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Habilitationsschrift

Nutzerzentrierte Analyse des Patientenmonitorings auf der Intensivstation sowie Entwicklung und Evaluation von Verbesserungsstrategien zur Steigerung der Patientensicherheit

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Abkürzungen

BMBF	Bundesministerium für Bildung und Forschung
BMG	Bundesministerium für Gesundheit
CFIR	Consolidated Framework for Implementation Research
CI	Cardiac Index
COVID-19	Coronavirus-Erkrankung 2019
EKG	Elektrokardiogramm
ENIAC	Electronic Numerical Integrator and Computer
ERIC	Expert Recommendations for Implementing Change
esCCO	ECG-estimated Continuous Cardiac Output
ESICM	European Society of Intensive Medicine
EWS	Early Warning Score
HCD	Human-centered-Design
HZV	Herzzeitvolumen
ITS	Intensivstation
KHZG	Krankenhauszukunftsgesetz
KI	Künstliche Intelligenz
MII	Medizininformatik-Initiative
PAC	Pulmonal Arterieller Katheter
PDMS	Patientendatenmanagementsystem
PPG	Photoplethysmogramm
PWTT	Pulswellentransitzeit
SD	Standardabweichung
SpHb	Puls CO-Oxymetrie Hämoglobin
SpO2	Pulsoxymetrisch gemessene Sauerstoffsättigung
UI	User Interface
VC	Volume Clamp
ZVK	Zentralvenöser Katheter

1. Einleitung

1.1. Monitoring der menschlichen Vitalparameter

Erste dokumentierte Versuche, die menschlichen Vitalparameter zu überwachen, datieren bis 1550 BC zurück. Hierbei wurde der Zusammenhang zwischen dem Puls und dem Herzschlag durch ägyptische Ärzt:innen festgehalten [1].

Etwa 3000 Jahre später, im Jahr 1625, gelang Santorio Santori mit Hilfe von Galileo Galilei die Entwicklung des sogenannten Pulsilogiums, mit dem man mittels eines Pendulums den Puls messen konnte, und läutete damit das Zeitalter der quantitativen Medizin ein [2]. Mit diesen Grundlagen konnte der englische Arzt John Floyer 1665 seine Pulse-Watch entwickeln, eine spezielle Taschenuhr, die erstmals auch einen Sekundenzeiger enthielt und damit eine exakte Messung der Pulsschläge pro Minute ermöglichte [3]. Mit der exakten Messung der Zeit konnten Extremwerte des Pulses dokumentiert und der Einfluss von beispielsweise Alter, Geschlecht, Krankheit oder Schlaf auf den Puls analysiert werden. Zusätzlich war es möglich, Atemzüge pro Minute zu dokumentieren.

Die Entwicklung des Quecksilberthermometers durch Gabriel Daniel Fahrenheit verhalf Carl Reinhold August Wunderlich dazu, Normalwerte für die menschliche Temperatur zu definieren sowie die Temperaturmessung in Abhängigkeit von der Tageszeit klinisch zu nutzen [4]. Genauso wie die Atem- und Pulsfrequenz wurde die Temperatur nun erstmals als ein Vitalparameter eingestuft und nicht als eine eigenständige Krankheit. Ab diesem Zeitpunkt wurden Puls, Atmung und Temperatur in Abhängigkeit von der Tageszeit grafisch dargestellt [5].

Neben diesen drei Vitalparametern ist der Blutdruck, dessen Quantifizierung 1733 mit Stephen Hales begann, ein weiterer essenzieller Bestandteil des heutigen Patientenmonitorings. Im Jahr 1824 konnte Jean Léonard Marie Poiseuille erstmals auf Grundlage dieser Quantifizierung den arteriellen Blutdruck mittels eines Quecksilber-Manometers messen [6]. Im selben Jahrhundert wurden innerhalb kürzester Zeit diverse Apparate zur nicht-invasiven Blutdruckmessung, sogenannte Sphygmomanometer, erfunden. Scipione Riva-Rocci berichtete 1896 von einem System, welches dem der heutigen Technik am nächsten kommt. Zur Blutdruckmessung nutzte er eine zirkumferente Gummitasche, die mittels eines Gummiballons aufgepumpt werden konnte. Die Gummitasche war an ein Quecksilber-Manometer angeschlossen. Wenn der Druck nun langsam aus der Tasche abgelassen wurde, fiel der Quecksilberstand und der Blutdruck konnte beim Wiedereintritt des Pulses abgelesen werden. In den folgenden Jahren

erfolgten mehrere Ergänzungen und Verbesserungen dieses Systems durch diverse Ärzte und Wissenschaftler (u. a. Recklinghausen, Korotkoff, Hill, Bernard).

Das elektronische Zeitalter der Medizin begann als Augustus Waller 1887 erstmals die elektrische Aktivität des Herzens dokumentierte. Basierend auf diesen Erkenntnissen konnte Willem Einthoven 1901 die heute bekannte PQRST-Kurve mittels eines 3-Kanal Elektrokardiogramms (EKG) ableiten [7]. Ärzte und Wissenschaftler erkannten Mängel an den ersten EKG-Systemen und entwickelten diese in mehreren Iterationen weiter. Erst ein halbes Jahrhundert später, 1954, wurde das heute bekannte 12-Kanal EKG erfunden. Gleichzeitig wurde mit der Entwicklung des Electronic Numerical Integrator and Computer (ENIAC), dem ersten elektronischen Digitalrechner, im Jahr 1945 das Computerzeitalter eingeläutet [8]. Als Display wurde das Oszilloskop eingeführt, mit dem unter anderem im Rahmen von herzchirurgischen Operationen das EKG visualisiert wurde [9]. Auch obere und untere Alarmgrenzen für die Herzfrequenzmessung wurden hierfür erstmalig festgesetzt.

Das Prinzip eines kontinuierlichen computerbasierten Patientenmonitorings für kritisch kranke Patient:innen wurde erstmals 1966 dokumentiert [10]. Hierfür wurden der arterielle und venöse Blutdruck alle 10 Sekunden automatisiert aufgezeichnet. Temperatur (mehrere Ableitungen) und Urinausscheidung wurden sogar sekündlich, ebenfalls automatisiert, erfasst. Bereits in dieser Zeit wurde das Problem der falsch positiven Alarme erkannt [11].

Als weiteres Standardmonitoring, zum Beispiel auf der Intensivstation (ITS), gilt heutzutage die Pulsoxymetrie. Erstmals erläutert wurde der Ansatz der Oxymetrie 1932 von Ludwig Nicolai [12]. Dieser benutzte die Oxymetrie zur Verlaufsmessung der Gewebsoxygenierung in den Händen. 1935 führte Kurt Kramer den Begriff der spektrophotometrischen Methode in Bezug auf die kontinuierliche Messung der Sauerstoffsättigung des Blutes ein [13]. Karl Matthes erschuf im selben Jahr das erste Sauerstoffmessgerät durch Transillumination des Ohres [14]. In den 1940ern, während des zweiten Weltkrieges, entwickelte Glenn Allan Millikan einen handlichen Ohroxymeter zur Überwachung der amerikanischen Militärpiloten [15]. Problem der ursprünglichen Oxymeter war, dass sie nicht zwischen der arteriellen und venösen Sauerstoffsättigung und der Gewebsabsorption unterscheiden konnten. Erst 1974 wurde die Idee des Pulsoxymeters durch den japanischen Ingenieur Takuo Aoyagi entwickelt [16]. Dieser verwendete die pulsatilen Schwankungen im arteriellen Blutfluss, um die Sauerstoffsättigung zu bestimmen. 1980 wurden die Oxymetrie und Plethysmografie von Yoshiya et al. in einem Messgerät zusammengeführt [17]. Seither sind Pulsoxymeter im Handel erhältlich und werden in verschiedenen Varianten angeboten.

Innerhalb dieser etwa 400 Jahre wurden die heute auf Überwachungsstationen und in Operationssälen standardmäßig verwendeten Monitoringsensoren entwickelt. Mittels EKG, nicht-invasiver oder invasiver Blutdruckmessung, Pulsoxymetrie und elektrischem Thermometer können die Vitalparameter Herz- und Pulsfrequenz, Blutdruck, Sauerstoffsättigung, Atemfrequenz und Temperatur kontinuierlich gemessen und dokumentiert werden.

1.2. Erweitertes Patientenmonitoring

Neben den in 1.1 dargestellten Standardsensoren werden in spezifischen Situationen weitere Sensoren eingesetzt, die unter anderem das Herzzeitvolumen (HZV) kritisch kranker Patient:innen quantifizieren. Als Goldstandard gilt hierfür die invasive Messung des HZV über einen Pulmonalen Arteriellen Katheter (PAC) [18]. Hierbei wird der PAC meist über die rechte Vena jugularis interna und über den rechten Vorhof in der rechten Herzkammer platziert. Durch den Verschluss einer kleinen Pulmonalvene durch einen aufblasbaren Ballon an der Spitze des Katheters kann der Lungenkapillarenverschlussdruck (Wedge-Druck) gemessen werden, der unter physiologischen Konditionen den Druckverhältnissen im linken Vorhof entspricht [19]. Mittels Thermodilutionsprinzip kann hierbei der Herzindex (Cardiac Index, CI = HZV/Körperoberfläche in qm) berechnet werden. Hierfür müssen 10 ml einer etwa 4 °C kalten NaCl-Lösung über den proximalen PAC Schenkel appliziert werden. Mittels Thermistor am distalen PAC-Ende wird die Temperaturerniedrigung pro Zeit gemessen und der CI mittels Stewart Hamilton Gleichung berechnet. In der Vergangenheit wurde der PAC häufig zur Messung des HZV genutzt, doch aufgrund der hohen Komplikationsrate sowie der fehlenden Mortalitätsreduktion nahm die Verbreitung seit 2007 deutlich ab [20,21]. In der Leitlinie 2017 der AWMF (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e.V.) zu hämodynamischem Monitoring herzchirurgischer Patient:innen wird der PAC in nur sehr komplexen Situationen empfohlen [22].

In einer aktuellen Studie konnte gezeigt werden, dass die Mortalität von Patient:innen im kardiogenen Schock durch erweitertes hämodynamisches Monitoring reduziert werden kann [23]. Hierzu zählen auch weniger invasive Systeme, wie zum Beispiel PiCCO® von Pulsion Medical Systems oder FloTrac® von Edwards Lifesciences [24], die hauptsächlich auf dem Prinzip der Pulskonturanalyse beruhen.

Bei weniger kritisch kranken Patient:innen kann durch nicht-invasives hämodynamisches Monitoring kontinuierlich der Blutdruck gemessen werden. Hierfür kann die Volume Clamp (VC) Methode, die Tonometrie sowie die Pulswellentransitzeit (PWTT) genutzt werden [25].

Die VC ist die aktuell am weitesten verbreitete Methode und nutzt eine kleine Manschette am Finger mit einem Photoplethysmogramm (PPG). Die Manschette bläst sich auf, um Änderungen des PPG-Wertes auszugleichen, wodurch der Blutdruck abgeleitet werden kann. Insbesondere bei älteren Patient:innen (>65 Jahre) und bei Patient:innen mit Nebenerkrankungen, wie zum Beispiel Diabetes, sind jedoch Fehlmessungen möglich. Anbieter solcher Systeme sind zum Beispiel Edwards Lifesciences (ClearSight) und CNSystems Medizintechnik (CNAP). Die Tonometrie wurde bereits 1963 erfunden, jedoch besteht ein großer Nachteil darin, dass die Kalibrierung und Sensormontierung fehleranfällig und zeitaufwendig sind. Derzeit gibt es keine weit verbreiteten kommerziellen Systeme hierzu. Die PWTT misst die Zeit zwischen der R-Welle eines EKG und dem Eintreffen der Pulswelle, die von einem Pulsoxymeter am Ohrläppchen gemessen wird [26]. Die Technologie wird zum Beispiel von Nihon Kohden angeboten [27]. Über die PWTT kann zudem das geschätzte kontinuierliche HZV (esCCO) berechnet werden [28]. Der Vorteil besteht darin, dass hierfür lediglich die Standardmonitoring-Sensoren (EKG, (nicht-)invasive Blutdruckmessung, Pulsoxymetrie) notwendig sind.

1.3. Patientenmonitoring in der Intensivmedizin

Neben der klinischen Untersuchung mit Beurteilung der peripheren Zirkulation stellt das Basismonitoring einen essenziellen Bestandteil der intensivmedizinischen Versorgung dar. Hierzu zählen laut Funcke et al. [29] und Janssens et al. [30] ein EKG, eine pulsoxymetrische Überwachung, eine nicht-invasive (nach Riva-Rocci) bzw. invasive Blutdruckmessung, Kontrolle der Urinausscheidung sowie Temperaturmessung. Aufbauend auf dem Schweregrad der Erkrankung, der Anamnese, der klinischen und labormedizinischen Untersuchung sowie dem zeitlichen Rahmen der notwendigen Überwachung wird ein erweitertes Patientenmonitoring vorgenommen.

Die European Society of Cardiology (ESC) publizierte 2005 Leitlinien zur Therapie akuter Herzinsuffizienz. Darin wurden erstmals Angaben zum Einsatz spezieller Monitoringverfahren unter Angabe von Evidenzgraden gemacht [31]. Im Juni 2010 veröffentlichten das European Board of Anaesthesiology (EBA), die European Society of Anaesthesiology (ESA) und das National Anaesthesia Societies Committee (NASC) die Helsinki Declaration on Patient Safety in Anaesthesiology [32]. Unterzeichnet wurde die Deklaration anschließend von mehreren Vertretern der europäischen Anästhesiologie sowie weiteren Interessengruppen [WHO, World Federation of Societies of Anaesthesiologists (WFSA), European Patients Federation (EPF)]. Sie stellt eine Empfehlung von praktischen

Schritten für Anästhesist:innen dar, die erfolgreich in den Klinikalltag integriert werden können. Die EBA und ESA haben parallel zur Deklaration eine gemeinsame Taskforce für Patientensicherheit gegründet, um die aufgeführten Empfehlungen in die Praxis umzusetzen.

Auch in der Intensivmedizin ist die Patientensicherheit von zentraler Bedeutung. Im Oktober 2009 startete die European Society of Intensive Medicine (ESICM) eine Initiative mit dem Ziel, auf nationaler und internationaler Ebene Repräsentant:innen von Intensivpflegegesellschaften sowie Partner:innen aus der Politik, Industrie und Patientenvertretung zusammenzubringen, um das Profil der Patientensicherheitsagenda zu schärfen und die Steigerung der Wirksamkeit der Interventionen zu gewährleisten. Zusammengetragen wurden die Ziele in der Declaration of Vienna [33].

Moderne Patientenmonitore und implementiertes Risikomanagement (einschließlich Alarmsystem und -management) müssen nach den zugelassenen und aktuellen internationalen Normen IEC 60601-1-1 1 [34] und IEC 80001-1 [35] aufgebaut sein.

Die Notwendigkeit von Monitoringsystemen zeigt sich im verbesserten klinischen Verlauf der intensivmedizinisch versorgten Patient:innen [36]. Ziel der hämodynamischen Überwachung ist die Bereitstellung von Daten, die bei der Optimierung der Sauerstoffversorgung von Endorgangewebe unterstützen sowie Gewebehypoxie, Schockzustände und Multiorganversagen vorbeugen. In den 1980ern wurden laut Cooper et al. um die 70% aller anästhesiebedingten unerwünschten Ereignisse (adverse events) durch menschliches Versagen verursacht [37].

Robert Loeb untersuchte die Reaktionszeit von Anästhesist:innen auf relevante Veränderungen der Vitalparameter von Patient:innen. Bei der Untersuchung kam heraus, dass diese eine mittlere Zeit von 61 Sekunden benötigten, um eine abnormale Veränderung der Vitalparameter zu erkennen. 16% der Veränderungen wurden über 5 Minuten nicht erkannt [38]. Mithilfe von automatisierten Überwachungssystemen (einschließlich Alarmen) können kritische Zustände frühzeitig erkannt und behandelt werden [39].

Intensivmediziner:innen werden durch Monitoringsysteme erfolgreich in der Umsetzung und Kontrolle ihrer Behandlungsziele unterstützt [36]. Denn die Optimierung der Hämodynamik und Temperatur der Patient:innen ist entscheidend für eine Verbesserung der Morbiditäts- und Mortalitätsraten. Insgesamt konnte auch durch die Einführung der Patientenmonitoringsysteme das heutige Mortalitätsrisiko durch Komplikationen bzw. unerwünschte Ereignisse (adverse events) in der Anästhesie und Intensivmedizin in

Australien, Europa und den Vereinigten Staaten auf 1 von 100.000 Fällen reduziert werden [32,33].

1.4. Die digitale Transformation der Intensivstation

Aufgrund des demografischen Wandels, des Mangels an medizinischem Personal und, in jüngster Zeit, der Coronavirus-Erkrankung 2019 (COVID-19) wird die Bedeutung moderner ITS immer deutlicher. Als Vision sollte hier eine in allen Bereichen digital transformierte ITS angestrebt werden. Dies beinhaltet die Nutzung neuartiger Technologien sowohl in Software als auch Hardware zur Überwachung von Vitalparametern von Patient:innen, und die automatisierte Nutzung dieser Hochfrequenzdaten für die Unterstützung klinischer Entscheidungen.

Neben der Überwachung der o. g. Vitalparameter ist es beispielsweise möglich, nicht-invasiv kontinuierlich das Puls-CO-Oxymetrie Hämoglobin (SpHb) zu messen [40]. Technologisch wird hierbei mit Hilfe eines Multiwellenlängen-Sensors zwischen sauerstoffreichem und sauerstoffarmen Blut, Blut mit Kohlenmonoxidgehalt, mit Sauerstoff angereichertem Blut und Blutplasma unterschieden. Die kontinuierliche Messung des Hb-Wertes kann insbesondere auf chirurgischen ITS von Vorteil sein [41,42]. Weiterhin konnten Preiser et al. zeigen, dass die kontinuierliche Glukosemessung intensivmedizinischer Patient:innen die Rate an Hypoglykämien oder Hyperglykämien reduziert und damit die Patientensicherheit erhöht [43,44]. Auch die Urinausscheidung kann kontinuierlich mittels Sensorik gemessen werden. Hierbei wurde gezeigt, dass eine Abnahme der Urinausscheidung als frühes Zeichen einer Hypovolämie und Blutung gewertet werden kann [45].

Auf dem Gebiet der Telemedizin sind derzeit deutliche technologische Fortschritte zu verzeichnen, die der Intensivmedizin zugute kommen können [46]. Hierbei werden Technologien wie zum Beispiel fahrbare Videokonferenzsysteme (Visitenroboter) unter anderem mit Infrarotkamera genutzt, um intensivmedizinische Expert:innen kontinuierlich in die Krankenversorgung mit einzubeziehen. Im Rahmen dessen könnte auch die Telemetrie im Sinne einer Fernüberwachung von Patient:innen durch Übertragung der Daten von Vitalparametersensoren an mobile Endgeräte (z. B. Tablet Computer, Smartphone) innerhalb des Krankenhauses dabei unterstützen, Behandlungsempfehlungen von Spezialisten zügiger zu erhalten [47].

Neben den Fortschritten in der Medizin und der Medizintechnik können Erkenntnisse aus der Mathematik, Informatik und Signalverarbeitung weitere wertvolle Verbesserungen bringen,

um die Gesundheitsversorgung auf der ITS zu optimieren [48]. Denn die Implementierung von digitalen Gesundheitstechnologien für die Patientenüberwachung hat das Potential, die Patientensicherheit weiter zu erhöhen. Paradoxerweise werden diese Fortschritte insbesondere in der letzten Dekade nur unzureichend in die klinische Routine implementiert. Heutige Lösungen zur Überwachung der Vitalparameter basieren noch auf dem Prinzip aus den 1970er Jahren [49,50]. Sobald ein vorab eingestellter Vitalparameter-Grenzwert über- oder unterschritten wird, ertönt ein Alarm. Grund für die mangelnde Implementierungsbereitschaft neuartiger Technologien auf der ITS könnte auf eine unzureichende Einbindung der Anwender:innen in Forschung und Entwicklung sein. Zudem gibt es keine umfassende Evidenz und Richtlinien für eine erfolgreiche Implementierung digitaler Gesundheitstechnologien in spezifischen klinischen Umgebungen wie der ITS.

Auf nationaler Ebene ist der Digitalisierungsstau in diversen Sektoren insbesondere im Gesundheitssystem unübersehbar. In einer Studie aus dem Jahr 2018 durch die Bertelsmann Stiftung belegt Deutschland im Vergleich zu 16 weiteren europäischen Nationen den vorletzten Platz [51]. Das Bundesministerium für Gesundheit (BMG) ist sich seit Jahrzehnten dieser Tatsache bewusst, doch erst im Jahr 2020 wurden mit dem Krankenhauszukunftsgesetz (KHZG) Krankenhäusern Investitionsmittel in Höhe von insgesamt 4,3 Mrd. Euro zugesagt, um den Weg in das digitale Zeitalter zu ebnen [52]. Fast zwei Jahre nach Inkrafttreten des Gesetzes ist jedoch in der Regelversorgung noch immer kaum etwas zu spüren. Sowohl die IT-Infrastruktur für den interdisziplinären und intersektoralen kontinuierlichen Datenaustausch in Echtzeit als auch die Vernetzung und Nutzung vor allem von Vitalparameterdaten mit weiteren Gesundheitsdaten für die personalisierte und prädiktive Medizin sind noch weiter auszubauen, um einen Mehrwert für Patient:innen bieten zu können. Versucht man die Digitalisierungsstrategie anderer Länder mit der Deutschlands zu vergleichen, stellt man ernüchternd fest, dass es bisher keinen strategischen Ansatz für Deutschland gibt. Statt Ressourcen zu bündeln entwickeln nun alle rund 1900 Krankenhäuser Deutschlands jeweils unabhängig voneinander Patientenportale, Konzepte für digitale Pflege- und Behandlungsdokumentation, klinische Entscheidungsunterstützungssysteme und vieles mehr [53]. Dennoch ist das KHZG als ein Meilenstein für die Digitalisierung der Regelversorgung einzustufen, mit deren Startschuss nun endlich die Möglichkeit geschaffen wird, den Investitionsstau aufzuholen, um über die Digitalisierung hinaus unser Gesundheitssystem digital zu transformieren.

2. Fragestellung und Zielsetzung

Aus der Implementierungswissenschaft ist bekannt, dass die Einbeziehung von Nutzer:innen in die Entwicklung und Implementierung neuartiger Systeme die erfolgreiche Implementierung verstärken kann. Dies liegt mitunter an der Tatsache, dass Nutzer:innen Probleme erkennen, die Außenstehende bzw. nicht in die Arbeitsroutine involvierte Personen übersehen oder denen sie keine Bedeutung zumessen. Die vermeintliche Verbesserung von Systemen durch externe Personen kann demnach zu einer Abweisung von Veränderungen durch die Anwender:innen führen.

Ziel dieser Arbeit ist es daher, das aktuelle Patientenmonitoring auf der ITS zunächst im Sinne einer Bestandsanalyse von Anwender:innen bewerten zu lassen. Anschließend sollen hieraus sicherheitsrelevante Aspekte identifiziert und Maßnahmen zur Steigerung der Patientensicherheit abgeleitet werden.

3. Ergebnisse

Die ersten zwei Originalarbeiten stellen Studien dar, in denen sicherheitsrelevante Aspekte in Bezug auf das aktuelle Patientenmonitoring der ITS aus der Perspektive der Anwender:innen identifiziert werden. In den darauf folgenden drei Arbeiten werden in weiterführenden Studien Strategien entwickelt, um Sicherheitsdefizite des Alarmmanagements und der Benutzeroberfläche von Patientenmonitoringsystemen zu entschärfen sowie die Implementierung solcher Systeme nachhaltig und nutzerzentriert zu gestalten.

