREE Full text] [doi: 10.1186/s13012-015-0295-0] [Medline: 26249843]
32. Damschroder LJ, Powell BJ, Waltz TJ. Expert recommendations for tailoring strategies to context. U.S. Department of Veteran Affairs. 2015. URL: https://www.hsrd.research.va.gov/for_researchers/cyber_seminars/archives/1060-notes.pdf [accessed 2020-04-20]
33. Proctor EK, Powell BJ, McMillen JC. Implementation strategies: recommendations for specifying and reporting. Implement Sci 2013;8:139 [FREE Full text] [doi: 10.1186/1748-5908-8-139] [Medline: 24289295]
34. Kumar A, Pore P, Gupta S, Wani AO. Level of stress and its determinants among intensive care unit staff. Indian J Occup Environ Med 2016;20(3):129-132 [FREE Full text] [doi: 10.4103/0019-5278.203137] [Medline: 28446837]
35. Kahn JM. What we talk about when we talk about intensive care unit strain. Ann Am Thorac Soc 2014;11(2):219-220. [doi: 10.1513/AnnalsATS.201311-406ED] [Medline: 24575987]
36. Drew BJ, Harris P, Zègre-Hemsey JK, Mammone T, Schindler D, Salas-Boni R, et al. Insights into the problem of alarm fatigue with physiologic monitor devices: a comprehensive observational study of consecutive intensive care unit patients. PLoS One 2014;9(10):e110274 [FREE Full text] [doi: 10.1371/journal.pone.0110274] [Medline: 25338067]
37. Harrison JP. Strategic planning and SWOT analysis. In: Harrison JP, editor. Essentials of Strategic Planning in Healthcare. Chicago, IL: Health Administration Press; 2016:91-97.
38. O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med 2014;89(9):1245-1251 [FREE Full text] [doi: 10.1097/ACM.0000000000000388] [Medline: 24979285]
39. Poncette AS, Meske C, Mosch L, Balzer F. How to overcome barriers for the implementation of new information technologies in intensive care medicine. In: 20th International Conference on Human Interface and the Management of Information. 2018 Presented at: HIMI '8; July 15-29, 2018; Las Vegas, NV p. 534-546. [doi: 10.1007/978-3-030-22649-7_43]
40. Vital SyncTM virtual patient monitoring platform 2.6. Medtronic. URL: https://www.medtronic.com/covidien/en-us/products/health-informatics-and-monitoring/vital-sync-virtual-patient-monitoring-platform-2-6.html [accessed 2019-01-15]
41. Dubois A, Gadde LE. Systematic combining: an abductive approach to case research. J Bus Res 2002;55(7):553-560. [doi: 10.1016/s0148-2963(00)00195-8]
42. Zainal Z. Case study as a research method. J Kemanus 2007;5(1):165 [FREE Full text]
43. Poncette AS, Spies C, Mosch L, Schieler M, Weber-Carstens S, Krampe H, et al. Clinical requirements of future patient monitoring in the intensive care unit: qualitative study. JMIR Med Inform 2019;7(2):e13064 [FREE Full text] [doi: 10.2196/13064] [Medline: 31038467]
44. Neyer FJ, Felber J, Gebhardt C. Entwicklung und Validierung einer Kurzskala zur Erfassung von Technikbereitschaft. Diagnostica 2012;58(2):87-99. [doi: 10.1026/0012-1924/a000067]
45. Harris PA, Taylor R, Thielke R, Payne J, Gonzalez N, Conde JG. Research electronic data capture (REDCap)--a metadata-driven methodology and workflow process for providing translational research informatics support. J Biomed Inform 2009;42(2):377-381 [FREE Full text] [doi: 10.1016/j.jbi.2008.08.010] [Medline: 18929686]
46. Harris PA, Taylor R, Minor BL, Elliott V, Fernandez M, O'Neal L, REDCap Consortium. The REDCap consortium: building an international community of software platform partners. J Biomed Inform 2019;95:103208 [FREE Full text] [doi: 10.1016/j.jbi.2019.103208] [Medline: 31078660]
47. Noble H, Smith J. Issues of validity and reliability in qualitative research. Evid Based Nurs 2015;18(2):34-35. [doi: 10.1136/eb-2015-102054] [Medline: 25653237]
48. Fereday J, Muir-Cochrane E. Demonstrating rigor using thematic analysis: a hybrid approach of inductive and deductive coding and theme development. Int J Qual Methods 2006;5(1):80-92. [doi: 10.1177/160940690600500107]
49. Boyatzis RE. Transforming qualitative information: thematic analysis and code development. London, UK: Sage Publications; 1998.
50. Crabtree BF, Miller WF. A template approach to text analysis: developing and using codebooks. In: Crabtree BF, Miller WL, editors. Doing qualitative research. Thousand Oaks, CA: Sage Publications; 1992:93-109.
51. VERBI software. MAXQDA. 2019. URL: https://www.maxqda.com/about [accessed 2019-11-30]
52. Strategy design. Consolidated Framework for Implementation Research. 2016. URL: https://cfirguide.org/choosing-strategies/ [accessed 2020-04-26]
53. Aref-Adib G, McCloud T, Ross J, O'Hanlon P, Appleton V, Rowe S, et al. Factors affecting implementation of digital health interventions for people with psychosis or bipolar disorder, and their family and friends: a systematic review. Lancet Psychiatry 2019;6(3):257-266. [doi: 10.1016/S2215-0366(18)30302-X] [Medline: 30522979]
54. Labrique AB, Wadhwani C, Williams KA, Lamptey P, Hesp C, Luk R, et al. Best practices in scaling digital health in low and middle income countries. Global Health 2018;14(1):103 [FREE Full text] [doi: 10.1186/s12992-018-0424-z] [Medline: 30390686]
55. Poncette AS, Mosch L, Spies C, Schmieding M, Schiefenhövel F, Krampe H, et al. Improvements in patient monitoring in the intensive care unit: survey study. J Med Internet Res 2020;22(6):e19091 [FREE Full text] [doi: 10.2196/19091] [Medline: 32459655]

