

Aus der Klinik für Anästhesiologie und Intensivmedizin
der Medizinischen Fakultät Charité – Universitätsmedizin Berlin

DISSERTATION

Die Evaluierung eines Feedback-Systems für Evidenz-basierte Prozessindikatoren eines Patienten-Daten-Management-Systems für Intensivstationen und deren Einfluss auf die Behandlungsqualität und den finanziellen Outcome

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1. Abkürzungen

AWMF	Arbeitsgemeinschaft der wissenschaftlichen medizinischen Fachgesellschaften e.V.
BPS	Behavioral Pain Scale
BQS	Bundesgeschäftsstelle Qualitätssicherung GGmbH
BZ	Blutzucker
CAM-ICU	Confusion Assessment Method for the Intensive Care Unit
CC7	Charité Zentrum 7 für Anästhesie und Intensivmedizin
COPRA	Computer-aided-Patient-Report-Assistant, digitale Patientenakte
DDS	Delirium Detection Score
DGAI	Deutsche Gesellschaft für Anästhesie und Intensivmedizin
DIVI	Deutsche interdisziplinäre Vereinigung für Intensivmedizin und Notfallmedizin
DNR	Do not resuscitate, Nicht Wiederbeleben
G-DRG	German Diagnosis Related Groups
ICU	Intensive Care Unit, Intensivstation
IMCU	Intermediate Care Unit, Überwachungsstation
KBS	Intensivmedizinischer Komplexbehandlungsscore
KPI	Key-Performance-Indikator
KHZG	Krankenhauszukunftsgesetz
LOS	Length of Stay, Dauer des Intensivaufenthaltes
MPG	Medizinproduktegesetz
NRS	Numerische Ratingskala (Schmerzskala 1-10)
PDMS	Patienten-Daten-Management-System
RASS	Richmond Agitation Sedation Scale
SAPS-II	Simplified Acute Physiology Score
SBT	Spontaneous Breathing Trial, Spontanatmungsversuch
SIRS	Systemic Inflammatory Response Syndrome
SOFA	Sequential Organ Failure Assessment
SOP	Standard Operating Procedures
TISS-28	Therapeutic Intervention Scoring System
VA	Verfahrens-Anweisungen
VAS	Visuelle Analogskala (Schmerzskala gelb => violett)

2. Tabellen und Grafiken

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3. Zusammenfassung

3.1 Abstrakt

Einführung: Ziel dieser kumulierten Arbeit war zu untersuchen, ob die Implementierungsrate von Standard Operating Procedures (SOP) für intensivmedizinische Behandlungsprozesse wie Sedierung, Beatmungsentwöhnung und Blutzuckermanagement durch Verwendung eines visuellen Feedback-Systems verbessert wird. Patienten Daten Management Systeme (PDMS) bieten sich als Plattform für solche Systeme an. Dabei soll eine zusätzliche Belastung der Mitarbeiter in der Intensivmedizin vermieden werden. Ebenso soll ein Einfluss auf ökonomische Effekte bei der Erhöhung der Compliance der protokollbasierten Intensivbehandlung untersucht werden.

Methodik: In einer ersten Studie wurden 205 Patienten untersucht, die 3 Monate vor nach Einführung des Feedback-Systems auf einer Intensivstation behandelt wurden. Dabei wurden die Erfüllungsgrade der Qualitätsindikatoren für die Überwachung von Sedierung, Delir und Schmerz und die Adhärenz an ein Beatmungsentwöhnungsprotokoll verglichen. In der zweiten Studie wurde die Behandlungsqualität durch Einführung des pflegebasierten Blutzuckerprotokolls bei 175 Patienten im Vergleich zu 384 retrospektiven manuellen Kontrollen untersucht. Die dritte Studie untersuchte die Beziehung zwischen klinischem und ökonomischen Outcome von 583 Patienten aus den Aufnahmejahren 2012 – 2017 abhängig von der SOP-Einhaltung zum Beatmungswaning. Dabei wurde eine Low Adherence Group (LAG; SOP-Adhärenz <65% und eine High Adherence Group (HAG; SOP-Adhärenz \geq 65%) verglichen.

Ergebnisse: Die Einhaltung der SOPs für die Schmerz- und Delir Überwachung und des Entwöhnungsprotokolls war durch die Einführung eines visuellen Feedbacksystems erhöht. Die Implementierung eines BZ-Protokolls führte schon ohne zeitnahes Feedbacksystem zu einer deutlichen Abnahme der Hypoglykämie-Vorfälle (31% zu 12 %, $P < 0,001$) ohne eine Erhöhung der Arbeitslast der Pflege zu verzeichnen. Die Steigerung der Adhärenz zu dem Weaning-Protokoll führte zwar nicht direkt zu einer Verringerung der Behandlungskosten, allerdings war ein indirekter Einfluss durch eine kürzere Liegezeit feststellbar, da mehr Patienten im gleichen Zeitraum behandelt werden konnten.

Schlussfolgerung: Die Einhaltung von protokollgestützten Verfahrensanweisungen kann durch die Verwendung eines täglichen visuellen Feedback-Systems verbessert werden. Es lassen sich Effekte im Bereich des Qualitätsmanagements ebenso feststellen, wie Auswirkungen auf Behandlungsergebnis und ökonomische Faktoren. Eine Weiterentwicklung elektronischer Feedbacksysteme scheint in der Zukunft sinnvoll.

3.2. Abstract

Introduction: The aim of this cumulative work was to investigate whether the implementation rate of Standard Operating Procedures (SOP) for intensive care treatment processes such as sedation, weaning from mechanical ventilation and blood glucose management is improved by using a visual feedback system. Patient Data Management Systems (PDMS) offer a platform for such systems. The aim is to avoid additional work load for intensive care staff. Likewise the influence on economic effects of improved compliance to protocol-based intensive treatment was investigated.

Methods: A first study examined 205 patients who had been treated in an intensive care unit 3 months before and after the introduction of the feedback system. The degree of compliance with the quality indicators for the monitoring of sedation, delirium and pain and the adherence to a ventilation weaning protocol was compared. The second study looked at the quality of treatment by introducing automated blood glucose protocol in 175 patients compared with 384 retrospective controls. The third study examined the relationship between clinical and economic outcomes of 583 patients admitted to the ICU between 2012 and 2017, with regard to SOP adherence for a protocol for weaning from mechanical ventilation. A low adherence group (LAG; SOP adherence <65% and a high adherence group (HAG; SOP adherence \geq 65%) were compared.

Results: Adherence to SOPs for pain and delirium monitoring and the weaning protocol was improved with the introduction of a visual feedback system. Even without a timely feedback system, implementation of a BG protocol resulted in a significant decrease in hypoglycemic events (31% to 12%, $P < 0.001$) without an increase in nursing workload. While increasing adherence to the weaning protocol did not directly reduce treatment costs, there was an indirect influence due to a shorter length of stay, as more patients could be treated in the same period of time.

Conclusion: Compliance with protocol-based procedural instructions can be improved by using a daily visual feedback system. Effects in the field of quality management can be identified as well as effects on treatment outcome and economic factors. Further development of electronic feedback systems seems to be reasonable in the future.

3.3 Einführung

Evidenzbasiertes Wissen findet immer noch nur langsam Eingang in klinische Prozesse. Daher sind in Hoch-Risiko-Bereichen wie Intensivstationen Standard Operating Procedures (SOP) eingeführt worden, um Arbeitsabläufe unter Berücksichtigung medizinischer Evidenz zu beschreiben. In dieser Arbeit soll gezeigt werden, dass zur Einhaltung solcher SOPs ein automatisiertes visuelles Feedback-System genutzt werden kann. Ziel ist die verbesserte Ergebnisqualität, z. B. durch eine verringerte Letalität, verkürzte Beatmungsdauer oder intensivmedizinische Behandlungsdauer. Angelehnt an die aus der Industrie bekannten Begriff Key-Performance-Indikatoren (KPI), wurden Prozessindikatoren identifiziert, evaluiert und implementiert sowie die automatisierte Überwachung ihres Erfüllungsgrades einschließlich eines anschließenden visuellen Feedbacks an die Anwender. Aus der Verknüpfung von Prozessindikatoren zur Einhaltung von SOPs und patientenrelevanter Ergebnisqualität ergibt sich die Möglichkeit, die Prozessqualität in einer für den Patienten relevanten Art und Weise zu steuern. Diese KPI sind in mehreren Studien (Kastrup et al., 2011; Kastrup et al., 2013; Kastrup et al., 2009; Nachtigall et al., 2009) und in einer Metaanalyse (Jebraeily et al., 2019) als relevant für die Ergebnisqualität identifiziert worden. Durch die Programmierung einer graphischen Oberfläche als Feedback-System (Dashboard) für die konsentierten KPI, sowie eines neuen Formulars für eine protokollgesteuerte Beatmungsentwöhnung in das bestehende PDMS COPRA5 (Patient Data Management System, Computer-Aided-Patient-Report-Assistent), sollte der Einhaltunggrad während des Behandlungsprozesses dem behandelnden Team visuell zugänglich gemacht werden. Das Behandlungsteam sollte so die Möglichkeit bekommen, während der Behandlung auf negative Trends hinsichtlich des Erfüllungsgrades der KPI reagieren zu können. Die vorliegende kumulierte Arbeit umfasst im Wesentlichen folgende Punkte:

1. Feasibility: Es soll gezeigt werden, dass durch retrospektives visuelles Feedback von Evidenz-basierte Prozessindikatoren in einem PDMS in der täglichen Routine einer Intensivstation ohne Mehraufwand für die Beteiligten der Erfüllungsgrad medizinischer Prozesse gesteigert werden kann.
2. Durch diese Erhöhung des Implementierungsgrades soll die Ergebnis-Qualität der Behandlungen (Verringerung der Letalität, Beatmungsdauer und Intensivbehandlungsdauer) verbessert werden.
3. Ein protokollbasiertes, pflegegestütztes Blutzucker-Management soll als neuer prozessorientierter KPI auf seine Tauglichkeit zur Steigerung der Prozess- und Ergebnisqualität in der klinischen Praxis evaluiert werden.
4. Für einen einzelnen KPI „Einhaltungsgrad des Weaning-Protokolls“, soll der Impact auf den ökonomischen Outcome untersucht werden.

Als Ergebnis soll dem pflegerischen und ärztlichen Behandlungsteam ein computergestütztes

Werkzeug zur internen Bewertung relevanter Prozessindikatoren (KPI) bereitgestellt werden. Die Effekte eines solchen Rückmeldesystems auf den Einhaltungsgrad der KPI sollen untersucht werden, einerseits um die Verbesserung des Einhaltungsgrades nachzuvollziehen und ebenso weitergehende Effekte auf Prozessqualität, Behandlungsergebnis und ökonomische Kennzahlen. Die Ergebnisse der Evaluation ermöglichen dann zielgerichtete Maßnahmen des Qualitätsmanagements wie Benchmarking und Peer-Reviews, da ausschließliches Monitoring von KPI ohne nachfolgende Maßnahmen nicht sinnvoll ist (Kumpf et al., 2021).

3.3.1 Programmiertechnische Vorarbeiten

Als Grundlage der folgenden Auswertungen musste vorab das PDMS COPRA5 um zwei neue Formulare erweitert werden. Diese Programmierungen wurden in der Sprache „C++“ mit dem Borland C++-Compiler Version 5.0 vorgenommen.

Die Daten zur Berechnung und Ausleitung der KPI waren in dem PDMS vorhanden. Diese befanden sich an verschiedenen Stellen und waren nicht „auf einen Blick“ erkennbar. Um eine übersichtliche Darstellung im „Ampelsystem“ des Dashboards zu gewährleisten, wurden im Rahmen der Vorbereitung der Untersuchungen dieser Arbeit diverse Programmierungen vorgenommen, um die eingangs geschilderten Punkte zu adressieren: es wurde ein neues Formular (siehe Abb. 1 + 2) programmiert, auf dem alle Outcome-relevanten Parameter auf einer Seite zusammengefasst dargestellt werden konnten, das KPI-Formular. Es wurde ebenfalls ein eigenes Weaning-Formular (siehe Abb. 5) erstellt, da das protokollbasierte Weaning ein relevanter KPI für das respiratorische System ist.

Die KPI wurden nach Organsystemen geordnet graphisch so dargestellt, dass eine visuelle Überprüfung des Erfüllungsgrades schnell und sicher durchführbar ist.

Der Erfüllungsgrad der KPI wurde täglich graphisch retrospektiv für den Vortag dargestellt. Das Ampelprinzip der Anzeige stellt die Werte bei einem Patienten, der die Ziele erreicht hat, als grünen Bereich graphisch dar (siehe Abb. 1). Wurde kein Ziel für den Tag formuliert, oder erreichte der Patient die Zielkriterien nicht, wechselte die Darstellung auf Rot (siehe Abb. 2). Für die Patienten, welche ein formuliertes Ziel hatten, aber dieses auf Grund ihrer Grundkrankheit und einer notwendigen Begründung (als Freitext) nicht erreichen konnten, erschien in der Ampel ein gelber Farbbalken.

Die einzelnen Ampeln wurden nach Organsystemen zusammengefasst dargestellt, so dass jederzeit erkennbar ist, in wie weit die Standards zu einem aktuellen Zeitpunkt eingehalten werden. Der Zeitraum, auf den sich eine Ampelschaltung bezog, war der jeweils vorhergehende klinische Tag. Unter folgenden Bedingungen wurde das Kennzahlencockpit deaktiviert und es mussten keine täglichen Ziele in diesem Tool festgelegt werden:

- Patienten mit den Status DNR (Do not resuscitate, bzw. Einfrieren der Therapie)
- Organspender
- Aufenthaltsdauer < 24 Stunden Aufenthaltsdauer
- Alter < 18 Jahre