3.1. Originalarbeit 1: Erhebung nutzerzentrierter klinischer Anforderungen an das Patientenmonitoring auf der Intensivstation mittels eines induktiven qualitativen Ansatzes

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Ziel dieser Studie war es, die klinischen und nutzerzentrierten Anforderungen eines Patientenmonitorings der Zukunft in der Intensivmedizin zu evaluieren. Hierzu sollten die Aussagen des medizinischen Personals der ITS zum aktuellen Patientenmonitoring und ihre Erwartungen an zukünftige technologische Entwicklungen untersucht werden. Die Studie wurde auf drei ITS der Charité – Universitätsmedizin Berlin zwischen April und Mai 2018 durchgeführt. Mittels eines zuvor entwickelten Leitfadens wurden Interviews mit fünf Ärzt:innen, sechs Pflegekräften und vier Atemtherapeut:innen durchgeführt und aufgezeichnet. Das Transkript wurde im Anschluss mit Hilfe des Grounded-Theory-Ansatzes, einem induktiven qualitativen Ansatz, ausgewertet.

Die Ergebnisse wurden aufgeteilt in 1) die Bewertung des aktuellen Patientenmonitorings, 2) die Erwartungen an ein zukünftiges System und 3) mögliche Barrieren für die Implementierung neuer Technologien. Bei 1), der Bewertung des aktuellen Systems, wurde durch die Mitarbeitenden der ITS ein großer Wert auf Benutzerfreundlichkeit, Intuitivität und Visualisierung gesetzt. Die Funktion, sich einen Trend von Vitalparametern anzeigen zu lassen, würde im klinischen Alltag selten genutzt. Als potenzielle Probleme für die Patientensicherheit wurde durch das Personal ein unzureichendes Alarmmanagement sowie die Verknotung der vielen verschiedenen Patientenmonitoringkabel eingestuft. Für 2), den Erwartungen an ein zukünftiges Patientenmonitoring, wurde erneut die Bedeutung einer

hohen Benutzerfreundlichkeit betont. Zudem wurden drahtlose, nicht-invasive und interoperable Überwachungssensoren gewünscht. Für ein Fernmonitoring von Patient:innen auf dem gesamten Klinikgelände wurden vom Personal Smartphones bzw. kleine Tablets gefordert. Laut der Interviewten werden zudem Lösungen für die Optimierung des Alarmmanagements benötigt. In diesem Kontext werden klinische Entscheidungsunterstützungssysteme auf der Basis von künstlicher Intelligenz (KI) als nützlich angesehen. Zu 3), den möglichen Barrieren für die Implementierung neuer Technologien, gehörten laut dem medizinischen Personal mangelndes Vertrauen in Technologien, Angst vor dem Verlust klinischer Fähigkeiten durch den Einsatz von Technologien, steigende Arbeitsbelastung durch insuffiziente bzw. nicht funktionierende Technologien und mangelnde Kenntnis von verfügbaren digitalen Technologien.

Diese qualitative Studie zum Thema Patientenmonitoring auf der ITS basiert auf Kernaussagen von Nutzer:innen dieser Technologie. Die Ergebnisse zeigen, dass diverse Entwicklungen, zum Beispiel im Bereich des Alarmmanagements, der mobilen Fernüberwachungssysteme oder der Interoperabilitätsstandards, notwendig sind. Technologische Fortschritte sollten sich noch stärker auf die von den Nutzer:innen gewonnenen Erkenntnisse konzentrieren, um die Nutzbarkeit und Akzeptanz dieser Systeme zu optimieren. Um das Vertrauen und das Bewusstsein für eine digitale Gesundheitsversorgung auf der ITS zu erhöhen, sollte das Personal auf den Einsatz neuer Technologien vorbereitet werden und in aktuelle Forschungstätigkeiten und die Produktentwicklung mit einbezogen werden.

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.

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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.

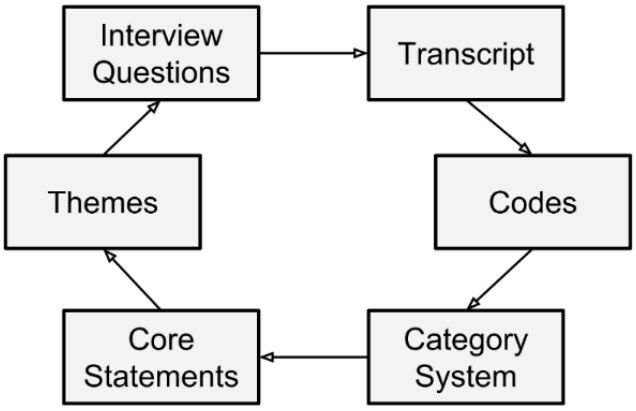
The datasets generated and analyzed during this study are not publicly available due to reasons of data privacy; however, they are available from the corresponding author (FB) upon reasonable request.

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 - medinform_v7i2e13064_app1.pdf]

Multimedia Appendix 2

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

[PDF File (Adobe PDF File), 215KB - medinform_v7i2e13064_app2.pdf]

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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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3.2. Originalarbeit 2: Validierung nutzerzentrierter klinischer Anforderungen an das Patientenmonitoring auf der Intensivstation anhand einer quantitativen Befragung

Poncette A, 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;22(6):e19091

Aufbauend auf der Originalarbeit 1 war es das Ziel dieser Studie, die Kernaussagen aus der vorherigen qualitativen Studie mittels einer quantitativen Befragung zu verifizieren. Dabei wurde der Fokus auf die Zufriedenheit des intensivmedizinischen Personals mit dem aktuellen Patientenmonitoring und ihre Vorschläge für zukünftige Verbesserungen gesetzt. Es sollte herausgefunden werden, welche Faktoren des Patientenmonitorings die Patientenversorgung stören bzw. gefährden, welche Anzeigegeräte (z. B. Displays) für die Fernüberwachung von Patient:innen eingesetzt werden sollten, welche Anwendungsfälle für KI aus Sicht des Personals denkbar wären und ob die Mitarbeitenden der ITS bereit wären, ihre digitalen Kompetenzen zu verbessern oder zur Verbesserung von Patientenmonitoringsystemen beizutragen. Zudem sollten Unterschiede in den Antworten der Berufsgruppen (Ärzt:innen, Pflegepersonal) aufgedeckt werden.

Diese quantitative Befragung wurde an vier Intensivstationen der Charité – Universitätsmedizin Berlin zwischen November 2019 und Januar 2020 durchgeführt. Der webbasierte Fragebogen mit 36 Fragen wurde auf Grundlage der vorangegangenen qualitativen Interviewstudie mit intensivmedizinischem Personal zu klinischen Anforderungen an die zukünftige Patientenüberwachung entwickelt. Die statistischen Analysen der Fragebogenergebnisse umfassten Medianwerte mit ihren bootstrapped 95 %-Konfidenzintervallen und Chi-Quadrat-Tests, um die Verteilungen der Fragebogenantworten der Berufsgruppen zu vergleichen. Insgesamt wurden 270 Ärzt:innen und Pflegefachpersonen der Intensivstationen per E-Mail kontaktiert. Zusätzlich wurde auf den Stationen mittels Aushängen und Flyern auf die Studie aufmerksam gemacht.

Sechsundachtzig der 270 kontaktierten Personen füllten den Fragebogen aus. Die Mehrheit gab an, sich im Umgang mit dem Patientenmonitoring sicher zu fühlen, jedoch wurden hohe Raten von falsch positiven Alarmen und die vielen Sensorkabel als störend für die Patientenversorgung angesehen. Gefordert wurden drahtlose Sensoren, die Reduzierung von falsch positiven Alarmen und die Entwicklung eines Krankenhaus-Standards für das Alarmmanagement. Die Antworten hinsichtlich der Anzeigegeräte für eine

Patientenfernüberwachung zeigten eine Tendenz zu kleinen Tablet-Computern. Die meisten Befragten würden diese dann bei Zuständigkeit für mehrere Stationen oder für eine frühere Alarmierung nutzen. Des Weiteren gaben die Befragten an, dass KI für Intensivstationen nützlich wäre, um Komplikationen und eine erhöhte Mortalität frühzeitig zu erkennen sowie Leitlinien für Therapie und Diagnostik vorgeschlagen zu bekommen. Dabei seien Transparenz, Interoperabilität, Benutzerfreundlichkeit und Schulung des Personals wesentlich, um die Nutzung einer KI zu fördern. Die Mehrheit wollte mehr über neue Technologien für die ITS erfahren und wünschte sich mehr Zeit dafür. Ärzt:innen zeigten weniger Vorbehalte als das Pflegepersonal gegenüber der Nutzung von Smartphones zur Fernüberwachung von Patient:innen und dem KI-basierten (intelligenten) Alarmmanagement.

Diese quantitative Befragung von intensivmedizinischem Personal zeigte wichtige Verbesserungen für die Patientenüberwachung in der Intensivmedizin auf. Krankenhausträger und Hersteller medizinischer Geräte sollten sich auf die Reduzierung von Fehlalarmen des Patientenmonitorings, die Implementierung von Krankenhaus-Standards für das Alarmmanagement, die Einführung drahtloser Sensoren, die Vorbereitung auf den Einsatz von KI und die Verbesserung der digitalen Kompetenz des intensivmedizinischen Personals fokussieren. Die Ergebnisse dieser Studie können dazu beitragen, die nutzerzentrierte Translation digitaler Technologien in die Praxis zu fördern, um damit aktuelle Herausforderungen in der Intensivmedizin anzugehen.

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

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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.

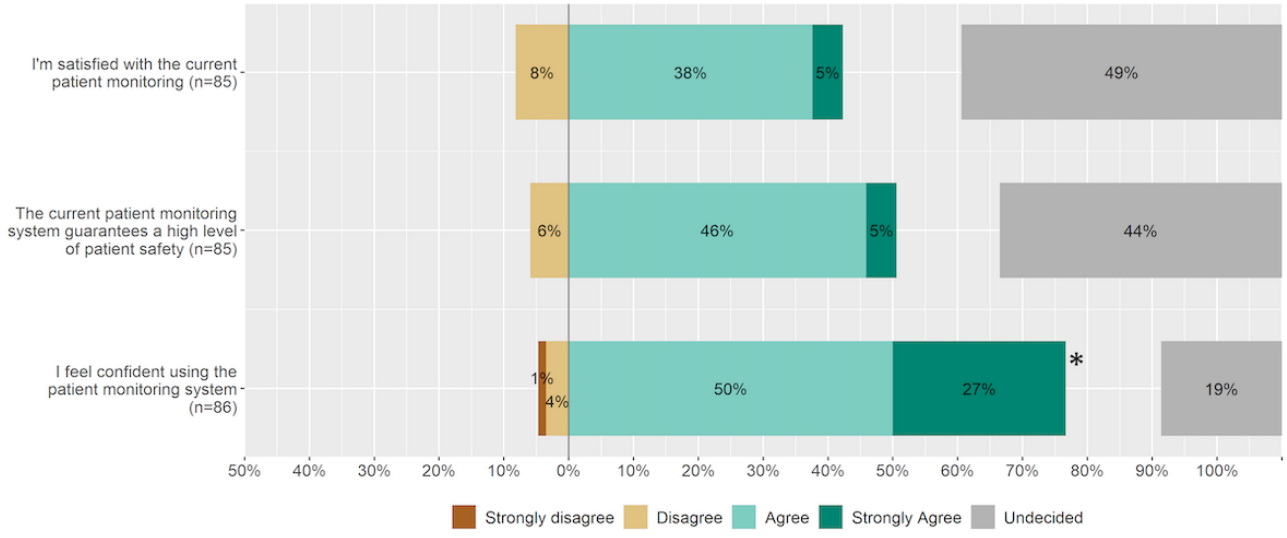
Results

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

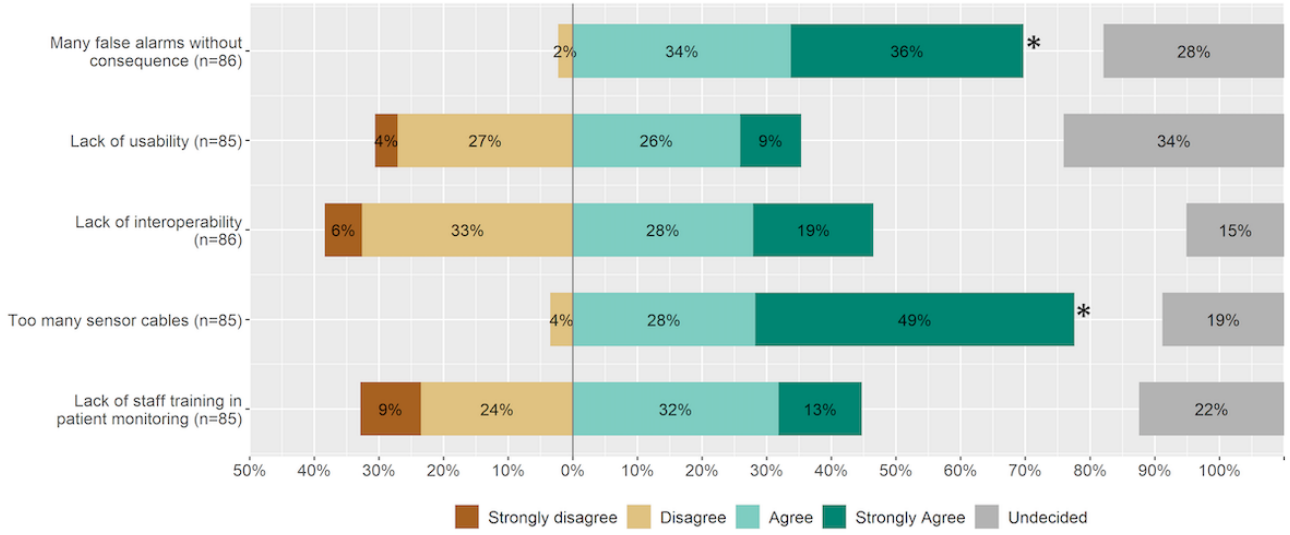
ICU Staff Experience

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.

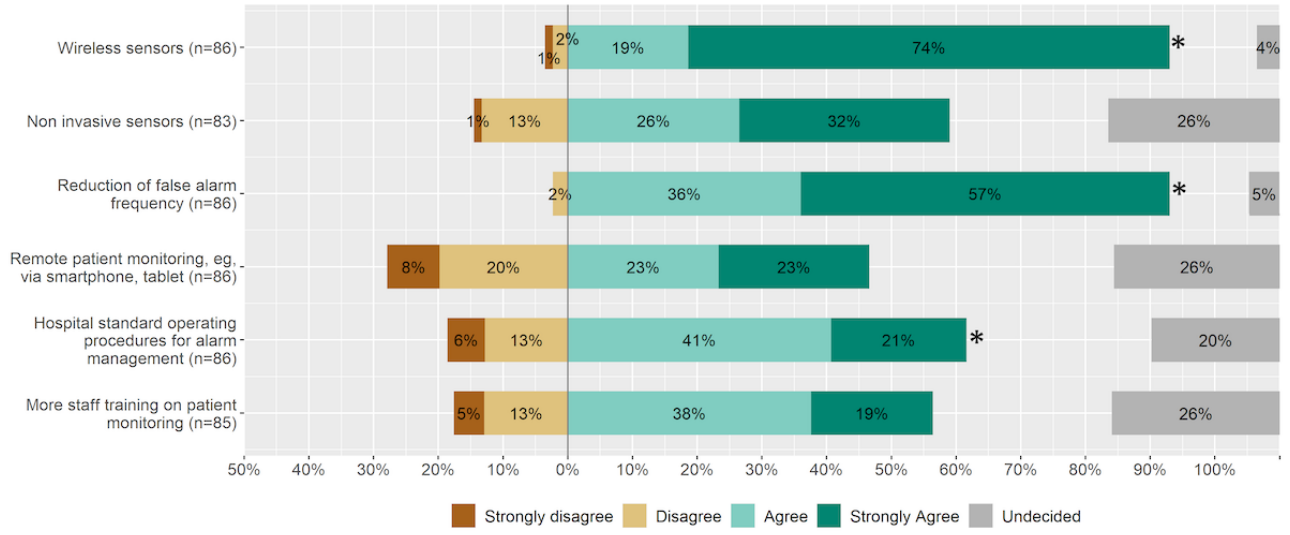


Suggestions for Future Patient Monitoring

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."

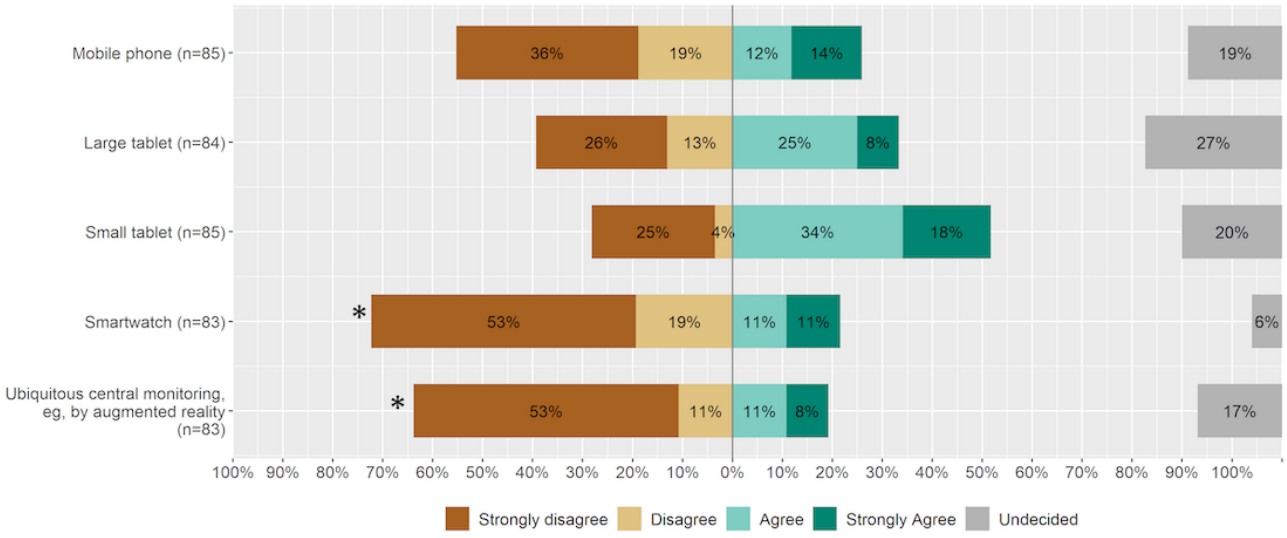
Figure 3. Improvements for future patient monitoring in the ICU. An asterisk indicates statistical significance. ICU: intensive care unit.



Display Devices and Use Cases for Remote Patient Monitoring

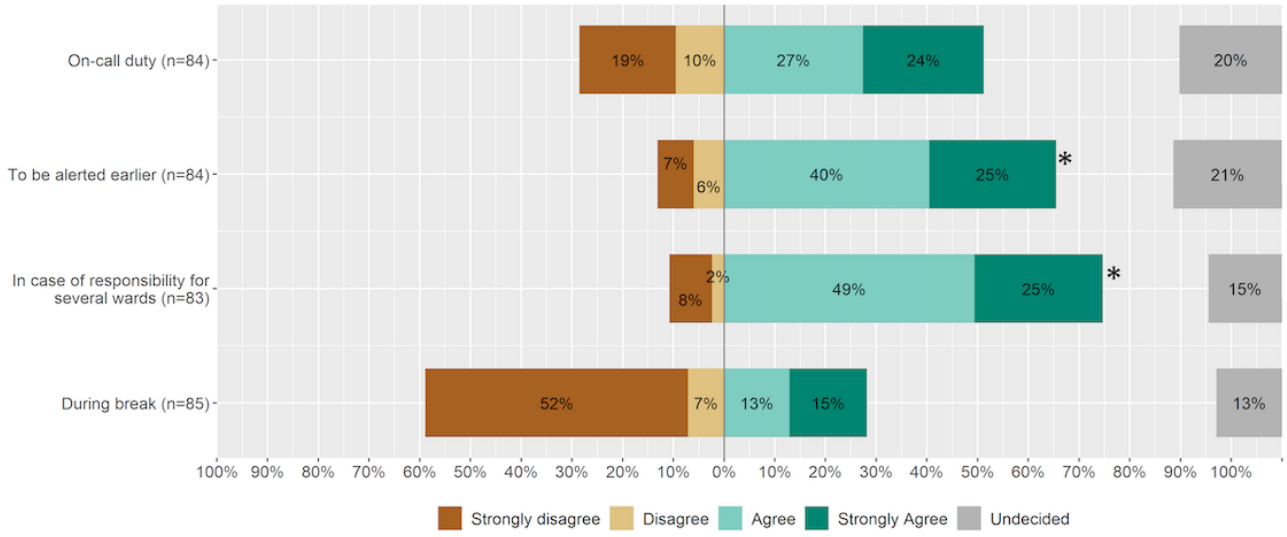
According to the survey results, none of the proposed display devices were desired by ICU staff (Figure 4). The use of smartwatches or augmented reality (AR) glasses in the ICU was rejected by 72% (n=60) and 64% (n=53) of respondents, respectively (those who chose "Strongly disagree" or "Disagree"). 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.

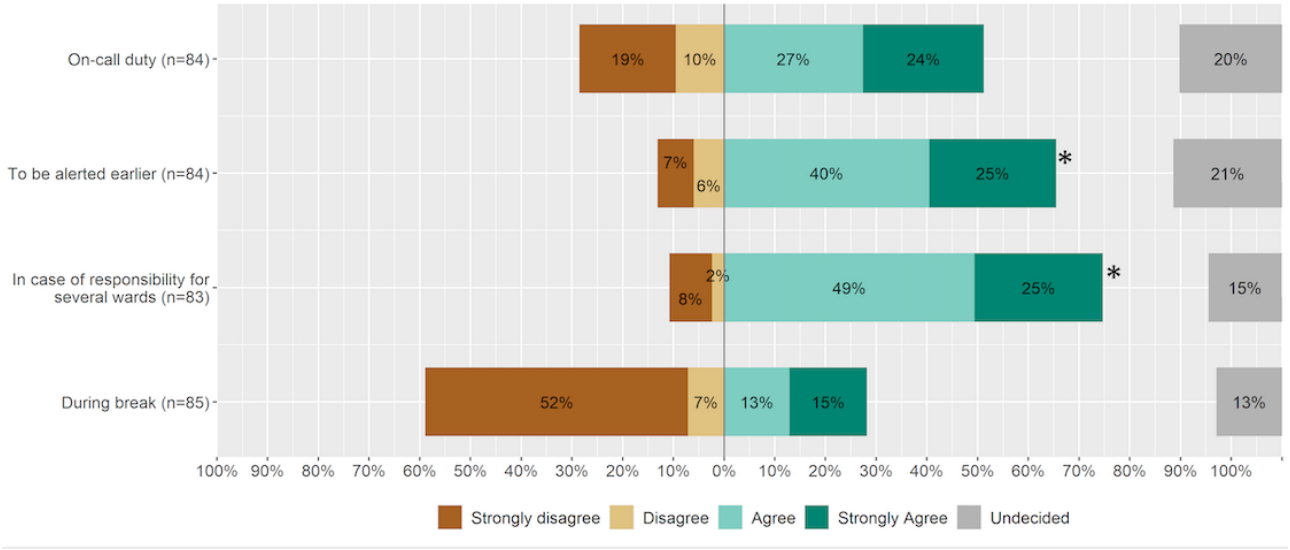
Figure 5. Use cases for remote patient monitoring on hospital premises for intensive care medicine. An asterisk indicates statistical significance.