56. Chochoiek N. Explaining the success of user-centered design - an empirical study across German B2C firms. Jr Manag Sci 2017;2(1):81-116. [doi: 10.5282/jums/v2i1pp81-116]
57. Andrade E, Quinlan LR, Harte R, Byrne D, Fallon E, Kelly M, et al. Investigation of the human factors, usability and user experience of patient monitors used in a hospital setting. In: International Conference on Human Systems Engineering and Design: Future Trends and Applications. 2018 Presented at: IHSED '18; October 25-27, 2018; Reims, France p. 352-357. [doi: 10.1007/978-3-030-02053-8_54]
58. Ross J, Stevenson F, Dack C, Pal K, May C, Michie S, et al. Developing an implementation strategy for a digital health intervention: an example in routine healthcare. BMC Health Serv Res 2018;18(1):794 [FREE Full text] [doi: 10.1186/s12913-018-3615-7] [Medline: 30340639]
59. Leeman J, Birken SA, Powell BJ, Rohweder C, Shea CM. Beyond "implementation strategies": classifying the full range of strategies used in implementation science and practice. Implement Sci 2017;12(1):125 [FREE Full text] [doi: 10.1186/s13012-017-0657-x] [Medline: 29100551]
60. Shaw J, Agarwal P, Desveaux L, Palma DC, Stamenova V, Jamieson T, et al. Beyond "implementation": digital health innovation and service design. NPJ Digit Med 2018;1:48 [FREE Full text] [doi: 10.1038/s41746-018-0059-8] [Medline: 31304327]
61. Halpern NA. Innovative designs for the smart ICU: part 1: from initial thoughts to occupancy. Chest 2014;145(2):399-403. [doi: 10.1378/chest.13-0003] [Medline: 24493512]
62. Broens S, Dahan A, van Velzen M. Challenges and pitfalls with a randomized clinical trial in the postanesthesia care unit. Sage Res Method Cases 2020:-. [doi: 10.4135/9781529731729]
63. Koenig MA. Telemedicine in the ICU. Cham, Switzerland: Springer International Publishing; 2019.
64. Moullin JC, Sabater-Hernández D, Fernandez-Llimos F, Benrimoj SI. A systematic review of implementation frameworks of innovations in healthcare and resulting generic implementation framework. Health Res Policy Syst 2015;13:16 [FREE Full text] [doi: 10.1186/s12961-015-0005-z] [Medline: 25885055]
65. Ray JM, Ratwani RM, Sinsky CA, Frankel RM, Friedberg MW, Powsner SM, et al. Six habits of highly successful health information technology: powerful strategies for design and implementation. J Am Med Inform Assoc 2019;26(10):1109-1114 [FREE Full text] [doi: 10.1093/jamia/ocz098] [Medline: 31265064]
66. Halpern NA, Anderson DC, Kesecioglu J. ICU design in 2050: looking into the crystal ball!. Intensive Care Med 2017;43(5):690-692. [doi: 10.1007/s00134-017-4728-x] [Medline: 28315042]
67. Falini S, Angelotti G, Cecconi M. ICU management based on big data. Curr Opin Anaesthesiol 2020;33(2):162-169. [doi: 10.1097/ACO.0000000000000834] [Medline: 32022730]
68. Guimarães T, Moreira A, Peixoto H, Santos M. ICU data management - a permissioned blockchain approach. Procedia Comput Sci 2020;177:546-551. [doi: 10.1016/j.procs.2020.10.076]
69. Krohn R, Metcalf D, Salber P. Connected health: improving care, safety, and efficiency with wearables and IoT solution. Boca Raton, FL: CRC Press; 2017.
70. Kang M, Park E, Cho BH, Lee KS. Recent patient health monitoring platforms incorporating internet of things-enabled smart devices. Int Neurourol J 2018;22(Suppl 2):S76-S82 [FREE Full text] [doi: 10.5213/inj.1836144.072] [Medline: 30068069]
71. Mahmud R, Koch FL, Buyya R. Cloud-fog interoperability in IoT-enabled healthcare solutions. In: Proceedings of the 19th International Conference on Distributed Computing and Networking. 2018 Presented at: ICDCN '18; January 4-7, 2018; Varanasi, India p. 1-10. [doi: 10.1145/3154273.3154347]
72. Egala BS, Priyanka S, Pradhan AK. SHPI: smart healthcare system for patients in ICU using IoT. In: IEEE International Conference on Advanced Networks and Telecommunications Systems. 2019 Presented at: ANTS '19; December 16-19, 2019; Goa, India p. 1-6. [doi: 10.1109/ants47819.2019.9118084]
73. Padhy RP, Patra MR, Satapathy SC. Cloud computing: security issues and research challenges. Int J Comput Sci Inf Technol 2011;1(2):136-146.
74. Jaleel A, Mahmood T, Hassan MA, Bano G, Khurshid SK. Towards medical data interoperability through collaboration of healthcare devices. IEEE Access 2020;8:132302-132319. [doi: 10.1109/access.2020.3009783]
75. Lehne M, Sass J, Essenwanger A, Schepers J, Thun S. Why digital medicine depends on interoperability. NPJ Digit Med 2019;2:79 [FREE Full text] [doi: 10.1038/s41746-019-0158-1] [Medline: 31453374]
76. Kang S, Baek H, Jung E, Hwang H, Yoo S. Survey on the demand for adoption of Internet of Things (IoT)-based services in hospitals: investigation of nurses' perception in a tertiary university hospital. Appl Nurs Res 2019;47:18-23. [doi: 10.1016/j.apnr.2019.03.005] [Medline: 31113540]
77. Kupwade Patil H, Seshadri R. Big data security and privacy issues in healthcare. In: 2014 IEEE International Congress on Big Data. 2014 Presented at: BigData Congress '14; June 27-July 2, 2014; Anchorage, AK p. 762-765. [doi: 10.1109/bigdata.congress.2014.112]
78. Wilkowska W, Ziefle M. Privacy and data security in E-health: requirements from the user's perspective. Health Informatics J 2012;18(3):191-201 [FREE Full text] [doi: 10.1177/1460458212442933] [Medline: 23011814]
79. Kruse CS, Frederick B, Jacobson T, Monticone DK. Cybersecurity in healthcare: a systematic review of modern threats and trends. Technol Health Care 2017;25(1):1-10. [doi: 10.3233/THC-161263] [Medline: 27689562]

