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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-045327
Article Type:	Original research
Date Submitted by the Author:	30-Sep-2020
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Keywords:	INTENSIVE & CRITICAL CARE, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, HEALTH ECONOMICS

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Key Words: Critical Care, Intensive Care Unit, Quality Indicator, Transparency, Health Economics

Type: Original Research

Word Count: 4,190

Supplementary and raw data: Dataset anonymized upon request

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.

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 all German hospitals

71 INTRODUCTION

72 In the last decades, the need for quality management (QM) in the hospital has been growing. On one
73 hand costs have been rising and on the other patients, health insurance and public pressure urge
74 hospitals to improve outcome and services by cutting or tying reimbursement to valid quality
75 indicators (QI) [1]. This is why in the medium and long run quality-oriented reimbursement (pay for
76 quality) might change the hospital landscape [2]. Economics of health have been established widely
77 in order to curb costs for the national health care system. Many countries introduced diagnosis
78 related groups (DRGs) in order to pay on averaged costs and on a generalized financial
79 reimbursement per case (fixed prices). The fee-for-service system induces hospitals to improve
80 internal processes and to work goal-oriented towards therapeutic aims [3].

81 In modern medicine, a major part of hospital costs arises from intensive care. The cost structure of a
82 German hospital shows that ca. 20% of costs are generated in intensive care units (ICU) [4].
83 Especially, mechanical ventilation is the main cost driver in ICUs [5]. Approximately 6% of the
84 patients in intensive care are affected by prolonged mechanical ventilation and weaning from
85 mechanical ventilation represents an essential element in the treatment of critically ill patients as it
86 can take up to 50% of the ventilation time [6]. As a consequence, up to 37% of all ICU resources are
87 allocated to these patients [7]. This means that weaning patients from mechanical ventilation is not
88 only essential for clinical outcomes like duration of ventilation or length of stay [8,9], but also a
89 critical step from an economic perspective as costs can be reduced. Therefore, this process is a
90 critical phase in intensive care. However, the ideal weaning process is still subject to debate [10].
91 About 40% of patients receiving mechanical ventilation will experience a complicated weaning
92 process [11]. Patients categorized in prolonged weaning, failing at least three spontaneous breathing
93 trials or receiving more than seven days of weaning after the first spontaneous breathing trials, have
94 an increased risk in developing hospital mortality, mainly through ventilator-associated pneumonia
95 (VAP) [6], but also through post intensive care syndrome (PICS) or chronic critical illness (CCI) [12].
96 Due to demographic changes and technological advances in intensive care, the number of older
97 patients with complex diseases or comorbidities needing ventilation is increasing [13,14]. This
98 generates growing costs, as the cohort of patients requiring respiratory support accounts for a
99 disproportionate percentage of the resources available in intensive care [15].

100 With the purpose of managing quality throughout the difficult framework conditions of hospital care,
101 a proactive and structured QM is essential [16]. In general, QM focuses on securing and improving
102 clinical services economically, performed by physicians or nurses according to the patient's needs
103 [17]. In Germany, in the context of European and national QM initiatives, consensus-based
104 standardized QIs were developed for intensive care medicine since 2010 – third version in 2017 – by
105 the German interdisciplinary society for intensive and emergency care (DIVI) in order to simplify the
106 measurement of relevant quality data, to record timely and to allow transparent comparisons of
107 patient data. The according quantification of QM helps measuring effectiveness and efficiency of
108 ICUs [18,19]. QIs enable a descriptive picture of the actual condition and are an indispensable
109 instrument for comparisons between different states of quality [18]. Potentially, widely-accepted QIs
110 can progress hospital economics and support the reduction of the national budget for health care,
111 even though a recent study has shown that cost-quality relationships are difficult to generate [20].