CDSS

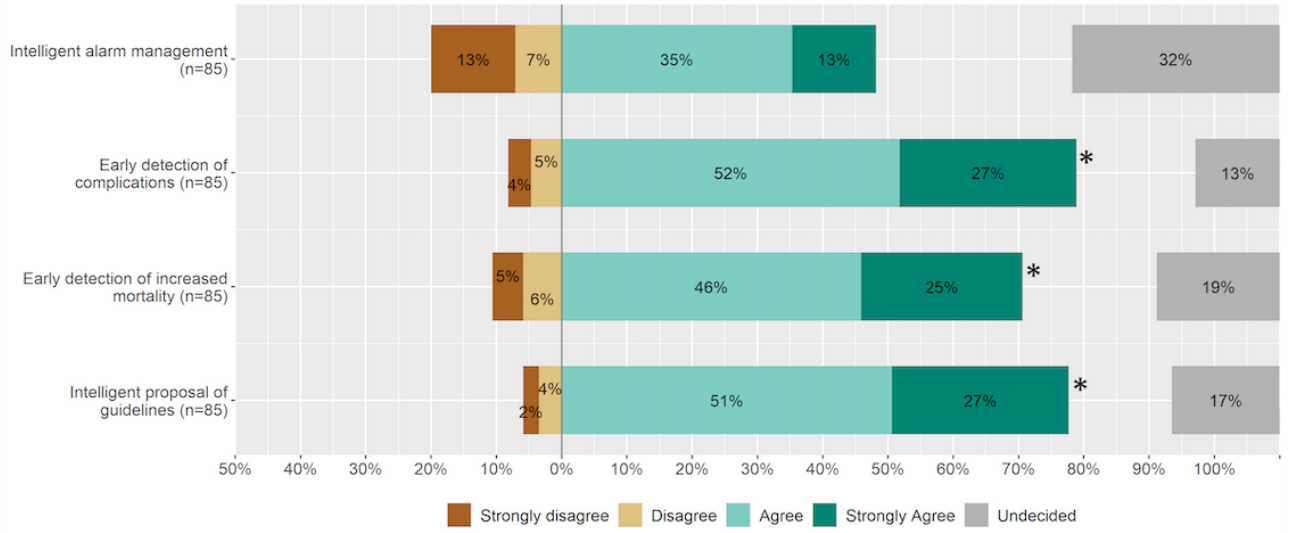
In the future, survey respondents would use a CDSS in the ICU that predicts complications (n=67, 79% chose "Strongly agree" or "Agree") or the risk of mortality of patients (n=60, 71% indicated "Strongly agree" or "Agree") as that intelligently proposes guidelines for therapy and diagnostics (n=66, 78% 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."

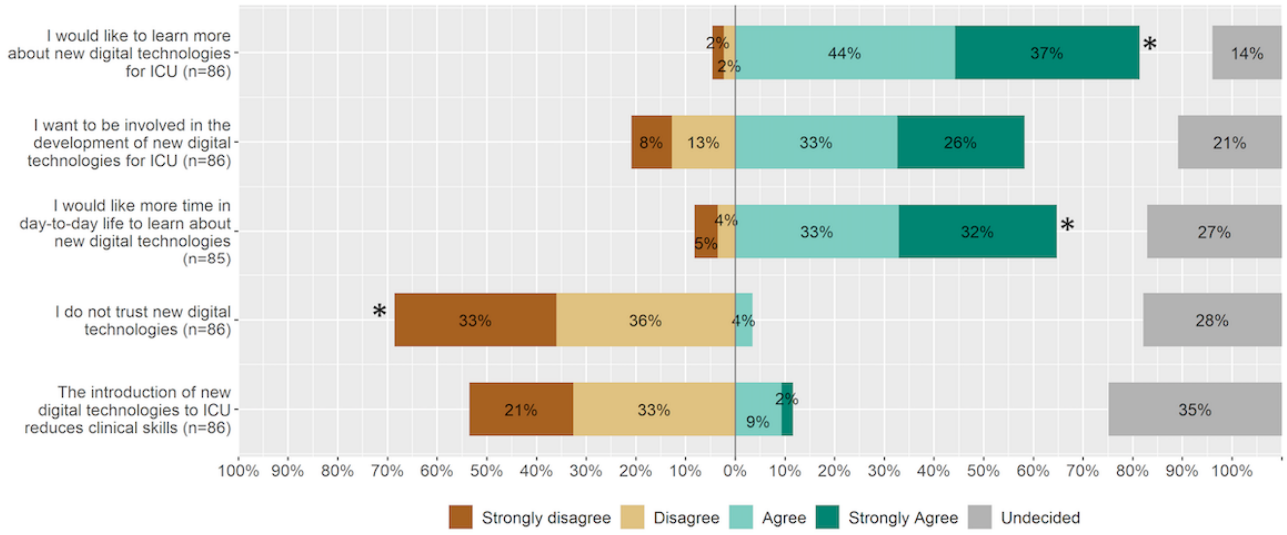
Figure 7. Aspects that promote the usage of clinical decision support systems based on artificial intelligence in the ICU. An asterisk indicates statistical significance. ICU: intensive care unit.



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

We express our gratitude to the ICU staff for their participation in this study. We would further like to thank the German Research Foundation (DFG), the Open Access Publication Funds of the Charité – Universitätsmedizin Berlin, and the Einstein Center Digital Future as well as the Medtronic for providing the aforementioned devices free of charge.

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]

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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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3.3. Originalarbeit 3: Retrospektive Alarm-log Analyse des Patientenmonitorings einer Intensivstation und Entwicklung einer Do-it-yourself-Anleitung für datengestütztes Alarmmanagement zur Reduktion der Alarmlast auf der Intensivstation

Poncette A, Wunderlich MM, Spies C, Heeren P, Vorderwülbecke G, Salgado E, Kastrup M, Feufel MA, Balzer F. Patient Monitoring Alarms in an Intensive Care Unit: Observational Study With Do-It-Yourself Instructions. J Med Internet Res 2021;23(5):e26494

Angelehnt an die nutzerzentrierten Ergebnisse aus der Originalarbeit 1 und 2 wurde in dieser Studie das Alarmmanagement des Patientenmonitoringsystems beleuchtet. Dabei lag der Fokus der Studie darauf, eine vollständige und wiederholbare Analyse der Alarm-Log-Daten des Patientenüberwachungssystems einer ITS zu ermöglichen. Das Ziel bestand darin, eine Do-it-yourself (DIY)-Anleitung für technisch versierte Pflegekräfte und Ärzt:innen zu entwickeln, mithilfe derer sie ihre Alarm-Log-Daten selbst analysieren können. Dies ist ein wesentliches Instrument für die Entwicklung effizienter und effektiver Strategien zur Alarmoptimierung.

Die Beobachtungsstudie wurde mit Alarm-Log-Daten durchgeführt, die im Jahr 2019 aus dem Patientenüberwachungssystem einer chirurgischen ITS mit 21 Betten der Charité – Universitätsmedizin Berlin extrahiert wurden. Die DIY-Anleitung wurde in informellen interdisziplinären Teamsitzungen iterativ entwickelt. Die Datenanalyse basierte auf einem Rahmenwerk aus insgesamt fünf Dimensionen mit jeweils spezifischen Metriken: Alarmlast (z. B. Alarme pro Bett pro Tag), Alarmflut-Situationen, Alarme pro Gerät und pro Kritikalität, vermeidbare Alarme (z. B. die Anzahl der technischen Alarme; Reaktionsfähigkeit), Alarmbehandlung (z. B. Alarmdauer), Sensibilisierung (z. B. Nutzung der Alarmpausenfunktion) und Exposition (z. B. Alarme pro Zimmertyp). Die Ergebnisse wurden mit dem R-Paket ggplot2 visualisiert.

Die entwickelte DIY-Anleitung beinhaltet insgesamt sechs Schritte, die schrittweise und iterativ vom Personal durchgeführt werden sollten. Im ersten Schritt sollten die Alarmlast-Metriken definiert werden, bevor die Alarm-Log-Daten gesammelt und analysiert werden. Im nächsten Schritt sollten intuitive Visualisierungen der Alarmmetriken erstellt und dem Personal präsentiert werden, um Muster in den Daten zu erkennen, damit effektive

Alarmmanagement-Maßnahmen entworfen und schließlich umgesetzt werden können. Das Ergebnis dieser Studie beinhaltet neben der DIY-Anleitung auch die exemplarische Datenanalyse und -visualisierung der Alarm-Log-Daten der o. g. ITS. Zudem wurde das R-Skript für die Datenaufbereitung und eine R-Markdown-Datei zur Verfügung gestellt, um umfassende Alarmberichte zu erstellen. Die Alarmlast auf der jeweiligen ITS wurde mit durchschnittlich 152,50 Alarmen pro Bett pro Tag (SD 42,20) und Alarmflut-Situationen mit durchschnittlich 69,55 pro Tag (SD 31,12) beziffert, die beide überwiegend in den Morgenschichten auftraten. Die meisten Alarme wurden durch das Beatmungsgerät, die invasive Blutdruckmessung und das EKG ausgelöst (hohe Atemfrequenz, hoher und niedriger Blutdruck, niedrige Herzfrequenz). Die Exposition gegenüber Alarmen pro Bett und Tag war in Einzelzimmern höher (26 %, Mittelwert 172,90/137,20 Alarme pro Tag und Bett).

Die Analyse von Alarm-Log-Daten der ITS lieferte wertvolle Einblicke in die Alarmsituationen. Die Ergebnisse bestätigen die Vorarbeiten (Originalarbeit 1 und 2), in denen die subjektive Belastung des Personals durch Alarme festgestellt wurde. Es sind nun dringend Alarmmanagement-Interventionen umzusetzen, die die Anzahl der Alarme effektiv reduziert. Dies ist zum einen wichtig, um die Patientensicherheit zu erhöhen, zum anderen auch, um die Zufriedenheit des intensivmedizinischen Personals zu gewährleisten.

Original Paper

Patient Monitoring Alarms in an Intensive Care Unit: Observational Study With Do-It-Yourself Instructions

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Abstract

Background: As one of the most essential technical components of the intensive care unit (ICU), continuous monitoring of patients' vital parameters has significantly improved patient safety by alerting staff through an alarm when a parameter deviates from the normal range. However, the vast number of alarms regularly overwhelms staff and may induce alarm fatigue, a condition recently exacerbated by COVID-19 and potentially endangering patients.

Objective: This study focused on providing a complete and repeatable analysis of the alarm data of an ICU's patient monitoring system. We aimed to develop do-it-yourself (DIY) instructions for technically versed ICU staff to analyze their monitoring data themselves, which is an essential element for developing efficient and effective alarm optimization strategies.

Methods: This observational study was conducted using alarm log data extracted from the patient monitoring system of a 21-bed surgical ICU in 2019. DIY instructions were iteratively developed in informal interdisciplinary team meetings. The data analysis was grounded in a framework consisting of 5 dimensions, each with specific metrics: alarm load (eg, alarms per bed per day, alarm flood conditions, alarm per device and per criticality), avoidable alarms, (eg, the number of technical alarms), responsiveness and alarm handling (eg alarm duration), sensing (eg, usage of the alarm pause function), and exposure (eg, alarms per room type). Results were visualized using the R package ggplot2 to provide detailed insights into the ICU's alarm situation.

Results: We developed 6 DIY instructions that should be followed iteratively step by step. Alarm load metrics should be (re)defined before alarm log data are collected and analyzed. Intuitive visualizations of the alarm metrics should be created next and presented to staff in order to help identify patterns in the alarm data for designing and implementing effective alarm management interventions. We provide the script we used for the data preparation and an R-Markdown file to create comprehensive alarm reports. The alarm load in the respective ICU was quantified by 152.5 (SD 42.2) alarms per bed per day on average and alarm flood conditions with, on average, 69.55 (SD 31.12) per day that both occurred mostly in the morning shifts. Most alarms were issued by the ventilator, invasive blood pressure device, and electrocardiogram (ie, high and low blood pressure, high respiratory rate, low heart rate). The exposure to alarms per bed per day was higher in single rooms (26%, mean 172.9/137.2 alarms per day per bed).

Conclusions: Analyzing ICU alarm log data provides valuable insights into the current alarm situation. Our results call for alarm management interventions that effectively reduce the number of alarms in order to ensure patient safety and ICU staff's

work satisfaction. We hope our DIY instructions encourage others to follow suit in analyzing and publishing their ICU alarm data.

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KEYWORDS

digital health; patient monitoring; intensive care unit; technological innovation; data science; alarm fatigue; alarm management; patient safety; ICU; alarm system; alarm system quality; medical devices; clinical alarms

Introduction

Background

In intensive care units (ICUs), monitoring of patients' physiologic parameters has significantly improved patient safety by alerting ICU staff through a visual or audible alarm [1] when a parameter deviates from the preset range (eg, apnea, sensor detachment). However, as one of the most digitized health care areas with a rising number of novel devices with their own alarms, the sheer number of alarms regularly overwhelms ICU staff. Some studies document more than 700 alarms per patient per day on average [2].

Being exposed to so many alarms can leave ICU staff alarm fatigued, a condition characterized by a desensitization to alarms, which can make ICU staff react inadequately (eg, responding with delay, turning down the alarm volume, turning alarms off) [3,4]. Due to the COVID-19 pandemic, this condition has been further exacerbated (eg, through the utilization of anesthesia ventilators in the ICU) [5]. Excessive alarms not only induce stress and distraction in ICU staff [6,7] but also directly impair patient recovery [8]. Ultimately, it can threaten patients' lives when ICU staff misses alarms or responds with delay. This is shown by the Joint Commission's sentinel event database, which lists 98 incidents between 2009 and 2012 that were related to alarms, of which 80 resulted in a patient's death [9]. Reporting to the database is voluntary, which likely makes this a conservative estimate. For 2020, the ECRI Institute listed an alarm-related hazard among their Top 10 Health Technology Hazards [10]. While in the United States, the Joint Commission declared it a national patient safety goal to reduce the harm associated with clinical alarm systems from 2014 onwards [11]; there is no such official endeavor in Germany.

One way to reduce harm associated with clinical alarms is alarm management, which aims to reduce the number of unnecessary alarms (that is, false, nonactionable, and avoidable technical alarms [12]) with the assumption that this reduces the overall number of alarms and thereby alleviates the staff's alarm fatigue. Traditional alarm management approaches that have been proven to reduce the overall number of alarms include the recommendation to mute alarms while examining a patient [13], introduce a delay between measuring and alarming [14], use individual thresholds for each patient instead of the monitoring device's default [15], turn off arrhythmia alarms that are not life threatening, and change electrocardiogram (ECG) leads on a daily basis [16].

To be most effective, alarm management should be adjusted to the specific conditions of each ICU [12,17]. A thorough analysis of the sociotechnical system of the ICU is necessary to sufficiently customize respective interventions. These efforts include the analysis of the alarm log data (eg, when an alarm occurred and by which device) [12,18]. Currently there is no software solution commercially available that addresses analysis of patient monitoring data.

Aim

Our aim is to develop do-it-yourself (DIY) instructions targeted at technically versed ICU staff (physicians and nurses) for self-analysis of patient monitoring alarm data, including an illustrative, complete, and repeatable analysis of device alarm data of an ICU's patient monitoring system. The application of the DIY instructions should help their users to identify patterns and trends in the alarm data and enable them to generate ideas on how the overall alarm frequency (and subsequently alarm fatigue) might be reduced.

Methods

Ethics Approval

The ethical approval for this study was granted by the Ethics Commission of the Charité – Universitätsmedizin Berlin (EA1/127/18).

Setting and Design

We conducted the study in a surgical ICU of a German university hospital. The unit consists of 21 beds in 15 rooms in which mainly patients after abdominal or neurosurgical operations are treated. The patient monitoring and alarm system used at the time of the study was the Philips IntelliVue patient monitoring system (MX800 software version M.00.03; MMS X2 software version H.15.41-M.00.04; Philips, Amsterdam, Netherlands) with bedside monitors, 3 client monitors summarizing 2-3 rooms, a central station (software version B), and 2 large hallway monitors displaying all 21 patients. Standard monitoring included oxygen saturation (SpO_2), heart rate, invasive (IBP) or noninvasive blood pressure (NIBP), and temperature. Within the Clinical Alarm Capability Maturity Model by Welch et al [19], the ICU was in the first stage at the time of this study, described as having many nonactionable alarms for unknown reasons, approaching alarm management ad hoc and not having or not consulting data to support change [19]. Accordingly, there was no hospital-wide consensus on alarm management.

We used an observational study design, which included retrospective data analysis of the patient monitoring alarm data. The DIY instructions were iteratively developed in informal interdisciplinary team meetings within the research group between February 2019 and November 2020 and adapted by the lessons learned from our own data analysis.

Data Collection and Deidentification

We manually collected clinical audit logs (which include the alarm data) 3 times during 2019 (in winter, summer, and autumn) via a USB stick from the central patient monitoring device in the ICU as previously described by others. The clinical audit log consists of the time, bed number, alarm type (ie, parameter, device, alarm criticality), and alarm handling (eg, threshold adjustments, use of the pause function). Each log file contains data from 31 days.

No actual patient-identifying data elements were collected. For further deidentification, dates were shifted into the future by a pseudorandom offset for all patients; the bed number was replaced by a pseudonym. Day and night rhythm, weekends, the season, and the bed characteristic (double room, single room) were not affected by this process. The deidentified raw data can be retrieved from an open data repository [20].

Data Analysis Framework

Overview

We organized our data analysis in a framework based on suggestions by Hüske-Kraus et al [12], who introduced quality dimensions along with metrics of an alarm system. Each dimension summarizes multiple metrics (Table 1).

Table 1. Data analysis framework applied in this study in line with the quality dimensions introduced by Hüske-Kraus et al [12] and including metrics suggested by Hüske-Kraus et al [12] as well as metrics suggested by other sources for each dimension, wherever possible.

Quality dimension	Definition	Metrics used in this study
Alarm load	Metrics related to the number of alarms	Alarms per bed per day, frequency of individual alarms, alarms per device, alarms per criticality (red, yellow, and blue; ie, alarm at high criticality, alarm at medium criticality, and technical alarm at low criticality, respectively), average temporal distribution of alarms and alarm flood conditions (10 or more alarms occurring within 10 minutes) [18]
Avoidable alarms	False-positive alarms, nonactionable alarms, and technical alarms	Technical alarms per bed per day, technical alarms per device
Responsiveness and alarm handling	Alarm duration, response time, muting of alarms, and corrective actions	Duration of alarms
Sensing	The quality of the technical infrastructure, such as consumable, overmonitoring, and undermonitoring	Average usage of the alarm pause function per bed per day, proper pause-to-pause ratio [12], redundant monitoring of physiological parameters
Exposure	How alarms are distributed in the unit	Average alarm frequencies per room and per bed per room type, number of beds issuing more alarms than the average

Data Analysis

We cleaned and analyzed the data with R [21] in combination with the packages *dplyr* [22], *tidyr* [23], and *stringr* [24]. We used the package *lubridate* [25] for date and time information and the package *ggplot2* [11] for the visualizations. The log entries were structured in 4 columns: Time, Bedname, Action, Devicename. New variables (eg, the time an alarm was generated and its criticality) were extracted for each log entry from the information contained in the column Action. In total, the alarm logs contain data from 93 days.

Alarm Load

Visualizing the frequency of individual alarm parameters helps to identify "bad actors" — alarms that occur much more frequently than others [8] while investigating the number of alarms each medical device issues — can help to prioritize alarm management interventions. The metric "alarms per bed per day" alone is not necessarily an indicator of the alarm load on respective ICUs and should be accompanied with information such as the criticality of the alarms (red, yellow, blue), the frequency of individual alarms, the frequency of alarms per device, the number of alarm flood conditions, and a temporal perspective. To conduct device-related analyses, we assigned each alarm parameter to 1 out of 7 devices (ventilator, ECG, IBP, intracranial pressure, temperature, NIBP, and pulse oximetry [SpO_2]). Technical alarms included alarms with a blue criticality and general monitoring device–related alarms (such as missing patient information, low batteries, or interrupted arterial blood pressure measurements). Devices, where the absolute cumulative frequency of alarms was less than 500 in the dataset were only included in the overall count of alarms (Multimedia Appendix 1).

To visualize the average distribution of alarms across 24 hours, we calculated the average number of alarms of each 1-minute bin between 12:00 am and 11:59 pm for the 3 devices issuing the most alarms and applied the scatterplot smoothing function of the R package ggplot2 [26].

Alarm flood conditions are described as situations in the ICU where multiple alarms are triggered within a short time frame. Metrics related to alarm flood conditions provide information that allow an additional perspective on the alarm load of an ICU and take an acute overload of ICU staff by alarms into account [18]. We grouped the data per bed and split each bed's data into 10-minute bins starting from the date-time stamp of the first log entry. All bins containing 10 or more alarms were counted as an alarm flood, as previously described [18].

Avoidable Alarms

Avoidable alarms are defined as nonactionable (including false positive alarms) or technical [12]. Since the alarm log data lack information on whether an alarm was true or false or if it was followed by a therapeutic intervention, we cannot provide metrics such as the positive predictive value of alarms. However, most technical alarms, whether they were responded to with an intervention or not, are avoidable nonetheless [12]. Therefore, we report the average number of technical alarms per bed per day as well as the individual frequency of technical alarms.

Responsiveness and Alarm Handling

We visualize the median alarm duration per medical device in absolute seconds and over the course of 24 hours for the 3 devices issuing the most alarms. The duration of an alarm was defined as the time difference between the timestamp of the log entry of a generated alarm and that of a terminated alarm. We opted for this method, because only the "true" time of generated alarms is documented but not the "true" time of terminated alarms, where only the time of the log entry is provided.

Sensing

Using the pause function of the monitoring devices is argued to prevent unnecessary alarms [16,27]. In the investigated ICU, the alarm pause function suspends all alarms for up to 3 minutes or until it is actively terminated by the medical team. This helps prevent alarms that would be triggered when, for example, a patient is being shifted from one position to another during a physical examination. A responsible use of the pause function demands its active termination to avoid undermonitoring of the patient due to the suspended alarms for the remainder of the pause function [12] once the health care provider leaves the patient. Hence, an alarm pause can be considered a proper pause if its duration is shorter than the monitor's default pause duration. The metric "proper pause-to-pause ratio" indicates the ratio of proper pauses to all pauses [12]. We count pauses that were re-enabled within 3 minutes after their termination as one continuous pause, since the default length might not have been sufficient for the bedside procedure.

We consider an overmonitoring of patients to be indicated when parameters that monitor the same physiological event, but stem from 2 different medical devices, are routinely issuing alarms.

Exposure

The present ICU has 2 different room types: a single bedroom and a double bedroom. We aimed to find out whether a bed in a single bedroom produces more, less, or equally as many alarms as a bed in a double bedroom and whether this differs depending on the alarm criticality. In total, there are 12 beds in double bedrooms and 9 beds in single bedrooms. The average alarm frequencies per bed per room type were calculated by dividing the number of alarms per room type by 12 or by 9, respectively.

Results

Overview

The results section is clustered into 2 parts: First, we provide the DIY instructions for self-analysis of alarm data from the patient monitoring system; second, we present the results of the illustrative alarm data analysis conducted on data from our ICU.

DIY Instructions

Step-by-Step Procedure

The DIY instructions for self-analysis of the ICU's patient monitoring alarm data consist of 6 steps: (1) define or re-evaluate metrics, (2) collect data, (3) analyze data, (4) visualize metrics, (5) present to staff and set goals together, and (6) design and implement interventions (see Figure 1).

