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Title:

Intensive Care Economics: Impact of Adherence to the Quality Indicator Weaning on Economic Outcome.

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ABSTRACT

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

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

Setting ICU of a German university hospital, reference center for acute respiratory distress syndrome.

Participants Records of 3,063 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 health care costs, clinical outcomes and patients' characteristics.

Results The LAG consisted of 378 patients with a median negative economic results of -3,969€, HAG of 205 (-1,030€) 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 in the LAG on ICU was 21 [12;35] days and 16 [11;25] days in the HAG (*P* <0.001). Length of stay 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 quality indicator is associated with better clinical outcome and improved economic returns. Therefore, the results support the adherence to quality indicator. However, the examined quality indicator does not influence economic outcome as the decisive factor.

<u>Strengths and limitations of this study:</u>

- 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 center specialized 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 all German hospitals

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 (QI) [1]. This is why in the medium and long 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 health care system. Many countries introduced diagnosis related groups (DRGs) in order to pay on averaged costs and on a generalized financial reimbursement per case (fixed prices). The fee-for-service system induces hospitals to improve internal processes and to work goal-oriented towards therapeutic aims [3].

In modern medicine, a major part of hospital costs arises from intensive care. The cost structure of a German hospital shows that ca. 20% of costs are generated in intensive care units (ICU) [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 [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 categorized in prolonged weaning, failing at least three spontaneous breathing trials or receiving more than seven days of weaning after the first spontaneous breathing trials, have an increased risk in developing hospital mortality, mainly through ventilator-associated pneumonia (VAP) [6], but also through post intensive 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 standardized 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 quality management 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, the 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 quality indicator evaluating the weaning process from invasive ventilation. We analyzed this by comparing economic results per case and clinical outcome parameters like length of stay (LOS) between two groups of either high 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 (CHEERS).

Study Center

We conducted this single study-center in a university hospital (Charité - Universitätsmedizin Berlin). This observational analysis was performed at a 14-bed intensive care unit (reference center), specialized for 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).

The study was approved by the Ethics Commission at Charité (EA2/139/20). Informed patient consent was waived due to retrospective study design. Confidentiality was guaranteed, no interventions were performed and only clinical routine data were collected. Data were retrieved from a PDMS called COPRA (Computer Organized Patient Report Assistant; COPRA System GmbH, 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 (e.g. LOS). Data were retrieved using a structured query. No patient identifiers were extracted in order to secure anonymity of patients' data.

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: (i) no additional workload required for documentation, (ii) the availability within the PDMS system, (iii) standardized values for all patients and the existence of standard operating procedures for each indicator and (iv) the relevance of the indicator for clinical decision-making [19,23].

Procedures

In this study, we used present KPIs in order to examine the adherence to the quality indicator "Early Weaning from Invasive Ventilation" until ICU discharge [8]. A small set of evidence-based key performance indicators (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. 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 "spontaneous breathing trial" (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].

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 categorize the patients into groups.

We used the adherence level of the examined quality indicator 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 cutoff point for dichotomously distinguishing between high-adherence and low-adherence of weaning quality, we combined recommendations from literature with our institutional standards. A cutoff value of 70% deemed as a suitable fulfillment-threshold for quality indicators [25]. However, due to partially high workload under certain circumstances in intensive care, we decided to lower the cutoff for 5% tolerance in order to account for missing values in documentation. Therefore, we inserted a cutoff for weaning protocol compliance at 65% adherence. The LAG was defined as adherence to QI of less than 65%. The HAG was defined as adherence to QI of equal or more than 65%. Once this threshold was reached, the QI was characterized as high-adherence.

Statistical Analyses

Descriptive analyses and statistical testing were performed using SPSS, version 14.0 (SPSS Inc., Chicago, IL, USA) for Windows. Results are expressed as median (interquartile range) 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 chi-squared statistics for independent variables as appropriate with a *P*-value below 0.05 regarded as significant.

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.

Patient and public involvement

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

RESULTS

All patients with complete electronic patient records (n=3,063 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 APACHE II admission score of 21 [14;27], a SAPS II admission score of 47 [34;61] and a SOFA admission score of 9 [7;12], the study population was characterized 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 analyzed 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 quality indicator adherence. With regard to economic outcome, the overall median economic results (loss) per case was -2,999€. There was an increase in profitability from a median loss of 3,696€ to 1,030€ ($P < 0.001$).

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 compared to 2 (1.0%) in the HAG. This gives room to assume a certain impact of weaning quality on mortality.

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

	All Patients	LAG QI < 65%	HAG QI ≥ 65%	*P-Value*
	n = 583	**n = 378**	**n = 205**	
Demographics				
Age [y]	57 [40;70]	57 [40;70]	55 [42;69]	0.770
Gender [m]	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				0.651
· 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 [h]	431 [250;709]	476 [248;769]	389 [247;608]	<0.001
Total Duration of Ventilation Hospital [h]	578 [338;924]	597 [310;992]	535 [361;821]	0.017
No. Spontaneous breathing trials (SBTs)	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				<0.001
· 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%)	
· Death	52 (8.9%)	50 (13.2%)	2 (1.0%)	
LOS Study-ICU [d]	19 [11;32]	21 [12;35]	16 [11;25]	<0.001
LOS Hospital [d]	33 [20;54]	36 [22;61]	26 [18;48]	0.001
Profit [€]	-2,999 [-15,946;7,730]	-3,696 [-21,170;6,828]	-1,030 [-11,134;9,449]	<0.001

Discrete variables are presented as a total number of encounters and were analyzed with Chi square test for nonparametric samples.