112 QIs empower advances in intensive care medicine to be measured and evaluated on a regular basis
113 [19]. QIs can be defined as representative figures for quality of structure, processes or outcome
114 within the medical care process. Thus, indicators are useful for measuring improvement in the
115 context of quality management and should be developed in line with evidence-based literature [21].
116 Ideally, measures for QIs can be extracted from routine patient data to avoid excess documentation

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4 117 work. Therefore, patient data management systems (PDMS) are pivotal for measuring complex
5 118 quality figures [18]. The economic aspects for the whole hospital of the introduction of QIs are not
6 119 well investigated. However, there is evidence that the application of QIs is a value-creating instrument
7 120 [12].
8

9 121 The objective of this study was, to determine the economic impact of adherence to a single quality
10 122 indicator evaluating the weaning process from invasive ventilation. We analyzed this by comparing
11 123 economic results per case and clinical outcome parameters like length of stay (LOS) between two
12 124 groups of either high or low quality adherence. Additionally, we sought to determine factors that
13 125 would influence a potential interaction between economic and outcome parameters.
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16 126 **METHODS**

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18 127 This original research is in accordance with the Consolidated Health Economic Evaluation Research
19 128 Standards (CHEERS).
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21 129 **Study Center**

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23 130 We conducted this single study-center in a university hospital (Charité - Universitätsmedizin Berlin).
24 131 This observational analysis was performed at a 14-bed intensive care unit (reference center),
25 132 specialized for acute respiratory distress syndrome in adult patients. All patients at our ICU were
26 133 treated according to guidelines and internal standard operating procedures for clinical practice [22].
27

28 134 **Study Design**

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30 135 This was a retrospective descriptive study, using data from multiple electronic databases used in
31 136 routine patient care and for routine administrative purposes. All patients admitted to and discharged
32 137 from the ICU between 1 January 2012 and 31 December 2017 who received invasive ventilation
33 138 during their stay were eligible to be included in this study. Furthermore, duration of ventilation <95
34 139 hours, receiving no invasive ventilation, terminal status, incomplete patient record or missing
35 140 readiness to be weaned were defined as exclusion criteria (see figure 1).
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37

38 141 The study was approved by the Ethics Commission at Charité (EA2/139/20). Informed patient
39 142 consent was waived due to retrospective study design. Confidentiality was guaranteed, no
40 143 interventions were performed and only clinical routine data were collected. Data were retrieved
41 144 from a PDMS called COPRA (Computer Organized Patient Report Assistant; COPRA System GmbH,
42 145 Berlin, Germany). Data are recorded both automatically by patient monitors and manually by
43 146 caregivers. The ICU staff validates all information manually. However, the design of the PDMS
44 147 prevents manual alterations to the data, for example adding missing values after discharge from the
45 148 ICU. PDMS data are also transferred to the clinical information and accounting system (SAP, Walldorf,
46 149 Germany). Based on this administrative system, cost unit accounting is performed annually. In
47 150 addition to basic demographic data, we assessed clinical and administrative parameters of in-patient
48 151 cases (e.g. LOS). Data were retrieved using a structured query. No patient identifiers were extracted
49 152 in order to secure anonymity of patients' data.
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53 153 PDMS data of patients included in the study were transferred to the study database, where we also
54 154 collected the administrative and cost accounting data respectively. We contrasted patient, intensive
55 155 care and economic parameters of the two adherence groups (see table 1). Then, we calculated the
56 156 profits per case by subtracting costs of reimbursement per case. In order to generate an economic
57 157 outcome per case for the dependent variable in multivariate linear regression. Besides administrative
58 158 data, we used different scores for assessing the QI for eligibility. Selection criteria were: (i) no
59 159 additional workload required for documentation, (ii) the availability within the PDMS system, (iii)

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4 160 standardized values for all patients and the existence of standard operating procedures for each
5 161 indicator and (iv) the relevance of the indicator for clinical decision-making [19,23].