Figure 1. Feedback loop regarding do-it-yourself (DIY) instructions for self-analysis of patient monitoring alarm data in the intensive care unit.

Define or Re-Evaluate Metrics

In an interdisciplinary team consisting of ICU physicians and nurses, alarm data metrics should be defined. We recommend to initially include all metrics presented in the aforementioned data analysis framework in order to get an accurate and complete picture of the alarm situation of the respective unit. After the first iteration of the feedback loop, new metrics may be added or existing ones modified.

Collect Data

Regular collection of patient monitoring data is crucial to conduct reliable data analyses, especially if interventions are being conducted at the respective ICU. The monitoring central station at our ICU stores data for up to 90 days; hence, every 90 days, data have to be manually extracted from the system [28].

Analyze Data

We provide the fully annotated R scripts that we used to conduct the alarm data analysis to enable even beginners in R to do likewise. Further explanations can be found in the Results section and in the scripts [20].

Visualize Metrics, Present to Staff, and Set Goals

Visualizations should be summarized in a clear and intuitive format (eg, using a presentation program) and discussed with ICU staff. Together, realistic goals should be set for each parameter and possible interventions deduced. On a quarterly basis, this feedback loop should be started from the beginning. The R-Markdown file on GitHub can also be used to create comprehensive alarm reports including all metrics and visualizations reported in this paper [20].

Design and Implement Interventions

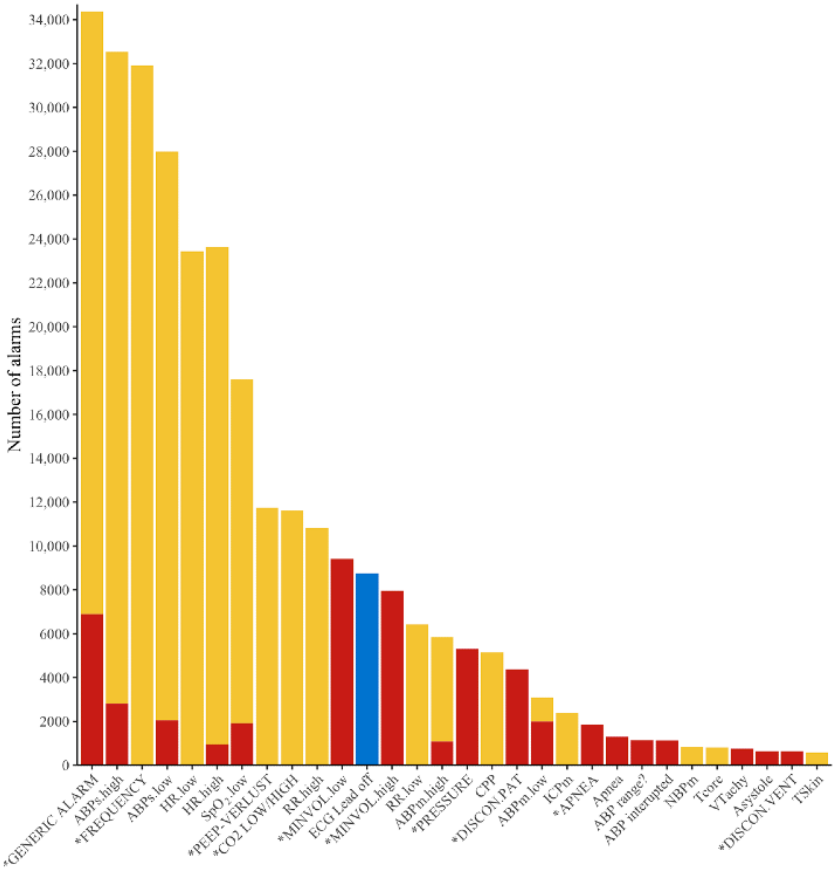
Potential interventions are deduced from the data analysis, the visualizations, and the interdisciplinary goal setting. ICU staff as the end users of the patient monitoring system should be actively involved in the intervention design and rotate regularly with new medical staff from the ICU to assess clinical relevance more reliably. Possible interventions could include adjusting the default alarm thresholds for the top 10 alarm parameters, focusing on customizing these parameters more frequently, introducing new ECG electrodes or skin preparation routines, or providing staff training (eg, on how to use the alarm pause function). Further interventions are elaborated elsewhere [29,30].

Data Analysis

Alarm Load

The analyzed alarm log data set contained, on average, 152.5 (SD 42.2) alarms per bed per day. Most alarms were type yellow (mean 120.3/152.5, SD 37.15 per day; 79%), followed by type red (mean 27.5/152.5, SD 9.37 per day; 18%). Few alarms were type blue (mean 4.6/152.5, SD 2.75 per day; 3%). The 5 most frequent alarms were a generic alarm of the ventilator, invasive systolic blood pressure (high and low), high respiratory rate issued by the ventilator, and low heart rate (see Figure 2).

Figure 2. Frequency of individual alarm parameters within 93 days. The colors correspond to the alarm criticalities (red, yellow, and blue). *: ventilator arm; ABPs: systolic arterial blood pressure; ECG: electrocardiogram; FREQUENCY: ventilator alarm indicating that the upper respiratory rate threshold has been exceeded; HR: heart rate; RR: respiratory rate derived from the ECG (see Multimedia Appendix 2 for all abbreviations).



After each alarm parameter was assigned to the corresponding medical device, it was evident that the ventilator generates the most alarms, followed by IBP and ECG (see Figure 3).

When put into a temporal perspective, the average distribution of alarms across 24 hours for the 3 devices that issue the most alarms shows a downward trend, with most alarms being issued in the morning shift and fewest during the night (see Figure 4). The mean number of alarms per minute per medical device during the morning, afternoon, and night shifts were: 1.09 (SD 0.2), 1.0 (SD 0.18), and 0.71 (SD 0.17) for the ventilator; 0.65 (SD 0.13), 0.56 (SD 0.1), and 0.45 (SD 0.09) for IBP; and 0.57 (SD 0.12), 0.51 (SD 0.1), and 0.45 (SD 0.09) for ECG, respectively.

Figure 3. Alarms from medical devices within 93 days subdivided into the criticality levels (red, yellow). ECG: electrocardiogram; IBP: invasive blood pressure; ICP: intracranial pressure; NIBP: noninvasive blood pressure; SpO_2: oxygen saturation.

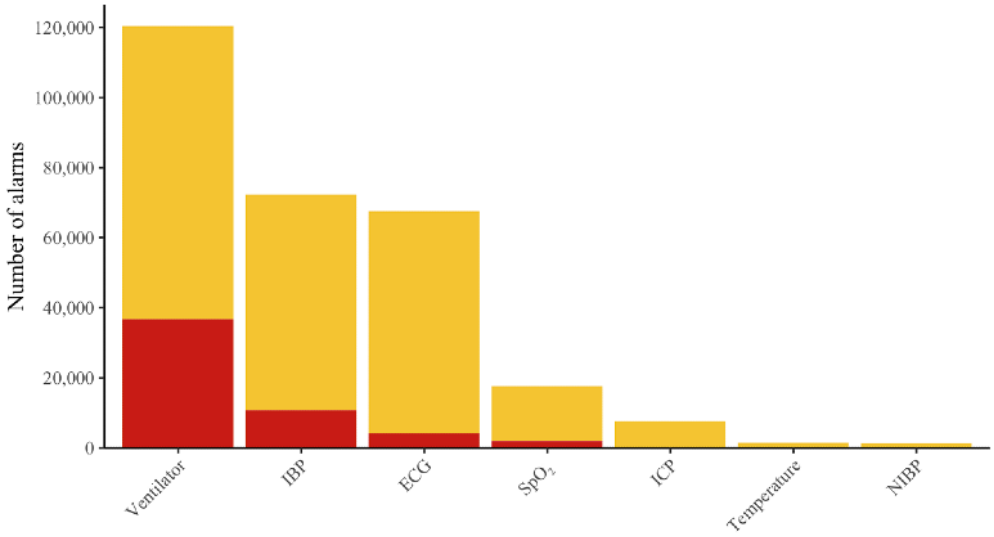
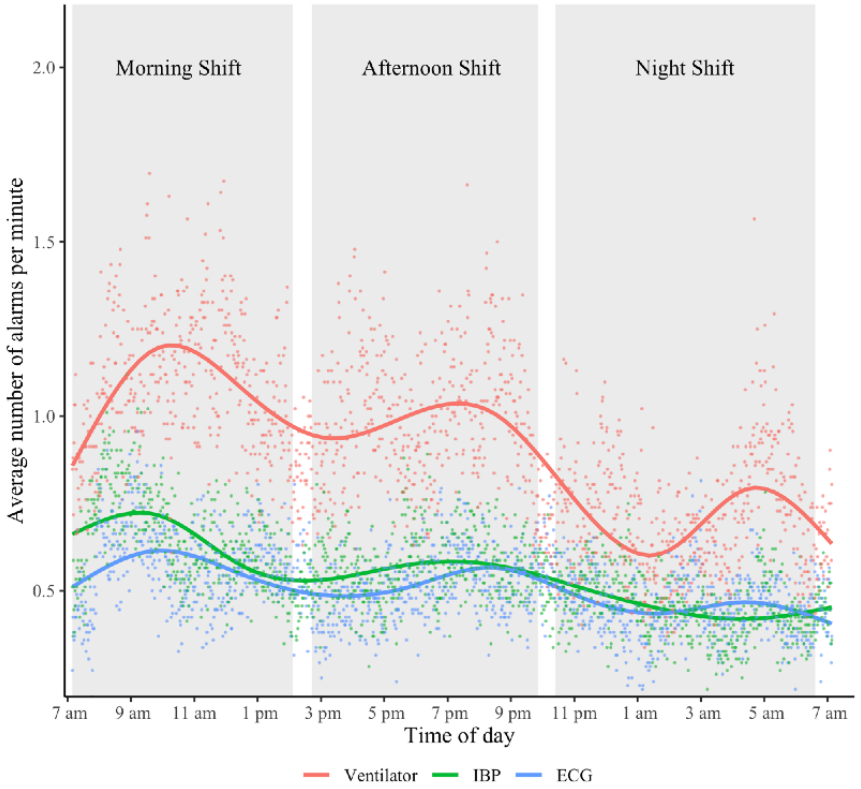
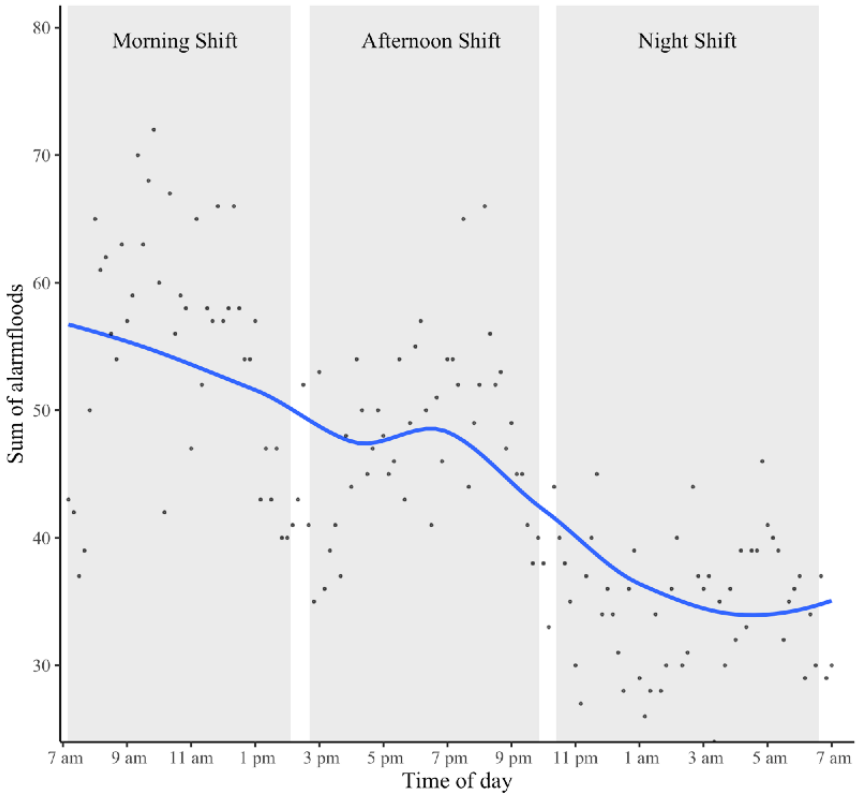


Figure 4. Average distribution of alarms across 24 hours. The white spaces between the grey bars (ie, shifts) visualize handover periods. Each dot shows the average alarm frequency of 1 minute for the specified device. The line for each device is calculated by ggplot2's smoothing function and represents a generalized additive model of the distribution (with the formula y ~ s(x, bs = "cs"). It serves to aid in detecting trends in the data. ECG: electrocardiogram; IBP: invasive blood pressure.



In total, 6468 alarm flood conditions occurred (mean 69.55, SD 31.0 per day; median 63; range 22-194), of which 5289 (82%) were comprised of between 10 and 20 alarms, 1012 (16%) between 20 and 40 alarms, and 159 (2%) between 40 and 100 alarms within 10-minute intervals. The temporal visualization over 24 hours shows a general downward trend with peaks in the morning and afternoon shifts (see Figure 5).

Figure 5. Temporal distribution of alarm flood conditions over 24 hours. Each dot indicates the sum of all alarm flood conditions that were initiated at the respective time of day in 10-minute intervals. For example, the first dot on the far left indicates that 43 alarm floods occurred between 7:10 and 7:20 AM across all days in the data. The blue line is a local regression, calculated by ggplot2's smoothing function (formula: y ~ x). The white spaces between the grey bars (ie, shifts) visualize handover periods.



Avoidable Alarms

In total, 10,846 technical alarms (red, yellow, and blue) are documented. This equals 5.6 (SD 2.8) technical alarms per bed per day, on average. With 8746 alarms (all blue), the ECG produced the most technical alarms (ECG lead fallen off), followed by IBP (1342 red alarms) and alarms related to the module cable connection (167 blue alarms).

Responsiveness and Alarm Handling

The alarm duration showed a distribution that is strongly skewed to the right (for clinical alarms: mean 109.3, SD 6109.15 seconds; median 8 seconds; range 0-2,291,314 seconds; for technical alarms: mean 221.5, SD 4,898 seconds; median 7 seconds; range 0-403,440 seconds), which is why we used the median as the measure of the center for further analyses and plots. Additionally, because some durations were calculated to be unrealistically high (in some instances, multiple days), we treat all durations longer than 8 hours (approximately the length of one shift) as outliers and do not include them in the analyses.

Median alarm durations of yellow and red alarms were similar (8 seconds; range 0-22,048 seconds; range 0-28,531 seconds), while the median alarm duration of blue alarms was slightly longer (9 seconds; range 0-26,049 seconds). Regarding devices, the median duration of alarms by NIBP was the longest (64 seconds; range 0-3845 seconds), followed by temperature (26 seconds; range 0-7796 seconds), SpO_2 (16 seconds; range 0-27,580 seconds), and IBP (14 seconds; range 0-28,531 seconds). ECG and the ventilator recorded the lowest median alarm duration (4 seconds; range 0-27,579 seconds and 7 seconds; range 0-22,048 seconds, respectively). Visualizing the alarm durations over 24 hours shows that the difference across devices was relatively stable over the course of an average day (see Figure 6). However, Figure 7 shows that there were substantial differences between the median duration to red and yellow ECG alarms.

Figure 6. Median alarm duration of the 3 medical devices that issue most alarms over 24 hours. Each dot represents the median alarm duration for each minute of the day of the respective device. The line for each device is based on ggplot2's smoothing function and represents a generalized additive model of the distribution (with the formula y ~ s(x, bs = "cs"). The white spaces between the grey bars (ie, shifts) visualize handover periods. ECG: electrocardiogram; IBP: invasive blood pressure.

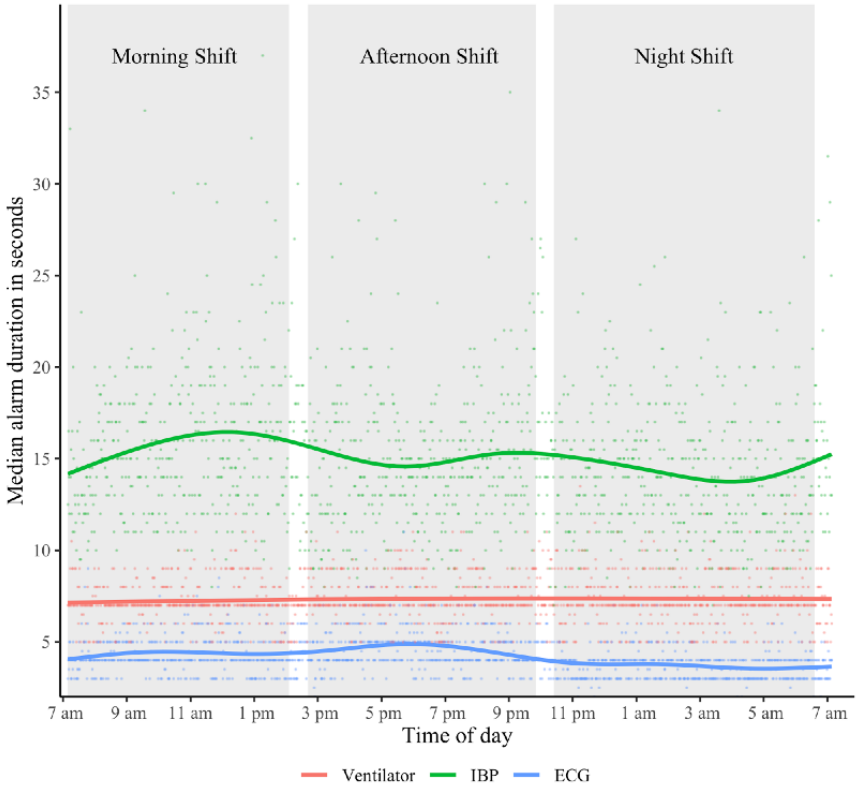
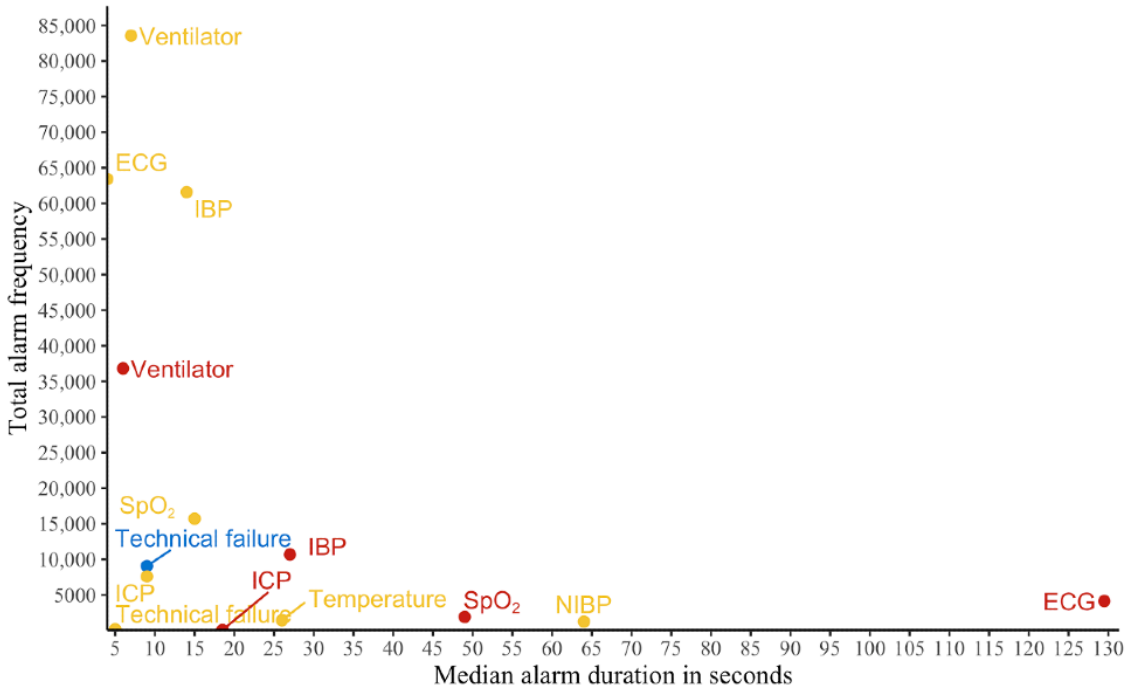


Figure 7. The median alarm duration from 8 medical devices plotted against the total number of alarms issued by the respective device. The colors correspond to the alarm criticalities (red, yellow, and blue). ECG: electrocardiogram; IBP: invasive blood pressure; ICP: intracranial pressure; NIBP: noninvasive blood pressure; SpO_2: oxygen saturation.



Sensing

On average, the alarm pause function was applied 10.86 (SD 2.6) times per bed per day. Of all pauses that were started, 92% (14,719/16,002) were not actively terminated but lasted for their default maximum length of 3 minutes and therefore do not qualify as proper pauses [10]. The ICU's proper pause-to-pause ratio is 0.09:1.

Of the ECG alarms, 16% (10,821/67,518) indicated a high respiratory rate, which amounted to 4% (10,821/297,830) of all alarms recorded in the data set, while the alarms from the ventilator related to a high respiratory rate covered another 11% (31,911/297,830) of all alarms. Additionally, both device groups had similar numbers of life-critical apnea alarms. This suggests an overmonitoring of the respiratory rate.

Exposure

A bed located in a single bedroom had, on average, 26% (172.9/137.2) more alarms per day than a bed located in a double bedroom. There were 32% more red alarms per bed in a single bedroom than in a double bedroom (2972.9/2250.3) and 25% more yellow alarms per bed in a single bedroom than in a double bedroom (12,638.8/10,105.2).

The calculated average alarms per bed per day yields 152.5 alarms (SD 42.2). On average, 36% (7.6/21, SD 1.6) of the 21 beds exceeded the units average every day, issuing on average 69% of all daily alarms (2199.9/3202.4, SD 651.2).

Discussion

Principal Findings

We aimed to provide technically versed ICU staff with a framework and the tools to conduct a self-analysis of patient monitoring alarm data in order to help them assess their unit's alarm situation, inspect potential root causes of excessive alarms, and derive alarm management interventions that might help to remedy alarm fatigue. Our framework consists of 6 steps that should be iteratively applied: (1) define or re-evaluate metrics, (2) collect data, (3) analyze data, (4) visualize metrics, (5) present to staff and set goals together, and (6) design and implement interventions. We designed the framework to be useful independent of the ICU's specialization (eg, COVID-19 units, neonatal ICUs, pediatric ICUs). In our observational study, we illustrated how the alarm log data of a large German ICU can be analyzed and how alarm metrics can be visualized using the scripts that we provide (steps 2 and 3 of the framework, respectively [20]). The data analysis was structured according to the aforementioned quality dimensions [12]: The alarm load was quantified by 152.5 (SD 42.2) alarms per bed per day on average, issued mostly by the ventilator, IBP measurement, and ECG in the morning shifts (ie, high/low blood pressure, high respiratory rate, high/low heart rate). Alarm flood conditions also mostly occurred in the morning shifts with, on average, 69.55 (SD 31.12) per day. With regard to avoidable alarms, technical alarms were mostly issued by the ECG (ie, lead fallen off). The dimension "responsiveness and alarm handling" included the metric "alarm duration." The calculation yielded a median duration of 8 (range 0-2,291,314) seconds for clinical alarms and 7 (range 0-403,440) seconds for technical alarms. Regarding "sensing," the alarm pause function is, on average, applied 10.86 (SD 2.6) times per bed per day, and in 92% (14,719/16,002) was not actively terminated, resulting in a proper pause-to-pause ratio of 0.09:1. The "exposure" to alarms per bed per day was higher in single rooms (26%, mean 172.9/137.2 alarms per day per bed). Most alarms were, on average, issued by 7.6 of 21 beds (36%).