18.06.08 - 19.06.08	6 ^h	8 ^h	10 ^h	12 ^h	14 ^h	16 ^h	18 ^h	20 ^h	22 ^h	0 ^h	2 ^h	4 ^h
KPI-STATUS <input checked="" type="checkbox"/> ORGANSPENDER <input checked="" type="checkbox"/> DNR <input checked="" type="checkbox"/> Therapie eingefroren <input checked="" type="checkbox"/>												
Sedierung <input checked="" type="checkbox"/>												
RASS	FD: <input checked="" type="checkbox"/> SD: <input checked="" type="checkbox"/> ND: <input checked="" type="checkbox"/> Scorewert / Schicht nicht erfasst RASS Zielwert / Tag nicht eingegeben RASS											
Soll-RASS (F2-2)	FD: <input checked="" type="checkbox"/> SD: <input checked="" type="checkbox"/> ND: <input checked="" type="checkbox"/> Scorewert / Schicht nicht erfasst NRS NRS > 4 und Analgetikagabe fehlt											
NRS und/oder BPS	FD: <input checked="" type="checkbox"/> SD: <input checked="" type="checkbox"/> ND: <input checked="" type="checkbox"/> Scorewert / Schicht nicht erfasst BPS BPS-Ziel: <= 6 BPS > 6 und Analgetikagabe fehlt											
Immer erhaben!	FD: <input checked="" type="checkbox"/> SD: <input checked="" type="checkbox"/> ND: <input checked="" type="checkbox"/> Scorewert / Schicht nicht erfasst CAM-ICU Scorewert / Schicht nicht erfasst weil:											
Behavioral Pain Scale	FD: <input checked="" type="checkbox"/> SD: <input checked="" type="checkbox"/> ND: <input checked="" type="checkbox"/> Scorewert / Schicht nicht erfasst DDS											
RASS >= -2	FD: <input checked="" type="checkbox"/> SD: <input checked="" type="checkbox"/> ND: <input checked="" type="checkbox"/> Scorewert / Schicht nicht erfasst DDS											
CAM-ICU	FD: <input checked="" type="checkbox"/> SD: <input checked="" type="checkbox"/> ND: <input checked="" type="checkbox"/> Scorewert / Schicht nicht erfasst DDS											
Delirium Detection Score	FD: <input checked="" type="checkbox"/> SD: <input checked="" type="checkbox"/> ND: <input checked="" type="checkbox"/> Scorewert / Schicht nicht erfasst DDS											
DDS wenn CAM-ICU positiv	FD: <input checked="" type="checkbox"/> SD: <input checked="" type="checkbox"/> ND: <input checked="" type="checkbox"/> Scorewert / Schicht nicht erfasst DDS											
Respiration	<input checked="" type="checkbox"/> Weaning-Protokoll nicht erfasst <input type="checkbox"/> Nein <input type="checkbox"/> Ja Wegfall Bestmungsindikation											
Soonatmung keine Bestmung/ECMO	<input checked="" type="checkbox"/> TV ml/PBW kg <input type="checkbox"/> TV-Ziel 4-6 ml/kg nicht erreicht Anzahl Werte > 6 ml/kg Werte > 6 / Gesamtanzahl											
PBW	<input checked="" type="checkbox"/> piP mbar <input type="checkbox"/> piP-Ziel <= 30 mbar nicht erreicht Anzahl Werte > 30 mbar Werte > 30 / Gesamtanzahl											
Herz-Kreislauf	<input checked="" type="checkbox"/> KEINE Inotrop./Vasopressoren <input type="checkbox"/> Zielwert nicht festgelegt											
MAD-Zielwert	<input checked="" type="checkbox"/> KEINE Inotrop./Vasopressoren <input type="checkbox"/> Zielwert nicht festgelegt											
Material	Arterial: 58.7, 97, 91.5, 81.1, 95.5, 101, 95.5, 83.7 Venous: 91.5, 81.1, 95.5, 101, 95.5, 83.7											
SV02 [%]	FD: <input checked="" type="checkbox"/> SD: <input checked="" type="checkbox"/> ND: <input checked="" type="checkbox"/> keine SvO2-Messung bei Gabe von Ino./Vaso Zielwert nicht festgelegt											
Zielwert SvO2 b. Ino./Vaso	FD: <input checked="" type="checkbox"/> SD: <input checked="" type="checkbox"/> ND: <input checked="" type="checkbox"/> keine SvO2-Messung bei Gabe von Ino./Vaso Zielwert nicht festgelegt											
Renal	<input checked="" type="checkbox"/> 1695 Diuresis 100, 130, 140, 70, 80, 110, 25, 80, 220, 80, 80, 150, 130, 220 <input checked="" type="checkbox"/> präop. Nierenversagen Diuresis-Ziel > 0.5 ml/kg nicht erreicht Diuresis < 0.3 ml/kg/h											
Patient an Dialyse	<input checked="" type="checkbox"/> Kreatinin 0.79 <input type="checkbox"/> Kreatinin <= 1.5-fach Aufnahmewert nicht erreicht <input type="checkbox"/> 2-3-fach Aufn.wert											
Kreatinin [mg/dl]	<input checked="" type="checkbox"/> keine enterale Ernährung Tag 1-3 oder ab Tag 4 Kalorienzufuhr nicht > 1 kcal/kg <input type="checkbox"/> kcal gesamt <input type="checkbox"/> davon kcal enteral <input type="checkbox"/> Keine vollständige enterale Ernährung weil:											
Keine enterale Ernährung	<input checked="" type="checkbox"/> ITS-Tag: 20 <input type="checkbox"/> post-OP-Tag: <input type="checkbox"/> Glucose 163, 217, 214, 217, 157, 186, 171, 176 <input checked="" type="checkbox"/> BZ-Ziel 80 - 180 mg/dl nicht erreicht Anz. Werte > 180 mg/dl Anz. Werte < 80 mg/dl Anz. Werte > 180 / Gesamtanz. BZ-Ziel nicht erreicht weil: dhfgh sdfgsdfg sdfgwsf sdfgsdf sdfgsdf sdfgsdf sdfgsdf											
Glucose [mg/dl]	<input checked="" type="checkbox"/> T > 38 od. < 36 °C 36.6 <input checked="" type="checkbox"/> HF > 90 57.2, 61.21, 75.47, 74.79, 72.5, 74.14, 80.5, 71.5, 90.27, 74.5, 88.53, 68.86, 91.4, 75.33, 85.07, 91.33, 81.4, 73.67, 75.57, 69.14, 67.67, 69, 68.07, 69.4 <input checked="" type="checkbox"/> AF > 20/min 23.47, 22.47, 21.73, 23.53, 24.53, 24.27, 25.57, 24.33, 27, 24, 25, 25.27, 22.19, 24, 22.27, 23.6, 23.67, 23.53, 24.27, 25.33, 24.8, 24, 24, 22.1 <input checked="" type="checkbox"/> pCO2 < 32mmHg 44.1, 49.2, 49, 53.4, 50.1, 31.2, 45.7, 51.6 <input checked="" type="checkbox"/> Leukos > 12k od. < 4k 6.96 <input type="checkbox"/> SIRS-Kriterien erfüllt											
aktuelle Stand KPI - Werte ?	<input checked="" type="checkbox"/> SIRS-Kriterien erfüllt											

Abb. 1: Beispiel für Erreichen aller KPI-Vorgaben; 100% Erfüllungsquote bei allen 6 Organsystemen Sedierung, Respiration, Herz-Kreislauf, Renales System, enterale Ernährung und SIRS (Systemic Inflammatory Response Syndrome), deshalb alle Teilwertungen sowie die Gesamtwertung (oberster Balken) grün (Ahlborn 2021)

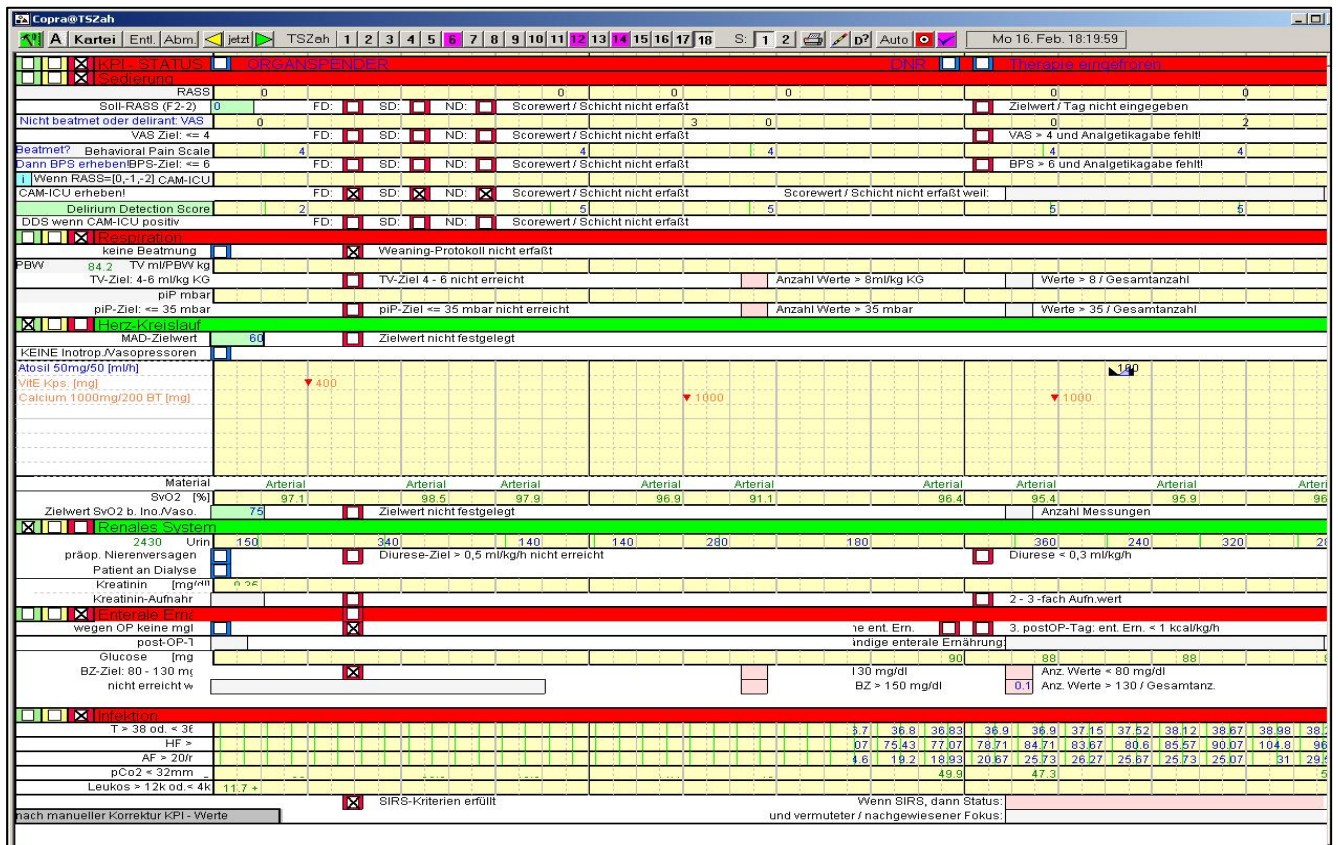


Abb. 2: Beispiel für teilweises Verfehlen der KPI-Vorgaben; 33% Erfüllungsquote, nur Herz-Kreislauf- und Renales System innerhalb der Zielvorgaben, Sedierung, Respiration, frühzeitige enterale Ernährung und SIRS außerhalb der vorgegebenen Grenzen, deshalb Gesamtwertung rot (Ahlborn 2021)

Da die manuelle Auswertung und Dokumentation der vielen beteiligten Einzelparameter (siehe Abb. 1 + 2) aufwendig und fehleranfällig erschien, wurde eine zeitgesteuerte automatische Routine in der externen MySQL-Datenbank Version 5.0.27 programmiert, welche bis 5 Uhr des Folgetages die Compliance der KPI-Parameter des vorherigen klinischen Tages auf dem Formular berechnete und dokumentierte, ohne das hierfür ein manueller Nutzereingriff nötig war (siehe Abb. 3).

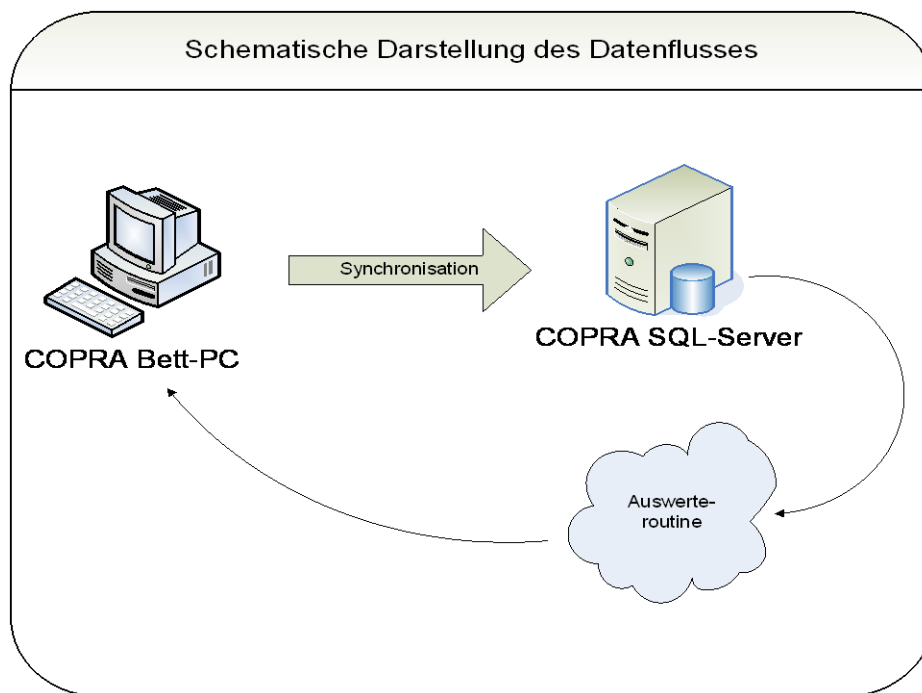


Abb. 3: Schematischer Datenfluss (Ahlborn 2021)

Stand Oktober 2021 gibt es laut Literaturrecherche im Web of Science und Pubmed bisher keine weiteren Publikationen, die die Implementierung vergleichbarer visueller Feedback-Systeme auf Intensivstationen berichten.

3.3.2 Methodik Arbeit 1: KPI und visuelles Feedback

Es wurde die Compliance dieser durch SOPs definierten KPI vor und nach der Einführung der automatischen Auswertung untersucht. Der erste Zeitraum von jeweils 3 Monaten der Auswertung des Vorher-Nachher-Vergleichs wurde so gewählt, dass die manuelle Erfüllungsrate der bereits festgelegten, konsentierten KPI nach den bereits erfolgten Schulungen erfasst werden konnte.

Nach einer Implementierungsphase von 2 Monaten, in der alle Mitarbeiter der Intensivstationen mit dem Erfassungstool der KPI vertraut gemacht wurden, erfolgte eine weitere Analyse über einen Beobachtungszeitraum von ebenfalls 3 Monaten nach Einführung der automatischen Auswertung.

Unter Beachtung der Ausschlusskriterien (Kastrup et al., 2011) für das KPI-Formular wurden 205 Patienten einer kardio-chirurgischen Intensivstation der Charité in die Studie aufgenommen, 111 vor und 94 nach der Implementierung. Beide Patientenkollektive wurden hinsichtlich nicht-normalverteilter metrischer oder ordinaler Variablen mit Hilfe des Mann-Whitney-U-Testes geprüft, für kategoriale Variablen anhand des Chi-Quadrat-Tests. Dies ergab keine signifikanten Unterschiede ($P < 0,05$), so dass beide Kollektive als gleichwertig angesehen werden konnten.

Für den Vergleich der beiden Zeiträume wurden als erster Schritt für die Liegetage je Patient die Erfüllungsgrade der untersuchten KPI als relative Häufigkeiten berechnet, für das Füllen des Weaning-Protokolls und das Eintragen des Soll-RASS gab es nur die Ausprägungen 0 oder 1, bei den pro Schicht zu erhebenden Scores wie RASS, CAM-ICU, VAS, BPS und DDS die vier Ausprägungen 0 | 0,33 | 0,66 | 1. Alleine das Weaning-Protokoll sollte am ersten Tag noch nicht ausgewertet werden, da es immer erst retrospektiv nach 24h anwendbar ist. Bei mehrfacher täglicher Erhebung wurden für die Score-Werte RASS, VAS und BPS die Mittelwerte berechnet. Zusätzlich wurde die Differenz des Mittelwerts RASS von dem, sofern vorhanden, eingetragenen Soll-RASS als Maß für die Abweichung von der Soll-Vorgabe ermittelt. Um Änderungen in der KPI-Einhaltungsrate sowie der absoluten Werte der Scores zwischen den zwei Untersuchungszeiträumen zu untersuchen, wurde im zweiten Schritt der Zeitverlauf der beobachteten KPI mittels einer nichtparametrischen multivariaten Varianzanalyse untersucht. Abschließend wurden Risikofaktoren (TISS-28, SOFA Score, SAPS II, APACHE II und KPI (die relative Häufigkeit der Ziel RASS-Dokumentation, der RASS-Erhebung, der BPS/VAS-Erhebung sowie die jeweiligen absoluten Werte dieser Scores, die relative Häufigkeit der CAM-ICU-Erhebung sowie das Ausfüllen des Weaningprotokolls) auf ihren Einfluss auf die Mortalität, Liegedauer, Beatmungsdauer und das Entstehen von Delir mittels logistischer Regressionsanalyse getestet.

3.3.3. Ergebnisse Arbeit 1: KPI und visuelles Feedback

Auffällig war eine signifikante Abnahme des dokumentierten Ziel-RASS-Scores in der Zeit nach der Einführung (-0,59 vor der Intervention gegenüber -0,89 nach der Intervention; $P = 0,02$), was auf eine beabsichtigte tiefere Sedierung der Patienten hinweist. Die Raten der NRS / BPS- und CAM-ICU-Score Erhebungen und die Compliance des Entwöhnungsprotokolls (von 0,27 +- 1,74 auf 41,9 +- 38,67) stiegen ebenfalls signifikant an ($P < 0,01$ für jeden dieser Vergleiche). Das Mortalitätsrisiko wurde signifikant von der Dokumentation des Ziel-RASS-Scores, des RASS-Scores und der Differenz zwischen Ziel-Vorgabe und eingetragenen RASS-Scores beeinflusst ($P = 0,013$, $P < 0,01$, $P = 0,049$). Die NRS / BPS-Compliance und der absolute NRS-Wert beeinflussten die Dauer der mechanischen Beatmung signifikant ($P < 0,05$ für alle Vergleiche). Die Dauer des Aufenthalts auf der Intensivstation (Length of Stay, LOS) wurde signifikant von der Dokumentation des SAPS II- und SOFA-Scores, dokumentierter RASS-Zielvorgabe, positiver CAM-ICU-Score (≥ 1), NRS / BPS-Compliance und absolutem NRS-Score Wert beeinflusst ($P < 0,05$ für alle Vergleiche). Die Delir Entwicklung wurde signifikant durch den dokumentierten RASS-Score, die Differenz zwischen der Zielgröße und dem dokumentierten RASS-Scores, die Dauer der mechanischen Beatmung sowie der Dauer des Aufenthalts auf der Intensivstation beeinflusst ($P < 0,05$ für alle Vergleiche) (Kastrup et al., 2011).