80. Jalali MS, Kaiser JP. Cybersecurity in hospitals: a systematic, organizational perspective. J Med Internet Res 2018;20(5):e10059 [FREE Full text] [doi: 10.2196/10059] [Medline: 29807882]
81. Topol E. Preparing the healthcare workforce to deliver the digital future. National Health Service. 2019. URL: https://topol.hee.nhs.uk/wp-content/uploads/HEE-Topol-Review-2019.pdf [accessed 2019-11-30]
82. Luetz A, Grunow JJ, Mörgeli R, Rosenthal M, Weber-Carstens S, Weiss B, et al. Innovative ICU solutions to prevent and reduce delirium and post-intensive care unit syndrome. Semin Respir Crit Care Med 2019;40(5):673-686. [doi: 10.1055/s-0039-1698404] [Medline: 31826268]
83. Ince C. Physiology and technology for the ICU in vivo. Crit Care 2019;23(Suppl 1):126 [FREE Full text] [doi: 10.1186/s13054-019-2416-7] [Medline: 31200744]
84. Human factors engineering lab - overview. Mayo Clinic. URL: https://www.mayo.edu/research/labs/human-factors-engineering/overview [accessed 2020-05-09]
85. Bauer MS, Damschroder L, Hagedorn H, Smith J, Kilbourne AM. An introduction to implementation science for the non-specialist. BMC Psychol 2015;3(1):32 [FREE Full text] [doi: 10.1186/s40359-015-0089-9] [Medline: 26376626]
86. Rycroft-Malone J, Seers K, Chandler J, Hawkes CA, Crichton N, Allen C, et al. The role of evidence, context, and facilitation in an implementation trial: implications for the development of the PARIHS framework. Implement Sci 2013;8:28 [FREE Full text] [doi: 10.1186/1748-5908-8-28] [Medline: 23497438]
87. Rycroft-Malone J, Kitson A, Harvey G, McCormack B, Seers K, Titchen A, et al. Ingredients for change: revisiting a conceptual framework. Qual Saf Health Care 2002;11(2):174-180 [FREE Full text] [doi: 10.1136/qhc.11.2.174] [Medline: 12448812]
88. May C, Finch T, Mair F, Ballini L, Dowrick C, Eccles M, et al. Understanding the implementation of complex interventions in health care: the normalization process model. BMC Health Serv Res 2007;7:148 [FREE Full text] [doi: 10.1186/1472-6963-7-148] [Medline: 17880693]
89. Stetler CB, Damschroder LJ, Helfrich CD, Hagedorn HJ. A guide for applying a revised version of the PARIHS framework for implementation. Implement Sci 2011;6:99 [FREE Full text] [doi: 10.1186/1748-5908-6-99] [Medline: 21878092]
90. Kukafka R, Johnson SB, Linfante A, Allegrante JP. Grounding a new information technology implementation framework in behavioral science: a systematic analysis of the literature on IT use. J Biomed Inform 2003;36(3):218-227 [FREE Full text] [doi: 10.1016/j.jbi.2003.09.002] [Medline: 14615230]
91. Meyers DC, Durlak JA, Wandersman A. The quality implementation framework: a synthesis of critical steps in the implementation process. Am J Community Psychol 2012;50(3-4):462-480. [doi: 10.1007/s10464-012-9522-x] [Medline: 22644083]
92. Mann H, Grant G, Mann IJ. Green IT: an implementation framework. In: Proceedings of the 15th Americas Conference on Information Systems. 2009 Presented at: AMCIS '09; August 6-9, 2009; San Francisco, CA p. 121.
93. Rosa RG, Teixeira C, Sjoding M. Novel approaches to facilitate the implementation of guidelines in the ICU. J Crit Care 2020;60:1-5. [doi: 10.1016/j.jcrc.2020.07.014] [Medline: 32731099]
94. Holdsworth LM, Safaeinili N, Winget M, Lorenz KA, Lough M, Asch S, et al. Adapting rapid assessment procedures for implementation research using a team-based approach to analysis: a case example of patient quality and safety interventions in the ICU. Implement Sci 2020;15(1):12 [FREE Full text] [doi: 10.1186/s13012-020-0972-5] [Medline: 32087724]