Alarm Metrics in Perspective

Cvach et al [29] suggested that most ICU patients have less than the average number of alarms per bed per day while a few have more than that. In their data analysis of adult telemetry, 19% (n=3) exceeded the unit's average on a single day; in our data analysis, on average, 36% (n=7.6) exceeded the unit's average.

Our data analysis shows that beds located in a single bedroom have a higher alarm load compared to a bed in a double bedroom. Further analysis of alarm data at the patient level could reveal whether the alarm load depends on the severity of the patient's illness. Upon presenting our results to ICU staff, they noted that patients in delirium are often treated in single bedrooms. Since delirium is a condition that can lead to erratic movements [31], this might explain the larger number of alarms coming from single bedrooms (eg, due to disconnected ECG leads). This anecdote highlights the importance of presenting the results of the data analysis to ICU staff, as suggested in Figure 1.

Slow response times can be an indicator of alarm fatigue [32]. However, response times to alarms can be slow for other reasons than alarm fatigue alone, such as the unit's floor layout and policies [17] or the staff members' individual personality traits [33]. Similarly, response times can be fast for other reasons than a well-functioning organization: ICU staff might be so severely desensitized to alarms that they start terminating them blindly, without properly evaluating the patient's situation [12]. Although response time and alarm duration are related, they are not the same. Response time describes the time between the generation of an alarm and its manual termination. Alarm duration describes the time between the generation of an alarm and any termination of that alarm (such as the auto-termination of alarms if an alarm with a higher priority is issued). Our data did not include information on whether an alarm was manually terminated or not, which is why we focused on analyzing the alarm duration.

Although the pause function of the monitoring devices can prevent unnecessary alarms [14,26], it should be used responsibly by terminating it before leaving the patient. Our data yielded a proper pause-to-pause ratio of 0.09:1, meaning that most pauses that were started were not actively terminated but lasted for their default maximum length of 3 minutes. This ratio is far from Hu¨ske-Kraus et al's [12] ideal ratio of 1, where all pauses would be a "proper pause." If it is indeed the case that health care providers leave patients with the alarm pause still engaged, then this aspect should be included in future staff training to promote a responsible use of the alarm pause function. However, other reasons for this pattern in the data should be considered as well. For example, sometimes even the maximum duration of an alarm pause is not long enough (eg, when ICU staff are in the middle of an intervention on the other

side of the bed, unable to reach the patient monitor, watching the pause automatically disengage). Hence, this nonideal proper pause ratio does not necessarily represent carelessness of ICU staff but could hint towards the maximum default length of alarm pauses as being too short.

Limitations

Quantification of the alarms does not reflect whether alarm fatigue is an issue in the respective ICU. In order to evaluate alarm fatigue as a complex sociotechnical phenomenon, the data analysis should be accompanied by a qualitative study (eg, by staff interviews or alarm fatigue surveys) [34]. Our applied grouping of metrics into dimensions is based on available literature, not delimited, and to some extent arbitrary. For example, the "alarm pause" metric could be assigned to the dimension "alarm handling" or the "alarm flood" metric to the dimension "exposure." The software version of our monitoring system does not log technical alarms with a low priority (soft inoperable alarms), and we did not include alarms from every medical device that issues alarms (eg, perfusion pump alarms are not included). Hence, the metrics reported underestimate the actual alarm load of the unit.

Conclusion

We demonstrated that basic data analysis skills can help generate valuable insights for designing alarm management interventions and how alarm data analyses might be embedded in an overarching framework that guides in developing such interventions. We hope the presented DIY instructions and the alarm processing and visualization scripts accompanying this publication will be helpful to other intensivists and researchers and spur the publication of many ICUs' alarm data and lessons learned from their alarm management efforts.

Acknowledgments

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Authors' Contributions

MK identified the need to improve the alarm situation in the ICU and initiated the study together with AP. The study was conceived by AP, CS, FB, MF, and MW. AP conducted data acquisition, supported by ES and GV. MW and AP analyzed the data, supported by PH as a computer scientist. AP wrote the manuscript, supported by MW. FB supervised all parts of the study. All authors critically reviewed and approved the manuscript. The article was extracted from the M.S. thesis of MW.

Conflicts of Interest

CS received public funding from the Stifterverband and the Einsteinstiftung, and received funding from different companies for the Leopolidna Meeting 2020 payed to the Charité - Universitätsmedizin Berlin. All other authors declare no conflicts.

Multimedia Appendix 1

Patient monitoring device group assignments.
[XLSX File (Microsoft Excel File), 11 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Alarm notification abbreviations.
[XLSX File (Microsoft Excel File), 31 KB-Multimedia Appendix 2]

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Abbreviations

DIY: do-it-yourself
ECG: electrocardiogram
ICU: intensive care unit
IBP: invasive blood pressure
NIBP: noninvasive blood pressure
SpO_2: oxygen saturation

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3.4. Originalarbeit 4: Nutzerzentrierte Evaluation der Benutzeroberfläche eines Patientenfernüberwachungssystems für die Intensivstation und Entwicklung eines verbesserten Prototypen mittels Human-centered-Design Ansatz

Poncette A, 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 Hum Factors 2022;9(1):e30655*

In der Originalarbeit 1 wurde durch das intensivmedizinische Personal eine hohe Benutzerfreundlichkeit (Usability) von Patientenmonitoring-Geräten als essenziell eingestuft. Hierbei wurde eine mangelnde Benutzerfreundlichkeit medizinischer Geräte als Barriere für die erfolgreiche Implementierung und als ein sicherheitsrelevantes Defizit identifiziert. Durch eine frühzeitige Einbeziehung des Personals in die Entwicklung neuer Produkte können solche Fehler vermieden werden. Ziel dieser Arbeit war es, mit einem Human-centered Design (HCD)-Ansatz die Benutzerfreundlichkeit einer Benutzeroberfläche (engl. User Interface, UI) eines Patientenfernüberwachungssystems auf der ITS zu evaluieren sowie Design-Änderungen zu konzipieren und zu bewerten.

Die Studie wurde als Mixed-Method Studie zwischen August 2019 und März 2020 im Rahmen der Implementierung eines Patientenfernüberwachungssystems auf einer ITS der Charité – Universitätsmedizin Berlin durchgeführt. Im ersten Schritt wurde das UI des neu eingeführten Patientenfernüberwachungssystems evaluiert. Hierfür wurden simulierte Nutzertests mit Think-Aloud-Protokollen mit Mitarbeiter:innen der ITS (n=5) durchgeführt und die daraus resultierenden qualitativen Daten (Transkripte) mittels deduktivem Ansatz analysiert. Basierend auf den hierdurch identifizierten Usability-Problemen wurden Design-Änderungen konzipiert und angewendet, um einen verbesserten Prototyp der Benutzeroberfläche zu entwickeln. Beim Vergleich der Benutzeroberflächen wurden die wahrgenommene Benutzerfreundlichkeit mit der System-Usability-Skala (SUS), die Leistungseffizienz mit der normativen Pfadabweichung (NPD) und die Effektivität durch Messung der Aufgabenerfüllungsrate (n=5) bewertet. Die Änderungen wurden mit einem t-Test bei zwei Stichproben, einer Poisson-Regression mit einem generalisierten linearen gemischten Modell und einem Chi-Quadrat-Test auf statistische Signifikanz geprüft. P-Werte <0,05 wurden als signifikant bewertet.

Es wurden insgesamt 37 Probleme der Benutzerfreundlichkeit des Patientenfernüberwachungs-UI identifiziert. Diese konnten 6 Subcodes zugeordnet werden: Nützlichkeit des Systems, Antwortzeit, Reaktionsfähigkeit, Bedeutung der Bezeichnungen, Funktion der UI-Elemente und Navigation. Zu den Ideen und Anforderungen der Benutzer:innen an die Benutzeroberfläche gehörten eine hohe Benutzerfreundlichkeit, Anpassbarkeit und die Bereitstellung von akustischen Alarmmeldungen. Es wurden grafische und gestalterische Änderungen vorgeschlagen, um eine bessere Navigation, Informationsdarstellung und räumliche Orientierung zu ermöglichen. Die Benutzeroberfläche wurde überarbeitet, indem ein Prototyp (Design B) mit einem responsiveren Design sowie Änderungen an der Beschriftung und den Elementen der Benutzeroberfläche erstellt wurde. Die statistische Analyse zeigte, dass sich die wahrgenommene Benutzerfreundlichkeit bei dem überarbeiteten Prototyp signifikant verbesserte (SUS Design A: Mittelwert 68,5, SD 11,26, n = 5; Design B: Mittelwert 89, SD 4,87, n = 5; P = 0,003), ebenso die Leistungseffizienz (NPD Design A: Mittelwert 8.8, SD 5.26, n = 5; Design B: Mittelwert 3.2, SD 3.03, n = 5; P = 0,001) und die Effektivität (Design A: 18 Versuche, 7-mal nicht bestanden, 11-mal bestanden; Design B: 20 Versuche, 0-mal nicht bestanden, 20-mal bestanden; P = 0,002).

Mithilfe von Usability-Tests durch Think-Aloud-Protokolle konnte ein Prototyp einer Patientenüberwachungs-UI mit deutlich verbesserter Usability, Performance und Effektivität entwickelt werden. In der klinischen Arbeitsumgebung der ITS kann Technologie mit insuffizienter Benutzerfreundlichkeit zu diversen Nachteilen oder gar Gefährdungen für Personal und Patient:innen führen. Daher sollten technische Geräte in der Intensivmedizin so gestaltet sein, dass sie effiziente und effektive Arbeitsabläufe unterstützen und keine Hindernisse darstellen. Unsere Ergebnisse legen nahe, dass dies durch die Anwendung von HCD-Methoden und -Prinzipien erreicht werden kann.

Original Paper

A Remote Patient-Monitoring System for Intensive Care Medicine: Mixed Methods Human-Centered Design and Usability Evaluation

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Abstract

Background: Continuous monitoring of vital signs is critical for ensuring patient safety in intensive care units (ICUs) and is becoming increasingly relevant in general wards. The effectiveness of health information technologies such as patient-monitoring systems is highly determined by usability, the lack of which can ultimately compromise patient safety. Usability problems can be identified and prevented by involving users (ie, clinicians).

Objective: In this study, we aim to apply a human-centered design approach to evaluate the usability of a remote patient-monitoring system user interface (UI) in the ICU context and conceptualize and evaluate design changes.

Methods: Following institutional review board approval (EA1/031/18), a formative evaluation of the monitoring UI was performed. Simulated use tests with think-aloud protocols were conducted with ICU staff (n=5), and the resulting qualitative data were analyzed using a deductive analytic approach. On the basis of the identified usability problems, we conceptualized informed design changes and applied them to develop an improved prototype of the monitoring UI. Comparing the UIs, we evaluated perceived usability using the System Usability Scale, performance efficiency with the normative path deviation, and effectiveness by measuring the task completion rate (n=5). Measures were tested for statistical significance using a 2-sample *t* test, Poisson regression with a generalized linear mixed-effects model, and the N-1 chi-square test. $P<.05$ were considered significant.

Results: We found 37 individual usability problems specific to monitoring UI, which could be assigned to six subcodes: usefulness of the system, response time, responsiveness, meaning of labels, function of UI elements, and navigation. Among user ideas and requirements for the UI were high usability, customizability, and the provision of audible alarm notifications. Changes in graphics and design were proposed to allow for better navigation, information retrieval, and spatial orientation. The UI was revised by creating a prototype with a more responsive design and changes regarding labeling and UI elements. Statistical analysis showed that perceived usability improved significantly (System Usability Scale design A: mean 68.5, SD 11.26, n=5; design B: mean 89, SD 4.87, n=5; $P=.003$), as did performance efficiency (normative path deviation design A: mean 8.8, SD 5.26, n=5; design B: mean 3.2, SD 3.03, n=5; $P=.001$), and effectiveness (design A: 18 trials, failed 7, 39% times, passed 11, 61% times; design B: 20 trials, failed 0 times, passed 20 times; $P=.002$).

Conclusions: Usability testing with think-aloud protocols led to a patient-monitoring UI with significantly improved usability, performance, and effectiveness. In the ICU work environment, difficult-to-use technology may result in detrimental outcomes

for staff and patients. Technical devices should be designed to support efficient and effective work processes. Our results suggest that this can be achieved by applying basic human-centered design methods and principles.

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

(JMIR Hum Factors 2022;9(1):e30655) doi: 10.2196/30655

KEYWORDS

digital health; patient monitoring; intensive care medicine; intensive care unit; technological innovation; user-centered design; usability; user experience; implementation science; qualitative research; interview; mixed methods; mobile phone

Introduction

Background

Continuous monitoring of vital signs is essential for patient safety in the intensive care unit (ICU) and emergency room [1]. It is also becoming increasingly relevant in general wards [2]. In the past decade, particularly in the context of the digital transformation of health care, vital sign monitoring has undergone constant change and is being transformed and augmented by important technological innovations such as less invasive sensors, remote monitoring technology [3-5], and artificial intelligence for clinical decision support [6,7]. Together, these innovations hold great promise for improving patient safety and health care provision [8,9].

Effective implementation of novel technologies, such as remote patient-monitoring devices, faces a variety of barriers [10-12], including lack of adoption by clinicians, often because of poor usability of the respective technologies [13-15]. In addition to its importance in successful implementation, usability is closely related to the efficacy of the technology [16,17]. A lack of usability may lead to medical errors, thus compromising patient safety [18,19]. Therefore, usability evaluation and identification of specific usability problems are essential in the development of a novel technology and its implementation in the clinical setting. However, to date, usability problems remain prominent in health information technology (IT), suggesting that usability aspects are often neglected in the health IT development process [20-22].

The human-centered design (HCD) approach is centered on the involvement of end users and their experiences with the product throughout the design and development process [23]. Applying HCD in the early stages of the design of novel digital health technologies can improve usability, staff adoption, effectiveness, and efficiency [24,25]. Several frameworks and guidelines for redesigning health care interfaces in accordance with HCD have been published; however, their adoption in health care has been lagging, and evidence on the impact of this topic on clinical performance outcomes is scarce [26-32].

Aim

We aim to evaluate the usability of a remote patient-monitoring system and, specifically, identify usability problems, positive findings, and user ideas. We hypothesize that an HCD approach will help to implement evidence-based design changes that will improve the subjectively perceived usability and objective measures of the effectiveness and efficiency of the technology.

Methods

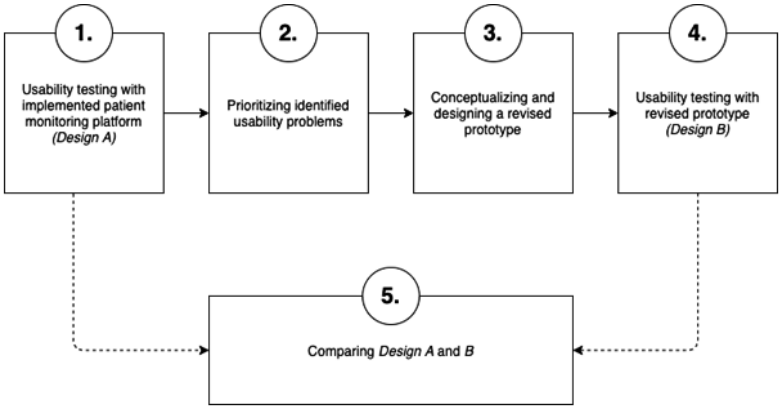
Ethics Approval and Consent to Participate

This study was approved by the ethics committee of the Charité–Universitätsmedizin Berlin (EA1/031/18). All participants provided consent before the study.

Study Design

Our usability study followed a five-step, mixed methods approach (Figure 1): (1) formative usability test of the implemented patient-monitoring platform interface design A [33], (2) identification and prioritization of usability problems, (3) conceptualization and design of prototype interface design B with informed design changes, (4) formative usability testing of design B, and (5) comparison of design A and design B. For usability testing, we applied simulated use tests with think-aloud protocols and performance measurements (subjectively perceived usability, efficiency, and effectiveness) [30,34]. For step 5, we chose a single-factor 2-group study design, as described by Gravetter and Forzano [35].

Figure 1. The research approach, beginning with usability testing and identification of major problems in design A, followed by prototyping of design B and its usability testing, concluding with a comparison between design A and design B.



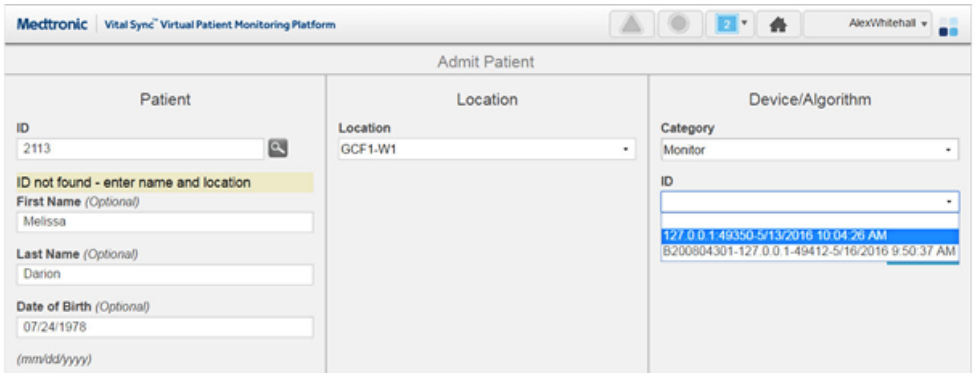
Study Setting and Technical Setup

This study was conducted in the context of implementing the Vital Sync 2.4 virtual patient-monitoring platform (Medtronic plc) in the Post Anesthesia Care Unit, an ICU primarily for postoperative patients requiring short-term intensive care treatment and monitoring. VitalSync was used to monitor patients in the ICU from portable tablet computers on hospital premises. The primary patient-monitoring system used was the IntelliVue patient monitoring system (MX800 software, version M.00.03; MMS X2 software, version H.15.41-M.00.04) from Koninklijke Philips NV.

Between May 2018 and June 2019, the VitalSync monitoring system was installed for 5 of the 10 ICU beds. Two sensors (for pulse oximetry and capnography) recorded peripheral capillary oxygen saturation, pulse rate, end-tidal carbon dioxide, and respiratory rate at a frequency of 1 Hz. The VitalSync user interface (UI) was displayed on a monitor at the central station and on six tablet computers (2 standard iPads, 2 iPad minis, and 2 Microsoft Surfaces). The UI of the system was structured where the home screen gave an overview of patients admitted to the system, displayed in tiles (Figure 2). Displayed were numerical values for the monitoring parameters, the patient's name and bed location, and specific information on alarms if any. Clicking on a patient tile took the user to a screen with details about the selected patient (eg, graphical curves for end-tidal carbon dioxide values) and other functions (eg, displaying patient reports, linking, or unlinking devices). There was also the option of clicking on each parameter to see a trend analysis of that value. To link a patient to the system, the *Admit Patient* screen was accessed, and the patient ID was entered, after which the bed location and monitoring device could be selected to complete the admission process (Figure 3) [36-38]. Further technical description and details regarding the use of the software can be found elsewhere [10].

Figure 2. Home screen of the implemented patient-monitoring platform (design A). etCO2: end-tidal carbon dioxide; PR: pulse rate; RR: respiratory rate; SPO2: peripheral capillary oxygen saturation [36-38].

Figure 3. Admit Patient screen of the implemented patient-monitoring platform (design A) [36-38].



Research Team

Following the principles of HCD [39], our research team members have multidisciplinary skills and perspectives. Specifically, the team included a physician with a background in anesthesiology, intensive care medicine, geriatrics, and digital health (ASP); a senior medical student with a focus on digital health (LM); 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); the anesthesiology department's head of staff (CS); and a professor of medical data science, who is also a consultant anesthesiologist and computer scientist (FB).

Data Collection

Data collection took place from August 23, 2019, to March 10, 2020. Our data comprised think-aloud transcripts of the first block of usability tests (ie, design A), researcher notes (including click patterns), and posttest questionnaires from the two blocks of usability tests (ie, design A and design B). We conducted 10 usability tests with ICU staff—5 (50%) tests each for design A (August and November 2019) and design B (February and March 2020). For recruitment, we contacted potential participants via email. We aimed to represent all professions working with the remote patient-monitoring system, namely anesthesiologists (3/10, 30%), ICU nurses (5/10, 50%), and respiratory therapists (2/10, 20%). Participation was voluntary, and no incentives were offered.

Usability testing of design A and design B was performed on an iPad mini 4 (model A1550). For testing sessions with design A, 5 patients in the ICU were connected to the system. This allowed real-time monitoring of the patients' vital signs on the iPad used by the participants. Testing of design B differed from testing of design A in that no patients were connected to actual sensors, and only one of the researchers was present during the testing sessions.

The testing sessions were conducted in German. Participants were asked about their profession and the number of years of professional experience in intensive care medicine. They were then given 4 tasks to complete while verbalizing their thoughts [40]. We provided the participants with the following use context: "A new patient was admitted to the unit and was connected to the $etCO_2$ and SpO_2 sensors (Mrs. Schmitt, born 01/01/1950, Patient-ID 12345, bed site 02)."

In accordance with the requirements for formative usability testing [41], participants were selected to complete the following key tasks during the simulated use test:

1. "Please add Mrs. Schmitt to the patients you want to monitor in Vital Sync™ ."
2. "You would like to see the trend of Mrs. Schmitt's oxygen saturation for the last two hours. How do you proceed?"
3. "You have identified that Mrs. Schmitt is actually not in bed 2 but in bed 6. You want to adjust this information in Vital Sync™ . How do you proceed?"
4. "Mrs. Schmitt has been discharged. Please disconnect Mrs. Schmitt's devices and delete her entry from Vital Sync™ ."

Audio recordings of the simulated use tests were transcribed verbatim. A researcher who had not performed the transcription reviewed the transcripts. Immediately after the simulated use tests of both designs A and B, participants were asked to complete a posttest questionnaire, including the System Usability Scale (SUS) [42,43].

Data Analysis

Qualitative Analysis and Identification of Usability Problems

To analyze data from the think-aloud transcripts of design A testing sessions, we adapted a deductive analytic approach [44]. A coding scheme introduced by Kushniruk and Patel [44] was refined to the topic of study (patient monitoring in ICUs; Multimedia Appendix 1). Using the qualitative data analysis software MAXQDA 2018 (VERBI GmbH), think-aloud transcripts were coded according to the developed scheme. Coded segments (ie, usability problems) were specified into the subcodes, which were further summarized and listed (eg, meaning of labels unclear).

To decide which problems to eliminate first in the subsequent design iteration, summarized usability problems were ranked in terms of severity and frequency [45,46]. To assess problem severity, impact scores were assigned to each usability problem by 2 physicians who were experienced in intensive care medicine. The following scores were available for selection:

- The solution to this problem is subtle and possible enhancement or suggestion (score 1)
- The problem has a minor effect on usability (score 2)
- The problem creates significant delay and frustration (score 3)

- The problem prevents task completion (score 4)

Subsequently, the probability of occurrence was calculated by dividing the number of participants who encountered a particular problem by the total number of participants. To categorize problem frequency, each usability problem was assigned to one of four frequency levels: frequency ≤10% (level 1), frequency 11% to 50% (level 2), frequency 51% to 89% (level 3), and frequency ≥90% (level 4). Finally, criticality was calculated by adding the impact score and frequency levels [45] (eg, when a usability problem was rated as creating significant delays [impact score 3], which was experienced by 80% of participants [level 3], resulting in a criticality score of 6).