3.3.4. Methodik Arbeit 2: Blutzucker-Protokoll

Bei der Evaluierung eines protokollgestützten Blutzuckermanagements als neuer KPI durch die Pflege zur Vermeidung von Hypoglykämie wurden in einer retrospektiven Studie auf einer Intensivstation der Charité 388 Patienten aus dem Zeitraum Januar bis Dezember 2013 als Vergleichsgruppe vor der Implementierung des Protokolls und 175 Patienten von Januar bis Juni 2015 für das Intervall nach den einstündigen Schulungen des Pflege-Personals im Jahr 2014 für die Anwendung des pflegegestützten Blutzuckermanagements inkludiert. Patienten mit Kontra-Indikationen wie Hyperglykämie, diabetischer Ketoazidose, hyperosmolarem diabetischem Koma und Aufenthalt unter 48h wurden von der Studie ausgeschlossen. Als Neuerung zu der tradierten Arbeitsweise, dass die Pflege nur auf ärztliche Anordnung eine Anpassung der Medikationen vornehmen kann, sollte die Pflege nun innerhalb eines Korridors von 70 – 300 mg/dl Blutzucker (BZ) selbstständig die Anpassungen der Laufrate des Insulinperfusors mit 1 IE/ml vornehmen (Abb. 3).

Blutzucker		Insulin	Kontrolle	Zuständigkeit
< 70 mg/dl		STOPP	30 min	Arzt sofort
70-139 mg/dl	unter Berücksichtigung	reduzieren/stoppen	1 – 2 h	Pflege ⁴
140-180 mg/dl	der Vorwerte	ggf. anpassen	≤ 4 h	Pflege ⁴
181-300 mg/dl	und Dynamik	ggf. anpassen	≤ 2 h	Pflege ⁴
> 300 mg/dl		ggf. anpassen	1 – 2 h	Arzt

Abb. 4: Verfahrensweisung BZ-Protokoll (Compton et al., 2017)

Es wurden nun für die ersten 5 Liegetage für Intervalle von 6 Stunden Dauer die Blutzuckerwerte, die Insulinlaufraten und die Anzahl der Blutzucker-Kontrollen ermittelt, sowie die Startzeitpunkte der Insulin- und Glukosegaben, respektive Ratenänderungen. Die Ergebnisse von kontinuierlichen Variablen wurden als Median und Interquartilsabstände durch den Wilcoxon-Rangsummentest ausgewertet, kategoriale Variablen durch Chi-Quadrat-Tests.

3.3.5. Ergebnisse Arbeit 2: Blutzucker-Protokoll

Beim Vergleich der beiden Studien-Kohorten fiel auf, dass in der zweiten Gruppe mit Führung der BZ-Protokolls der Median des SAPS signifikant höher ausfiel (52 zu 43, $P > 0,001$), es mehr beatmete Patienten gab (69% zu 60%, $P = 0,03$) und dass es weniger Patienten mit bei Aufnahme vorhandenem Diabetes gab (55% zu 68%, $P = 0,002$).

Die Anzahl der BZ-Messungen pro Patient hatte sich durch die Einführung des BZ-Protokolls nicht signifikant erhöht, vorher waren es 59 (29 – 135) Messungen zu nachher 58 (29 – 120), $P = 0,85$. Der Median des minimalen BZ-Wertes je Fall stieg von 80 (66-95, Interquartilsabstand) auf 93 (79 – 105), $P < 0,001$. Die Anzahl der Hypoglykämien (BZ < 70 mg/dl) hat sich durch die Einführung des Protokolls deutlich verringert, von 117 (31%) auf 22 (13%), $P < 0,001$.

Hyperglykämische Episoden traten im Median seltener auf. In der Kontrollgruppe traten 2 (1-3) auf und in der Protokollgruppe nur 1 (1-1), $P = 0,001$. (Compton et al., 2017).

3.3.6. Methodik Arbeit 3: Auswirkungen des Weaning-KPI auf den ökonomischen Outcome

In einer weiteren retrospektiven Studie wurde der Effekt der Compliance des Weaning-Protokolls (KPI: Frühe Entwöhnung v. d. maschinellen Beatmung) auf die Ergebnisqualität (LOS, Beatmungsdauer) und die Kostenträgerrechnung untersucht. Die Compliance wurde täglich aus den drei Komponenten „Dokumentation Readiness to wean“, „Ausschluss Kriterien für SBT (Spontaneous Breathing Trial) ermittelt“ und der „Dokumentation des SBT“ ermittelt (Abb. 4). Wenn ein Patient als „Ready to wean“ eingestuft wurde, mussten im nächsten Schritt potentielle Ausschlusskriterien für einen SBT ermittelt werden, wenn diese nicht vorhanden waren, sollte als finaler Schritt die Durchführung des SBT oder stattdessen ein Grund für dessen Undurchführbarkeit dokumentiert werden. Es wurden von insgesamt 3063 dann 583 Patienten aus dem Zeitraum Januar 2012 bis Dezember 2017 inkludiert, welche neben den bekannten Ausschluss Kriterien für die KPI länger als 4 Tage beatmet sein mussten und bei denen mindestens ein SBT und die Extubation dokumentiert worden sind. Aus den Erfahrungen der ersten Studien (Kastrup et al., 2011; Kastrup et al., 2009) heraus wurden hier als Cut-Off für die 2 Vergleichsgruppen (LAG = Low Adherence Group, HAG = High Adherence Group) 66% Erfüllungsgrad der KPI-Dokumentation im zeitlichem Verlauf für das frühe Entwöhnen zwischen der Intubation und der Entlassung festgelegt. Die LAG beinhaltete 378 Patienten gegenüber 205 in der HAG. Beide Patientenkollektive wurden hinsichtlich ordinaler Variablen mit Hilfe des ungepaarten T-Testes geprüft, für kategoriale Variablen anhand des Chi-Quadrat-Tests.

($P < 0,001$) festzustellen war, da bis auf die Jahre 2015 - 2016 die Aufwände nicht von den erzielten Einnahmen gedeckt wurden.

Mittels multivariaten Regressionsanalysen über die gesamte Studienkohorte wurde ermittelt, dass die stärksten Einflüsse auf den finanziellen Outcome durch den LOS der Station ($P > 0,001$), den LOS des Krankenhauses ($P = 0,015$), den durchschnittlichen täglichen SOFA ($P = 0,002$; Sequential Organ Failure Score) sowie die durchschnittlichen täglichen Kosten pro Patient ($P = 0,032$) verursacht werden. So verringert jeder weitere Tag auf der Station den Erlös um 529€, wohingegen ein Sinken des SOFA- Durchschnitts über den LOS auf der Station um einen Punkt eine Erhöhung des Gewinns um 1.608€ bedeutet.

3.4. Diskussion

Es gibt zahlreiche Publikationen, welche die durch die Implementierung spezifischer manueller oder computergestützter Leitlinien und Protokolle erhöhte Qualität der Behandlung von Patienten auf Intensivstationen zum Inhalt haben. Die konsequente Anwendung von klinischen Behandlungspfaden führt zu einer deutlich geringeren postoperativen Morbidität und zu einer Verkürzung der Krankenhausverweildauer (Braun et al., 2003; Braun et al., 2005; Hensel et al., 2005; Kumpf et al., 2017; Langelotz et al., 2005).

So wird der positive Effekt der Einführung von schriftlichen Behandlungsstandards (Protokolle für tägliche medizinische Zielvorgaben, Dokumentation der therapeutischen Effektivität, Entlassungsprotokolle) auf die Mortalitätsrate (Verringerung von 35,2% auf 16,3%, $P < 0,05$), die Liegedauer und die Kosten pro Überlebenden von Hochrisiko-Patienten mit einem Apache-II Score von 20 bis 30 Punkten (Verringerung von 15.000,- € auf 6.750,- €, $P < 0,05$) nachgewiesen (Kern & Kox, 1999), weiterhin werden die Vorteile (kürzere Liegedauern, kürzere Beatmungsepisoden, geringere Letalität (38% zu 59% in der Vergleichsgruppe, $P = 0,009$) von patientenspezifischen Behandlungsprotokollen mit individuellen Zielvorgaben gegenüber den allgemeiner gehaltenen Leitlinien beschrieben (Morris, 2003).

Wir konnten in unserer Arbeitsgruppe an der Charité nachweisen, dass unter anderen die für Sedierung und Delir-Monitoring relevanten KPI wie RASS-Ziel (Richmond Agitation Sedation Scale), RASS-Messwert und der BPS (Behavior Pain Scale) als kontinuierliche Score Dokumentation einen positiven Einfluss auf den Outcome haben (Kastrup et al., 2011). Durch die Einführung von Weaning-Protokollen (Entwöhnung von der Beatmung) für die mechanische Beatmung konnte eine signifikante Verringerung der Beatmungsstunden um 35% von durchschnittlich 140 auf 90 Stunden erzielt werden (Marx et al., 1999). In einer Metaanalyse wurden von 26 untersuchten Studien bei 19 die Vorteile von Protokollen bei der Entwöhnung von der maschinellen Beatmung auf Intensivstationen nachgewiesen (Girard, 2008).

In einer multizentrischen Studie in 35 Intensivstationen konnte durch die Implementierung eines sog. Ventilatory-Bundles die Rate beatmungsassoziierter Pneumonien um 44,5 % reduziert werden. Es konnten positive Einflüsse (geringere Wiederaufnahmequoten, geringere Anzahl Reintubationen) nach der Einführung von kontinuierlichen Verbesserungsprozessen auf Intensivstationen, einhergehend mit der Verbreitung von elektronischen Patientenakten, nachgewiesen werden (McMillan & Hyzy, 2007).

In einer prospektiven Observationsstudie an 524 Patienten konnten eine signifikante Reduzierung der primären Pneumoniebehandlungsdauer von fast 4 Tagen (10,11; SD 7,95 versus 6,22; SD 3,27; $p=0.001$) und der Beatmungsdauer von fast 140h (317,59; SD 336,18 versus 178,07; SD 191,33; $p=0.017$) in der Gruppe mit höherer SOP-Compliance nachgewiesen werden (Nachtigall et al., 2009). Der positive Einfluss einer Protokoll gestützten Blutzucker-Einstellung konnte nachgewiesen werden (Compton et al., 2017). Die positiven Aspekte von multidisziplinären Teams und der Einführung von Leitlinien bei der Sepsis-Prävention wurden durch den Nachweis des Rückganges der nosokomialen Infektionen (von 7,5 zu 3,2 pro 1000 Beatmungstage, $P=0,04$) und der Verkürzung der Liegedauer (von 5,92 Tagen im Jahr 2001 zu 4,71 Tagen) aufgezeigt (Brunkhorst, 2006; Jain et al., 2006).

Da nur eine begrenzte Anzahl von Informationen ($\sim 7 \pm 2$) gleichzeitig verarbeitet werden können (Miller, 1956), kann durch die Anwendung moderner Informationstechnologien als Feedback-Instrument im Rahmen dieser patientenspezifischen Protokolle, z. B. durch die Einführung eines softwaregesteuerten visuellen KPI- und Weaning-Protokolls, einerseits die Rate an Fehlermöglichkeiten und andererseits die interklinische Variabilität in der Therapie verringert werden (Baddeley, 2000). Um ein Benchmarking auch mit externen Quellen zu ermöglichen, sollten hierzu die zu untersuchenden Daten nicht zu umfangreich und standardisiert sein. Allerdings gibt es noch keine genaue Definition aller Parameter, welche die Behandlungsqualität erfassen sollen. In einer Metaanalyse werden 50 bisher bekannte und evaluierte KPI aufgeführt (Jebraeily et al., 2019). Ein Hauptproblem bei der zurzeit durchgeführten Qualitätskontrolle und Sicherung ist das Fehlen adäquater Kontrollmechanismen zur Überprüfung der Einhaltung dieser Standards und Leitlinien, dieses Problem wird hier durch das KPI-Formular in COPRA behoben. Die aktuellen Ergebnis-relevanten KPI sind dabei Organ-bezogen im Konsensus Programm durch die Intensivmediziner des Zentrums für Anästhesiologie und Intensivmedizin der Charité (CC7) anhand der Leitlinien der AWMF, DIVI und DGAI (Martin et al., 2010; Weber-Carstens & Putensen, 2017) wie folgt festgelegt:

- Monitoring der Analgosedierung und des Delirs
- Respiratorisches System
- Herz-Kreislauf-System

- Renales System
- Frühe enterale Ernährung
- Infektions-Screening

Als Ergebnis kann man eine signifikante Erhöhung der Dokumentationsrate von KPI nach der Implementierung eines visuellen Feedback-Systems feststellen. Den stärksten Effekt hierbei hatte hier die Dokumentation des Ziel-RASS, dieser beeinflusste alle drei Ergebnis-Qualitäts-Indikatoren: Mortalität, Liegedauer und Beatmungsdauer.

Die Abnahme des dokumentierten Ziel-RASS-Scores sowie die erhöhte Mortalitätsrate des Patientenkollektivs nach der Implementierung des Feedback-Systems kann durch saisonale Besonderheiten induziert worden sein, da die erste Phase von April bis Juni, die zweite Phase hingegen von November bis Januar lief.

Der Effekt der deutlich höheren Compliance des Weaning-Protokolls in der zweiten Phase der Studie auf die Beatmungsdauer wurde nicht untersucht, da es zu 575 dokumentierten Beatmungstagen nur 214 assoziierte Weaning-Protokolle gab, diese zu niedrige Implementierungsrate hätte keine validen Schlüsse zugelassen.

Die Dissertation von Nolting (Nolting, 2011), welche für den gleichen Datensatz nur die jeweils ersten 5 Liegetage untersuchte, ergab ebenfalls eine teilweise deutliche Steigerung der Implementierungsrate der KPI, welche umso höher ausfiel, je niedriger die Ausgangscompliance war, jedoch wurden auch hier von keinem KPI die geforderten 70% oder mehr auf Dauer erreicht. Diese bisherige Zielvorgabe besagte, dass erst eine Erfüllungsquote von mindestens 70% der SOPs einen positiven Einfluss auf den Outcome bei der Behandlung von Pneumonien ergab (Nachtigall et al., 2009). Anhand dieser unbefriedigenden deskriptiven Auswertung wurde dann in Absprache mit allen Beteiligten des CC7 die prozentuale Mindestanforderung von 70% auf 66% herabgesetzt, welche realistisch betrachtet die realen Arbeitsbedingungen eines 3-Schicht-Betriebs auf den assoziierten Intensivstationen deutlich besser abbildet. Vereinfacht gesagt, wenn in 2 von 3 Schichten die Mindestanforderungen erfüllt waren, war der jeweilige Indikator somit ebenfalls erfüllt. Da es bei den KPI außerdem insgesamt 6 als gleichwertig angesehene Organsysteme gibt, kann man nur Vielfache von 16,6% erreichen, max. 100%. Auch deshalb war eine Adjustierung der Zielgröße auf 66% sinnvoll, da man um die geforderten 70% zu erreichen, die bereits nächstfolgende Stufe hätte erreicht werden müssen, das wären dann 82,6%. Diese Adjustierungen der Zielvorgaben haben das frustrane Erleben des betroffenen Personals verringert, da die Zielgrößen nun leichter zu erreichen und vor allem transparenter (2 von 3, 4 von 6 als gut bewertet) dargestellt waren. Zusammenfassend kann man sagen, dass eine hohe Compliance der KPI durch visuelles Feedback (KPI-Formular) einen positiven Impact erzeugt, wobei eine protokoll-gestützte SOP-Implementierung, ebenfalls visuell dargestellt (Weaning-Formular), unterstützend wirkt.

allerdings noch mit entsprechend aufbereitetem Datenmaterial „geschult“, um die gewünschten Zusammenhänge dann zukünftig selbsttätig erkennen zu können. Durch die gute Datenlage ließe sich aber auch ein „unsupervised Learning“ implementieren, bei diesem unüberwachtem maschinellen Lernen sollen die Algorithmen nicht gekennzeichnete Daten selbstständig analysieren, um versteckte Muster aufzudecken.

Das Feedback sollte zukünftig schneller, nicht mehr erst am Folgetag, sondern nach Möglichkeit bereits während der jeweiligen Schicht erfolgen. Diese Möglichkeit bestand zwar bereits, wurde jedoch kaum genutzt, musste sie doch manuell durch den Benutzer angestoßen werden.

Bisher waren aus technischen Gründen auch nicht alle Qualitätsindikatoren durch das KPI-Dashboard abgebildet worden, diese Einschränkung lässt sich nun ebenso wie das Feedback in Echtzeit durch die Einführung der neuen Dokumentationssoftware COPRA6 auf den Intensivstationen korrigieren, da mehr Möglichkeiten zur automatischen Datenauswertung vorhanden sind als in der älteren Version 5. Zukünftig wäre auch eine Darstellung dieses Feedbacks als „Erinnerungsfunktion“ die tägliche Behandlungsroutine begleitend vorstellbar, nicht mehr wie bisher retrospektiv am Folgetag. Hierbei muss allerdings beachtet werden, diese Software nicht durch zu frühes Eingreifen in die ärztliche Handlungskompetenz nach dem Medizinproduktegesetz (MPG) als eigenständiges Medizinprodukt ansehen zu müssen. Dies wäre dann der Fall, wenn die Software, hier COPRA6, ausschließlich „der Erkennung, Überwachung, Behandlung und Linderung von Krankheiten und Verletzungen zu dienen bestimmt ist“ (§ 3 Nr. 1 MPG). Derzeit wird COPRA noch als reines Dokumentationstool, also nicht MPG-pflichtig angesehen.