Abbreviations

CFIR: Consolidated Framework for Implementation Research
ERIC: Expert Recommendations for Implementing Change
ICU: intensive care unit
IMCU: intermediate care unit
IoT: Internet of Things
PDMS: patient data management system
REDCap: Research Electronic Data Capture

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Agha-Mir-Salim L, **Mosch L**, Klopfenstein SAI, Wunderlich MM, Frey N, Poncette A-S, Balzer F. Artificial Intelligence Competencies in Postgraduate Medical Training in Germany. In: Séroussi B, Weber P, Dhombres F, Grouin C, Liebe J-D, Pelayo S, Pinna A, Rance B, Sacchi L, Ugon A, Benis A, Gallos P, editors. Studies in Health Technology and Informatics [Internet] IOS Press; 2022 [cited 2022 Sep 26]. [doi: 10.3233/SHTI220589]

Mosch L, Agha-Mir-Salim L, Sarica MM, Balzer F, Poncette A-S. Artificial Intelligence in Undergraduate Medical Education. In: Séroussi B, Weber P, Dhombres F, Grouin C, Liebe J-D, Pelayo S, Pinna A, Rance B, Sacchi L, Ugon A, Benis A, Gallos P, editors. Studies in Health Technology and Informatics [Internet] IOS Press; 2022 [cited 2022 Sep 26]. [doi: 10.3233/SHTI220597]

Seemann RJ, Mielke AM, Glauert DL, Gehlen T, Poncette AS, **Mosch LK,** Back DA. Implementation of a digital health module for undergraduate medical students: A comparative study on knowledge and attitudes. Technology and Health Care IOS Press; 2022 Jan 1;Preprint(Preprint):1–8. [doi: 10.3233/THC-220138] - IF 1.205