APACHE II, Acute physiology and chronic health evaluation; SAPS, Simplified acute physiology score; SOFA, Sequential organ failure assessment; Average SOFA, Averaged sequential organ failure assessment; ICU, Intensive care unit; SBT, Spontaneous breathing trial; LOS, Length of stay, PACU, Post anesthesia care unit; OT, Operating theatre

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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 of illness. The fixed variables age, sex and percentage of quality indicator 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 ($P = 0.015$), the averaged daily SOFA score ($P = 0.002$) and the averaged daily costs per patient ($P = 0.032$) 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 1,608€ [CI: 892€, 2,323€] 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 SAPSII, SOFA and APACHEII. When these scores were included, the statistical significances remained unchanged for the remaining variables that were analyzed (s. 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.

Table 2 - Multiple linear regression analysis of factors affecting the profit of 583 intensive care patients who underwent the weaning process

Variable	B (95% CI)	SE	*P-Value*
Age [y]	-16 (-119; 87)	52	0.765
Gender [m]	1,139 (-2,628; 4,906)	1,918	0.553
Quality[1] [%]	3,732 (-2,457; 9,920)	3,151	0.237
LOS Study-ICU [d]	-529 (-671; -387)	72	<0.001
LOS Hospital [d]	-143 (-213;-71)	36	<0.001
Reintubations	-928 (-2.457; 602)	779	0.234
Average SOFA	1,608 (892; 2,323)	364	<0.001
Daily Costs [€]	-7.6 (-11; -4)	2	<0.001

[1] Quality, Adherence to the quality indicator "Early Weaning from invasive ventilation"

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 [h]	660 [480; 977]	451 [230; 667]	400 [206; 673]	439 [261; 720]	374 [239; 602]	364 [210; 619]
Case-Mix Index[1]	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[2] [€]	-12,517 [-24,848; -806]	-11,011 [-28,547; 999]	-945 [-14,141; 8,843]	390 [-11,340; 12,201]	3,439 [-7,494; 8,784]	-3,136 [-22,012; 8,284]

[1]Case-Mix Index, Averaged case-mix per case according to German DRG-System
[2]Averaged financial result per case

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 quality indicator “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 (e.g. intermediate care) since a prolonged ICU-stay might be inappropriate, dangerous and costly [23,25].

Highly specialized ICUs are resource- and cost-intensive and not universally available. By implementing QM as a method to constantly eliminating the factors 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 70-80% of all patients receiving >24h 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 health care, resulting in better outcome [31]. In particular, transparent quality indicators 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 quality indicator “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 quality indicator. Current economic prediction models in intensive care usually describe interventions of entire quality management programs [30] 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 Diagnosis Related Groups System) based on a performance-oriented compensation for inpatients. Within DRG-Systems

[30], the case-mix of weaning patients does not provide adequate economic incentives for quality based critical care since the reimbursement is mainly focused on 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]. In this study, we used comprehensive per-patient cost data. 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 center 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].

The results of this study can inform policy makers on the following points: In Germany, the application of quality indicators 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. 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 organization 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. Contrary to the majority of ward care, which benefits from shorter length of stay within the flat-compensation system, a decrease in length of stay 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 center of reimbursement in intensive care for better clinical outcomes, following the approach of valued-based payment (pay for quality), where ICUs are checked upon costs and quality of service [38]. Furthermore, because keeping patients on the ICU and on mechanical ventilation economically-incentivized is proven to be dangerous for the patient [8] and inefficient for the organization [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 favor 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 quality indicators, also the patient who should be in the center of healthcare does.

Unanswered questions and future research

As noted previously, the study was conducted in a tertiary university hospital, which is characterized by specific and well established medical processes and structures. A transfer of our observations to other intensive care units is not feasible. 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 (e.g. demographic change or pandemic crisis), the challenge to provide high quality but cost-effective services will only become more important. We examined a single indicator for quality and found proof that high-adherence to it lead to significantly better clinical outcome. 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 quality indicator 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.

Abbreviations

QM: Quality management; QI: Quality indicator; DRG: Diagnosis-related groups; ICU: Intensive care unit; PDMS: Patient data management system, LOS: Length of stay; KPI: Key performance indicator; SBT: Spontaneous breathing trial; SOFA: Sequential organ failure assessment; APACHEII: Acute physiology and chronic health evaluation II; SAPS II: Simplified acute physiology score; Average SOFA: Averaged daily SOFA score; PACU: Post-acute care unit; OT: Operating theatre; CI: Confidence interval.

Author contributions:

FB perceived the idea. RA and AZ performed data collection. AZ conducted statistical analysis; drafted the manuscript and shared responsibility for design, coordination and finalization of the manuscript; contributed to interpretation of the data, and had full access to the data. OK consulted in quality management, QI and ICU therapy. All other critically reviewed and advised with their expertise on the manuscript.

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Patient Consent: Not required.