Analysis of Effectiveness, Efficiency, and Subjective Usability

The task completion rate [47,48] was measured to evaluate the effectiveness of design A and design B. Normative path deviation [49] was assessed based on participants' click patterns to account for efficiency. The sequence of steps users took when interacting with the interface to complete a task was compared with an optimal sequence of goal-directed steps defined by the researchers for each task. The difference between the normative path and observed path for each user and each task was calculated using the Levenshtein algorithm [33,49]. The SUS was used to assess the perceived usability of design A and design B [42,43,50].

Prototype Design

Design solutions were conceptualized by ASP and LS for all identified usability problems. This resulted in a list of ranked usability problems with the suggested design solutions. The identified usability problems from design A were revised by building design B, a clickable prototype, using Axure RP 9. A feedback loop was used to develop design B: one researcher (LS) built the prototype, and another researcher (ASP) reviewed the design and provided feedback from an intensivist's perspective.

Statistical Analysis

To assess the level of improvement between design A and design B, we hypothesized that the task completion rate for design B would be higher than that of design A, design B would lead to lower normative path deviation values than design A, and the SUS scores for design B would be higher than that of design A.

We used the N-1 chi-square test to compare the task completion rates of both designs [45]. To compare the normative path deviations for both designs, we used a Poisson regression drawing upon a generalized linear mixed-effects model with participants as random effects, as introduced by Schmettow et al [33]. A 2-sample *t* test was conducted to compare the SUS scores between design A and design B, as recommended by Sauro and Lewis [45]. We tested for normality using the Shapiro–Wilk test [51] and homoscedasticity (homogeneity of variance) using the Levene test [52].

Results

Overview and Sample

Measured by task completion rate, normative path deviation, and SUS score, design B was found to be significantly improved compared with design A. We first elaborate on the results of the qualitative analyses and then report the quantitative results.

The sample comprised a total of 10 ICU staff, aged 25 to 39 years, with work experience ranging from 1 to 20 years, who were divided into groups (5, 50% each) for the evaluation of the 2 designs.

Qualitative Results

Summary

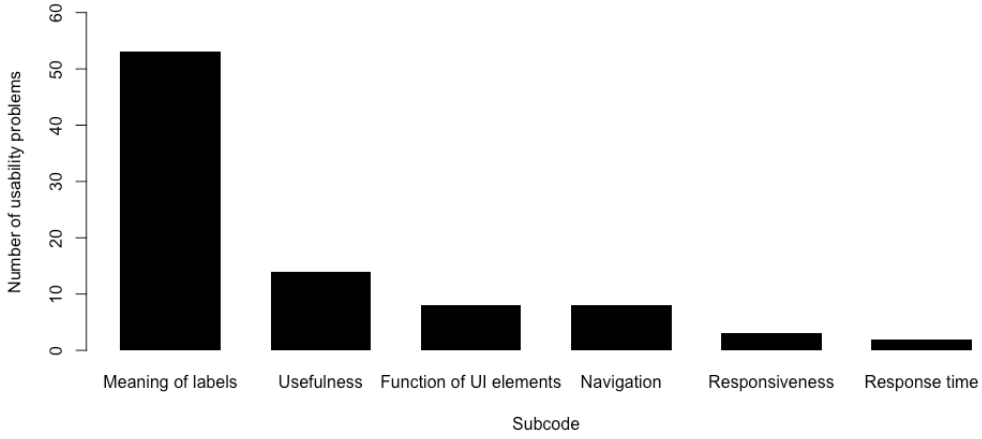
The coding of the transcripts revealed three main codes: usability problems, user ideas and requirements, and positive findings. The codes are visualized with a sunburst diagram (Figure 4; see Multimedia Appendix 1 for the adapted coding scheme by Kushniruk and Patel [44]). Items from the transcripts of the think-aloud protocols were mapped to the subcodes derived by Kushniruk and Patel [44] for the main categories—usability problems and positive findings. For usability problems, the items were assigned to the subcodes of usefulness of the system, response time, responsiveness, meaning of labels, function of UI elements, and navigation; for positive findings, the items were assigned to usefulness, overall ease of use, function of UI elements, layout/screen organization, and color.

Figure 4. Results of qualitative analysis of the think-aloud transcript. Three main codes were identified (inner ring) and subcoded (middle ring). The outer ring represents further information derived from the concrete items that were assigned to the subcodes (ie, specific user ideas or positive findings). UI: user interface.

Usability Problems

In total, 37 specific usability problems were identified (Multimedia Appendix 2). The number of usability problems related to the respective codes is visualized in Figure 5; most issues were related to labeling (53/88, 60%). The meaning of labels was mostly unclear—that is, participants were not familiar with certain terms (eg, the meaning of exclamation marks, abbreviations such as those for pulse rate [PR] and integrated pulmonary index [IPI], or terms such as *polardiagramm*). Users were concerned about whether a certain function was useful for the requirements of their clinical work or when a given task could not be accomplished (eg, participants selected the wrong bed site tile and participants were not sure about the correct patient or device ID; 14/88, 16%). There were difficulties in using or understanding the function of UI elements such as buttons (eg, gray circle or telescope symbols; 8/88, 9%). Furthermore, participants seemed to have problems navigating the monitoring system (ie, finding the right click path to admit patients to the platform; 8/88, 9%). Users criticized the responsiveness of the system (ie, the system did not behave as expected; 3/88, 3%) and the response time (ie, they complained about the time it took the device to respond; 2/88, 2%).

Figure 5. Number of occurrences for each subcode of usability problems. Meaning of labels (n=53), usefulness (n=14), function of UI elements (n=8), navigation (n=8), responsiveness (n=3), response time (n=2). UI: user interface.



User Ideas and Requirements

Users emphasized that the system's ease of use was particularly important to ensure its usability in emergency situations. The tool should be customizable to add other relevant vital signs (eg, intracranial pressure) or to display additional patient information. Participants required audible alarm notifications and the ability to share information regarding relevant patient events with colleagues (eg, about critical patient conditions). Vector graphics were suggested to allow zooming in and out of the vital sign curves. Moreover, participants demanded the ability to see curves of different parameters in an overlapping representation to be able to make inferences from one vital parameter to another. To facilitate spatial orientation, it was suggested that the beds be displayed in the UI according to the physical ward floor plan. Other ideas included adding a drag-and-drop function to rearrange multiple beds at once in the UI and integrating a high-frequency recording function to capture critical events.

Positive Findings

Participants stated that the system's scope of functionality was limited compared with other monitoring solutions. However, the reduced complexity was considered helpful in hospital wards with high patient turnover or stressful environments to get a quick overview of the patient's health condition. The system's mobility and overall ease of use were perceived as positive. Participants seemed to be familiar with the following basic UI elements: the home button depicted by a house, the editing symbol depicted by a pen, and the alarm symbol depicted by a warning triangle. Simplicity in the design and use of color was also rated as positive.

Design Iteration

The 37 distinct usability problems were ranked in relation to severity and frequency of occurrence (Multimedia Appendix 2). Potential solutions were assigned to the problems and were realized in design B (Figures 6 and 7). In total, 5 design iterations were performed between ASP and LS.

The main improvements in the prototype version compared with the previous interface were as follows:

- More responsive design
- Unknown labels were replaced or removed
- Unknown UI elements were replaced or removed
- A dashboard that counted beds, patients, and monitoring systems was added
- A confirmation dialog before replacing bed numbers was added
- State-of-the-art dark theme design was adapted from material.io

Figure 6. Redesign of the user interface of the prototype (design B) patient admission screen.

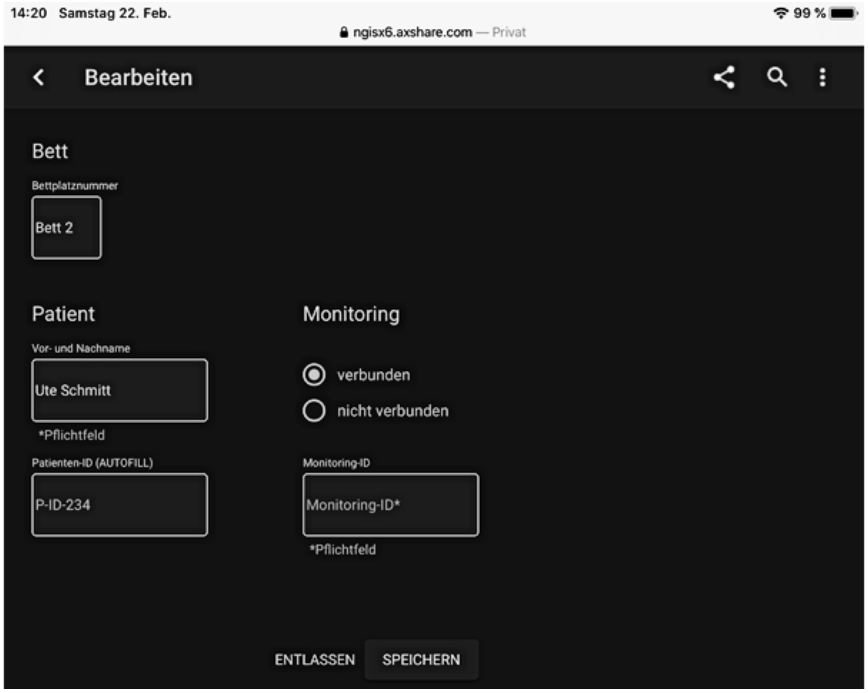
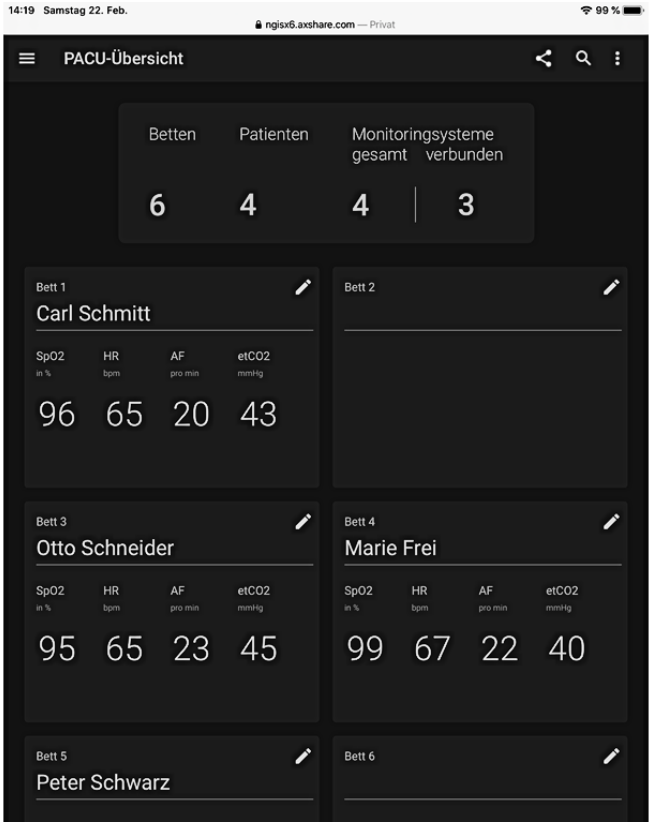


Figure 7. Redesign of the user interface of the prototype (design B) patient tile overview.



Quantitative Results

Effectiveness

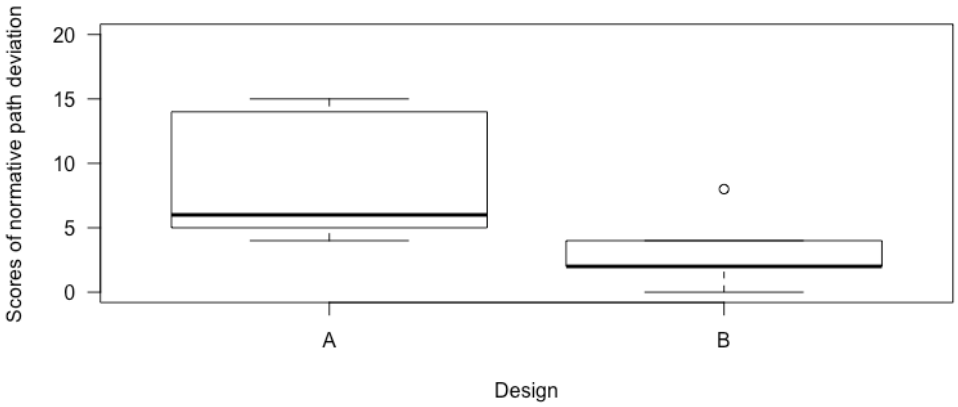
The task completion rate was higher for design B (attempts=20; 0/20, 0% failed and 20/20, 100% passed) than for design A (attempts=18; 7/18, 39% failed and 11/18, 61% passed). A 1-tailed N-1 chi-square test suggests that this is a statistically significant difference (χ^2_1=9.3; *P*=.002).

Efficiency

The average normative path deviation of design B (mean 3.2, SD 3.03; 5/10, 50%) was 63.4% lower than that of design A (mean 8.8, SD 5.26; 5/10, 50%; Figure 8). Poisson mixed-effects regression suggests that this reduction in the normative path

deviation is statistically significant ($\beta_{design\ B}$=−1.04, 95% CI −2.09 to −0.13; exp [$\beta_{design\ B}$]=1.13; *P*<.001).

Figure 8. Scores of normative path deviation for design A and design B. The circle symbolizes outliers. Outliers are defined in the box plots as values that have 1.5 times the distance between Q1 and Q3 (Q1 is the lower line of the box, and Q3 is the upper line of the box).



Usability

The average SUS score of design B (mean 89, SD 4.87; 5/10, 50%) was higher than that of design A (mean 68.50, SD 11.26; 5/10, 50%). This difference was statistically significant with a 1-tailed *t* test (t_8=3735; *P*=.003).

Discussion

Principal Findings

This study evaluated the usability of a remote patient-monitoring system (design A) by identifying the individual usability problems that informed the conceptualization and design of a revised prototype version (design B). Most of the usability problems identified were related to labeling, followed by the perceived lack of usefulness of the monitoring system [10,53,54]. The UI's navigation was frequently criticized by participants. Further identified usability problems include unclear UI elements, poor responsiveness, and increased response time. The resolution of the usability problems resulted in a significant increase in the perceived usability, efficiency, and effectiveness of the system.

Usability of Technologies in Intensive Care Medicine

Over the past 2 decades, the usability of health IT has been investigated in multiple studies applying different methodologies, revealing relatively poor usability and late involvement of end users in the development process [22,55]. This is reflected in our results; based on an HCD approach, we found a relatively high number of easy-to-solve usability problems, the resolution of which led to a significant improvement in the usability of the remote patient-monitoring solution. Most of the usability problems identified were related to labeling, an important issue that is addressed by regulatory requirements [30,56]. The UI's navigation was frequently criticized by participants. UI navigation problems can affect the overall usability of medical devices, especially in high-stress situations [57-59]. In this regard, simple, intuitive, and role-specific designs are beneficial [60-62], which is also reflected in the user ideas generated by the participants in our study.

The ICU is an exceptional environment that places diverse demands on health IT to be used there. High stress levels and patients who are unstable and critically ill, with varying care and treatment requirements, are among the conditions that must be considered [63-67]. Multiple digital devices already in place increase the cognitive load on staff as they are required to operate the devices and interpret their output [62,67]. Health care professionals applying physiological monitoring systems underuse the range of features currently available [28]. This might also be because of inadequate digital skills among health professionals and insufficient training of staff in the use of digital technologies [68-72].

With the increasing complexity and expanding the functionality of digital technologies and their increased use in all clinical settings, usability considerations have become all the more important to realize the full potential of such innovations. Given our findings, we suggest that HCD plays an important role in realizing the potential of IT in health care.

HCD in the Implementation of Digital Health Technology

Applying an HCD approach, the inclusion of usability testing and prototyping of a new UI for a remote patient-monitoring system increased usability, according to our findings. HCD encompasses the involvement of end users (ie, health care professionals) in the design and evaluation process, and the required efforts have been shown to be both worthwhile and beneficial in all development phases of a novel digital health technology, enhancing usability and performance [28,59,73]. Research suggests that user knowledge and beliefs about the technology to be implemented are key factors for the successful implementation of the technology [74]. Therefore, HCD should be applied not only during the design and development processes but also during implementation [55]. This could be achieved by establishing innovation and usability laboratories in universities and maximum care hospitals [75]. In the future, HCD is likely to be indispensable for improving both the performance and implementation of IT in health care.

Despite many publications demonstrating the benefits and relevance of usability testing and HCD in health care, there still seems to be a lack of awareness of its importance and the value

of involving key users in the early stages of technology development. The reasons for this may be the perceived costs and frequent lack of incentives to conduct usability evaluations. Moreover, as was the case in our study, the design and implementation of health technologies are often separate processes, making it difficult to apply an HCD approach across all development and implementation phases [22,73]. Further research needs to be conducted to explore how to overcome these barriers to obtain the most out of IT products in health care for both staff and patients.

Limitations

In this study, we showcase an HCD approach to improve the usability of a remote patient-monitoring system in a hospital setting. However, from a scientific perspective, there are several limitations to the scope of the study and the interpretation of results. Owing to the qualitative research design, it is not possible to quantify or generalize the usability problems identified to other health technologies and settings. In addition, translation of our results to other hospital settings or countries is limited because of the single-center design of this study and the relatively small sample size. It was not possible to draw samples randomly, which needs to be considered as a potential source of bias when interpreting the results. The comparison between design A, which was a working medical product installed in the ICU, and design B, a prototype mock-up, may be potentially unfair with a number of confounders in the 2 arms. Nonetheless, given the observed effects of meaningful labeling and easy-to-understand UIs on efficiency and effectiveness, our results help to underline the importance and potential of HCD for realizing the potential of IT in health care. Follow-up studies should be envisioned in collaboration with medical device manufacturers using design B.

We did not perform a usability test of all features of the remote patient-monitoring device, which comprises more than just the remote monitoring device UI (eg, sensors, bedside monitors, or cables are also part of it). We focused on tablet use for this study as it distinguishes remote patient monitoring from regular patient monitoring, and the tablet is the touchpoint with which the user interacts most frequently. Thus, we restricted the study scope to the UI of the tablet version of the remote monitoring system; that is, the smartphone and desktop UI versions were not investigated. We only tested the German version of the UI, which limits certain findings (eg, regarding the labeling) to German-speaking regions.

We were not able to refer to a standardized checklist or protocol for reporting the results of this study. The development of such a checklist or protocol could be an interesting area for further research, as it could improve the quality and reproducibility of usability study reports.

Conclusions

Applying an HCD approach with usability testing and conceptualized design of a revised prototype version significantly improved the usability of the remote patient-monitoring system for the end points of perceived ease of use, efficiency, and effectiveness. Technical devices should be designed to support efficient and effective work processes, especially in the sensitive working environment of the ICU, with usability being an essential facilitator of maximum performance, successful implementation, and ultimately patient safety. Our results suggest that HCD methods and principles can help realize the goals and potential of IT in health care. However, currently, HCD methods are often not applied early enough in the development process of digital health technologies for ICUs. Further research should explore how to increase early product evaluations in hospitals with end users to take better advantage of their input, not only for the development of user-friendly IT solutions but also for their successful implementation in clinical settings.

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, FB, and LKM. LS, ASP, and LKM conducted data acquisition and analysis. ASP and LKM wrote the manuscript, supported by LS. MAF supported the design of the study, conception of methodology, and interpretation of results. FB supervised all parts of the study. All authors critically reviewed and approved the manuscript. The paper was extracted from the MS thesis of LS.

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

Coding scheme adapted from Kushniruk and Patel [44].
[PNG File , 55 KB-Multimedia Appendix 1]

Multimedia Appendix 2

Usability ranking.
[XLSX File (Microsoft Excel File), 24 KB-Multimedia Appendix 2]

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Abbreviations

HCD: human-centered design
ICU: intensive care unit
IT: information technology
SUS: System Usability Scale
UI: user interface

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3.5. Originalarbeit 5: Nutzerzentrierte Entwicklung eines Implementierungsleitfadens für die nachhaltige Einführung und Anwendung digitaler Gesundheitstechnologien in der Intensivmedizin

Mosch LK, Poncette A*, 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 Form Res 2022;6(4):e22866*

Die Einführung neuartiger Technologien in die intensivmedizinische Routine – von Patientenfernüberwachungstechniken bis hin zu KI-gesteuerten klinischen Entscheidungsunterstützungssystemen – können die Patientenversorgung verbessern. Jedoch gibt es kaum umfassende Evidenz und Richtlinien für eine erfolgreiche Implementierung digitaler Gesundheitstechnologien auf einer ITS. Aufbauend auf den vorherigen Arbeiten war es das Ziel, im Rahmen der Implementierung eines Patientenfernüberwachungssystems auf der ITS einen Leitfaden für die Implementierung digitaler Gesundheitstechnologien auf der ITS zu entwickeln.

Die Studie wurde von Mai 2018 bis März 2020 auf einer ITS der Charité – Universitätsmedizin Berlin im Rahmen der Implementierung eines Patientenfernüberwachungssystems als ergänzendes Monitoring durchgeführt. Einem hybriden qualitativen Ansatz mit induktiven und deduktiven Elementen folgend, nutzten wir das Consolidated Framework for Implementation Research (CFIR) und die Expert Recommendations for Implementing Change (ERIC), um die Transkripte von sieben semi-strukturierten Interviews mit klinischem Personal sowie deskriptive Fragebogenergebnisse zu analysieren. Die Ergebnisse der qualitativen Analyse bildeten zusammen mit den Erkenntnissen aus informellen Treffen, Feldbeobachtungen und vorangegangenen Explorationen die Grundlage für den Leitfaden.

Die Studie zeigte im Ergebnis einen unzureichenden Implementierungsprozess aufgrund des geringen wahrgenommenen Nutzens des Patientenfernüberwachungssystems sowie einer mangelnden Involvierung der klinischen Mitarbeitenden. Als weiteres Implementierungshindernis wurde die hohe Personal- und Patientenfluktuation genannt. Der Implementierungsleitfaden umfasst Strategien, die vor und während der Implementierung anzuwenden sind: Einbeziehung aller Beteiligten auf der ITS, Bewertung inwiefern die zu implementierende Technologie der spezifischen ITS angepasst werden kann, Unterstützung

des Implementierungsprozesses (z. B. regelmäßige Einweisungen und Übungen) und die Entwicklung einer Feedback-Kultur. Die Etablierung einer Implementierungseinheit unter Einbeziehung von Implementierungsexpert:innen und vorhandenen institutionellen Kapazitäten könnte den Implementierungsprozess weiter verbessern.

Einer Implementierung neuartiger Technologien auf der ITS sollte eine gründliche Bewertung des Innovationsbedarfs und der Veränderungsbereitschaft vorangestellt werden. Dies gelingt durch Einbindung aller Stakeholder der ITS, transparente Kommunikation über die Ziele und kontinuierliches Feedback in einer gemeinschaftlichen Atmosphäre, wobei die Führungsrollen im Rahmen der Implementierung klar definiert sein müssen. Der entwickelte Leitfaden kann andere Intensivstationen mit konkreten, evidenzbasierten und schrittweisen Empfehlungen in der Implementierungspraxis unterstützen und damit die Einführung von neuartigen Technologien auf der ITS fördern.

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.