6 7 162 **Procedures**

8
9 163 In this study, we used present KPIs in order to examine the adherence to the quality indicator “Early
10 164 Weaning from Invasive Ventilation” until ICU discharge [8]. A small set of evidence-based key
11 165 performance indicators (KPIs) was established in 2009, providing indicators that were already
12 166 available within the PDMS. The KPIs in intensive care medicine proved helpful for practical use and
13 167 compliance with standard operating procedures. Within the weaning therapy, fast visual feedback
14 168 for “readiness to wean” and “weaning protocol compliance” were implemented. If both KPIs were
15 169 positive, the according result of the “spontaneous breathing trial” (SBT) was recorded [23]. Once the
16 170 patient was assessed to be ready to wean since the primary disease showed clinical improvement,
17 171 the standard weaning protocol activities were conducted on a daily basis according to standard
18 172 operating procedures. Congruent with clinical guidelines in place, weaning protocols were adapted to
19 173 evaluate the progress of respirator therapy [22]. The subsequent result was recorded in the weaning
20 174 protocol. For each patient, we monitored the daily weaning protocol compliance between readiness
21 175 to wean and ICU-discharge in order to evaluate the percentage of adherence. Within the weaning
22 176 process, the SBT represents the major diagnostic test to evaluate if the patient can be extubated
23 177 successfully [10]. The SBT is successful if the patient succeeded the trial and does not have to be re-
24 178 intubated within 48 hours [24].

28 29 179 **Outcome Parameters**

30
31 180 In this study, we investigated for economic results, clinical outcome parameters per case and the
32 181 respective adherence to quality. Economic results were defined as the profit or loss per case, by
33 182 subtracting all assigned costs from the reimbursement on a case level. Clinical outcomes as a
34 183 representative for clinical effectiveness were measured in order to set economic outcomes in
35 184 relation to the purpose of medicine. Adherence to quality was calculated on a per case level in order
36 185 to categorize the patients into groups.

37
38 186 We used the adherence level of the examined quality indicator in order to create two quality groups.
39 187 We calculated the final quality level by averaging the daily indicator results for the duration with
40 188 equal weights per day. In order to set the optimal cutoff point for dichotomously distinguishing
41 189 between high-adherence and low-adherence of weaning quality, we combined recommendations
42 190 from literature with our institutional standards. A cutoff value of 70% deemed as a suitable
43 191 fulfillment-threshold for quality indicators [25]. However, due to partially high workload under
44 192 certain circumstances in intensive care, we decided to lower the cutoff for 5% tolerance in order to
45 193 account for missing values in documentation. Therefore, we inserted a cutoff for weaning protocol
46 194 compliance at 65% adherence. The LAG was defined as adherence to QI of less than 65%. The HAG
47 195 was defined as adherence to QI of equal or more than 65%. Once this threshold was reached, the QI
48 196 was characterized as high-adherence.

52 53 197 **Statistical Analyses**

54
55 198 Descriptive analyses and statistical testing were performed using SPSS, version 14.0 (SPSS Inc.,
56 199 Chicago, IL, USA) for Windows. Results are expressed as median (interquartile range) or frequency
57 200 (%). We controlled data for risk and severity by exclusion as patients and therapies in intensive care
58 201 are heterogenic, as studies have shown [18]. Differences between the adherence groups in terms of
59 202 outcome parameters were tested using the univariate unpaired t-test and chi-squared statistics for
60 203 independent variables as appropriate with a *P*-value below 0.05 regarded as significant.

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4 204 In order to investigate the influencing factors in more detail, parameters that were found to be
5 205 statistically significant on univariate analysis or out of discussion among the experts underwent
6 206 stepwise multivariate analyses. We used multiple linear regression analyses to model the
7 207 relationship between the independent variables and the outcome of profitability. Regression
8 208 coefficients (95% CI) and the corresponding *P*-values were calculated for each factor. Testing the
9 209 dataset for outliers was performed using the cook distance test, based on the model. The test did not
10 210 indicate the need to dismiss cases from the sample. Due to an exploratory character of the research,
11 211 no adjustments for multiple testing were made.

14 212 **Patient and public involvement**

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16 213 Patients and the public were not directly involved in this observational study.

18 214 **RESULTS**

19
20 215 All patients with complete electronic patient records (n=3,063 patients) were screened for eligibility.
21 216 After selection regarding inclusion and exclusion criteria, 583 patients were included in the final
22 217 analysis (Figure 1). Of these patients, 378 showed low-adherence if the indicator was below 65% and
23 218 205 showed high-adherence. The median age of admitted patients was 57 [40;70] years; 64.7 % of
24 219 patients were male. There were significantly (*P* = 0.038) more male patients within the HAG (70.2%)
25 220 than in the LAG (61.6%). As reflected by a median APACHE II admission score of 21 [14;27], a SAPS II
26 221 admission score of 47 [34;61] and a SOFA admission score of 9 [7;12], the study population was
27 222 characterized by severe medical conditions. Patient demographics are displayed in Table 1. Along the
28 223 line, at discharge patients generated an average daily SOFA score of 8.2 [6.6;10.3] indicating
29 224 resource-intensive monitoring and treatment of the patient.