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AZ has nothing to declare. Dr. Kumpf has nothing to disclose. CS reports grants from Aridis Pharmaceutical Inc., grants from B. Braun Melsungen AG, grants from Drägerwerk AG & Co. KGaA, grants from Deutsche Forschungsgemeinschaft / German Research Society, grants from Deutsches Zentrum für Luft- und Raumfahrt e. V. (DLR) / German Aerospace Center, grants from Einstein Stiftung Berlin / Einstein Foundation Berlin, grants from European Society of Anaesthesiology, grants from Gemeinsamer Bundesausschuss / Federal Joint Committee (G-BA), grants from Inneruniversitäre Forschungsförderung / Inner University Grants, grants from Projektträger im DLR / Project Management Agency, grants from Stifterverband / Non-Profit Society Promoting Science and Education, grants from WHOCC, grants from Baxter Deutschland GmbH, grants from Cytosorbents Europe GmbH, grants from Edwards Lifesciences Germany GmbH, grants from Fresenius Medical Care, grants from Grünenthal GmbH, grants from Masimo Europe Ltd., grants from Pfizer Pharma PFE GmbH, personal fees from Georg Thieme Verlag, grants from Dr. F. Köhler Chemie GmbH, grants from Sintetica GmbH, grants from European Commission, grants from Stifterverband für die deutsche Wissenschaft e.V. / Philips, grants from Stiftung Charité, grants from AGUETTANT Deutschland GmbH, grants from AbbVie Deutschland GmbH & Co. KG, grants from Amomed Pharma GmbH, grants from InTouch Health, grants from Copra System GmbH, grants from Correvio GmbH, grants from Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V., grants from Deutsche Gesellschaft für Anästhesiologie & Intensivmeidzin (DGAI), grants from Stifterverband für die deutsche Wissenschaft e.V. / Medtronic, grants from Philips Electronics Nederland BV, grants from BMH, outside the submitted work; In addition, Prof. Spies has a patent 10 2014 215 211.9 licensed, a patent 10 2014 215 212.9 licensed, a patent 10 2018 114 364.8 licensed, and a patent 10 2018 110 275.5 licensed. MH has nothing to disclose. MD has nothing to disclose. RA has nothing to disclose. JK has nothing to disclose. RJ has nothing to disclose. FB reports grants from Einstein Foundation, personal fees from Axon Publishiing, grants from Vifor Pharma, personal fees from Elsevier

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Data Availability Statement: The datasets analyzed during the current study are available from the corresponding author on reasonable request.

Clinical Trial Registration: Not applicable.

Patient and Public Involvement statement: Patients and the public were not directly involved in this observational study.

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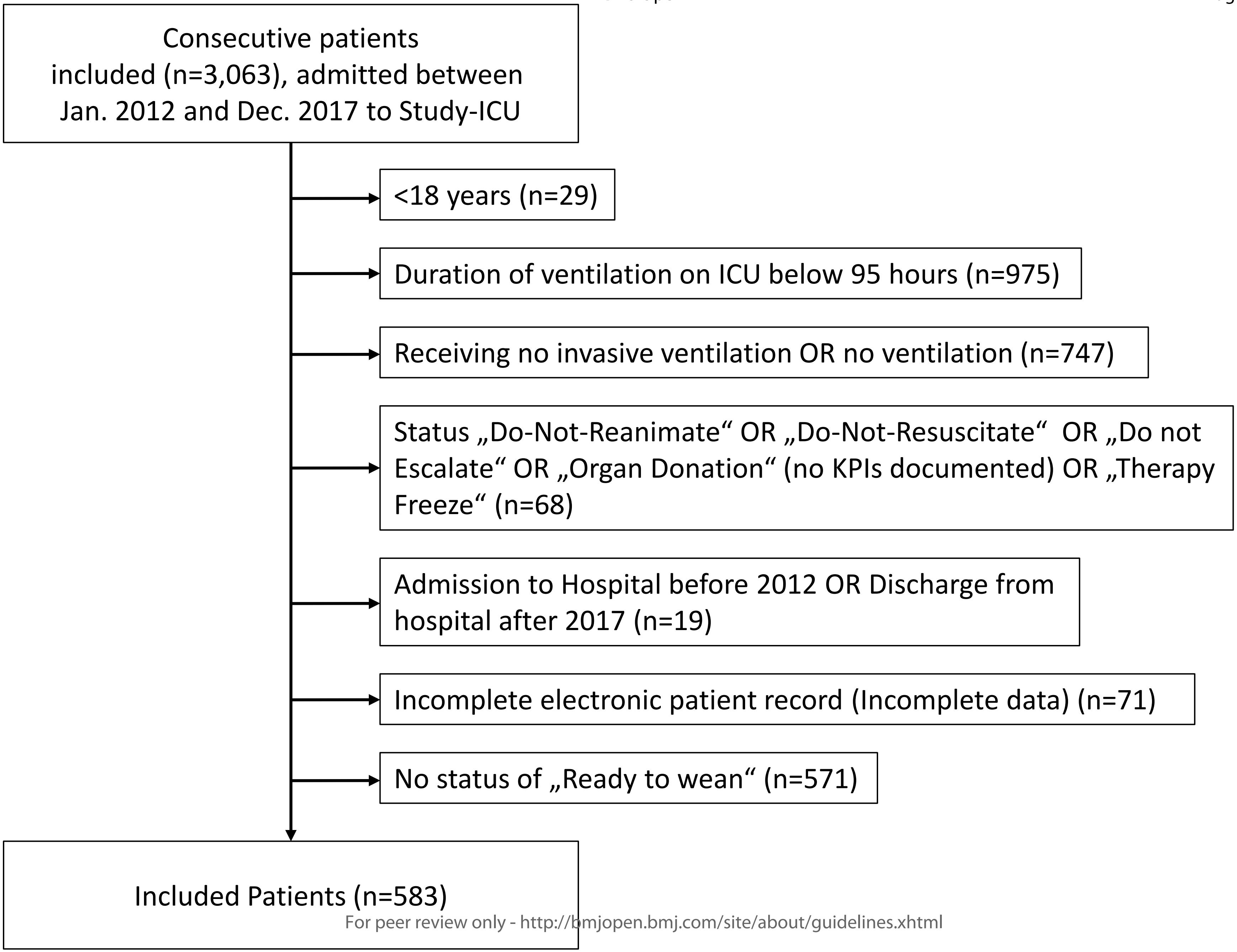
Figure Legend:

Figure 1 Patient Inclusion and Exclusion Criteria. Flowchart of the process used in the present study for patient record inclusion. Numbers listed are number of patients in each group


Consecutive patients included (n=3,063), admitted between Jan. 2012 and Dec. 2017 to Study-ICU
<18 years (n=29)
Duration of ventilation on ICU below 95 hours (n=975)
Receiving no invasive ventilation OR no ventilation (n=747)
Status „Do-Not-Reanimate“ OR „Do-Not-Resuscitate“ OR „Do not Escalate“ OR „Organ Donation“ (no KPIs documented) OR „Therapy Freeze“ (n=68)
Admission to Hospital before 2012 OR Discharge from hospital after 2017 (n=19)
Incomplete electronic patient record (Incomplete data) (n=71)
No status of „Ready to wean“ (n=571)
Included Patients (n=583)

CHEERS Checklist

Items to include when reporting economic evaluations of health interventions

The **ISPOR CHEERS Task Force Report**, *Consolidated Health Economic Evaluation Reporting Standards (CHEERS)—Explanation and Elaboration: A Report of the ISPOR Health Economic Evaluations Publication Guidelines Good Reporting Practices Task Force*, provides examples and further discussion of the 24-item CHEERS Checklist and the CHEERS Statement. It may be accessed via the *Value in Health* or via the ISPOR Health Economic Evaluation Publication Guidelines – CHEERS: Good Reporting Practices webpage: http://www.ispor.org/TaskForces/EconomicPubGuidelines.asp

Section/item	Item No	Recommendation	Reported on page No/ line No
Title and abstract			
Title	1	Identify the study as an economic evaluation or use more specific terms such as “cost-effectiveness analysis”, and describe the interventions compared.	
Abstract	2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions.	
Introduction			
Background and objectives	3	Provide an explicit statement of the broader context for the study. Present the study question and its relevance for health policy or practice decisions.	
Methods			
Target population and subgroups	4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	
Setting and location	5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	
Study perspective	6	Describe the perspective of the study and relate this to the costs being evaluated.	
Comparators	7	Describe the interventions or strategies being compared and state why they were chosen.	
Time horizon	8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	
Discount rate	9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate.	
Choice of health outcomes	10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed.	
Measurement of effectiveness	11a	*Single study-based estimates:* Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.	

	11b	*Synthesis-based estimates:* Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data.	
Measurement and valuation of preference based outcomes	12	If applicable, describe the population and methods used to elicit preferences for outcomes.	
Estimating resources and costs	13a	*Single study-based economic evaluation:* Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	
	13b	*Model-based economic evaluation:* Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	
Currency, price date, and conversion	14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	
Choice of model	15	Describe and give reasons for the specific type of decision-analytical model used. Providing a figure to show model structure is strongly recommended.	
Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytical model.	
Analytical methods	17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	
Results			
Study parameters	18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	
Incremental costs and outcomes	19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	
Characterising uncertainty	20a	*Single study-based economic evaluation:* Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact	

		of methodological assumptions (such as discount rate, study perspective).	
	20b	*Model-based economic evaluation:* Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	
Characterising heterogeneity	21	If applicable, report differences in costs, outcomes, or cost-effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	
Discussion			
Study findings, limitations, generalisability, and current knowledge	22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	
Other			
Source of funding	23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support.	
Conflicts of interest	24	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations.	

For consistency, the CHEERS Statement checklist format is based on the format of the CONSORT statement checklist

The **ISPOR CHEERS Task Force Report** provides examples and further discussion of the 24-item CHEERS Checklist and the CHEERS Statement. It may be accessed via the *Value in Health* link or via the ISPOR Health Economic Evaluation Publication Guidelines – CHEERS: Good Reporting Practices webpage: http://www.ispor.org/TaskForces/EconomicPubGuidelines.asp

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Husereau D, Drummond M, Petrou S, et al. Consolidated health economic evaluation reporting standards (CHEERS)—Explanation and elaboration: A report of the ISPOR health economic evaluations publication guidelines good reporting practices task force. Value Health 2013;16:231-50.

Reporting checklist for economic evaluation of health interventions.

Based on the CHEERS guidelines.