Ähnlich wie beim BZ-Protokoll sollte man zukünftig auch bei anderen geeigneten KPI nicht nur die reine Ergebnisqualität (Grenzwerte über-, bzw. unterschritten) als Kriterien ansehen, sondern alternativ oder auch parallel den Prozess der Einhaltung dieser Wertekorridore als Kriterien für die Prozessqualität auswerten. Dies hätte dann den Charakter einer Steuerungsfunktion nach dem Qualitätsregelkreis (Plan-Do-Check-Act) (Deming, 1982). Dieses Vorgehen wäre zumindest in der Einführungsphase einer SOP hilfreich, um existierende Schwachstellen schnell aufspüren und beseitigen zu können. Da der Qualitätsaspekt einer Intensivbehandlung derzeit nicht direkt honoriert wird, wäre eine Aufnahme dieser qualitativen KPI als neuer Leistungsbereich in den strukturierten Dialog der BQS (Bundesgeschäftsstelle Qualitätssicherung GGmbH) wünschenswert. Da das im Oktober 2020 in Kraft getretene Krankenhauszukunftsgesetz (KHZG) eine Förderung der elektronischen Dokumentation von Pflege- und Behandlungsleistungen und digitalem Medikationsmanagement vorsieht, sollten die hierfür nötigen Strukturen bald auch in der Breite vorhanden sein.

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4. Eidesstattliche Versicherung

„Ich, Robert Ahlborn, versichere an Eides statt durch meine eigenhändige Unterschrift, dass ich die vorgelegte Dissertation mit dem Thema:

Die Evaluierung eines Feedback-Systems für Evidenz-basierte Prozessindikatoren eines Patienten-Daten-Management-Systems für Intensivstationen und deren Einfluss auf die Behandlungsqualität und den finanziellen Outcome

selbstständig und ohne nicht offengelegte Hilfe Dritter verfasst und keine anderen als die angegebenen Quellen und Hilfsmittel genutzt habe.

Alle Stellen, die wörtlich oder dem Sinne nach auf Publikationen oder Vorträgen anderer Autoren/innen beruhen, sind als solche in korrekter Zitierung kenntlich gemacht. Die Abschnitte zu Methodik (insbesondere praktische Arbeiten, Laborbestimmungen, statistische Aufarbeitung) und Resultaten (insbesondere Abbildungen, Graphiken und Tabellen) werden von mir verantwortet.

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

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

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

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

Datum

Unterschrift

5. Anteilserklärung an den erfolgten Publikationen

Robert Ahlborn hatte folgenden Anteil an diesen Publikationen:

Publikation 1: Co-Autorenschaft

Marc Kastrup, Minna Nolting, Robert Ahlborn, Jan-Peter Braun, Heiko Grubitzsch, Klaus D. Wernecke, Claudia D. Spies,

“An Electronic Tool for Visual Feedback to Monitor the Adherence to Quality Indicators in Intensive Care Medicine”,

The Journal of International Medicine Research 2011, 39(6):2187–2200,

Impact factor (2009): 1,122

Beitrag im Einzelnen:

Festlegung des Studiendesigns mit den Koautoren, alleinige Datenausleitung u. Datenbereinigung, deskriptive Statistik, Interpretation der Daten, Überarbeitung des Manuskripts in Absprache mit den Koautoren, Programmierung der KPI-Formulare, Impact factor (2013): 7,357, TOP-Journal

Publikation 2: Geteilte Erstautorenschaft

Friederike Compton*, *Robert Ahlborn*, * Authors contributed equally, Torsten Weidehoff,

“Nurse-Directed Blood Glucose Management in a Medical Intensive Care Unit“, CriticalCareNurse Vol 37, No. 3, JUNE 2017,

Beitrag Robert Ahlborn im Einzelnen: Festlegung des Studiendesigns mit der Koautorin, alleinige Datenrecherche sowie Datenausleitung u. Datenbereinigung folgender Daten von inkludierten 347 Patienten mit insgesamt 3136 Liegetagen:

- Alter (Geburtsdatum)
- Geschlecht
- Aufnahmedatum
- Entlassungsdatum
- Entlassungsart (tot/überlebt)
- Scores bei Aufnahme (SAPS, TISS)
- Labor bei Aufnahme (Leukos, Hb, Thrombos, Kreatinin, Harnstoff, Natrium, Kalium, CRP, GPT, Bilirubin)
- Beatmung für sämtliche untersuchten Tage ja/nein
- Behandlungsdauer Intensivstation 32b > 48 Stunden?

- Minimaler Blutzucker über den gesamten Behandlungszeitraum
- Insulinlafrate zum Zeitpunkt des minimalen Blutzuckerwertes
- Glucoseinfusionsrate zum Zeitpunkt des minimalen Blutzuckerwertes (einzeln für G20%, G50%, G70%)
- Maximaler Blutzuckerwert über den gesamten Behandlungszeitraum
- Insulinlafrate zum Zeitpunkt des maximalen Blutzuckerwertes
- Glucoseinfusionsrate zum Zeitpunkt des maximalen Blutzuckerwertes (einzeln für G20%, G50%, G70%)
- Minimaler und maximaler Blutzuckerwert an jedem der ersten 5 Behandlungstage
- Insulinlafraten zu den Zeitpunkten der minimalen und maximalen Blutzuckerwerte an diesen 5 Tagen
- Blutzuckerwert 0 Uhr, 6 Uhr, 12 Uhr, 18 Uhr (oder der Wert am nächsten zu diesem Zeitpunkt) an jedem der ersten 5 Behandlungstage incl. 6h vorher
- Insulinlafraten zu diesen Zeitpunkten
- Glucoseinfusionsrate zu diesen Zeitpunkten (einzeln für G20%, G50%, G70)
- Median des Blutzuckerwertes pro Patient über die gesamte Liegedauer
- Median des Blutzuckerwertes pro Patient für Tag 1-5 einzeln

, deskriptive Statistik, Interpretation der Daten, aus den Ergebnissen meiner statistischen Auswertung sind die Tabellen 1-6 entstanden, Überarbeitung des Manuskripts in Absprache mit der Koautorin, Erstellung der Auswerteroutinen für das KPI-Formular
 Beitrag Friederike Compton im Einzelnen: Idee, Festlegung des Studiendesigns mit Ko-Autor, explorative Statistik mit SPSS, Erstellung aller Grafiken, Erstellen des Textes, Korrespondierender Autor.

Impact factor (2017): 1,707, Rank 28 von 118, TOP-Journal

Publikation 3: Co-Autorenschaft

Zuber A, Kumpf O, Spies C, Höft M, Deffland M, Ahlborn R, Kruppa J, Jochem R and Balzer F,

“Intensive Care Economics: Impact of Adherence to the Quality Indicator Weaning on Economic Outcome”, BMJ Open,

Beitrag im Einzelnen:

Festlegung des Studiendesigns mit den Koautoren, alleinige Datenausleitung u. Datenbereinigung aus COPRA, deskriptive Datenauswertung, Interpretation der Daten, Überarbeitung des Manuskripts in Absprache mit den Koautoren

Impact factor (2021): 2,496

Unterschrift, Datum und Stempel des betreuenden Hochschullehrers

Unterschrift des Doktoranden

6. Publikationen

6.1. An Electronic Tool for Visual Feedback to Monitor the Adherence of Quality Indicators in Intensive Care Medicine

The Journal of International Medical Research

2011; 39: xxx – xxx

An Electronic Tool for Visual Feedback to Monitor the Adherence to Quality Indicators in Intensive Care Medicine

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Evidence-based medicine is often inadequately implemented in intensive care units (ICU); the aim of this study was to improve its implementation via a technical feedback system, using key performance indicators (KPI). The study evaluated 205 patients treated in a cardiac surgical ICU over a 6-month period (3 months before and 3 months after implementation of the feedback system). KPI adherence ratios for sedation, delirium and pain monitoring, and completion of a weaning protocol before and after the implementation of the

feedback system, were compared. Adherence ratios for pain and delirium monitoring, and implementation of the weaning protocol, were significantly increased by the intervention. Adherence to KPIs for sedation, which were high at baseline, could not be further improved. Daily display of KPI implementation had a positive effect on adherence to standard operating procedures. Adherence to guidelines may be improved by using this feedback system as part of the clinical routine.

KEY WORDS: KEY PERFORMANCE INDICATORS; FEEDBACK; CRITICAL CARE; ICU; OUTCOME; MORTALITY; QUALITY IMPROVEMENT; GUIDELINE IMPLEMENTATION

Introduction

Patient mortality rate in the intensive care unit (ICU) ranges between 8% and 33%.¹ In order to improve ICU care it is necessary to define and quantify quality of care. The American Institute of Medicine defines this as ‘the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge’.² Evidence-

based guidelines have been developed in order to assist in closing the gap between theoretical quality and practice.^{3,4} Controlled clinical trials have demonstrated that such guidelines improve ICU patient outcomes including length of stay, duration of mechanical ventilation and mortality rates.⁵ In spite of the evidence supporting their benefits, guideline implementation is not satisfactory: approximately 50% of patients do not receive care that is supported by current scientific evidence.^{6,7}

^aM Kastrup and MJ Nolting contributed equally to this article. [QUERY 1]

Despite numerous studies on guideline dissemination and implementation strategies, there is no single intervention (or group of interventions) that results in the effective improvement of guideline use. Teaching, educational materials, various types of reminder, audit and feedback, and multifaceted interventions have resulted in moderate improvements in care ranging from 6.0 to 14.1%.⁸ Substantial resources may be available for quality improvement initiatives in the general health system, but individual organizations must balance the potential quality and outcome benefits with their limited resources. Consequently, current information systems should be evaluated for their value as part of a guideline-implementation process.

Feedback is one such strategy that can be used to improve practice. The aim of feedback is to show the recipient their behaviour and thereby encourage them to change their performance.⁹ Studies have analysed the use of feedback to improve quality in medical care and found wide variations in the effect of reminders and feedback.^{9,10}

It is important to define quality indicators carefully in order to acquire data easily and automatically, regarding quality of care. Valid indicators can be used to quantify guideline implementation¹¹ and can therefore serve as a measurable feedback system.¹² The definition of quality indicators^{11,13} allows them to be used to monitor daily practice and outcome in the ICU, as key performance indicators (KPI). KPIs are defined as 'measurable elements of practice performance, for which there is evidence or consensus that it can be used to access the quality and hence change it'.¹⁴

Studies have used data from patients' charts to give daily feedback; for example, the use of daily paper-based quality rounds'

checklists to improve the implementation of a ventilator-associated pneumonia bundle.¹⁵ A further study collected data from the patient data management system (PDMS) and generated a summarized printout for healthcare providers.¹⁶ Both systems improved the adherence rates for significant prophylactic measures, but had to be manually completed or printed and distributed daily within the team.^{15,16}

The aim of this study was to develop and introduce a technical feedback system into the PDMS, to monitor and report the compliance of certain KPI in the ICU, and to analyse whether this system can improve the adherence of healthcare providers (namely, physicians and nurses) to selected standard operating procedures (SOPs). Data from a 3-month period before, and a 3-month period after, the implementation of the feedback system were compared, with 4 months elapsing between the evaluation periods. It is hypothesized that the KPI monitoring frequency may influence outcome, in terms of ICU mortality and length of stay.

Patients and methods

STUDY POPULATION

Consecutive patients admitted to an 11-bed cardiac surgical ICU at the Charité University Hospital, Berlin, Germany, between 1 April 2008 and 30 June 2008 (preintervention) and between 1 November 2008 and 31 January 2009 (postintervention) were included in this study. Exclusion criteria were: (i) age < 18 years; (ii) documented limitation of therapies at the time of admission; (iii) organ donors; and (iv) duration of ICU stay < 24 h. The study was approved by the Ethics Committee of Charité University Hospital (EA1/126/08), which waived the need for individual informed consent since confidentiality was guaranteed, no

interventions were performed and only routine clinical data were collected.

KEY PERFORMANCE INDICATORS

In 2007, an Institutional Board consisting of the leading physicians of the Department of Anaesthesiology and Intensive Care Medicine, Charité University Hospital Berlin, established a bundle of KPIs as part of a SOP, which were reviewed by an external audit of intensive care specialists. These KPIs were in accordance with German evidence and consensus-based guidelines for the management of analgesia, sedation and delirium in intensive care, and quality indicators that are used to monitor and improve the quality of care.^{11,17} [see QUERY 19] The KPIs included the assessment of sedation, analgesia, delirium and spontaneous breathing (Table 1) [see QUERY 2].

Sedation was evaluated using the Richmond agitation sedation scale (RASS) score.¹⁸ In addition, a goal RASS score was documented by the attending physician once daily for each patient. The RASS score was evaluated three times daily by nursing staff (once per 8-h nursing shift).

Analgesia was evaluated by the Numeric Rating Scale (NRS)^{19,20} or Behavioural Pain Scale (BPS).²⁰ Either or both of the NRS and BPS²¹ were evaluated at least three times daily by nursing staff (at least once per 8-h nursing shift), depending on the patient's neurological situation. The NRS value was ideally maintained at < 5, and the BPS value at < 6; nursing staff were advised to adapt analgesia to patients' needs. [see QUERY 15]

Delirium was assessed using the Confusion Assessment Method for the Intensive Care Unit (CAM-ICU) test.²² This evaluation was undertaken three times daily by nursing staff (once per 8-h nursing shift). In the event of a positive CAM-ICU test,

physicians and nursing staff were advised to begin immediate treatment using a consensus-based algorithm.²³

The spontaneous breathing protocol (weaning protocol) was originally proposed by MacIntyre *et al.*²⁴ and adapted to meet local needs.²⁵ [QUERY 4] For every patient who had been ventilated for > 24 h, the protocol was evaluated once daily by the designated physician; the results (including any weaning failures) were documented in the patients' charts. [QUERY 5] Apart from two manual values, the weaning protocol was completed automatically, using data available within the PDMS: the physician needed to initiate calculations for cardiac ischaemia and adequate cough by activating fields within the system.

All KPIs were integrated into SOPs²⁵ that were available on the hospital intranet to all staff members, and could be directly accessed (without a personal log-in) from the bedside of every ICU patient.

The ICU in which the patients were treated utilized an electronic 'Computer Organized Patient Report Assistant' (COPRA) chart system (COPRA GmbH, Sasbachwalden, Germany). This chart recorded medical and care information, both of which were documented by caregivers and automatically transferred by patient monitors and mechanical ventilators. Laboratory data, input from monitoring systems, and ventilator settings were validated within the system by ICU staff. The PDMS was designed to prevent manual alterations to the data, such as entering missing values after discharge from the ICU.

STUDY INTERVENTION

A technical feedback system based on the KPIs was introduced into the PDMS between the two evaluation periods. This system collected KPI data from PDMS entries and

TABLE 1:
[QUERY 2] Definition and specification of key performance indicators for control of quality of care in the intensive care unit

Parameter	Definition	Specification
Goal RASS score documentation	Documentation of sedation goal, once per day	Percentage of patients with a documented goal RASS score in pre- and postintervention periods
Goal RASS score	Absolute value of documented goal RASS	Mean \pm SD of documented goal RASS scores in pre and postintervention periods
RASS evaluation	RASS evaluation, once per 8-h shift	Percentage of evaluated RASS scores compared with target number of evaluations (according to SOP) in pre- and postintervention periods
Difference between goal and evaluated RASS scores	Difference between mean evaluated and documented goal RASS scores for the same patient on the same day	Mean \pm SD difference between goal and documented RASS scores in pre- and postintervention periods
RASS score	Absolute value of evaluated RASS	Mean \pm SD of evaluated RASS scores in pre- and postintervention periods
NRS or BPS	Analgesia evaluated by NRS (nonsedated and nonventilated patients) or BPS (sedated patients), once per 8-h shift	Percentage of evaluated NRS/BPS compared with target number of evaluations (according to SOP) in pre- and postintervention periods
NRS, absolute value	Value of evaluated NRS	Mean \pm SD of all evaluated NRS values in pre- and postintervention periods
CAM-ICU test	Delirium evaluated by CAM-ICU test once per 8-h shift, if evaluated RASS was ≥ -2 in the same shift	Percentage of evaluated CAM-ICU tests compared with target number of evaluations (according to SOP) in pre- and postintervention periods
Spontaneous breathing (weaning) protocol ^{24,25}	Completion of weaning protocol, once per day (for ventilated patients)	Percentage of completed weaning protocols for days on vent in pre- and postintervention periods

RASS, Richmond agitation sedation scale;¹⁸ NRS, numerical rating scale;^{19, 20} BPS, behavioural pain scale;²⁰ CAM-ICU, confusion assessment method for the intensive care unit;²² SOP, standard operating procedures.

presented them on a summary page for feedback. [QUERY 6] The user was only required to undertake two manual tasks in the system (i.e. activating the fields for cardiac ischaemia and adequate cough, as described above). All other information was collected automatically from the documentation of routine data within the PDMS; no further user action was necessary. Each summary page covered a 24-h period, divided into three columns corresponding to each 8-h nursing shift. The technical feedback system visualized the achieved daily goals and completeness of KPI data entry to the attending team. The KPI report was marked in green if fully completed and in red if items were not documented or specific goals were not met [QUERY 7]. The evaluated and marked record was made available in the COPRA for all staff the next morning. The KPI summary chart formed part of the electronic patient chart, not part of the printed chart. Fig. 1 [QUERY 8] shows a representative daily KPI summary page [QUERY 9].