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31
32 225 In order to account for the remaining clinical patient outcomes after grouping, we analyzed the
33 226 ventilation parameters. Overall in the median, patients were ventilated for 431 [250;709] hours on
34 227 the ICU and 578 [338;924] throughout their hospital stay. Following the division into two adherence
35 228 groups, there was a significant reduction in duration of ventilation on ICU from 476 to 389 hours (*P* <
36 229 0.001). Overall in-hospital duration of ventilation was decreased from 597 to 535 hours (*P* = 0.017).
37 230 Concerning the number of SBTs and reintubations, there was no significant finding (*P* = 0.456 and *P* =
38 231 0.531). In addition to the significant decrease in ventilation parameters seen between the differences
39 232 in adherence, the LOS was decreased by 5 days from 21 to 16 (*P* < 0.001) and overall in-hospital LOS
40 233 decreased from 36 to 26 days per patient (*P* = 0.001) in the median, indicating strong arguments for
41 234 quality indicator adherence. With regard to economic outcome, the overall median economic results
42 235 (loss) per case was -2,999€. There was an increase in profitability from a median loss of 3,696€ to
43 236 1,030€ (*P* < 0.001).

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47 237 Considering the discharge of the patients, there was a highly significant difference (*P* < 0.001)
48 238 between both groups. Most patients were discharged to intermediate care (44.6%), other ICUs
49 239 (27.6%) or rehabilitation (18.9%). Within the LAG, 50 (13.2%) patients died compared to 2 (1.0%) in
50 240 the HAG. This gives room to assume a certain impact of weaning quality on mortality.

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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

243

244 **Multiple Linear Regression**

245 The results of the multivariate linear regression analysis of the complete study population of 583
246 patients are given in table 2. The parameters were not adjusted for severity of illness. The fixed
247 variables age, sex and percentage of quality indicator adherence examined did not show significant
248 effects on profitability.

249 In the linear regression analysis, the LOS on the study-ICU ($P < 0.001$), the LOS in the hospital ($P =$
250 0.015), the averaged daily SOFA score ($P = 0.002$) and the averaged daily costs per patient ($P = 0.032$)
251 were shown to have significant effects on the profitability (table 2). Strong effects were found for the
252 averaged daily SOFA score, which increased profits per case by 1,608€ [CI: 892€, 2,323€] for each
253 SOFA point. Furthermore, the LOS on the ICU decreased profits per case for 529€ for every day
254 longer on the ICU. To the best of our knowledge, multivariate regression for economic outcome has
255 not yet been conducted for these factors. The regression model was performed without the
256 admission scores for SAPSII, SOFA and APACHEII. When these scores were included, the statistical
257 significances remained unchanged for the remaining variables that were analyzed (s. table 2).

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

263

264

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"

265

266

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]