		Reporting Item	Page Number
Title			
	#1	Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared.	1
Abstract			
	#2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions	2
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Methods			
Target population and subgroups	#4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	4
Setting and location	#5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	4
Study perspective	#6	Describe the perspective of the study and relate this to the costs being evaluated.	4
Comparators	#7	Describe the interventions or strategies being compared and state why they were chosen.	5

Time horizon	#8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	4
Discount rate	#9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate	5
Choice of health outcomes	#10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed	6
Meaurement of effectiveness	#11a	Single study-based estimates: Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data	4
Measurement of effectiveness	#11b	Synthesis-based estimates: Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data	5
Measurement and valuation of preference based outcomes	#12	If applicable, describe the population and methods used to elicit preferences for outcomes.	n/a
**Estimating resources and costs **			
	#13a	Single study-based economic evaluation: Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs	6
Methods			
Estimating resources and costs	#13b	Model-based economic evaluation: Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or secondary research methods for valuing each resource	n/a

		item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	
Currency, price date, and conversion	#14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	n/a
Choice of model	#15	Describe and give reasons for the specific type of decision analytical model used. Providing a figure to show model structure is strongly recommended.	6
Assumptions	#16	Describe all structural or other assumptions underpinning the decision-analytical model.	6
Analytical methods	#17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	6
Results			
Study parameters	#18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	6
Incremental costs and outcomes	#19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	6-7
Characterising uncertainty	#20a	Single study-based economic evaluation: Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact of methodological assumptions (such as discount rate, study perspective).	n/a

Characterising uncertainty	#20b	Model-based economic evaluation: Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	7
Characterising heterogeneity	#21	If applicable, report differences in costs, outcomes, or cost effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	n/a
Discussion			
Study findings, limitations, generalisability, and current knowledge	#22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	11
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 This checklist was completed on 09. September 2020 using https://www.goodreports.org/, a tool made by the EQUATOR Network in collaboration with Penelope.ai

BMJ Open

Does adherence to a quality indicator regarding early weaning from invasive ventilation improve economic outcome? A single-center retrospective study.

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Secondary Subject Heading:	Intensive care, Health policy
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Title:

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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 center study, based on electronic medical and administrative records.
Setting Intensive Care Unit (ICU) of a German university hospital, reference center for acute respiratory distress syndrome.
Participants Records of 3,063 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 health care costs, clinical outcomes and patients' characteristics.
Results The LAG consisted of 378 patients with a median negative economic results of -3,969€, HAG of 205 (-1,030€) 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 quality indicator is associated with better clinical outcome and improved economic returns. Therefore, the results support the adherence to quality indicator. However, the examined quality indicator does not influence economic outcome as the decisive factor.

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 center specialized 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

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 [1]. This is why in the medium and long 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 health care system. Many countries introduced diagnosis related groups (DRGs) in order to pay on averaged costs and on a generalized 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 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 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 categorized in prolonged weaning, failing at least three spontaneous breathing trials or receiving more than seven days of weaning after the first spontaneous breathing trials, have an increased risk in developing hospital mortality, mainly through ventilator-associated pneumonia (VAP) [6], but also through post intensive 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 standardized 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 quality management 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, the 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 quality indicator evaluating the weaning process from invasive ventilation. We analyzed this by comparing economic results per case and clinical outcome parameters like LOS between two groups of either high 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 (CHEERS).

Patient and public involvement

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

Study Center

We conducted this single study-center in a university hospital (Charité - Universitätsmedizin Berlin). This observational analysis was performed at a 14-bed ICU (reference center), specialized 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).

The study was approved by the Ethics Commission of Charité – Universitätsmedizin Berlin (EA2/139/20). The need for patient's consent was waived due to the retrospective nature of the study. Confidentiality was guaranteed, no interventions were performed and only clinical routine data were collected. Data were retrieved from a PDMS called COPRA (Computer Organized Patient Report Assistant; COPRA System GmbH, 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 (e.g. LOS). Data were 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: (i) no additional workload required for documentation, (ii) the availability within the PDMS system, (iii) standardized values for all patients and the existence of standard operating procedures for each indicator and (iv) the relevance of the indicator for clinical decision-making [19,23].

Procedures

In this study, we used present KPIs in order to examine the adherence to the quality indicator "Early Weaning from Invasive Ventilation" until ICU discharge [8]. A small set of evidence-based key performance indicators (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 the supplementary 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 "spontaneous breathing trial" (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 the supplementary 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 categorize the patients into groups.

We used the adherence level of the examined quality indicator 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 cutoff point for dichotomously distinguishing between high-adherence and low-adherence of weaning quality, we combined recommendations from literature with our institutional standards. A cutoff value of 70% deemed as a suitable fulfillment-threshold for quality indicators [25]. However, due to partially high workload under certain circumstances in intensive care, we decided to lower the cutoff for 5% tolerance in order to account for missing values in documentation. Therefore, we inserted a cutoff for weaning protocol compliance at 65% adherence. The LAG was defined as adherence to QI of less than 65%. The HAG was defined as adherence to QI of equal or more than 65%. Once this threshold was reached, the QI was characterized as high-adherence.

Statistical Analyses

Descriptive analyses and statistical testing were performed using SPSS, version 14.0 (SPSS Inc., Chicago, IL, USA) for Windows. Results are expressed as median (interquartile range) 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 chi-squared statistics for independent variables as appropriate with a *P*-value below 0.05 regarded as significant.

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% Confidence Interval (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=3,063 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 APACHE II admission score of 21 [14;27], a SAPS II admission score of 47 [34;61] and a SOFA admission score of 9 [7;12], the study population was characterized 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 analyzed 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 quality indicator adherence. With regard to economic outcome, the overall median economic results (loss) per case was -2,999€. There was an increase in profitability from a median loss of 3,696€ to 1,030€ ($P < 0.001$).