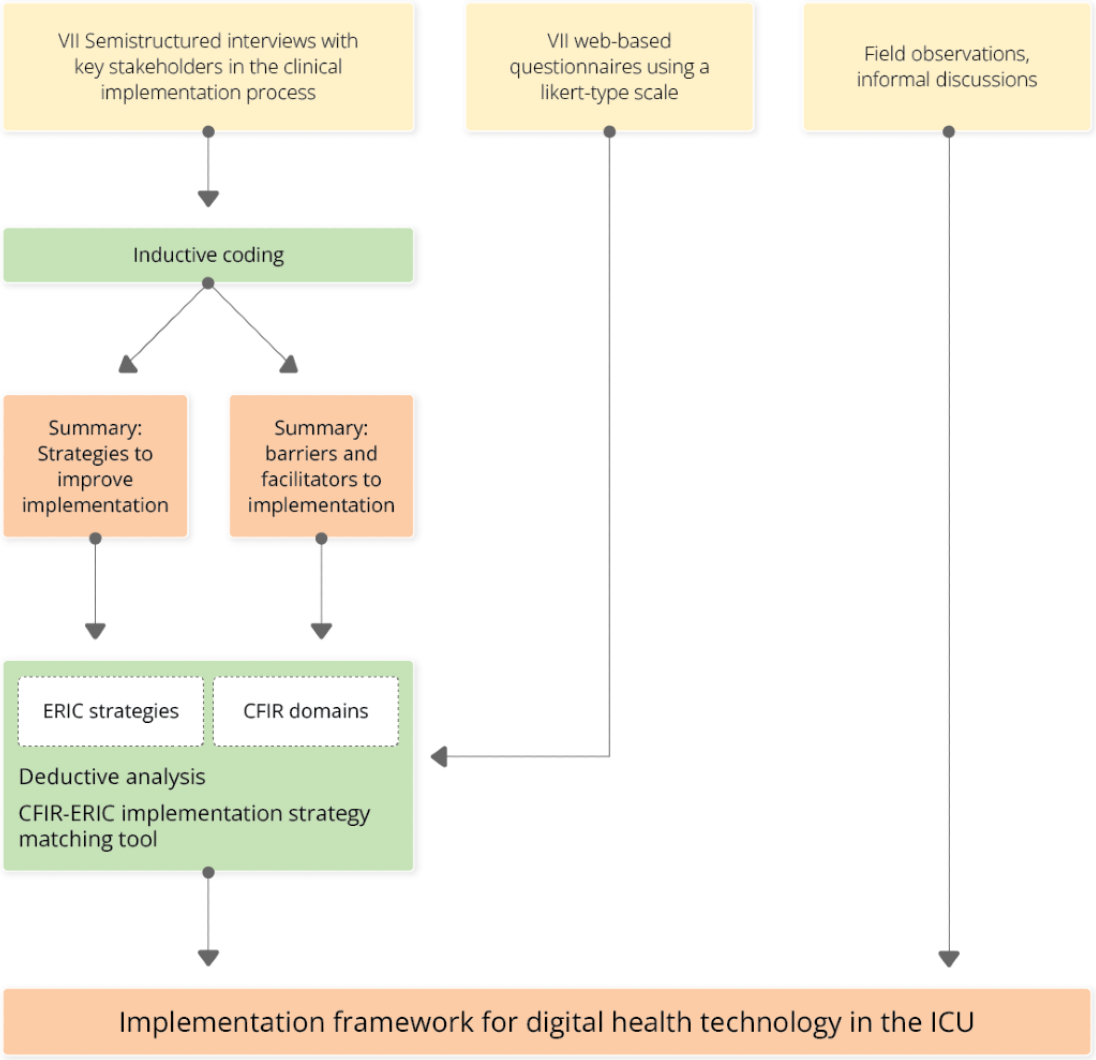
The remote monitoring system was installed between May 2018 and June 2019 in 50% (5/10) of the beds of the postanesthesia care unit, an ICU mainly for postoperative patients that need short-term intensive care treatment and monitoring. The system included 2 sensors (the pulse oximetry and the capnography) 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.

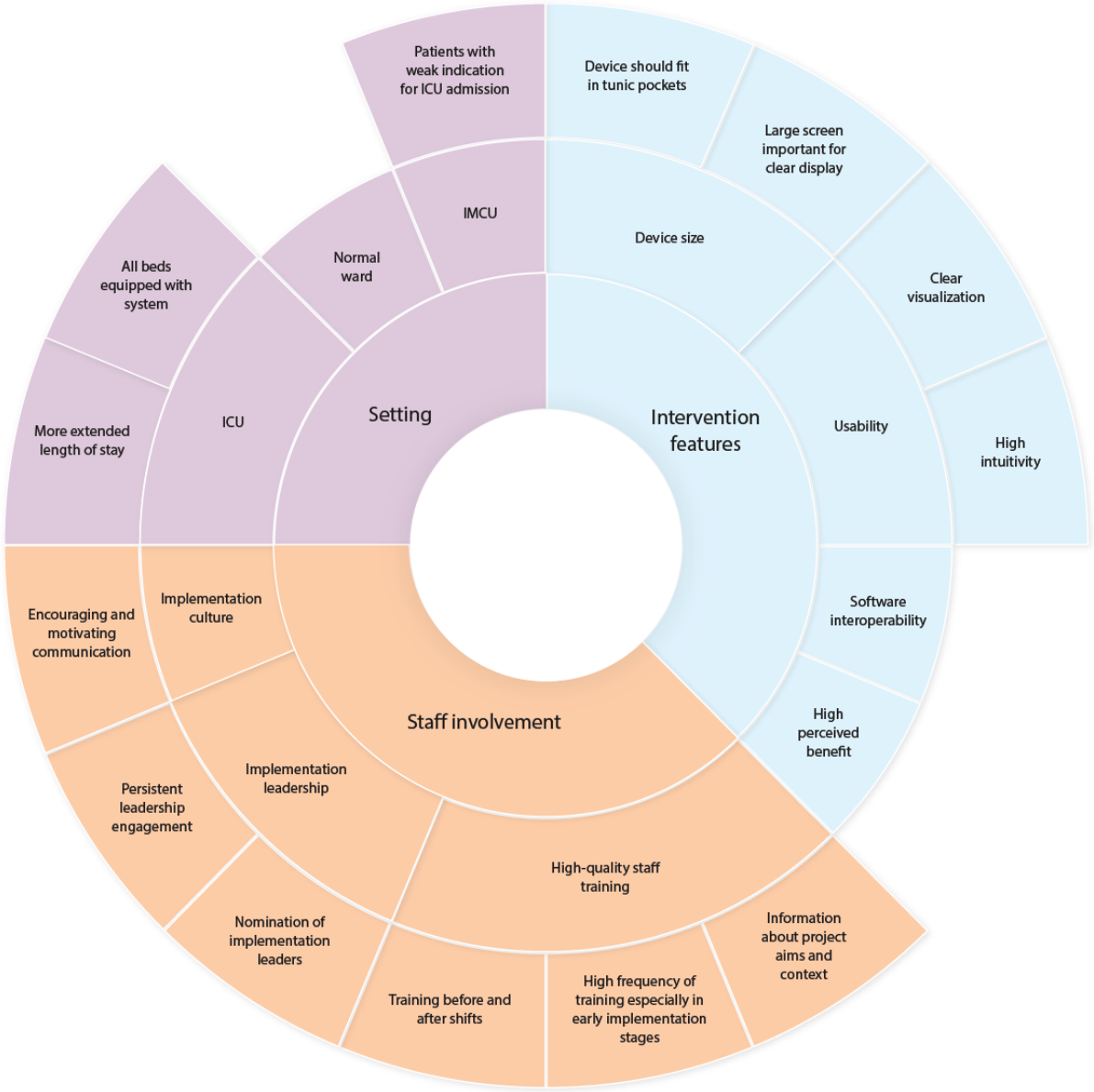
Setting

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

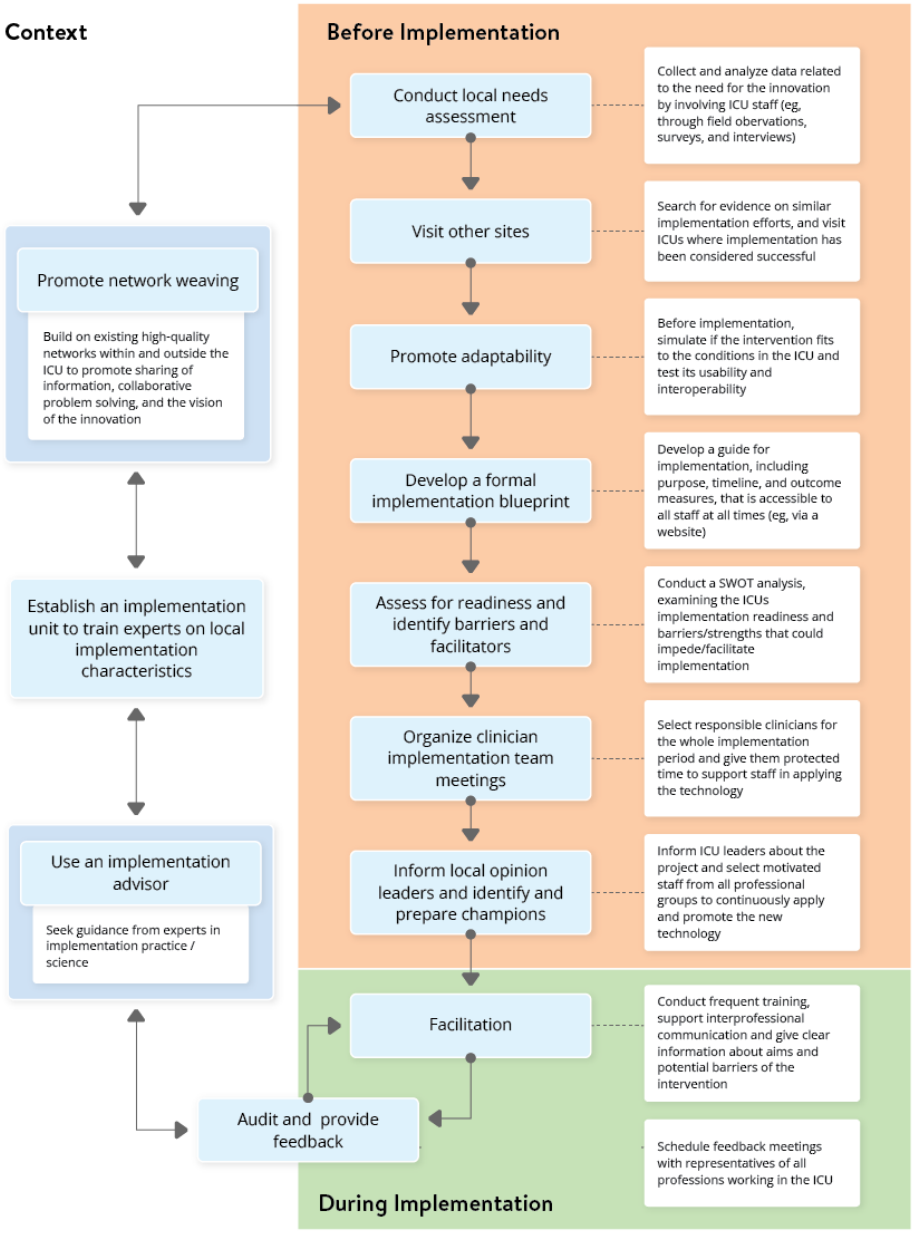
Change infrastructure

- 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 e*stablish 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.

Acknowledgments

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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]

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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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4. Diskussion

In dieser Habilitationsschrift wurde das aktuelle Patientenmonitoringsystem auf der ITS auf potentiell sicherheitsrelevante Aspekte untersucht und Maßnahmen zur Steigerung der Patientensicherheit entwickelt. Durch einen induktiven nutzerzentrierten Ansatz wurden in Originalarbeit 1 diverse Maßnahmen identifiziert, die die Patientensicherheit erhöhen können. Folgende Maßnahmen wurden anschließend in der Originalarbeit 2 durch eine quantitative Befragung des ITS-Personals validiert:

- Reduktion der falsch positiven Alarme,
- Implementierung eines krankenhausweiten Alarmmanagement-Standards,
- Einführung von kabellosen Sensoren,
- Einführung von KI-augmentierten klinischen Entscheidungssystemen mit einer hohen Benutzerfreundlichkeit und Interoperabilität sowie
- Erhöhung der digitalen Kompetenz des Personals.

Zur Verbesserung der Alarmsituation wurde in Orginalarbeit 3 ein datengestützter Ansatz des Alarmmanagements vorgestellt, womit die Alarmlast auf einer ITS gezielt reduziert und der Einfluss von Interventionen gemessen werden kann. Eine Folgestudie wurde kürzlich gestartet, um diese Erkenntnisse in die klinische Routine umzusetzen. In Bezug auf die Benutzerfreundlichkeit von Systemen wurde in Originalarbeit 4 gezeigt, wie durch die partizipative Einbeziehung des ITS-Personals mittels Think-Aloud-Protokollen die Benutzerfreundlichkeit einer Softwareoberfläche eines Patientenfernüberwachungssystems verbessert werden kann. Dies sollte auch bei der Implementierung zukünftiger Technologien von großer Relevanz sein und standardmäßig von einer zentralen Stelle innerhalb des Krankenhausbetriebs übernommen werden. In der Originalarbeit 5 wurde schließlich ein Leitfaden entwickelt, der es ermöglichen soll, neuartige Technologien erfolgreicher und nachhaltiger in die Intensivmedizin zu implementieren. Hierbei liegt der Fokus auf der partizipativen Gestaltung der Implementierung der neuen Technologie in die Krankenhausroutine, welche von einer dezidierten klinischen Einheit gesteuert werden sollte.

4.1. Das Alarmmanagement erfordert neue Prozesse und Standardisierungen

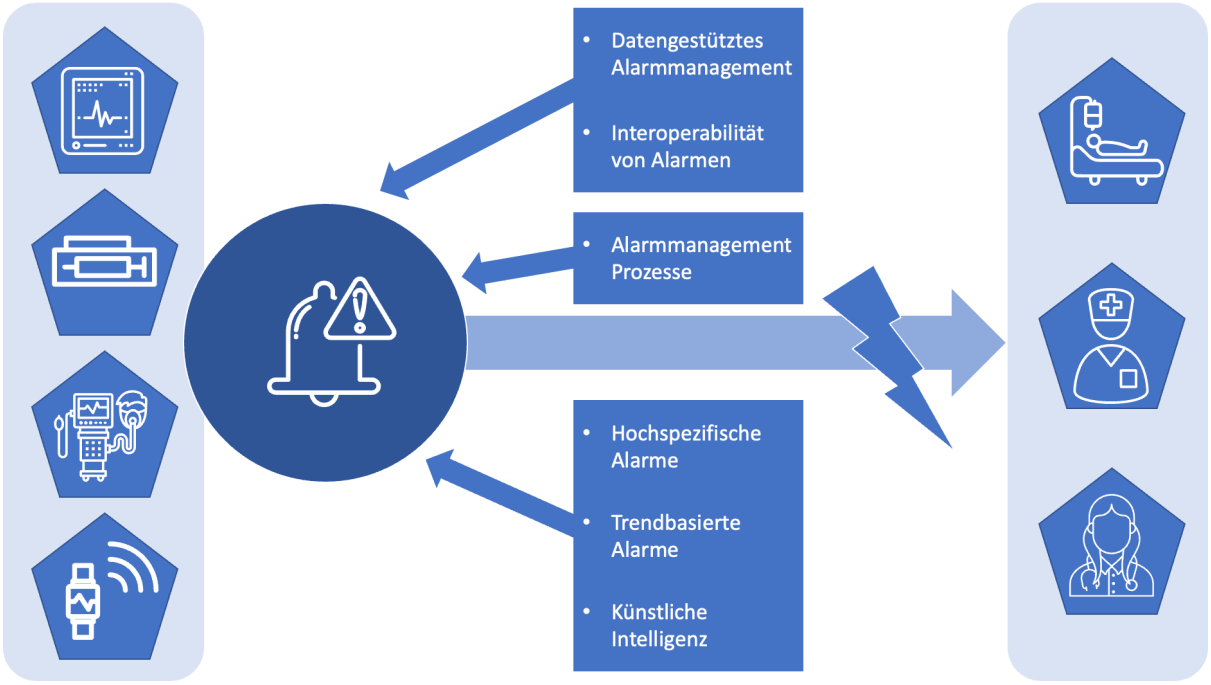
In der Intensivmedizin hat die kontinuierliche Überwachung der Vitalparameter von Patient:innen die Patientensicherheit signifikant erhöht, indem sie das Personal visuell und

auditiv alarmiert, wenn ein Parameter den voreingestellten Grenzbereich über- oder unterschreitet. Doch die große Anzahl von Alarmen überfordert regelmäßig das Personal und kann zu einer Alarmmüdigkeit führen, ein Zustand, der auch in Zukunft durch die Einführung weiterer neuartiger (Monitoring-)Technologien in die Krankenversorgung eskalieren und potentiell Patient:innen gefährden kann [54]. In den Originalarbeiten 1 und 2 betonte das Personal, dass die Anzahl falsch positiver Alarme dringend reduziert werden sollte.

Bemerkenswerterweise wurde bereits in den 1960er Jahren das Problem der falsch positiven Alarme adressiert, welche heute mit 80 bis 99% den Hauptteil der Alarmlast auf der ITS ausmachen [11,54]. Die Gründe für diesen hohen Anteil falsch positiver Alarme sind multifaktoriell. Aus technologischer Sicht waren in den 60er Jahren sowohl die Sensoren als auch die Software dem heutigen Stand deutlich unterlegen, sodass Fehlmessungen häufiger zu falsch positiven Alarmen führten. Auch heute noch sind falsch positive Alarme, die keine klinische Intervention benötigen, auf exogene Interferenzen (z. B. Bewegungs-, Lichtartefakte), Kontaktstörung (z. B. insuffiziente EKG-Klebeelektroden) und menschliche Faktoren (z. B. zu enge Alarmgrenzen) zurückzuführen. Viel bedeutender könnte jedoch der Fakt sein, dass Patientenmonitoringgeräte aus regulatorischer und rechtlicher Sicht standardmäßig so ausgelegt sind, dass sie zwar eine hohe Sensitivität, jedoch eine niedrige Spezifität aufweisen. Denn ein Hersteller kann aktuell zwar dafür haftbar gemacht werden, wenn nachweislich kritische Patientenzustände durch das Monitoringgerät nicht gemeldet werden, jedoch nicht für die Probleme, die durch zu viele falsch positive Alarme entstehen [55,56]. Es könnte also seitens der Hersteller der intrinsische Anreiz fehlen, Alarmsysteme in Bezug auf falsch positive Alarme zu optimieren, während gleichzeitig der Austausch zwischen Herstellern, Nutzer:innen und Wissenschaftler:innen unzureichend ist. Nicht zuletzt ist eine weitere Ursache die fehlende Möglichkeit, die Alarmlast auf der ITS zu überwachen, um darauf basierend neue Alarmmanagement Prozesse zu etablieren.

In Grafik 1 wird die Interaktion zwischen Alarmen medizinischer Geräte und Patient:innen sowie potenzielle Gegenmaßnahmen visualisiert (siehe Grafik 1). Das datengestützte Alarmmanagement basiert auf der Tatsache, dass Verbesserung nur mit der Überwachung und einem Benchmarking möglich sind. Sofern die aktuelle Alarmlast unbekannt ist, kann keine Verbesserung sinnvoll umgesetzt bzw. gemessen werden. In der Originalarbeit 3 konnte erstmals für eine deutsche ITS die Alarmlast inklusive der Datengrundlage veröffentlicht werden. Zur Messung der Alarmlast kommen diverse Alarmmetriken zur Anwendung, wobei international aktuell noch kein Konsens besteht, welche Metrik die Alarmlast am besten widerspiegelt [57]. In unserer Studie kamen folgende Metriken zur

Quantifizierung der Alarmlast zur Anwendung: Alarme pro Bett und Tag, Häufigkeit einzelner Alarme, Alarme pro Gerät, Alarme nach Kritikalität (rot, gelb und blau; d. h. Alarm mit hoher Kritikalität, Alarm mit mittlerer Kritikalität, technischer Alarm mit niedriger Kritikalität), durchschnittliche zeitliche Verteilung der Alarme und Alarmflutsituationen (10 oder mehr Alarme innerhalb von 10 Minuten). Neben diesen Metriken gaben andere, wie beispielsweise die Reaktionszeit des Personals pro Alarm oder die Nutzung der Pause-Funktion, die Reaktionsfähigkeit und den Umgang des Personals mit Alarmen wieder. Anhand dieser Metriken wird das Personal ermächtigt, die aktuelle Alarmlast und die Alarmquellen bzw. Ursachen einzuordnen, Strategien zur Verbesserung zu etablieren und deren Umsetzung zu bewerten [58]. Wilken et al. schlugen 2019 hierzu ein Konzept vor, das es dem Personal ermöglichen soll, sich in Echtzeit einen umfassenden Überblick über die Alarmsituation zu verschaffen und problematische Ursachen sowie Auswirkungen von Alarm-Fatigue zu identifizieren. Die derzeitige technologische Infrastruktur der Monitoringgeräte bzw. Medizingeräte ist jedoch sowohl auf der technischen als auch der syntaktischen und semantischen Interoperabilitätsebene nicht auf solche Aufgaben ausgerichtet. Im Rosetta Terminology Mapping werden basierend auf ISO/IEEE 11073 Informationen standardisiert, die von medizinischen Geräten zum Beispiel an die elektronische Patientenakte gesendet werden [59]. Insgesamt finden sich dort lediglich 16 Einträge zu Alarmen.



Grafik 1: Interaktion von Alarmen medizinischer Geräte mit dem Gesundheitspersonal und Patient:innen sowie Gegenmaßnahmen zur Reduktion der Alarmlast (eigene Grafik)

Das kontinuierliche Patientenmonitoring, beispielsweise als episodisches postoperatives Monitoring, wird bald auch auf der Normalstation zum klinischen Alltag gehören. Damit verbunden sind ebenfalls Alarm-Fatigue-Situationen des Personals auf den Normalstationen, sofern keine Lösungen für exzessive Alarmbelastungen entwickelt und implementiert werden. Dies wurde in einer qualitativen Interviewstudie von Prgomet et al. festgestellt [60]. Auch im ambulanten Gesundheitssektor sind Alarme bereits heute omnipräsent. Dies beinhaltet jegliche Medizingeräte (z. B. Insulinpumpen, Dialysegeräte, Schrittmacher), Wearables (z. B. EKG-, Blutdruck-, SpO_2-Geräte) sowie Applikationen auf dem Smartphone (z. B. Diabetes-, Diät-, Depressions-App).