A summary assessment of all KPIs was reported to the physicians and nurses at the end of each month. [QUERY 10] Along with the feedback system, the ICU team was instructed on how to evaluate sedation and analgesia scores, complete the weaning protocol, access the summary page and interpret the results.

DATA COLLECTION

Patient KPI data from the preintervention period were used as the baseline for comparison with data from the postintervention period (collected after implementation of the technical feedback system). Preintervention data were collected via the PDMS, and were not presented to the team or individual persons involved in patient care. Data presentation testing and

optimization was performed during this period. [see QUERY 10] After the preintervention period, teaching sessions regarding goals and the required theoretical and practical skills were given regularly to all staff, and the KPI summary page was available via the PDMS to the ICU team.

Adherence ratios were calculated using patient chart data. The actual number of items documented was divided by the target number (which should ideally be documented for each patient throughout their ICU stay) and reported as a percentage, in accordance with other studies.^{26,27} An adherence ratio of 100% meant that all items were fully documented for a patient throughout their admission to the ICU.

The following data were collected from electronic patient records: age (years); gender; daily therapeutic intervention scoring system (TISS-28) score;²⁸ daily severity of disease classification system (SAPS II) score;²⁹ daily sequential organ failure assessment (SOFA) score;³⁰ daily acute physiology and chronic health evaluation (APACHE II) score;³¹ duration of ICU stay (days); duration of ventilator support (h); mortality rate.

STATISTICAL ANALYSES

Data are expressed as mean \pm SD, median (interquartile range) [QUERY 11] or frequency (%). Pre- and postintervention patient characteristics were compared via the Mann-Whitney *U*-test or the χ^2 -test. [QUERY 12]. Due to differences in sample sizes, all tests were carried out in an exact version. Univariate comparisons of mortality rates were performed using Fisher's exact test [QUERY 13] and multivariate comparisons were made via logistic regression analysis. Logistic regression analyses generated odds ratios (OR) with 95% confidence intervals (CI). Multiple linear regression analyses were

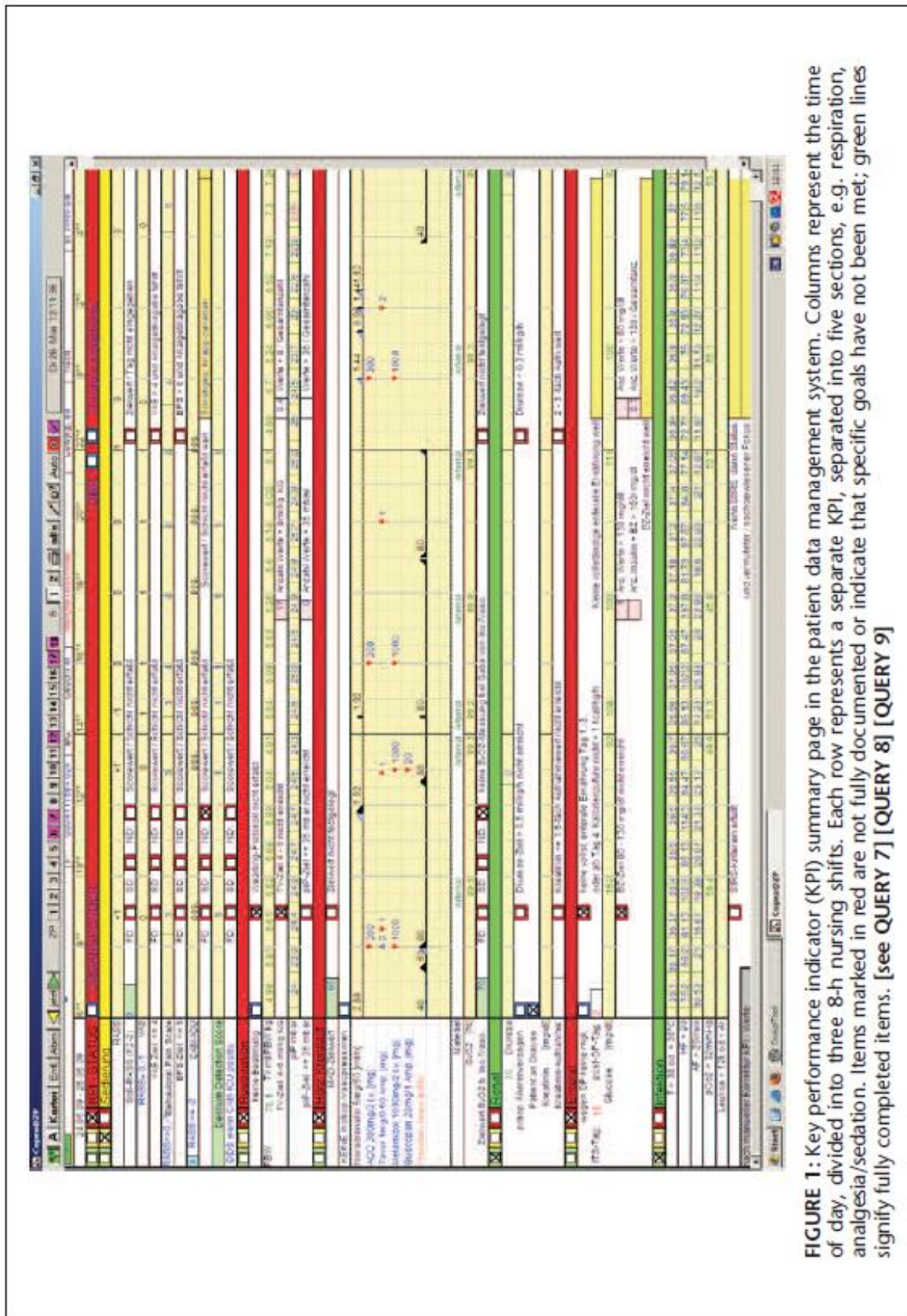


FIGURE 1: Key performance indicator (KPI) summary page in the patient data management system. Columns represent the time of day, divided into three 8-h nursing shifts. Each row represents a separate KPI, separated into five sections, e.g. respiration, analgesia/sedation. Items marked in red are not fully documented or indicate that specific goals have not been met; green lines signify fully completed items. [see QUERY 7] [QUERY 8] [QUERY 9]

used to model the relationship between duration of ICU stay or duration of ventilation and adherence to the KPI (documented goal RASS score, RASS score evaluation, pain evaluation, completion of weaning protocol, TISS-28, SAPS II, SOFA, APACHE II scores). Regression coefficients (95% CI) and the corresponding *P*-values were calculated for each factor.

In order to calculate the effect on the outcome variables, pre- and postintervention data were pooled. Regression analyses included the following risk factors: SOFA score; TISS-28 score; SAPS II score; APACHE II score; documentation rate of goal RASS score; RASS score evaluation rate; NRS value; CAM-ICU test; weaning protocol; difference between documented goal and evaluated RASS scores. Statistical analyses were

performed using the SPSS® statistical package, version 18.0 (SPSS Inc., Chicago, IL, USA) for Windows® and the SAS® statistical package, version 9.2 (SAS Institute Inc., Cary, NC, USA). A *P*-value < 0.05 was considered statistically significant. No adjustments were made for multiple testing.

Results

The study included a total of 205 patients: 111 in the preintervention period, and 94 in the postintervention period (Fig. 2). Patient characteristics are given in Table 2. There were no significant between-group differences in age, SOFA score, TISS-28 score, SAPS II score or APACHE II score.

Data regarding adherence to KPI monitoring and KPI results are given in Table 3. Documentation of goal RASS score, and

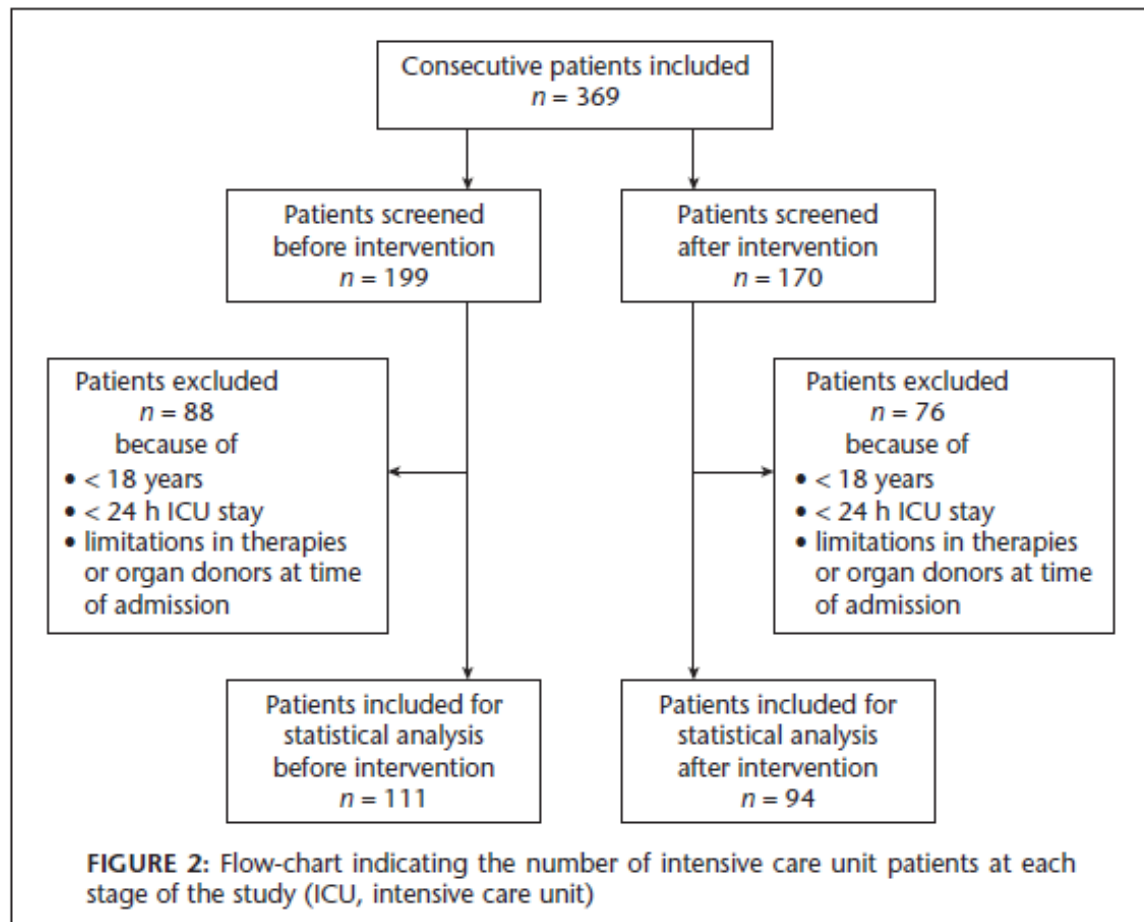


TABLE 2:
Characteristics of the 205 cardiac surgical intensive care unit patients included in the study who were recruited before (preintervention group) or after (postintervention group) implementation of a technical feedback system

Characteristics	Preintervention <i>n</i> = 111	Postintervention <i>n</i> = 94
Females/males	39/72 (35/65)	29/65 (31/69)
Age, years	65.9 ± 12.9	69.3 ± 10.1
Weight, kg	80.7 ± 17.0	81.3 ± 18.4
SOFA score	6.67 ± 4.40	6.74 ± 3.30
TISS-28 score	36.00 ± 7.17	36.91 ± 7.30
SAPS II score	41.94 ± 1.25	43.34 ± 1.40
APACHE II score	21.27 ± 0.56	21.38 ± 0.66

Data presented as mean ± SD, or number (%).

No statistically significant between-group differences ($P > 0.05$); Mann–Whitney U -test or χ^2 -test. [QUERY 14] SOFA, sequential organ failure assessment;³⁰ TISS-28, therapeutic intervention scoring system;²⁸ SAPS II, severity of disease classification system;²⁹ APACHE II, acute physiology and chronic health evaluation.³¹

TABLE 3:
Adherence to key performance indicator (KPI) monitoring and KPI results for 205 cardiac surgical intensive care unit patients who were recruited before (preintervention group) or after (postintervention group) implementation of a technical feedback system

Performance Indicator	Preintervention <i>n</i> = 111	Postintervention <i>n</i> = 94	Statistical significance ^a
Goal RASS score documentation, %	80.7 ± 18.5	70.2 ± 20.4	NS
Documented goal RASS score, absolute value	-0.59 ± 0.57	-0.89 ± 0.91	$P = 0.02$
RASS evaluation, %	64.7 ± 15.6	65.7 ± 16.9	NS
Difference between goal and evaluated RASS scores	0.74 ± 0.72	1.11 ± 0.90	NS
RASS, absolute value	-1.28 ± 1.02	-1.72 ± 1.17	NS
NRS or BPS evaluation, %	61.6 ± 18.5	65.6 ± 16.0	$P < 0.01$
NRS, absolute value	1.34 ± 1.38	1.2 ± 1.6	NS
CAM-ICU evaluation, %	0.5 ± 2.1	38.4 ± 25.8	$P < 0.01$
Diagnosis of delirium (≥ 1 positive CAM-ICU test; number)	1 (<i>n</i> = 4)	20 (<i>n</i> = 69)	NS
Completion of weaning protocol, %	0.27 ± 1.74	41.90 ± 38.67	$P < 0.01$

Data presented as mean ± SD, mean percentage ± SD or number, as indicated. [QUERY 16]

^aMann–Whitney U -test or χ^2 -test.

RASS, Richmond agitation sedation scale;¹⁸ NRS, numerical rating scale;^{19,20} BPS, behavioural pain scale;²⁰ CAM-ICU, confusion assessment method for the intensive care unit;²² NS, not statistically significant ($P > 0.05$).

evaluation of RASS and NRS/BPS, were higher than the 60% implementation ratio before feedback [QUERY 15]. Consequently, feedback intervention did not result in any significant improvement in documentation of goal RASS score or RASS evaluation rate.

There was a significant decrease in documented goal RASS score in the postintervention period (-0.59 pre-intervention versus -0.89 postintervention; $P = 0.02$; Table 3), indicating an intended deeper sedation of patients. There was a

significant postintervention increase in the rates of NRS/BPS and CAM-ICU evaluations, and completion of weaning protocol ($P < 0.01$ for each of these comparisons; Table 3).

Results of a multivariate logistic regression analysis of the influence of KPIs on mortality rates are given in Table 4. Documentation of goal RASS score, documented goal RASS score, evaluated RASS score and the difference between goal and evaluated RASS scores significantly influenced mortality risk ($P = 0.013$, $P < 0.01$, $P < 0.01$ and $P = 0.049$, respectively; Table 4). In addition, TISS-28, SAPS II, APACHE II and SOFA scores significantly influenced ICU mortality risk ($P < 0.01$ for all comparisons).

The results of a multivariate logistic regression analysis of the influence of KPIs on the duration of mechanical ventilation are given in Table 5. Duration of ICU stay, TISS-28, SAPS II, SOFA, APACHE II, evaluated RASS and documented goal RASS scores, together with NRS/BPS evaluation and absolute NRS value significantly influenced the duration of mechanical ventilation ($P < 0.05$ for all comparisons; Table 5).

The results of the multivariate linear regression analysis with duration of ICU stay as the dependent variable are given in Table 6. SAPS II and SOFA score, documented goal RASS score, ≥ 1 positive CAM-ICU test, NRS/BPS evaluation and NRS value significantly influenced the duration of ICU stay ($P < 0.05$ for all comparisons; Table 6).

Table 7 gives the results of a multivariate linear regression analysis of factors influencing the risk of delirium development (≥ 1 positive CAM-ICU test). Delirium was significantly influenced by evaluated RASS score, difference between goal and evaluated RASS scores, duration of mechanical ventilation and duration of ICU stay ($P < 0.05$ for all comparisons; Table 7).