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 to 2 (1.0%) in the HAG. This gives room to assume a certain impact of weaning quality on mortality. However, since we didn’t include diagnosis data, we cannot exclude an influence from this fact.

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

	All Patients	LAG QI < 65%	HAG QI ≥ 65%	*P-Value*
	n = 583	**n = 378**	**n = 205**	
Demographics				
Age [y]	57 [40;70]	57 [40;70]	55 [42;69]	0.770
Gender [m]	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				0.651
· 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 [h]	431 [250;709]	476 [248;769]	389 [247;608]	<0.001
Total Duration of Ventilation Hospital [h]	578 [338;924]	597 [310;992]	535 [361;821]	0.017
No. Spontaneous breathing trials (SBTs)	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				<0.001
· 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 [d]	19 [11;32]	21 [12;35]	16 [11;25]	<0.001
LOS Hospital [d]	33 [20;54]	36 [22;61]	26 [18;48]	0.001
Profit [€]	-2,999 [-15,946;7,730]	-3,696 [-21,170;6,828]	-1,030 [-11,134;9,449]	<0.001

Discrete variables are presented as a total number of encounters and were analyzed with Chi square test for nonparametric samples.

APACHE II, Acute physiology and chronic health evaluation; SAPS, Simplified acute physiology score; SOFA, Sequential organ failure assessment; Average SOFA, Averaged sequential organ failure assessment; ICU, Intensive care unit; SBT, Spontaneous breathing trial; LOS, Length of stay

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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 of illness. The fixed variables age, sex and percentage of quality indicator 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 1,608€ [CI: 892€, 2,323€] 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 SAPSII, SOFA and APACHEII. When these scores were included, the statistical significances remained unchanged for the remaining variables that were analyzed (s. 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.

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Table 2 - Multiple linear regression analysis of factors affecting the profit of 583 intensive care patients who underwent the weaning process			
Variable	B (95% CI)	SE	*P-Value*
Age [y]	-16 (-119; 87)	52	0.765
Gender [m]	1,139 (-2,628; 4,906)	1,918	0.553
Quality[1] [%]	3,732 (-2,457; 9,920)	3,151	0.237
LOS Study-ICU [d]	-529 (-671; -387)	72	<0.001
LOS Hospital [d]	-143 (-213;-71)	36	<0.001
Reintubations	-928 (-2.457; 602)	779	0.234
Average SOFA	1,608 (892; 2,323)	364	<0.001
Daily Costs [€]	-7.6 (-11; -4)	2	<0.001

[1] Quality, Adherence to the quality indicator "Early Weaning from invasive ventilation"

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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 [h]	660 [480; 977]	451 [230; 667]	400 [206; 673]	439 [261; 720]	374 [239; 602]	364 [210; 619]
Case-Mix Index[1]	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[2] [€]	-12,517 [-24,848; -806]	-11,011 [-28,547; 999]	-945 [-14,141; 8,843]	390 [-11,340; 12,201]	3,439 [-7,494; 8,784]	-3,136 [-22,012; 8,284]

[1]Case-Mix Index, Averaged case-mix per case according to German DRG-System
[2]Averaged financial result per case

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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 quality indicator "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 (e.g. intermediate care) since a prolonged ICU-stay might be inappropriate, dangerous and costly [23,25].

Highly specialized ICUs are resource- and cost-intensive and not universally available. By implementing QM as a method to constantly eliminating the factors 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 70-80% of all patients receiving >24h 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 health care, resulting in better outcome [31]. In particular, transparent quality indicators 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 quality indicator "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 quality indicator. Current economic prediction models in intensive care usually describe interventions of entire quality management programs [30] 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 Diagnosis Related Groups System) based on a performance-oriented compensation for inpatients. Within DRG-Systems

[30], the case-mix of weaning patients does not provide adequate economic incentives for quality based critical care since the reimbursement is mainly focused on procedures, e.g. 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-centered outcomes. For example, the prevention of ventilator-associated pneumonia, post intensive care syndrome and chronic critical illness. 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 center 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 quality indicators 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-centered 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 organization 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 center of reimbursement in intensive care for better clinical outcomes, following the approach of valued-based payment (pay for quality), where ICUs are checked upon costs and quality of service [38]. Furthermore, because keeping patients on the ICU and on mechanical ventilation economically-incentivized is proven to be dangerous for the patient [8] and inefficient for the organization [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 favor 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 quality indicators, also the patient who should be in the center of healthcare does.

Unanswered questions and future research

As noted previously, the study was conducted in a tertiary university hospital, which is characterized 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 (e.g. 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 center 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 quality indicator 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.

Abbreviations

QI: Quality indicator; ICU: Intensive care unit; HAG: High adherence group; LAG: Low adherence group; LOS: Length of stay; QM: Quality management; DRG: Diagnosis-related groups; VAP: ventilator-associated pneumonia ; PICS: post intensive care syndrome; CCI: chronic critical illness; PDMS: Patient data management system, KPI: Key performance indicator; SBT: Spontaneous breathing trial; CI: Confidence interval; APACHE II: Acute physiology and chronic health evaluation II; SAPS II: Simplified acute physiology score; SOFA: Sequential organ failure assessment; Average SOFA: Averaged daily SOFA score.