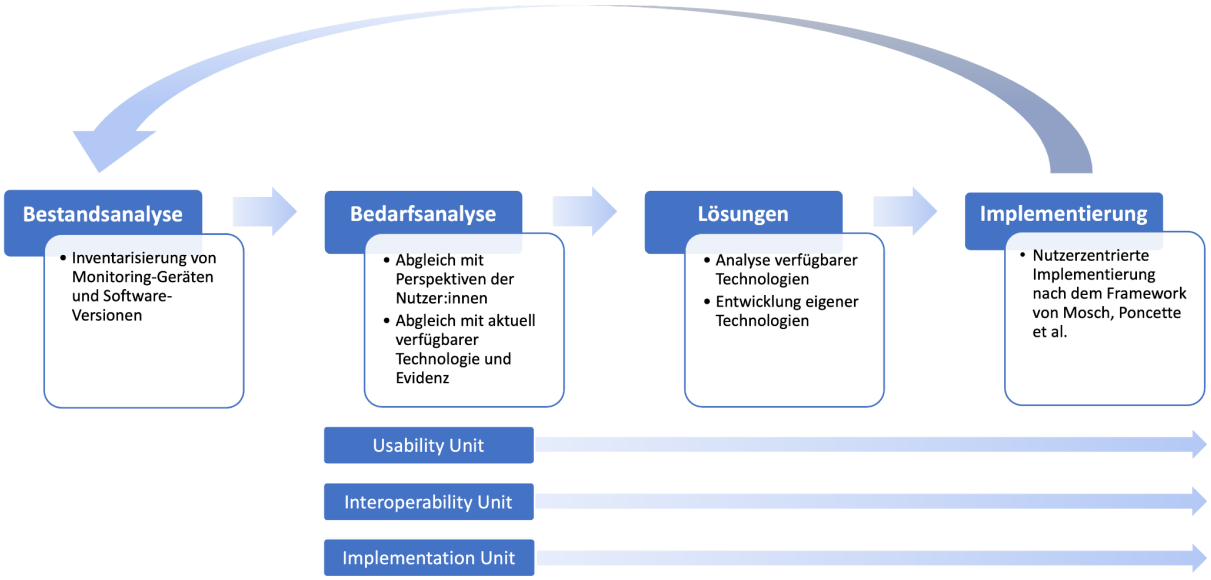
Alarmmanagement in der Medizin wird in der nächsten Dekade aufgrund der zunehmenden Überwachung von Gesundheitszuständen von Patient:innen in jeglichen Situationen eine immer größere Rolle spielen. Mit der Implementierung von Software basierend auf KI werden weitere Benachrichtigungen bzw. Verbesserungsvorschläge hinzukommen. Um einer ständigen akuten Unterbrechung der klinischen Routine (für das Personal) bzw. des täglichen (Arbeits-)lebens (für Patient:innen) aufgrund vermeintlich kritischer Situationen einhalt zu gebieten und um Alarmen wieder eine Bedeutung zu geben, werden neuartige Alarmmanagement-Konzepte dringend benötigt.

Eine Möglichkeit wäre die Einführung einer weiteren Eskalationsstufe von hoch-spezifischen Alarmen, d. h. Alarme dieser Stufe warnen mit einer hohen Spezifität vor einer kritischen, mit dem Leben schwer vereinbarenden, Situation. Aufgrund der hohen Spezifität sollte die Alarm-Fatigue der Nutzer:innen gegenüber dieser Art von Alarmen minimal sein. Derzeit werden im intensivmedizinischen Bereich verschiedene kritische rote Alarme gleichgesetzt. So kann eine Asystolie mit derselben Akuität ertönen wie eine mäßige Desaturierung oder Tachykardie. Eine auditive oder visuelle Unterscheidung ist hier nicht vorgesehen. Durch die Einführung dieser hoch-spezifischen Alarme könnten insbesondere Alarme der mittleren Stufe primär einer Benachrichtigung gleichgestellt werden und gebündelt, zum Beispiel einmal pro Stunde, oder bei personeller Verfügbarkeit abgearbeitet werden. Neuartige Alarmierungssysteme beziehen die Trenderfassung mit ein, um sukzessive Gesundheitsverschlechterungen frühzeitiger erkennen zu können. Dies sind jedoch nur Vorzeichen für Systeme, die Methoden der künstlichen Intelligenz nutzen und patientenbezogene Gesundheitsdaten in die Priorisierung kritischer Gesundheitszustände mit einzubeziehen, um damit einen essenziellen Teil der modernen Präzisionsmedizin abzudecken.

4.2. Die effiziente Implementierung von Patientenmonitoring erfordert eine kontinuierliche Evaluation des Status quo

Durch den exponentiellen technologischen Fortschritt, der in naher Zukunft weiterhin an Tempo zunehmen wird, sehen sich Gesundheitssysteme weltweit gleichermaßen einer Chance und Herausforderung ausgesetzt. Zum einen bietet der technologische Fortschritt enorme Vorteile in Bezug auf eine effiziente, hochqualitative Gesundheitsversorgung. Auf der anderen Seite ist eine hohe Turnaround-Rate neuartiger Technologien immer mit Ressourcenverbrauch verbunden, dessen Abwägung (Implementierung oder lieber Abwarten) eine Herausforderung sein wird. Schon heute ist abzusehen, dass Einrichtungen mit einem hohen technologischen Stand nicht zwangsläufig auch in 10 Jahren weiterhin führend in Bezug auf z. B. Digitalisierung sein werden. Dies hängt vielmehr davon ab, inwiefern Prozesse zur Implementierung und Exnovation in eine Organisationsstruktur eingebettet sind.

Um einen hohen Nutzen aus Patientenmonitoring-Technologien zu erzielen, sind iterativ und im Sinne eines Feedback-Loops regelmäßig die Stationen 1) Bestandsanalyse, 2) Bedarfsanalyse, 3) Lösungen und 4) Implementierung zu durchlaufen (siehe Grafik 2). Die Bestandsanalyse beinhaltet die Inventarisierung aller Geräte inklusive Softwareversionen. Die Bedarfsanalyse sollte im Sinne der Originalarbeit 1 und 2 sowohl qualitativ als auch mit quantitativen Komponenten gestaltet sein, um den Status quo mit der Nutzerperspektive als auch mit international verfügbaren Technologien und aktuellen Evidenzen abzugleichen. Dies beinhaltet ebenfalls die Freistellung klinisch tätiger Expert:innen für Workshops und Experteninterviews. In enger Zusammenarbeit mit den Nutzenden und den Herstellern sollten anschließend Lösungen gefunden werden, um die Lücke zwischen Bestand und Bedarf zu schließen. Dazu werden bereits verfügbare Technologien verwendet bzw. adaptiert, als auch eigene Lösungen entwickelt. Die Implementierung erfolgt schließlich partizipativ im Sinne des in Originalarbeit 5 entwickelten Implementierungsleitfadens mit den Nutzenden. Nach der Implementierung beginnt der Zyklus wieder bei der Bestandsanalyse. Ab der Bedarfsanalyse sollten zentrale Einheiten zur Gewährleistung einer hohen Usability, Interoperabilität und nachhaltigen Implementierung eingesetzt werden, um eine hohe Qualität in diesen Bereichen erreichen zu können.



Grafik 2: Darstellung der kontinuierlichen Evaluation von Patientenmonitoring-Technologie im Sinne eines Feedback-Loops mit den Stationen 1) Bestandsanalyse, 2) Bedarfsanalyse, 3) Lösungen und 4) Implementierung sowie der zentralen Einheiten zur Gewährleistung einer hohen Usability, Interoperabilität und nachhaltigen Implementierung (eigene Grafik).

In Originalarbeit 4 konnte gezeigt werden, dass durch die Verwendung von Usability-Tests die Benutzeroberfläche eines Monitoringsystems für Patient:innen signifikant verbessert werden konnte. Dies beinhaltete die partizipative Gestaltung des Systems gemeinsam mit den Nutzenden. Eine Usability-Unit innerhalb eines Krankenhauses dient dazu, den maximalen Nutzen eines Systems bei gleichzeitig vorliegender Überzeugung der Nutzenden von der entsprechenden Technologie zu erzielen, um damit eine erfolgreiche und nachhaltige Implementierung zu ermöglichen [61].

In Originalarbeit 1 und 2 konnte gezeigt werden, dass aktuell verwendete Monitoringtechnologien aus Sicht der Nutzenden an Interoperabilität mangeln. Dass Interoperabilität die Grundlage für ein funktionierendes Gesundheitssystem darstellt, ist seit Längerem bekannt [62,63]. Dies führte zur Etablierung des Interop Councils der Gematik auf Basis der Gesundheits-IT-Interoperabilitäts-Governance-Verordnung im Jahr 2021 zur zentralen Steuerung und Koordination nationaler Interoperabilitätsprojekte in Deutschland [64,65]. Es erklärt sich damit von selbst, dass ein Krankenhaus der Maximalversorgung eine Interoperability-Unit aufbauen sollte, um ebenfalls zentral Expertise aufbauen und disseminieren zu können.

Schließlich wurde in Originalarbeit 5 ein Leitfaden entwickelt, der zukünftige Implementierungsvorhaben digitaler Technologien unterstützen soll. Durch diese

Standardisierung soll eine effektive Implementierung mit minimalem Ressourcenverbrauch erfolgen. In Krankenhäusern sollten die Ressourcen zur Unterstützung von Implementierungsvorhaben zentral mit der Domänenexpertise durch eine Implementation-Unit gesteuert werden.

4.3. Die Rolle des kontinuierlichen Patientenmonitorings über die Intensivstation hinaus

Derzeit spielt die kontinuierliche Überwachung der Vitalparameter von Patient:innen, insbesondere auf Intensiv- oder Überwachungsstationen (z. B. kardiologische Telemetriestation), eine zentrale Rolle, um das Personal bei kritischen Ereignissen sofort zu alarmieren und durch die automatisierte Übertragung an ein elektronisches PDMS die Grundlage für die medizinische Behandlung zu bieten. Zusätzlich bilden die aufgezeichneten Daten die Grundlage bei der Entwicklung von sogenannten Early Warning Scores (EWS) [66] sowie diversen Prädiktionsmodellen basierend auf Methoden der KI [67,68]. Diese Vorteile, die das Patientenmonitoring mit sich bringt, werden bei technologischem Fortschritt und fallenden Anschaffungskosten auch auf der Normalstation sowie im ambulanten Umfeld eine wichtige Funktion einnehmen.

Während der Großteil der kontinuierlichen Überwachung der Vitalparameter auf der ITS stattfindet, ereignen sich fast die Hälfte aller unerwünschten Ereignisse bei stationären Patient:innen auf den Normalstationen [69,70]. Die Einführung von (episodisch) kontinuierlichen, nicht-invasiven, drahtlosen Patientenmonitoringsystemen auf nicht-intensivmedizinischen Stationen bietet diverse klinische Vorteile [71–73] und verringert die Zahl der verpassten kritischen Situationen oder Notfälle, insbesondere während der Abend- und Nachtschichten [74]. Nicht-invasive, drahtlose Patch-on-Geräte sind vielversprechend für das kontinuierliche Patientenmonitoring auf Normalstationen, da sie weniger fehleranfällig sind, die Benutzerfreundlichkeit erhöhen und die Erfahrungen von Patient:innen und Pflegepersonal verbessern [75]. Neben der Verbesserung der klinischen Ergebnisse kann die Einführung von Patientenmonitoring dazu führen, dass sich die Patient:innen sicherer fühlen und in der Lage sind, ihre eigenen visualisierten Vitalparameter bzw. Genesungsfortschritte im Sinne eines Biofeedbacks zu würdigen [76]. Zudem können durch das Patientenmonitoring Komplikationen früher erkannt und die Krankenhausverweildauer verkürzt werden, wodurch die Behandlungskosten reduziert werden [77,78]. Eine großflächige Einführung des kontinuierlichen Patientenmonitorings auf der Normalstation ist zunächst für die episodische Überwachung von Patient:innen mit einer

hohen Prätestwahrscheinlichkeit für das Auftreten von Komplikationen (z. B. postoperative Blutung oder Sepsis) zu erwarten. Die Abschätzung dieser Prätestwahrscheinlichkeit sollte durch Methoden der KI augmentiert werden.

Trotz der Vorteile hinkt die Implementierung von kontinuierlichen Monitoringtechnologien auf Normalstationen weit hinterher. Zu den Hindernissen für die Implementierung dieser Technologie gehören die Informationsflut und die Menge an Alarmen, die mit der Einführung von Grenzen-basierten Alarmsystemen einhergehen würden, sowie die Befürchtung des Personals, dass das Patientenmonitoring eine Normalstation in eine intensivmedizinische Umgebung verwandeln würde [76]. Hohe Gerätekosten und der Bedarf an Fachkenntnissen des Personals bei der Dateninterpretation sind weitere Hürden für eine umfassende Einführung [79]. Schließlich fehlt es an konkreten Leitlinien für die Implementierung von Monitoringtechnologien auf der Normalstation sowie an Erkenntnissen über die klinischen Anforderungen an das Monitoring in verschiedenen Stationsumgebungen (z. B. Chirurgie, Innere Medizin, Pädiatrie, Psychiatrie).

Wesentlich für die Erkennung der klinischen Verschlechterung von Patient:innen sind die Mittel zur korrekten Interpretation der vom Patientenmonitoring überwachten Variablen. Hierfür werden interoperable Krankenhausinformationssysteme benötigt, um sicherzustellen, dass Monitoringdaten automatisch an das PDMS übermittelt werden. Automatisierte Vorhersagemodelle können auf Basis dieser Daten Hochrisikopatient:innen frühzeitig erkennen [80]. Eine solche KI-gestützte Echtzeit-Analyse von Monitoringdaten kann die Patientensicherheit verbessern und so den Bedarf an höherer Akutversorgung durch Komplikationen verringern, die Verweildauer im Krankenhaus und die Aufnahmekosten reduzieren sowie die stationäre Mortalität reduzieren [79].

Um die digitale Transformation des Gesundheitssystems voranzutreiben und damit neue, bisher unmögliche Prozesse und Systeme zu etablieren, ist weitere Forschungsarbeit insbesondere in der Nutzbarmachung dieser Monitoringdaten unabdingbar. So hat sich die 2015 vom Bundesministerium für Bildung und Forschung (BMBF) gestartete Medizininformatik-Initiative (MII) zum Ziel gesetzt, Forschung und Versorgung enger zu verknüpfen und damit Gesundheitsdaten für die Regelversorgung und Forschung verfügbar zu machen [81]. Im Zuge der Augmentierung der Regelversorgung durch KI-Technologien hat das Patientenmonitoring als verlässliche und hochfrequente Datenquelle insbesondere in Kombination mit weiteren Gesundheitsdaten einen zentralen Stellenwert. Um diese Biosignale für die Forschung und perspektivisch für KI-Technologien in der Regelversorgung nutzbar machen zu können, werden im Rahmen der MII Kerndatensatzmodule erstellt, die

die Interoperabilität auf allen Ebenen sicherstellt. Dies konnte für den intensivmedizinischen Bereich bereits begonnen werden.

In einer weiteren Ausschreibung des BMG werden seit 2019 digitale Innovationen für die Verbesserung der patientenzentrierten Versorgung im Gesundheitswesen gefördert [82]. Im Mittelpunkt des Förderschwerpunkts stehen die Zusammenführung und Nutzung von Daten sowie die Erprobung und praktische Umsetzung von KI-gestützten Anwendungen. In einer Netzwerkveranstaltung Anfang 2022 kamen alle geförderten Projektteams zusammen und konnten sich über Herausforderungen und Synergien austauschen [83]. Auch im Rahmen dieser Förderlinie wird u. a. die heterogene oder fehlende Datenaufbereitung moniert, wobei Bestrebungen der MII diese Defizite in der Datenstandardisierung noch nicht ausreichend adressiert habe. Stattdessen werden qualitätsgesicherte Open-Source-Trainingsdatensätze gefordert. Doch im Rahmen der MII werden genau solche Forschungs- und Versorgungsdaten in Datenintegrationszentren aufbereitet und zusammengefasst, um eine standortübergreifende Datennutzung für die Regelversorgung und Forschung zu gewährleisten. Eine bessere Kommunikation und Ressourcenallokation könnte hier als Katalysator dienen, um gemeinsame Ziele effizienter und früher zu erreichen.

Mit dem KHZG im Jahr 2020 wurde ein Meilenstein in der Digitalisierung der Krankenhäuser in Deutschland erreicht, dessen Auswirkungen in den nächsten Jahren in der Regelversorgung spürbar sein sollten [52]. Angelehnt an dem schwedischen Vorbild *Vision for eHealth 2025* sollten wir nun auch für Deutschland eine gemeinsame Vision und Mission entwickeln, wie unsere Regelversorgung in zehn Jahren aussehen sollte [53]. Denn nur mit einer konsentierten Zielsetzung und einem regen interdisziplinären Austausch werden wir die vielen Digitalisierungsprojekte in Deutschland synchronisieren können.

4.4. Ausblick

In Zukunft werden die Vitalparameter aller Patient:innen im Krankenhaus kontinuierlich überwacht. Technologische Fortschritte werden ein allgegenwärtiges kontaktloses Monitoring, zum Beispiel durch Ultraschall, Radartechnologie oder Photoplethysmographie, ermöglichen [84–86]. Im Sinne eines Paradigmas vernetzter medizinischer Geräte (engl. networked-device paradigm) laufen alle Patienteninformationen zentral an ein KI-augmentiertes System, welches potentiell kritische Situationen erkennt bzw. antizipiert, teilweise durch closed-loop Systeme (z. B. bei Hypotension, Erhöhung der Noradrenalinrate) selbst beseitigt bzw. verhindert und situationsadaptiert patienten- und nutzerspezifische Benachrichtigungen priorisiert an das passende Personal sendet [87,88]. Im Sinne der

datengetriebenen Medizin (engl. high-definition medicine) wird durch die hochfrequente Messung von Vitalparametern in Kombination mit weiteren Biosensoren in Zukunft die Charakterisierung individueller ereignis- und situationsbezogener Risiken möglich sein [89].

Neben technologischen, soziotechnischen und implementierungswissenschaftlichen Herausforderungen ergeben sich aus dieser Vision diverse komplexe ethische und soziale Fragestellungen, die bereits heute interdisziplinär mit Zentrierung auf die Patient:innen angegangen werden sollten. Der Zusammenhang von eingeschränkter Privatsphäre und höherer Patientensicherheit konnte bereits im Rahmen von Telemonitoring von Patient:innen mit COVID-19 beschrieben werden [90]. Welche Folgen die Einführung von KI-Systemen in die klinische Routine haben wird und welche Vorsichtsmaßnahmen, zum Beispiel von Ärzt:innen bei Interaktion mit solchen Systemen, notwendig sind, sollte in die medizinische Aus- und Weiterbildung bereits heute mit aufgenommen werden [91,92]. Denn die Steigerung der digitalen Kompetenz des Krankenhauspersonals ermöglicht eine nachhaltige und sinnvolle Implementierung neuartiger Technologien, die konsekutiv zu einem Mehrwert in der Gesundheitsversorgung führen.

Unser Ziel ist nicht etwa das Krankenhaus der Zukunft; unser Ziel ist der Weg dorthin. Und damit befinden wir uns in einer kontinuierlichen Revolution für Neues. Essenziell für einen nachhaltig hohen Innovationsgrad innerhalb eines Krankenhauses sind etablierte zentrale Einheiten u. a. für Usability, Interoperabilität und Implementierung. Alle Nutzenden aus der Klinik müssen dazu befähigt werden, sich über eine klinische Freistellung partizipativ an der Implementierung neuartiger Technologien einbringen zu können. Nur damit erreichen wir, dass durch die Digitalisierung nicht nur Analoges in Digitales übersetzt wird, sondern eine Transformation des Gesundheitswesens mit neuen Produkten und Prozessen bewirkt wird.

5. Zusammenfassung

Die Implementierung von Systemen zur Überwachung der Vitalparameter von Patient:innen auf der ITS konnte die Patientensicherheit in der Intensivmedizin signifikant erhöhen. Seit Ende der 1960er Jahre stellt das Monitoring neben der klinischen Untersuchung von Patient:innen auf der ITS einen wesentlichen Bestandteil der intensivmedizinischen Versorgung dar und ist seit 2005 in diversen Leitlinien aufgenommen worden. Trotz innovativer Fortschritte im Bereich der Medizin, Informatik und Signalverarbeitung konnten neuere Ansätze jedoch nur unzureichend in die klinische Routine translatiert werden. Diese Habilitationsschrift fokussiert sich daher darauf, welche Aspekte des aktuellen Patientenmonitorings aus Sicht der Nutzer:innen auf der ITS sicherheitsrelevante Defizite aufweisen und wie die Patientensicherheit durch Umsetzung spezifischer Maßnahmen erhöht werden kann.

Im Rahmen einer qualitativen Interviewstudie und einer quantitativen Befragung mittels Online-Fragebogen (Originalarbeit 1 und 2) konnte der Status quo des Patientenmonitorings evaluiert werden. Hierbei zeigten sich fünf relevante Angriffspunkte für eine Erhöhung der Patientensicherheit: Reduktion der falsch positiven Alarme, Implementierung eines krankenhausweiten Alarmmanagement-Standards, Einführung von kabellosen Sensoren, Einführung von KI-augmentierten klinischen Entscheidungssystemen mit einer hohen Benutzerfreundlichkeit und Interoperabilität sowie die Erhöhung der digitalen Kompetenz des Personals.

Aufbauend auf den Ergebnissen aus den ersten beiden Arbeiten wurde in Orginalarbeit 3 ein datengestützter Ansatz des Alarmmanagements entwickelt, mit dem die Alarmlast auf einer ITS anhand einer deskriptiven Alarmdatenanalyse quantifiziert und somit die Wirkung von Interventionen gemessen werden kann. Die publizierte Do-it-yourself-Anleitung kann von technisch versierten Pflegekräften und Ärzt:innen genutzt werden und bietet die Grundlage für ein zielgerichtetes und fokussiertes Alarmmanagement. In Originalarbeit 1 wurde durch das ITS-Personal eine hohe Benutzerfreundlichkeit von Patientenmonitoringgeräten als essenziell eingestuft. Daran orientierend wurde in Originalarbeit 4 durch die partizipative Einbeziehung der Nutzer:innen im Rahmen eines Human-centered-Design (HCD)-Ansatzes ein Think-Aloud-Protokoll angewendet und damit die Benutzerfreundlichkeit einer Softwareoberfläche eines Patientenfernüberwachungssystems signifikant verbessert. Der Einsatz von HCD-Methoden vor der Implementierung technischer Geräte auf der ITS könnte sicherstellen, dass diese Geräte effiziente und effektive Arbeitsabläufe unterstützen und keine Hindernisse darstellen. Dieser sicherheitsrelevante Aspekt wurde ebenfalls in den

entwickelten Leitfaden für die Implementierung von digitalen Technologien in die intensivmedizinische Routine (Originalarbeit 5) mit aufgenommen. Hierbei wurde ein hybrider qualitativer Ansatz mit induktiven und deduktiven Elementen verfolgt und die bestehenden Strukturen des Consolidated Framework for Implementation Research (CFIR) und der Expert Recommendations for Implementing Change (ERIC) genutzt. Der entwickelte Leitfaden sollte Implementierungsvorhaben auf der ITS unterstützen und könnte perspektivisch auf den Bereich der Normalstation adaptiert werden.

Zusammenfassend ist festzustellen, dass durch die vorliegenden Arbeiten diverse sicherheitsrelevante Aspekte des Patientenmonitorings aus Sicht der Nutzenden identifiziert wurden und die entwickelten Maßnahmen in den Bereichen Alarmmanagement, Benutzerfreundlichkeit und Implementierungswissenschaft maßgeblich zu einer höheren Patientensicherheit in der Krankenversorgung beitragen können. Entscheidend für die Weiterentwicklung der datengetriebenen personalisierten Medizin ist das Patientenmonitoring, sodass diese Erkenntnisse darüber hinaus die digitale Transformation des Gesundheitswesens vorantreiben können.

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Erklärung

§ 4 Abs. 3 (l) der HabOMed der Charité

Hiermit erkläre ich, dass

1) weder früher noch gleichzeitig ein Habilitationsverfahren durchgeführt oder angemeldet wurde,

2) die vorgelegte Habilitationsschrift ohne fremde Hilfe verfasst, die beschriebenen Ergebnisse selbst gewonnen sowie die verwendeten Hilfsmittel, die Zusammenarbeit mit anderen Wissenschaftlern/ Wissenschaftlerinnen und mit technischen Hilfskräften sowie die verwendete Literatur vollständig in der Habilitationsschrift angegeben wurden,

3) mir die geltende Habilitationsordnung bekannt ist.

Ich erkläre ferner, dass mir die Satzung der Charité – Universitätsmedizin Berlin zur Sicherung Guter Wissenschaftlicher Praxis bekannt ist und ich mich zur Einhaltung dieser Satzung verpflichte.

Berlin, 5. August 2022
..... Ort, Datum ..... Unterschrift