Discussion

Several studies have revealed clinically significant positive effects of sedation guidelines on patient outcomes.^{32–35} In addition, the early detection of delirium may decrease the frequency of adverse events by permitting more rapid treatment induction.³⁶ The use of weaning protocols

TABLE 4:
Multivariate logistic regression analysis of factors affecting mortality in 205 cardiac surgical intensive care unit patients

Variable	B	SE	Statistical significance	OR (95% CI)
TISS-28 score	0.280	0.050	$P < 0.01$	1.323 (1.198, 1.460)
SAPS II score	0.154	0.028	$P < 0.01$	1.166 (1.103, 1.233)
APACHE II score	0.292	0.058	$P < 0.01$	1.340 (1.196, 1.501)
SOFA score	0.449	0.093	$P < 0.01$	1.566 (1.304, 1.881)
Goal RASS score documentation	0.638	0.258	$P = 0.013$	1.893 (1.141, 3.142)
Documented goal RASS score	-1.492	0.266	$P < 0.01$	0.225 (0.134, 0.379)
RASS evaluation	-1.599	0.278	$P < 0.01$	0.202 (-0.117, -0.348)
Difference between goal and evaluated RASS scores	0.430	0.219	$P = 0.049$	1.537 (1.002, 2.360)

ICU, intensive care unit; TISS-28, therapeutic intervention scoring system;²⁸ SAPS II, severity of disease classification system;²⁹ APACHE II, acute physiology and chronic health evaluation;³¹ SOFA, sequential organ failure assessment;³⁰ RASS, Richmond agitation sedation scale;¹⁸ OR, odds ratio; 95% CI, 95% confidence interval. [see QUERY 13]

TABLE 5: Multivariate logistic regression analysis of factors (key performance indicators) affecting duration of mechanical ventilation for 205 cardiac surgical intensive care unit (ICU) patients

Variable	B (95% CI)	SE	Statistical significance
Age	1.180 (-0.738, 3.098)	0.973	NS
Duration of ICU stay	0.928 (0.888, 0.969)	0.020	$P < 0.01$
TISS-28 score	4.814 (1.755, 7.873)	1.552	$P = 0.002$
SAPS II score	2.862 (1.212, 4.512)	0.837	$P = 0.001$
SOFA score	9.353 (3.092, 15.614)	3.176	$P = 0.004$
APACHE II score	4.779 (1.114, 8.444)	1.859	$P = 0.011$
RASS evaluation	-18.796 (-36.203, -1.388)	8.829	$P = 0.034$
NRS or BPS evaluation	-220.796 (-301.156, -140.436)	40.719	$P < 0.01$
NRS value	-19.754 (-37.785, -1.722)	9.133	$P = 0.032$
Documented goal RASS score	-50.732 (-87.856, -13.608)	18.823	$P = 0.008$

TISS-28, therapeutic intervention scoring system;²⁸ SAPS II, severity of disease classification system;²⁹ SOFA, sequential organ failure assessment;³⁰ APACHE II, acute physiology and chronic health evaluation;³¹ RASS, Richmond agitation sedation scale;¹⁸ NRS, numerical rating scale;^{19,20} BPS, behavioural pain scale;²⁰ 95% CI, 95% confidence interval; NS, not statistically significant ($P > 0.05$).

TABLE 6: Multivariate logistic regression analysis of factors affecting duration of stay in the cardiac surgical intensive care unit for 205 patients

Variable	B (95% CI)	SE	Statistical significance
SAPS II score	2.550 (0.559, 4.541)	1.008	$P = 0.012$
SOFA score	6.697 (0.189, 13.206)	3.301	$P = 0.044$
Documented goal RASS score	-53.509 (-94.269, -12.749)	20.646	$P = 0.010$
Hours on ventilator	0.794 (0.342, 1.246)	0.217	$P = 0.002$
≥ 1 positive CAM-ICU test	83.682 (30.640, 136.723)	25.428	$P = 0.004$
NRS or BPS evaluation	-205.930 (-289.149, -122.711)	42.167	$P < 0.01$
NRS value	-17.962 (-31.737, -4.187)	6.945	$P = 0.011$

SAPS II, severity of disease classification system;²⁹ SOFA, sequential organ failure assessment;³⁰ RASS, Richmond agitation sedation scale;¹⁸ NRS, numerical rating scale;^{19,20} BPS, behavioural pain scale;²⁰ CAM-ICU, confusion assessment method for the intensive care unit;²² 95% CI, 95% confidence interval.

and spontaneous breathing trials have been shown to decrease the duration of mechanical ventilation and improve patient outcome.³⁷

The current study found that routine PDMS data can be used to improve the adherence to evidence-based medicine by displaying performance results daily within the patient's chart. It was not possible, however, to achieve a consistent adherence

rate of ≥ 70% for all of the KPIs investigated. Improvement was dependent on the baseline implementation rate: high preintervention adherence ratios could not be improved, whereas low preintervention adherence ratios (including CAM-ICU tests and the weaning protocol) were significantly increased. These findings are in accordance with a study that found the adjusted risk difference of compliance with desired

TABLE 7: Multivariate logistic regression analysis of factors influencing risk of delirium development (≥ 1 positive CAM-ICU test) for 205 cardiac surgical intensive care unit patients

Variable	B	SE	Statistical significance	OR (95% CI)
Evaluated RASS score	0.611	0.159	$P < 0.01$	1.842 (1.349, 2.515)
Difference between goal and evaluated RASS scores	-0.410	0.157	$P = 0.009$	0.664 (0.488, 0.903)
NRS value	1.292	0.661	NS	3.640 (0.997, 13.296)
Duration of mechanical ventilation	-0.003	0.001	$P = 0.001$	0.997 (0.996, 0.999)
Duration of ICU stay	0.003	0.001	$P = 0.025$	1.003 (1.000, 1.006)

ICU, intensive care unit; RASS, RASS, Richmond agitation sedation scale;¹⁸ NRS, numerical rating scale;^{19,20} CAM-ICU, confusion assessment method for the intensive care unit;²² OR, odds ratio; 95% CI, 95% confidence interval; NS, not statistically significant ($P > 0.05$).

practice varied between -0.16 (a 16% absolute decrease) and 0.70 (a 70% increase).³⁸ Greater effectiveness was associated with low baseline compliance and a high intensity of audit and feedback.

Feedback on KPI adherence was available with a delay of 24 h in the present study. Minimizing this time delay and introducing additional reminders at the bedside may have positive effects on compliance, since healthcare providers would have the opportunity to change their behaviour more immediately.^{39,40} [QUERY 17] For technical reasons, neither real-time feedback nor reminders were possible in the ICU where the study was conducted. However, in this unit, PDMS-based feedback was always visible for all staff. Because patients were assigned to particular nurses and physicians, staff members had the opportunity to receive personal feedback on their performance on the previous day. This allows feedback on both team and individual performance. It is still unclear in the literature whether feedback should be given individually or in a group,⁴¹ and technical restrictions do not allow for real-time feedback of each entry to be displayed immediately in the PDMS.

Documentation of the goal RASS score

was > 70% before the implementation of the feedback system in the present study; this value could not be further increased. RASS evaluation was > 60% in both observation periods, which represents a markedly higher percentage than that reported in other studies. In a follow-up sedation survey of 261 German ICUs, 51% used a sedation scale regularly, and only one used the validated RASS.³ Despite being unable to increase sedation evaluation to once per shift, the present study demonstrates the importance of regular evaluation of sedation; regression analysis demonstrated an association between the duration of mechanical ventilation and goal and evaluated RASS scores. These results are consistent with other studies showing that an excessive use of sedatives prolongs mechanical ventilation and duration of ICU stay.^{42,43} The documentation of patient care goals on a daily sheet helps healthcare providers to gain an enhanced understanding of patient care plans and how to achieve them.⁴⁴ RASS scores evaluated in the present study, which represent actual sedation of a patient, showed a mean deviation from the pre- and postoperative goal RASS scores of 0.74 and 1.11, respectively, thereby showing a good

application of the theoretical sedation goal.

The implementation rate of systematic pain assessment was significantly increased after the introduction of the feedback system. A prospective observational study of pain management practices revealed a 37 – 42% rate of pain assessment.²⁶ The results from both periods of the current study were higher than this, but it was not possible to achieve a constant adherence rate of $\geq 70\%$. Feedback intervention has been found to increase the adherence to a pain assessment schedule significantly.^{27,45} Higher adherence ratios may be achieved by giving individual feedback and focusing on pain assessment.

There was no decrease in NRS values after intervention in this study. This is in contrast to the findings of Chanques *et al.*,²¹ who reported an increase in pain evaluation rates and a decreased incidence of pain with the implementation of a systematic evaluation of pain and agitation that included the use of the BPS, NRS and RASS by nurses, and the alerting of physicians to cases of pain. The NRS values in the present study are comparable with those in a report on the effect of remifentanyl versus fentanyl in mechanically ventilated patients.⁴⁶

In the present study, linear regression analysis revealed a significant association between a positive CAM-ICU test and the duration of ICU stay. This demonstrates the importance of delirium detection, which was increased by the implementation of the technical feedback system and short tutorials for the ICU staff. The CAM-ICU test is a novel tool for delirium detection, and compliance with this protocol is increasing. In a 2004 survey, 27% of responding healthcare providers reported daily delirium screening with only 7% using CAM-ICU tests.²² A survey in 2008 found that 47% of nurses screened their patients at least every 12 h and 36% used CAM-ICU tests.⁴⁷ A 1-day

observational prevalence study in 2011 reported that 55% of ICUs implemented validated delirium monitoring (mostly CAM-ICU tests) and that 30% monitored delirium every 8 h.⁴⁸ These findings are similar to those of the current study, which also demonstrated the insufficient implementation of routine delirium monitoring. Further education is required to continue the improvement in awareness of the importance of delirium.

The present study revealed extremely limited use of the weaning protocol in the preintervention period, despite it being easily available in the PDMS. The introduction of the feedback system and staff education significantly increased the adherence rate. These findings are in accordance with another study, where staff education and computerized ICU documentation significantly increased the documentation of weaning parameters.¹⁶ Other studies have achieved even higher compliance rates, possibly due to the assignment of additional respiratory therapists and nurses, who took over these duties from the responsible physicians.^{49,50}

A combined spontaneous awakening and spontaneous breathing trial by Girard *et al.*³⁷ demonstrated better outcomes for mechanically ventilated patients with regard to mortality, duration of mechanical ventilation and duration of hospitalization. The patients in the present study were treated like the control patients of the Girard *et al.*³⁷ study because of the missing spontaneous awakening trial with complete interruption of sedatives, which is not part of routine treatment at the Charité University Hospital, Berlin. The spontaneous awakening patients in Girard's study were observed by a team for ≥ 4 h after discontinuation of sedatives, but this procedure is difficult to adopt without

additional staff. A barrier to the wide implementation of combined spontaneous awakening and spontaneous breathing trials may be the fear of long-term negative cognitive and psychological outcomes, although adverse results and psychological outcomes have been shown to be comparable between these two groups [QUERY 18].⁵¹

There are several limitations to the present study, which must be considered when interpreting the results. The effect of the feedback system on the clinical course must be interpreted with caution, despite the fact that there were no between-group differences in patient characteristics. Another study revealed seasonal variations in cardiac surgery outcomes (risk-adjusted mortality and duration of stay).⁴² Similar findings have been reported in studies from Finland and England, where illness-adjusted hospital mortality is higher in winter than in other seasons.^{43,44} There were no significant differences in age or duration of stay of patients in the postintervention period (which ran between November and January) in the present study compared with the preintervention period (which ran between April and June).

Rather than conducting a randomized controlled trial, in the present study routine data available from the patients' charts were used in an effort to improve the quality of

care. Since many tools used in clinical studies are not used for quality improvement there is a risk of bias, which cannot be accurately estimated and may be invisible.⁵²

The KPIs in the present study agree with the current evidence and consensus-based German guidelines for the management of analgesia, sedation, delirium and weaning from ventilation in intensive care.²³ [see QUERY 19] This is the first study to demonstrate that adherence to KPIs can be influenced by the introduction of a technical feedback system into the PDMS. This feedback system – which featured a daily display of the implementation of various clinical parameters – had a positive effect on adherence to SOPs, depending on the baseline level of implementation. Adherence to guidelines can be monitored via PDMS with KPIs. The adherence to guidelines may be improved by using these data for a feedback system as part of the clinical routine.

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Conflicts of interest

The authors had no conflicts of interest to declare in relation to this article.

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[QUERY 19] References

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6.2. Nurse-Directed Blood Glucose Management in a Medical Intensive Care Unit
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BMJ Open Does adherence to a quality indicator regarding early weaning from invasive ventilation improve economic outcome? A single-centre retrospective study

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ABSTRACT

Objectives To measure and assess the economic impact of adherence to a single quality indicator (QI) regarding weaning from invasive ventilation.

Design Retrospective observational single-centre study, based on electronic medical and administrative records.

Setting Intensive care unit (ICU) of a German university hospital, reference centre for acute respiratory distress syndrome.

Participants Records of 3063 consecutive mechanically ventilated patients admitted to the ICU between 2012 and 2017 were extracted, of whom 583 were eligible adults for further analysis. Patients' weaning protocols were evaluated for daily adherence to quality standards until ICU discharge. Patients with <65% compliance were assigned to the low adherence group (LAG), patients with ≥65% to the high adherence group (HAG).

Primary and secondary outcome measures Economic healthcare costs, clinical outcomes and patients' characteristics.

Results The LAG consisted of 378 patients with a median negative economic results of –€3969, HAG of 205 (–€1030), respectively ($p<0.001$). Median duration of ventilation was 476 (248; 769) hours in the LAG and 389 (247; 608) hours in the HAG ($p<0.001$). Length of stay (LOS) in the LAG on ICU was 21 (12; 35) days and 16 (11; 25) days in the HAG ($p<0.001$). LOS in the hospital was 36 (22; 61) days in the LAG, and within the HAG, respectively, 26 (18; 48) days ($p=0.001$).

Conclusions High adherence to this single QI is associated with better clinical outcome and improved economic returns. Therefore, the results support the adherence to QI. However, the examined QI does not influence economic outcome as the decisive factor.

INTRODUCTION

In the last decades, the need for quality management (QM) in the hospital has been growing. On one hand costs have been rising and on the other patients, health insurance and public pressure urge hospitals to improve outcome and services by cutting or tying reimbursement to valid quality indicators (QIs).¹ This is why in the medium and long

Strengths and limitations of this study

- This is the first study evaluating whether a quality indicator on weaning has effects on the economic outcome parameters on a per case basis.
- Results of the cost unit accounting practice is well established and is thus representative for a detailed examination of unit costs.
- The test and validation sample was taken from a reference centre specialised on acute respiratory distress syndrome in adult patients with severe medical conditions.
- Control for interactions with other quality indicators is necessary as the examined quality indicator is potentially connected with other ones.
- The study results are based on German reimbursement system and might be typical for a tertiary university hospital rather than German hospitals in general

run quality-oriented reimbursement (pay for quality) might change the hospital landscape.² Economics of health have been established widely in order to curb costs for the national healthcare system. Many countries introduced diagnosis-related groups (DRGs) in order to pay on averaged costs and on a generalised financial reimbursement per case (fixed prices). Reimbursement for inpatients is linked to DRG accounting and updated annually based on reported data from hospitals. The fee-for-service system induces hospitals to improve internal processes as reimbursement is predefined and to work goal-oriented towards therapeutic aims.³

In modern medicine, a considerable part of hospital costs arises from intensive care. The cost structure of a tertiary German hospital shows that ca. 20% of costs are generated in intensive care units (ICUs).⁴ Especially, mechanical ventilation is the main cost driver in ICUs.⁵ Approximately 6% of the patients in intensive care are affected by prolonged



mechanical ventilation and weaning from mechanical ventilation represents an essential element in the treatment of critically ill patients as it can take up to 50% of the ventilation time.⁶ As a consequence, up to 37% of all ICU resources are allocated to these patients.⁷ This means that weaning patients from mechanical ventilation is not only essential for clinical outcomes like duration of ventilation or length of stay (LOS),^{8,9} but also a critical step from an economic perspective as costs can be reduced. Therefore, this process is a critical phase in intensive care. However, the ideal weaning process is still subject to debate.¹⁰ About 40% of patients receiving mechanical ventilation will experience a complicated weaning process.¹¹ Patients categorised in prolonged weaning, failing at least three spontaneous breathing trials (SBTs) or receiving more than 7 days of weaning after the first SBTs, have an increased risk in developing hospital mortality, mainly through ventilator-associated pneumonia (VAP),⁶ but also through postintensive care syndrome (PICS) or chronic critical illness (CCI).¹² Due to demographic changes and technological advances in intensive care, the number of older patients with complex diseases or comorbidities needing ventilation is increasing.^{13,14} This generates growing costs, as the cohort of patients requiring respiratory support accounts for a disproportionate percentage of the resources available in intensive care.¹⁵

With the purpose of managing quality throughout the difficult framework conditions of hospital care, a proactive and structured QM is essential.¹⁶ In general, QM focuses on securing and improving clinical services economically, performed by physicians or nurses according to the patient's needs.¹⁷ In Germany, in the context of European and national QM initiatives, consensus-based standardised QIs were developed for intensive care medicine since 2010—third version in 2017—by the German interdisciplinary society for intensive and emergency care (DIVI) in order to simplify the measurement of relevant quality data, to record timely and to allow transparent comparisons of patient data. The according quantification of QM helps measuring effectiveness and efficiency of ICUs.^{18,19} QIs enable a descriptive picture of the actual condition and are an indispensable instrument for comparisons between different states of quality.¹⁸ Potentially, widely accepted QIs can progress hospital economics and support the reduction of the national budget for health-care, even though a recent study has shown that cost-quality relationships are difficult to generate.²⁰

QIs empower advances in intensive care medicine to be measured and evaluated on a regular basis.¹⁹ QIs can be defined as representative figures for quality of structure, processes or outcome within the medical care process. Thus, indicators are useful for measuring improvement in the context of QM and should be developed in line with evidence-based literature.²¹ Ideally, measures for QIs can be extracted from routine patient data to avoid excess documentation work. Therefore, patient data management systems (PDMS) are pivotal for measuring complex quality figures.¹⁸ The economic aspects for the whole

hospital of the introduction of QIs are not well investigated. However, there is evidence that the application of QIs is a value-creating instrument.¹²

The objective of this study was, to determine the economic impact of adherence to a single QI evaluating the weaning process from invasive ventilation. We analysed this by comparing economic results per case and clinical outcome parameters like LOS between two groups of either high-quality or low-quality adherence. Additionally, we sought to determine factors that would influence a potential interaction between economic and outcome parameters.