¹Case-Mix Index, Averaged case-mix per case according to German DRG-System

²Averaged financial result per case

267

268 DISCUSSION

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

283 Highly specialized ICUs are resource- and cost-intensive and not universally available. By
284 implementing QM as a method to constantly eliminating the factors of chance, hospitals are trying to
285 reduce complexity in defining, measuring and learning from QIs. Furthermore, QM is associated as a
286 necessity for certification processes and therefore incremental part of critical care concepts [1]. The
287 importance of weaning protocols and according adherence is based on studies that have proven
288 between 70-80% of all patients receiving >24h invasive ventilation could already be weaned after the
289 first SBT [8,27,28]. This is why in 2011, a study at our institution investigated that the support of fast
290 visual feedback for adherence to standard operating procedures within the PDMS led to decreased
291 duration of mechanical ventilation and higher documentation compliance, supporting our findings
292 [29]. The approach of measuring and steering quality with indicators carries several direct and
293 indirect economic incentives. First, less loss per patient due to better clinical outcome has positive
294 effects on the general economic results of the department. Second, decreased LOS on the ICU gives
295 room to available beds earlier and therefore other patients to fill in the existing resource [30]. Third,
296 because of public reporting and potential pay for quality structures, indicators are important
297 methods for measuring quality and safety in health care, resulting in better outcome [31]. In
298 particular, transparent quality indicators allow department leaders to identify weak spots and initiate
299 improvement in a structured and measurable way [2]. Our matched with a study performed in 2008,
300 showing positive clinical outcome effects of ventilator weaning protocol measures [32]. Patients
301 spent less time on mechanical ventilation, and thus less time in intensive care and in the hospital. We
302 found that the more patients that could be weaned per year, the less time they spent on the
303 ventilator and better the economic results followed, since more patients generating contribution
304 margins covered fixed costs. This effect shows that redundant capacities can be used for new
305 admissions and thus higher throughput, similar to a former study at our institution [33].

306 This study is the first to find that high-adherence to the quality indicator “Early weaning from
307 invasive ventilation” above a proven threshold of 65% showed higher economic returns (or less
308 losses) than low-adherence. Furthermore, the study is unique in using a case defined data set to
309 examine the economic effect of a single quality indicator. Current economic prediction models in
310 intensive care usually describe interventions of entire quality management programs [30] or changes
311 in staffing [33]. Overall, we found that the median financial return for a hospital is negative when
312 focusing on weaning from ventilation. This is independent of their QI adherence results. In Germany,
313 insurance companies reimburse hospitals using the G-DRG System (German Diagnosis Related
314 Groups System) based on a performance-oriented compensation for inpatients. Within DRG-Systems

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4 315 [30], the case-mix of weaning patients does not provide adequate economic incentives for quality
5 316 based critical care since the reimbursement is mainly focused on duration of ventilation. This is
6 317 consistent with other studies that found higher process quality led to decreased ventilator
7 318 dependence and reduced reimbursement [25,26,34]. In this study, we used comprehensive per-
8 319 patient cost data. At our institution, a case-related cost calculation is well established and highly
9 320 accurate for reimbursement per case and costs since we have been substantial cost-accounting
10 321 reference center since the beginning of the G-DRG-system. Therefore, we used this administrative
11 322 data to calculate the economic outcome per case [35]. In Germany, a representative mix of hospitals
12 323 gather case-related treatment costs on a yearly basis in order to report them to the Institute for the
13 324 Hospital Reimbursement System for continuous development [36].

16 325 The results of this study can inform policy makers on the following points: In Germany, the
17 326 application of quality indicators in critical care is so far not mandatory [12]. Since positive effects of
18 327 clinical and economic parameters can be found measuring the adherence to only one indicator of the
19 328 DIVI set (n=10), it is recommended to establish QIs widely. Over the years examined, we found that
20 329 weaning and the according QI have developed positively as the number of patients receiving weaning
21 330 increased while the duration of ventilation per patient decreased. The relation between these two
22 331 parameters shows that the quality of care increased and the organization for the volume effect
23 332 became more efficient, which is a dominant economic factor according to Nguyen et al. [37].
24 333 However, in order to evolve further in this direction, intensive care needs adequate reimbursement.
25 334 Contrary to the majority of ward care, which benefits from shorter length of stay within the flat-
26 335 compensation system, a decrease in length of stay in intensive care is not rewarded with higher
27 336 reimbursement. Literature confirms our analyses [36]. This is why we recommend that efforts for
28 337 quality should be shifted in the center of reimbursement in intensive care for better clinical
29 338 outcomes, following the approach of valued-based payment (pay for quality), where ICUs are
30 339 checked upon costs and quality of service [38]. Furthermore, because keeping patients on the ICU
31 340 and on mechanical ventilation economically-incentivized is proven to be dangerous for the patient
32 341 [8] and inefficient for the organization [30]. This structural change can ensure the incentives for
33 342 intensivists to adhere to quality standards instead of collecting ventilation hours. Our argument is
34 343 supported by a recent publication of a group of experts in intensive care. They argue in favor for a
35 344 reform in hospital reimbursement, away from flat-compensation towards progressive levels of
36 345 intensive care. Moreover, they suggest a central planning of all system relevant intensive care
37 346 infrastructures and according criteria for quality standards [39]. In the end, hospitals benefit from
38 347 investments in quality, as clinical quality has subsequent effects on economic returns. Thus, not only
39 348 hospitals, insurance companies and policy makers profit from adherence to quality indicators, also
40 349 the patient who should be in the center of healthcare does.