Author contributions:

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. 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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Research Ethics Approval: The study was approved by the Ethics Commission of Charité – Universitätsmedizin Berlin (EA2/139/20). The need for patient's consent was waived due to the retrospective nature of the study.

Data Availability Statement: The datasets analyzed during the current study are available from the corresponding author on reasonable request.

Clinical Trial Registration: Not applicable.

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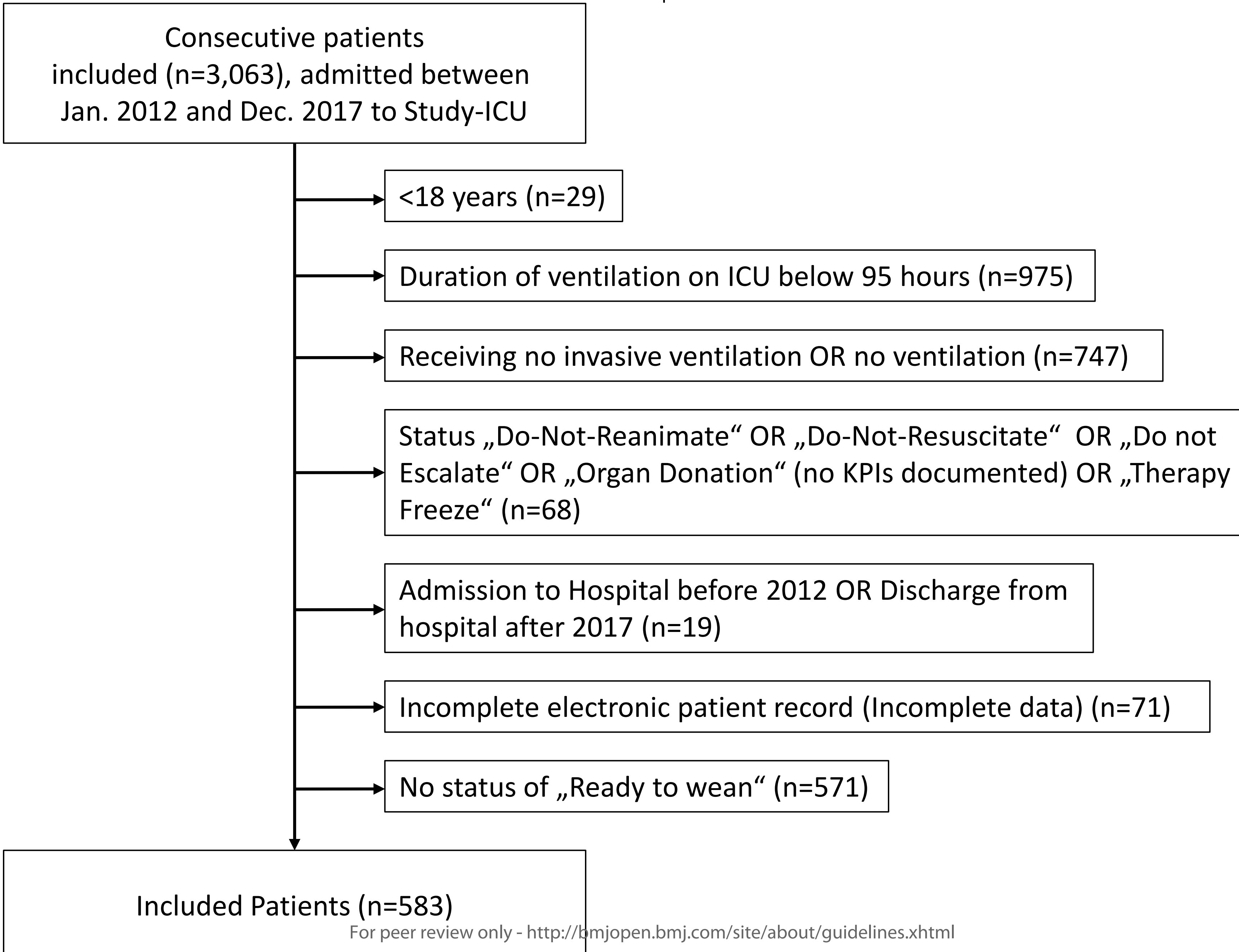
Figure Legend:

Figure 1 Patient Inclusion and Exclusion Criteria. Flowchart of the process used in the present study for patient record inclusion. Numbers listed are number of patients in each group


Consecutive patients included (n=3,063), admitted between Jan. 2012 and Dec. 2017 to Study-ICU
<18 years (n=29)
Duration of ventilation on ICU below 95 hours (n=975)
Receiving no invasive ventilation OR no ventilation (n=747)
Status „Do-Not-Reanimate“ OR „Do-Not-Resuscitate“ OR „Do not Escalate“ OR „Organ Donation“ (no KPIs documented) OR „Therapy Freeze“ (n=68)
Admission to Hospital before 2012 OR Discharge from hospital after 2017 (n=19)
Incomplete electronic patient record (Incomplete data) (n=71)
No status of „Ready to wean“ (n=571)
Included Patients (n=583)