METHODS

This original research is in accordance with the Consolidated Health Economic Evaluation Research Standards.

Patient and public involvement

Patients and the public were not directly involved in this observational study.

Study centre

We conducted this single study-centre in a university hospital (Charité-Universitätsmedizin Berlin). This observational analysis was performed at a 14-bed ICU (reference centre), specialised in treatment of acute respiratory distress syndrome in adult patients. All patients at our ICU were treated according to guidelines and internal standard operating procedures for clinical practice.²²

Study design

This was a retrospective descriptive study, using data from multiple electronic databases used in routine patient care and for routine administrative purposes. All patients admitted to and discharged from the ICU between 1 January 2012 and 31 December 2017 who received invasive ventilation during their stay were eligible to be included in this study. Furthermore, duration of ventilation <95 hours, receiving no invasive ventilation, terminal status, incomplete patient record or missing readiness to be weaned were defined as exclusion criteria (see figure 1).

Confidentiality was guaranteed, no interventions were performed and only clinical routine data were collected. Data were retrieved from a PDMS called (Computer Organised Patient Report Assistant; COPRA System, Berlin, Germany). Data are recorded both automatically by patient monitors and manually by caregivers. The ICU staff validates all information manually. However, the design of the PDMS prevents manual alterations to the data, for example adding missing values after discharge from the ICU. PDMS data are also transferred to the clinical information and accounting system (SAP, Walldorf, Germany). Based on this administrative system, cost unit accounting is performed annually. In addition to basic demographic data, we assessed clinical and administrative parameters of in-patient cases (eg, LOS). Data were

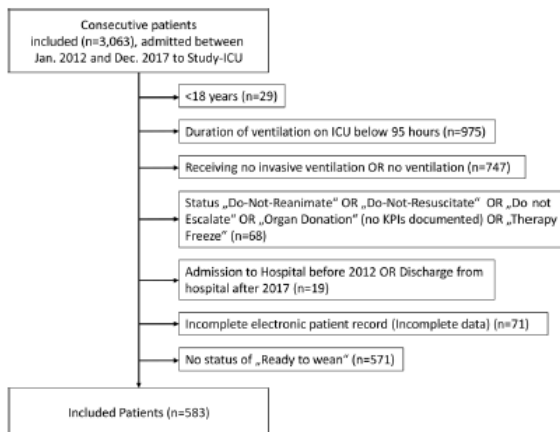


Figure 1 Patient inclusion and exclusion criteria. Flow chart of the process used in this study for patient record inclusion. Numbers listed are number of patients in each group. ICUs, intensive care units; KPIs, key performance indicators.

retrieved using a structured query. No patient identifiers were extracted in order to secure anonymity of patients' data. Data related to diagnoses were not retrieved from the administrative systems.

PDMS data of patients included in the study were transferred to the study database, where we also collected the administrative and cost accounting data, respectively. We contrasted patient, intensive care and economic parameters of the two adherence groups (see table 1). Then, we calculated the profits per case by subtracting costs of reimbursement per case. In order to generate an economic outcome per case for the dependent variable in multivariate linear regression. Besides administrative data, we used different scores for assessing the QI for eligibility. Selection criteria were: (1) no additional workload required for documentation, (2) the availability within the PDMS system, (3) standardised values for all patients and the existence of standard operating procedures for each indicator and (4) the relevance of the indicator for clinical decision making.^{19 23}

Procedures

In this study, we used present key performance indicators (KPIs) in order to examine the adherence to the QI 'Early Weaning from Invasive Ventilation' until ICU discharge.⁸ A small set of evidence-based KPIs was established in 2009, providing indicators that were already available within the PDMS. The KPIs in intensive care medicine proved helpful for practical use and compliance with standard operating procedures. A description of the KPI is provided in online supplemental material. Within the weaning therapy, fast visual feedback for 'readiness to wean' and 'weaning protocol compliance' were implemented. If both KPIs were positive, the according result of the SBT was recorded.²³ Once the patient was assessed to be ready to wean since the primary disease showed clinical improvement, the standard weaning protocol activities

were conducted on a daily basis according to standard operating procedures. Congruent with clinical guidelines in place, weaning protocols were adapted to evaluate the progress of respirator therapy.²² The subsequent result was recorded in the weaning protocol. For each patient, we monitored the daily weaning protocol compliance between readiness to wean and ICU-discharge in order to evaluate the percentage of adherence. Within the weaning process, the SBT represents the major diagnostic test to evaluate if the patient can be extubated successfully.¹⁰ The SBT is successful if the patient succeeded the trial and does not have to be re-intubated within 48 hours.²⁴ This process is directly linked to a specific QI for weaning derived from the DIVI-QI.¹⁹ A definition of the indicator is presented in online supplemental material.

Outcome parameters

In this study, we investigated for economic results, clinical outcome parameters per case and the respective adherence to quality. Economic results were defined as the profit or loss per case, by subtracting all assigned costs from the reimbursement on a case level. Clinical outcomes as a representative for clinical effectiveness were measured in order to set economic outcomes in relation to the purpose of medicine. Adherence to quality was calculated on a per case level in order to categorise the patients into groups.

We used the adherence level of the examined QI in order to create two quality groups. We calculated the final quality level by averaging the daily indicator results for the duration with equal weights per day. In order to set the optimal cut-off point for dichotomously distinguishing between high-adherence and low-adherence of weaning quality, we combined recommendations from literature with our institutional standards. A cut-off value of 70% deemed as a suitable fulfillment-threshold for QIs.²⁵ However, due to partially high workload under certain circumstances in intensive care, we decided to lower the cut-off for 5% tolerance in order to account for missing values in documentation. Therefore, we inserted a cut-off for weaning protocol compliance at 65% adherence. The low adherence group (LAG) was defined as adherence to QI of less than 65%. The high adherence group (HAG) was defined as adherence to QI of equal or more than 65%. Once this threshold was reached, the QI was characterised as high adherence.

Statistical analyses

Descriptive analyses and statistical testing were performed using SPSS, V.14.0 (SPSS) for Windows. Results are expressed as median (IQR) or frequency (%). We controlled data for risk and severity by exclusion as patients and therapies in intensive care are heterogenic, as studies have shown.¹⁸ Differences between the adherence groups in terms of outcome parameters were tested using the univariate unpaired t-test and χ^2 statistics for independent variables as appropriate with a $p < 0.05$ regarded as significant.


Table 1 Patient demographics and outcome parameters in comparison between QI adherence groups

	All patients n=583	LAG QI <65% n=378	HAG QI ≥65% n=205	P value
Demographics				
Age (years)	57 (40; 70)	57 (40; 70)	55 (42; 69)	0.770
Gender (male)	377 (64.7%)	233 (61.6%)	144 (70.2%)	0.038
ICU score on admission				
APACHE II	21 (14;27)	21 (15;27)	21 (14;27)	0.986
SAPS II	47 (34;61)	47 (35;60)	47 (34;62)	0.860
SOFA	9 (7;12)	9 (7;12)	9 (7;13)	0.526
Average SOFA	8.2 (6.6;10.3)	8 (6.5;10.1)	8.4 (6.8;10.7)	0.140
Type of admission to Study-ICU				
Medical	290 (49.7%)	190 (50.3%)	100 (48.8%)	
Emergency surgery	232 (39.8%)	146 (38.6%)	86 (41.9%)	
Elective surgery	61 (10.5%)	42 (11.1%)	19 (9.3%)	
Outcome parameter				
Duration of Ventilation Study-ICU (hour)	431 (250;709)	476 (248;769)	389 (247;608)	<0.001
Total duration of ventilation hospital (hour)	578 (338;924)	597 (310;992)	535 (361;821)	0.017
No spontaneous breathing trials	1 (0;2)	1 (0;2)	1 (0;2)	0.456
No reintubation	0 (0;1)	0 (0;1)	0 (0;1)	0.531
Type of discharge of study-ICU				
ICU	161 (27.6%)	100 (26.5%)	61 (29.8%)	
Intermediate/ward	260 (44.6%)	172 (45.5%)	88 (42.9%)	
Rehabilitation	110 (18.9%)	56 (14.8%)	54 (26.3%)	
ICU mortality	52 (8.9%)	50 (13.2%)	2 (1.0%)	
LOS Study-ICU (days)	19 (11;32)	21 (12;35)	16 (11;25)	<0.001
LOS hospital (days)	33 (20;54)	36 (22;61)	26 (18;48)	0.001
Profit (€)	-2999 (-15 946; 7730)	-3696 (-21 170; 6828)	-1030 (-11 134; 9449)	<0.001

Discrete variables are presented as a total number of encounters and were analysed with χ^2 test for non-parametric samples. APACHE II, Acute Physiology and Chronic Health Evaluation II; HAG, high adherence group; ICU, Intensive care unit; LAG, low adherence group; LOS, Length of stay; QI, quality indicator; SAPS, Simplified Acute Physiology Score; SOFA, Sequential Organ Failure Assessment.

In order to investigate the influencing factors in more detail, parameters that were found to be statistically significant on univariate analysis or out of discussion among the experts underwent stepwise multivariate analyses. We used multiple linear regression analyses to model the relationship between the independent variables and the outcome of profitability. Regression coefficients (95% CI) and the corresponding p values were calculated for each factor. Testing the dataset for outliers was performed using the cook distance test, based on the model. The test did not indicate the need to dismiss cases from the sample. Due to an exploratory character of the research, no adjustments for multiple testing were made.

RESULTS

All patients with complete electronic patient records (n=3063 patients) were screened for eligibility. After selection regarding inclusion and exclusion criteria, 583 patients were included in the final analysis (figure 1). Of these patients, 378 showed low-adherence if the indicator was below 65% and 205 showed high adherence. The median age of admitted patients was 57 (40; 70) years; 64.7% of patients were male. There were significantly (p=0.038) more male patients within the HAG (70.2%) than in the LAG (61.6%). As reflected by a median Acute Physiology and Chronic Health Evaluation II (APACHE II) admission score of 21 (14; 27), a Simplified Acute Physiology Score II (SAPS II) admission score of 47 (34; 61) and a Sequential Organ Failure Assessment (SOFA) admission score of 9 (7; 12), the study population was characterised by severe medical conditions. Patient

demographics are displayed in table 1. Along the line, at discharge patients generated an average daily SOFA score of 8.2 (6.6; 10.3) indicating resource-intensive monitoring and treatment of the patient.

In order to account for the remaining clinical patient outcomes after grouping, we analysed the ventilation parameters. Overall in the median, patients were ventilated for 431 (250; 709) hours on the ICU and 578 (338; 924) throughout their hospital stay. Following the division into two adherence groups, there was a significant reduction in duration of ventilation on ICU from 476 to 389 hours ($p<0.001$). Overall in-hospital duration of ventilation was decreased from 597 to 535 hours ($p=0.017$). Concerning the number of SBTs and reintubations, there was no significant finding ($p=0.456$ and $p=0.531$). In addition to the significant decrease in ventilation parameters seen between the differences in adherence, the LOS was decreased by 5 days from 21 to 16 ($p<0.001$) and overall in-hospital LOS decreased from 36 to 26 days per patient ($p=0.001$) in the median, indicating strong arguments for QI adherence. With regard to economic outcome, the overall median economic results (loss) per case was $-€2999$. There was an increase in profitability from a median loss of $€3696$ – $€1030$ ($p<0.001$).

Considering the discharge of the patients, there was a highly significant difference ($p<0.001$) between both groups. Most patients were discharged to intermediate care (44.6%), other ICUs (27.6%) or rehabilitation (18.9%). Within the LAG, 50 (13.2%) patients died on the ICU compared with 2 (1.0%) in the HAG. This gives room to assume a certain impact of weaning quality on mortality. However, since we did not include diagnosis data, we cannot exclude an influence from this fact.

Multiple linear regression

The results of the multivariate linear regression analysis of the complete study population of 583 patients are given in table 2. The parameters were not adjusted for severity

Variable	B (95% CI)	SE	P value
Age (years)	-16 (-119 to 87)	52	0.765
Gender (male)	1139 (-2628 to 4906)	1918	0.553
Quality (%)*	3732 (-2457 to 9920)	3151	0.237
LOS Study-ICU (days)	-529 (-671 to -387)	72	<0.001
LOS hospital (days)	-143 (-213 to -71)	36	<0.001
Reintubations	-928 (-2.457 to 602)	779	0.234
Average SOFA	1608 (892 to 2323)	364	<0.001
Daily costs (€)	-7.6 (-11 to -4)	2	<0.001

*Quality, adherence to the quality indicator 'early weaning from invasive ventilation'.
ICU, intensive care unit; LOS, length of stay; SOFA, Sequential Organ Failure Assessment.

of illness. The fixed variables age, sex and percentage of QI adherence examined did not show significant effects on profitability.

In the linear regression analysis, the LOS on the study-ICU ($p<0.001$), the LOS in the hospital ($p<0.001$), the averaged daily SOFA score ($p<0.001$) and the averaged daily costs per patient ($p<0.001$) were shown to have significant effects on the profitability (table 2). Strong effects were found for the averaged daily SOFA score, which increased profits per case by $€1608$ (95% CI $€892$ to $€2323$) for each SOFA point. Furthermore, the LOS on the ICU decreased profits per case for $€529$ for every day longer on the ICU. To the best of our knowledge, multivariate regression for economic outcome has not yet been conducted for these factors. The regression model was performed without the admission scores for SAPS II, SOFA and APACHE II. When these scores were included, the statistical significances remained unchanged for the remaining variables that were analysed (see table 2).

Comparing the cumulative parameters of weaning patients along the years (see table 3), a higher number of patients weaned as well as a higher average SOFA-score can be associated with a higher number of median economic result. The observation over time supports the outcome parameters of table 1. Considering the development since 2012, there is an increase in the number of patients weaned per year and a decrease in the median hours of ventilation per patient.

DISCUSSION

The most important finding was that clinical and economic results were better within the HAG than the LAG. We sought to evaluate whether adherence above a certain quality threshold leads to a better economic result per case for the hospital. Our univariate model confirmed our hypothesis that higher quality leads to better LOS and hospital costs of intensive care patients. However, an improvement of the QI 'early weaning' was not directly associated with a significant impact on the profitability per case. In the regression model, we were not able to prove that more quality lead to higher earnings. Instead, significant factors were clinical outcome parameters (LOS ICU, LOS Hospital and averaged daily SOFA score), which had direct effects on profitability. Moreover, these parameters were also superior within the HAG, indicating a certain quality effect. This sequence of effects shows that quality affects the economic results indirectly via clinical outcome. This means that quality leads to clinical efficiency. Literature already proposes a more effective use of the costly resource ICU.²⁶ Thus, from an economic perspective it is recommended to transfer patients as early as possible from ICU downstream (eg, intermediate care) since a prolonged ICU-stay might be inappropriate, dangerous and costly.^{23 25}

Highly specialised ICUs are resource-intensive and cost-intensive and not universally available. By implementing QM as a method to constantly eliminating the factors

**Table 3** Financial demographics in median over time of 583 patients who underwent the weaning process

Variable	2012	2013	2014	2015	2016	2017
Weaning patients	65	82	100	114	125	97
Average SOFA	7.5 (5.6; 9.3)	8.3 (6.7; 11.0)	8.2 (6.5; 10.1)	8.1 (6.6; 9.6)	8.9 (7.0; 10.7)	8.3 (6.7; 11.0)
Duration of ventilation (hour)	660 (480; 977)	451 (230; 667)	400 (206; 673)	439 (261; 720)	374 (239; 602)	364 (210; 619)
Case-Mix Index*	22.7 (19.1; 30.1)	18.0 (11.0; 23.9)	19.6 (11.6; 28.1)	18.8 (10.9; 23.8)	17.7 (11.6; 29.1)	23.2 (13.9; 32.2)
Profits per case (€)†	-12 517 (-24 848; -806)	-11 011 (-28 547; 999)	-945 (-14 141; 8843)	390 (-11 340; 12201)	3439 (-7494; 8784)	-3136 (-22 012; 8284)

*Case-Mix Index, Averaged case-mix per case according to German DRG-system.