47 350 **Unanswered questions and future research**

49 351 As noted previously, the study was conducted in a tertiary university hospital, which is characterized
50 352 by specific and well established medical processes and structures. A transfer of our observations to
51 353 other intensive care units is not feasible. Some aspects of our analysis deserve comment on
52 354 limitation. First, the weaning process has constantly evolved during the years between 2012 and
53 355 2017. Since the importance of the weaning protocol emerged throughout the years, the focus on
54 356 measures hereof and according documentation improved over the years as documentation became
55 357 mandatory at our institution [8]. Furthermore, it was not possible matching the qualifications of
56 358 staffing as a determinant of adherence to quality and curbing of costs. There is supposed to be a
57 359 connection between experience and cost awareness [40]. Second, even though indicators and our
58 360 study-ICU can be examined independently for research purposes, the QI and its progression are
59 361 substantially connected to other intensive care indicators [19]. For further research, the interactions

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4 362 between the QIs and the progression on other ICUs need to be considered. Our results provide a
5 363 robust assessment of the impact of changes of the quality adherence and robust evaluation of their
6 364 effects.

8 365 **CONCLUSION**

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10 366 While the need for critical care increases constantly for various reasons (e.g. demographic change or
11 367 pandemic crisis), the challenge to provide high quality but cost-effective services will only become
12 368 more important. We examined a single indicator for quality and found proof that high-adherence to
13 369 it lead to significantly better clinical outcome. Within the univariate analysis, major clinical
14 370 parameters were significantly better in the HAG. Furthermore, we showed that adherence for 65% or
15 371 higher generated significantly higher median earnings within our univariate analysis. However, we
16 372 also showed that the investigated quality indicator does not significantly affect economic results in
17 373 our multivariate analysis. Instead, by using clinical parameters as proxies for clinical outcome, they
18 374 were found to be the main drivers for according economic success. The reason for this is the
19 375 increased number of patients who could be treated due to more total capacity, when LOS decreased
20 376 due to higher quality. This is why the focus of this study is not only on reimbursement and on costs,
21 377 but also on the direct effect of quality on the clinical outcome, which subsequently influences
22 378 economic results.

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26 379 Overall, quality matters for reimbursement, but reimbursement is not adjusted to the costs of
27 380 providing quality. Since there is no central, structured and timely publication of comparable quality
28 381 data in Germany, it is difficult for politics and assurances to reimburse on a pay for quality model as
29 382 the basis for comparisons is missing as not mandatory. Still, as quality in treatment is decisive for the
30 383 patient's hospital choice and the results of the treatment, QIs will be essential for public information
31 384 and health economics as the patient decides where to be treated.

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4 386 **Abbreviations**

5 387 QM: Quality management; QI: Quality indicator; DRG: Diagnosis-related groups; ICU: Intensive care
6 388 unit; PDMS: Patient data management system, LOS: Length of stay; KPI: Key performance indicator;
7 389 SBT: Spontaneous breathing trial; SOFA: Sequential organ failure assessment; APACHEII: Acute
8 390 physiology and chronic health evaluation II; SAPS II: Simplified acute physiology score; Average SOFA:
9 391 Averaged daily SOFA score; PACU: Post-acute care unit; OT: Operating theatre; CI: Confidence
10 392 interval.

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13 393 **Author contributions:**

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15 394 FB perceived the idea. RA and AZ performed data collection. AZ conducted statistical analysis;
16 395 drafted the manuscript and shared responsibility for design, coordination and finalization of the
17 396 manuscript; contributed to interpretation of the data, and had full access to the data. OK consulted
18 397 in quality management, QI and ICU therapy. All other critically reviewed and advised with their
19 398 expertise on the manuscript.