Mosch LK, Poncette A-S, Spies C, Weber-Carstens S, Schieler M, Krampe H, Balzer F. Creation of an Evidence-Based Implementation Framework for Digital Health Technology in the Intensive Care Unit: Qualitative Study. *JMIR Formative Research* 2022 Apr 8;6(4):e22866. [doi: 10.2196/22866] IF expected 2023

Poncette A-S, **Mosch LK**, Stablo L, Spies C, Schieler M, Weber-Carstens S, Feufel MA, Balzer F. A Remote Patient-Monitoring System for Intensive Care Medicine: Mixed Methods Human-Centered Design and Usability Evaluation. *JMIR Human Factors* 2022 Mar 11;9(1):e30655. [doi: 10.2196/30655] IF expected 2023

Mosch L, Back DA, Balzer F, Bernd M, Brandt J, Erkens S, Frey N, Ghanaat A, Glauert DL, Göllner S, Hofferbert J, Klopfenstein SAI, Lantwin P, Mah D-K, Özden GM, Poncette A-S, Rampelt F, Sarica MM, Schmieding M, Schmidt J, Wagnitz J, Wunderlich MM. Lernangebote zu Künstlicher Intelligenz in der Medizin [Internet]. *Zenodo*; 2021 Sep. [doi: 10.5281/ZENODO.5497668]

Poncette, Akira-Sebastian, Daniel-Leon Glauert, **Lina Mosch**, Katarina Braune, Felix Balzer, und David Alexander Back. 2020. „Undergraduate Medical Competencies in Digital Health and Curricular Module Development: Mixed Method Study“. *Journal of Medical Internet Research*, 20. Juli 2020. https://doi.org/10.2196/22161. IF 7.08

Machleid, Felix, Robert Kaczmarczyk, Doreen Johann, Justinas Balčiūnas, Beatriz Atienza-Carbonell, Finn von Maltzahn, und **Lina Mosch**. „Digital Health in Medical Education: Findings from a Mixed-Methods Survey among European Medical Students“. *Journal of Medical Internet Research*, 14. August 2020. https://doi.org/10.2196/19827. IF 7.08

Poncette, Akira-Sebastian, **Lina Mosch**, Claudia Spies, Malte Schmieding, Fridtjof Schiefenhövel, Henning Krampe, und Felix Balzer. „Improvements in Patient Monitoring for the Intensive Care Unit: Survey Study“. *Journal of Medical Internet Research*, 13. Mai 2020. https://doi.org/10/ggx2nm. IF 7.08

Rodzinka, Marcin, Annabel Seebohm, Eugene Pozniak, **Lina Mosch,** Lara De Luca, Jill McArdle, Reinhard Griebenow, und Margarita Velcheva. „Regulating for Bias in Medical Education – Reaction to the Pharmaceutical Industry Updated EFPIA Code of Practice“. *Journal of European CME* 8, Nr. 1 (1. Januar 2019): 1685771. https://doi.org/10.1080/21614083.2019.1685771.

Mosch, Lina, Felix Machleid, Justinas Balciunas, Paulius Povilonis, Irem Aktar, Robert Kaczmarczyk, Fatemeh Nokhbatolfoghahai, und Finn von Maltzan. „Digital Health in the Medical Curriculum: Addressing the Needs of the Future Health Workforce“. *European Medical Students' Association*, Policy Statements, 4. September 2019.

Mosch, Lina, Justinas Balciunas, Rowen De Jong, und Orsolya Réka Süli. „Conflicts of Interest in Medical Education Settings“. *European Medical Students' Association*, Policy Statements, 26. April 2019.

Poncette, Akira-Sebastian, Christian Meske, **Lina Mosch**, und Felix Balzer. „How to Overcome Barriers for the Implementation of New Information Technologies in Intensive Care Medicine“. In *Human Interface and the Management of Information. Information in Intelligent Systems*, herausgegeben von Sakae Yamamoto und Hirohiko Mori, 11570:534–46. Cham: Springer International Publishing, 2019. https://doi.org/10.1007/978-3-030-22649-7_43.

Poncette, Akira-Sebastian, Claudia Spies, **Lina Mosch**, Monique Schieler, Steffen Weber-Carstens, Henning Krampe, und Felix Balzer. „Clinical Requirements of Future Patient Monitoring in the Intensive Care Unit: Qualitative Study“. *JMIR Medical Informatics* 7, Nr. 2 (30. April 2019): e13064. https://doi.org/10.2196/13064. IF 3.23

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