†Averaged financial result per case.

DRG, diagnosis-related group; SOFA, Sequential Organ Failure Assessment.

of chance, hospitals are trying to reduce complexity in defining, measuring and learning from QIs. Furthermore, QM is associated as a necessity for certification processes and therefore incremental part of critical care concepts.¹ The importance of weaning protocols and according adherence is based on studies that have proven between 70% and 80% of all patients receiving >24 hour invasive ventilation could already be weaned after the first SBT.^{8 27 28} This is why in 2011, a study at our institution investigated that the support of fast visual feedback for adherence to standard operating procedures within the PDMS led to decreased duration of mechanical ventilation and higher documentation compliance, supporting our findings.²⁹ The approach of measuring and steering quality with indicators carries several direct and indirect economic incentives. First, less loss per patient due to better clinical outcome has positive effects on the general economic results of the department. Second, decreased LOS on the ICU gives room to available beds earlier and therefore other patients to fill in the existing resource.³⁰ Third, because of public reporting and potential pay for quality structures, indicators are important methods for measuring quality and safety in healthcare, resulting in better outcome.³¹ In particular, transparent QIs allow department leaders to identify weak spots and initiate improvement in a structured and measurable way.² Our matched with a study performed in 2008, showing positive clinical outcome effects of ventilator weaning protocol measures.³² Patients spent less time on mechanical ventilation, and thus less time in intensive care and in the hospital. We found that the more patients that could be weaned per year, the less time they spent on the ventilator and better the economic results followed, since more patients generating contribution margins covered fixed costs. This effect shows that redundant capacities can be used for new admissions and thus higher throughput, similar to a former study at our institution.³³

This study is the first to find that high adherence to the QI 'early weaning from invasive ventilation' above a proven threshold of 65% showed higher economic returns (or less losses) than low adherence. Furthermore,

the study is unique in using a case defined data set to examine the economic effect of a single QI. Current economic prediction models in intensive care usually describe interventions of entire QM programmes³⁰ or changes in staffing.³³ Overall, we found that the median financial return for a hospital is negative when focusing on weaning from ventilation. This is independent of their QI adherence results. In Germany, insurance companies reimburse hospitals using the G-DRG System (German DGRs System) based on a performance-oriented compensation for inpatients. Within DRG-Systems,³⁰ the casemix of weaning patients does not provide adequate economic incentives for quality based critical care since the reimbursement is mainly focused on procedures, for example, duration of ventilation. This is consistent with other studies that found higher process quality led to decreased ventilator dependence and reduced reimbursement.^{25 26 34} To avoid wrong incentives, reimbursement should potentially be tied to patient-centred outcomes. For example, the prevention of VAP, PICS and CCIs. In this study, we used comprehensive per-patient cost data, based exclusively on the DRG-system. At our institution, a case-related cost calculation is well established and highly accurate for reimbursement per case and costs since we have been substantial cost-accounting reference centre since the beginning of the G-DRG-system. Therefore, we used this administrative data to calculate the economic outcome per case.³⁵ In Germany, a representative mix of hospitals gather case-related treatment costs on a yearly basis in order to report them to the Institute for the Hospital Reimbursement System for continuous development.³⁶ On an annual basis, cost weights are adjusted for each DRG, potentially leading to higher reimbursement per case. Hospitals can also benefit from economies of scale, considering more cases per year with fixed reimbursement values. This may explain why in 2015 and 2016 profits per case were higher.

The results of this study can inform policy-makers on the following points: In Germany, the application of QIs in critical care is so far not mandatory.¹² Since positive effects of clinical and economic parameters can be found



measuring the adherence to only one indicator of the DIVI set (n=10), it is recommended to establish QIs widely and combine patient-centred outcomes with economic outcomes systematically. Over the years examined, we found that weaning and the according QI have developed positively as the number of patients receiving weaning increased while the duration of ventilation per patient decreased. The relation between these two parameters shows that the quality of care increased and the organisation for the volume effect became more efficient, which is a dominant economic factor according to Nguyen *et al.*³⁷ However, in order to evolve further in this direction, intensive care needs adequate reimbursement. Higher assessment scores as SAPS II or SOFA play an important role in ICU reimbursement and might induce higher DRG reimbursement. Considering QM, contrary to the majority of ward care, which benefits from shorter LOS within the flat-compensation system, a decrease in LOS in intensive care is not rewarded with higher reimbursement. Literature confirms our analyses.³⁶ This is why we recommend that efforts for quality should be shifted in the centre of reimbursement in intensive care for better clinical outcomes, following the approach of valued-based payment (pay for quality), where ICUs are checked on costs and quality of service.³⁸ Furthermore, because keeping patients on the ICU and on mechanical ventilation economically-incentivised is proven to be dangerous for the patient⁸ and inefficient for the organisation.³⁰ This structural change can ensure the incentives for intensivists to adhere to quality standards instead of collecting ventilation hours. Our argument is supported by a recent publication of a group of experts in intensive care. They argue in favour for a reform in hospital reimbursement, away from flat-compensation towards progressive levels of intensive care. Moreover, they suggest a central planning of all system relevant intensive care infrastructures and according criteria for quality standards.³⁹ In the end, hospitals benefit from investments in quality, as clinical quality has subsequent effects on economic returns. Thus, not only hospitals, insurance companies and policy-makers profit from adherence to QIs, also the patient who should be in the centre of healthcare does.

Unanswered questions and future research

As noted previously, the study was conducted in a tertiary university hospital, which is characterised by specific and well-established medical processes and structures. A transfer of our observations to other ICUs or reimbursement systems is not feasible. The current study is subject to its retrospective design and potential selection bias, as some of the cases with incomplete data or special diagnoses were not detected during the observation period. We could have used neurological and neurosurgical diagnoses to exclude patients with low chances for weaning outcome, but in our administrative system there is no time point matched to it accordingly as diagnoses are often added just before discharge. For example, patients developing specific neurological conditions after their stay

on the study-ICU. Some aspects of our analysis deserve comment on limitation. First, the weaning process has constantly evolved during the years between 2012 and 2017. Since the importance of the weaning protocol emerged throughout the years, the focus on measures hereof and according documentation improved over the years as documentation became mandatory at our institution.⁸ Furthermore, it was not possible matching the qualifications of staffing as a determinant of adherence to quality and curbing of costs. There is supposed to be a connection between experience and cost awareness.⁴⁰ Second, even though indicators and our study-ICU can be examined independently for research purposes, the QI and its progression are substantially connected to other intensive care indicators.¹⁹ For further research, the interactions between the QIs and the progression on other ICUs need to be considered. Our results provide a robust assessment of the impact of changes of the quality adherence and robust evaluation of their effects.

CONCLUSION

While the need for critical care increases constantly for various reasons (eg, demographic change or pandemic crisis), the challenge to provide high-quality but cost-effective services will only become more important. Available resources differ among the various hospital sizes and types. Although we examined a single indicator for quality in a university reference centre and found proof that high adherence to it lead to significantly better clinical outcome, we think patients and hospitals in general benefit from high adherence to quality measures. Within the univariate analysis, major clinical parameters were significantly better in the HAG. Furthermore, we showed that adherence for 65% or higher generated significantly higher median earnings within our univariate analysis. However, we also showed that the investigated QI does not significantly affect economic results in our multivariate analysis. Instead, by using clinical parameters as proxies for clinical outcome, they were found to be the main drivers for according economic success. The reason for this is the increased number of patients who could be treated due to more total capacity, when LOS decreased due to higher quality. This is why the focus of this study is not only on reimbursement and on costs, but also on the direct effect of quality on the clinical outcome, which subsequently influences economic results.

Overall, quality matters for reimbursement, but reimbursement is not adjusted to the costs of providing quality. Since there is no central, structured and timely publication of comparable quality data in Germany, it is difficult for politics and assurances to reimburse on a pay for quality model as the basis for comparisons is missing as not mandatory. Still, as quality in treatment is decisive for the patient's hospital choice and the results of the treatment, QIs will be essential for public information and health economics as the patient decides where to be treated.



Contributors CS introduced quality indicator based treatment for critically ill patients at Charité hospital in terms of both research and implementation in patient care. She perceived the underlying idea for this study. CS and FB set the aims and design of this study. They accept full responsibility for the work, had access to the data and controlled the decision to publish. AZ and RA performed data collection. AZ conducted statistical analysis supervised by JK. AZ shared responsibility for the study design, had full access to the data and drafted the manuscript. CS and OK contributed to the interpretation of data from a medical point of view, and specifically from the perspective of quality indicators. MH and MD contributed from the perspective of economics, RJ from the perspective of quality science. FB supervised the overall coordination of the study and contributed from the data science perspective. All authors critically reviewed and advised with their expertise on the manuscript.

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Data availability statement Data are available on reasonable request.

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Supplemental table 1: Institutional Criteria – Readiness to Wean

Prerequisite for performing a spontaneous breathing trial (SBT).	
clinical criteria	<ul style="list-style-type: none"> • Ventilation > 24 h • Disappearance of indication for ventilation
respiratory criteria	<ul style="list-style-type: none"> • $FiO_2 \leq 0.4$ • Oxygen saturation $\geq 90\%$ • PEEP ≤ 8 cmH₂O (> 1h) • AMV < 15l /min • AF < 35 / min
Rapid Shallow Breathing Index (RSBI) (breathing frequency divided by tidal volume in litres)	<p>Goal is < 100-105 breaths / min/l</p> <p>RSBI can predict successful SBT with a sensitivity of 97% and a specificity of 65%</p>
haemodynamic criteria	<ul style="list-style-type: none"> • no acute myocardial ischaemia, no cardiogenic shock • No catecholamines: (allowed: norepinephrine/adrenaline $\leq 0.2 \mu\text{g} / \text{kg KG} / \text{min}$, Enoximone $\leq 5 \mu\text{g} / \text{kg KG} / \text{min}$ or Dobutamine $\leq 5 \mu\text{g} / \text{kg KG} / \text{min}$) • no new haemodynamically relevant arrhythmia
Criterion alertness	<ul style="list-style-type: none"> • RASS score 0 or – 1 • where applicable. GCS ≥ 8 in neurosurgical/neurological patients • Protective reflexes (coughing and swallowing) present
metabolic criteria	<ul style="list-style-type: none"> • Temperature < 38.5 °C

Supplemental table 2: Quality indicator (Weaning and other measures to prevent ventilator associated pneumonias (short: Weaning/VAP Bundle)) (Displayed are only items of the indicator relevant to weaning, for complete display see full version of the publication)

Name of the indicator	Weaning and other measures to prevent ventilator associated pneumonias (short: Weaning/VAP Bundle)	
Dimension	Effectiveness and risk	
Justification	<p>Ventilator associated pneumonias are a large problem in intensive care medicine. Pathogens typically get into the subglottic respiratory tract via aspiration of nasopharyngeal colonization (micro aspiration). The quality indicator IV should result in the prevention and reduction of ventilator associated pneumonias. It is measured by two processes in daily routine care:</p> <p>a) Measures to reduce the length of ventilator support (including non-invasive ventilation and weaning) and</p> <p>b) Measures effective with this regard are:</p> <p>a) Weaning protocol/concept in combination with sedation goals. In every mechanically ventilated patient (controlled ventilation) a daily evaluation for weaning possibility should be performed. This has to be seen in the context of QI II. This represents a daily sedation goal and documentation and</p> <p>b) Measures to reduce the microaspiration of pathogenic agents.</p>	
Structure	Daily documentation of goals for ventilatory support /Weaning: yes/no and...	
Process	Peer review	
Population	All mechanically ventilated patients	
Formula (process) QI IVa	Number of mechanically ventilated patients with daily documentation of a weaning trial (begin or ongoing) has been started Total number of all mechanically ventilated patients	x100
Type	Structure, process and outcome	
Source of data	1. Structure: Query 2. Process: Morning round (Visitation) Check: NIV-indication yes/no (Patient file, PDMS, Peer Review), VAP-Bundle implemented 3. Outcome: Results of the KISS/SARI-ICU Surveillance (annual report)	
Standard: Structure: yes/no Execution: yes/no	1. Structure: yes >95% 2. Process: >70% Number of positive answers 3. Missing values <20%	
Explanation of the terminology	<p><i>Weaning trial</i>: Planned intention to disconnect the patient from ventilatory support by beginning a spontaneous breathing trial with one of the following methods:</p> <ul style="list-style-type: none"> o T-piece o Pressure support ventilation (support pressure 7cmH2O o Continuous positive airway pressure of 5cmH2O (CPAP) o Synchronized intermittent mandatory ventilation (SIMV) is excluded o Non-invasive ventilation includes measures for ventilatory support without transalaryngeal devices 	
Comments	<p>In the view of the authors, it seems more practicable to define this indicator with patients on mechanical ventilation rather than days on mechanical ventilation, especially since weaning trials are not routinely detected by IT-systems and this also helps keeping the exclusion criteria.</p> <p>Measures for point 2, 4, 5 can be extracted from the patients file measures under point 3 should be defined in a standard be checked there.</p> <p>QI IVa: We recommend evaluation if daily trials have been attempted and if they were attempted in patients meeting inclusion criteria for such a trial.</p>	

Full version at: GMS Ger Med Sci 2013;11:Doc09; doi: 10.3205/000177

7. Lebenslauf

Mein Lebenslauf wird aus datenschutzrechtlichen Gründen in der elektronischen Version meiner Arbeit nicht veröffentlicht.

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8. Publikationsliste

Publikationen mit Peer-Review-Verfahren:

Marc Kastrup, Vera von Dossow, Matthes Seeling, Robert Ahlborn, Andre Tamarkin, P. Conroy, Willehad Boemke, Klaus D. Wernecke, Claudia D. Spies, "Key Performance Indicators in Intensive Care Medicine. A Retrospective Matched Cohort Study", The Journal of International Medicine Research 2009, 37:1265–1284,
Impact factor (2009):1,202

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Impact factor (2009):1,122

Marc Kastrup, Robert Powollik, Felix Balzer, Susanne Röber, Robert Ahlborn, Vera von Dossow-Hanfstingl, Klaus D. Wernecke, Claudia D. Spies, "Predictive Ability of the Stability and Workload Index for Transfer Score to Predict Unplanned Readmissions after ICU Discharge", Critical Care Medicine 2013, 41:1608–1615,
Impact factor (2013): 7,357, TOP-Journal

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10.1007/s00268-013-1926-8
Impact factor (2013): 2,348

Friederike Compton*, Robert Ahlborn*, (* Authors contributed equally), Torsten Weidehoff,
"Nurse-Directed Blood Glucose Management in a Medical Intensive Care Unit",
CriticalCareNurse Vol 37, No. 3, JUNE 2017,
Impact factor (2017): 1,707, Rank 28 von 118, TOP-Journal

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Journal American Society of Nephrology, 2019 May 30(5):795-810.

Impact factor (2019): 9,274, Rank 5 von 85, TOP-Journal

Zuber A, Kumpf O, Spies C, Höft M, Deffland M, Ahlborn R, Kruppa J, Jochem R and Balzer F,

“Intensive Care Economics: Impact of Adherence to the Quality Indicator Weaning on Economic Outcome”,

BMJ Open 2021, Impact factor (2020): 2,496

Julian Pohlan , Denis Witham , Maria Isabel Opper Hernando , Gloria Muench , Melina Anhamm , Alexandra Schnorr , Lara Farkic , Karim Breiling , Robert Ahlborn , Kerstin Rubarth , Damaris Praeger , Marc Dewey,

„Relevance of computed tomography for detection of septic foci: diagnostic performance in a retrospective cohort of medical intensive care patients”,

Clinical Radiology 2021, Impact factor (2020): 2,350

Monographien:

Robert Ahlborn, “Analyse und Bewertung von Softwareprogrammen für die Bereiche Qualitätssicherung und Qualitätsmanagement im Krankenhaus“, Diplomarbeit am Institut für Qualitätswissenschaften TU-Berlin, 1998, Endnote sehr gut

Publikationen mit laufendem Peer-Review-Verfahren:

Marc Kastrup^{1*}, Robert Ahlborn^{2*}, * Authors contributed equally,

“Influence of a feedback-system on Enteral Nutrition Delivery in Intensive Care Patients: A single centre observational pilot study”,

Clinical Nutrition

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