Supplemental table 1: Institutional Criteria – Readiness to Wean

Prerequisite for performing a spontaneous breathing trial (SBT).	
clinical criteria	• Ventilation > 24 h • Disappearance of indication for ventilation
respiratory criteria	• FiO2 ≤ 0. 4 • Oxygen saturation ≥ 90% • PEEP ≤ 8 cmH2O (> 1h) • AMV < 15l /min • AF < 35 / min
Rapid Shallow Breathing Index (RSBI) (breathing frequency divided by tidal volume in litres)	Goal is < 100-105 breaths / min/l RSBI can predict successful SBT with a sensitivity of 97% and a specificity of 65%
haemodynamic criteria	• no acute myocardial ischaemia, no cardiogenic shock • No catecholamines: (allowed: norepinephrine/adrenaline ≤ 0. 2 µg / kg KG /min, Enoximone ≤ 5 µg / kg KG /min or Dobutamine ≤ 5 µg / kg KG /min) • no new haemodynamically relevant arrhythmia
Criterion alertness	• RASS score 0 or – 1 • where applicable. GCS ≥ 8 in neurosurgical/neurological patients • Protective reflexes (coughing and swallowing) present
metabolic criteria	• 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	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: a) Measures to reduce the length of ventilator support (including non-invasive ventilation and weaning) and b) Measures effective with this regard are: 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 b) Measures to reduce the microaspiration of pathogenic agents.
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	*Weaning trial:* Planned intention to disconnect the patient from ventilatory support by beginning a spontaneous breathing trial with one of the following methods: 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 translaryngeal devices
Comments	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. 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. 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.

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

Reporting checklist for economic evaluation of health interventions.

Based on the CHEERS guidelines.

		Reporting Item	Page Number
Title			
	#1	Identify the study as an economic evaluation or use more specific terms such as "cost-effectiveness analysis", and describe the interventions compared.	1
Abstract			
	#2	Provide a structured summary of objectives, perspective, setting, methods (including study design and inputs), results (including base case and uncertainty analyses), and conclusions	2
Introduction			
Background and objectives	#3	Provide an explicit statement of the broader context for the study. Present the study question and its relevance for health policy or practice decisions	3
Methods			
Target population and subgroups	#4	Describe characteristics of the base case population and subgroups analysed, including why they were chosen.	4
Setting and location	#5	State relevant aspects of the system(s) in which the decision(s) need(s) to be made.	4
Study perspective	#6	Describe the perspective of the study and relate this to the costs being evaluated.	4
Comparators	#7	Describe the interventions or strategies being compared and state why they were chosen.	5

Time horizon	#8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	4
Discount rate	#9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate	5
Choice of health outcomes	#10	Describe what outcomes were used as the measure(s) of benefit in the evaluation and their relevance for the type of analysis performed	6
Meaurement of effectiveness	#11a	Single study-based estimates: Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data	4
Measurement of effectiveness	#11b	Synthesis-based estimates: Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data	5
Measurement and valuation of preference based outcomes	#12	If applicable, describe the population and methods used to elicit preferences for outcomes.	n/a
**Estimating resources and costs **			
	#13a	Single study-based economic evaluation: Describe approaches used to estimate resource use associated with the alternative interventions. Describe primary or secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs	6

Methods

Estimating resources and costs	#13b	Model-based economic evaluation: Describe approaches and data sources used to estimate resource use associated with model health states. Describe primary or	n/a

		secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.	
Currency, price date, and conversion	#14	Report the dates of the estimated resource quantities and unit costs. Describe methods for adjusting estimated unit costs to the year of reported costs if necessary. Describe methods for converting costs into a common currency base and the exchange rate.	n/a
Choice of model	#15	Describe and give reasons for the specific type of decision analytical model used. Providing a figure to show model structure is strongly recommended.	6
Assumptions	#16	Describe all structural or other assumptions underpinning the decision-analytical model.	6
Analytical methods	#17	Describe all analytical methods supporting the evaluation. This could include methods for dealing with skewed, missing, or censored data; extrapolation methods; methods for pooling data; approaches to validate or make adjustments (such as half cycle corrections) to a model; and methods for handling population heterogeneity and uncertainty.	6
Results			
Study parameters	#18	Report the values, ranges, references, and, if used, probability distributions for all parameters. Report reasons or sources for distributions used to represent uncertainty where appropriate. Providing a table to show the input values is strongly recommended.	6
Incremental costs and outcomes	#19	For each intervention, report mean values for the main categories of estimated costs and outcomes of interest, as well as mean differences between the comparator groups. If applicable, report incremental cost-effectiveness ratios.	6-7
Characterising uncertainty	#20a	Single study-based economic evaluation: Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness	n/a

		parameters, together with the impact of methodological assumptions (such as discount rate, study perspective).	
Characterising uncertainty	#20b	Model-based economic evaluation: Describe the effects on the results of uncertainty for all input parameters, and uncertainty related to the structure of the model and assumptions.	8
Characterising heterogeneity	#21	If applicable, report differences in costs, outcomes, or cost effectiveness that can be explained by variations between subgroups of patients with different baseline characteristics or other observed variability in effects that are not reducible by more information.	n/a
Discussion			
Study findings, limitations, generalisability, and current knowledge	#22	Summarise key study findings and describe how they support the conclusions reached. Discuss limitations and the generalisability of the findings and how the findings fit with current knowledge.	10
Other			
Source of funding	#23	Describe how the study was funded and the role of the funder in the identification, design, conduct, and reporting of the analysis. Describe other non-monetary sources of support	13
Conflict of interest	#24	Describe any potential for conflict of interest of study contributors in accordance with journal policy. In the absence of a journal policy, we recommend authors comply with International Committee of Medical Journal Editors recommendations	13