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21
22 399 **Funding:** This research received no specific grant from any funding agency in the public, commercial
23 400 or not-for-profit sectors. This analysis is part of a quality improvement effort from the Department of
24 401 Anesthesiology and Operative Intensive Care Medicine of the Charité Universitätsmedizin – Berlin,
25 402 Campus Mitte and Virchow-Klinikum.

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27 403 **Patient Consent:** Not required.

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29 404 **Competing interests:** The authors declare that they have no competing interests related to this
30 405 article. ICJME forms have been submitted to the editorial office.

31
32 406 AZ has nothing to declare. Dr. Kumpf has nothing to disclose. CS reports grants from Aridis
33 407 Pharmaceutical Inc., grants from B. Braun Melsungen AG, grants from Drägerwerk AG & Co. KGaA,
34 408 grants from Deutsche Forschungsgemeinschaft / German Research Society, grants from Deutsches
35 409 Zentrum für Luft- und Raumfahrt e. V. (DLR) / German Aerospace Center, grants from Einstein
36 410 Stiftung Berlin / Einstein Foundation Berlin, grants from European Society of Anaesthesiology, grants
37 411 from Gemeinsamer Bundesausschuss / Federal Joint Committee (G-BA), grants from
38 412 Inneruniversitäre Forschungsförderung / Inner University Grants, grants from Projektträger im DLR /
39 413 Project Management Agency, grants from Stifterverband / Non-Profit Society Promoting Science and
40 414 Education, grants from WHOCC, grants from Baxter Deutschland GmbH, grants from Cytosorbents
41 415 Europe GmbH, grants from Edwards Lifesciences Germany GmbH, grants from Fresenius Medical
42 416 Care, grants from Grünenthal GmbH, grants from Masimo Europe Ltd., grants from Pfizer Pharma PFE
43 417 GmbH, personal fees from Georg Thieme Verlag, grants from Dr. F. Köhler Chemie GmbH, grants
44 418 from Sintetica GmbH, grants from European Commission, grants from Stifterverband für die deutsche
45 419 Wissenschaft e.V. / Philips, grants from Stiftung Charité, grants from AGUETTANT Deutschland
46 420 GmbH, grants from AbbVie Deutschland GmbH & Co. KG, grants from Amomed Pharma GmbH,
47 421 grants from InTouch Health, grants from Copra System GmbH, grants from Correvio GmbH, grants
48 422 from Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V., grants from Deutsche
49 423 Gesellschaft für Anästhesiologie & Intensivmedizin (DGAI), grants from Stifterverband für die
50 424 deutsche Wissenschaft e.V. / Medtronic, grants from Philips Electronics Nederland BV, grants from
51 425 BMH, outside the submitted work; In addition, Prof. Spies has a patent 10 2014 215 211.9 licensed, a
52 426 patent 10 2014 215 212.9 licensed, a patent 10 2018 114 364.8 licensed, and a patent 10 2018 110
53 427 275.5 licensed. MH has nothing to disclose. MD has nothing to disclose. RA has nothing to disclose. JK
54 428 has nothing to disclose. RJ has nothing to disclose. FB reports grants from Einstein Foundation,
55 429 personal fees from Axon Publishing, grants from Vifor Pharma, personal fees from Elsevier

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4 430 Publishing, grants from Federal Ministry of Health, Germany, grants from Berlin Institute of Health,
5 431 outside the submitted work.

6
7 432 **Research Ethics Approval:** The study was approved by the written consent of the Ethics Commission
8 433 – Charité – Universitätsmedizin Berlin (EA2/139/20). The need for patient’s consent was waived due
9 434 to the retrospective nature of the study.

10
11 435 **Data Availability Statement:** The datasets analyzed during the current study are available from the
12 436 corresponding author on reasonable request.

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14 437 **Clinical Trial Registration:** Not applicable.

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16 438 **Patient and Public Involvement statement:** Patients and the public were not directly involved in this
17 439 observational study.

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545 **Figure Legend:**

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

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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	<i>Single study-based estimates:</i> Describe fully the design features of the single effectiveness study and why the single study was a sufficient source of clinical effectiveness data.	_____



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2		11b	<i>Synthesis-based estimates:</i> Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data.	<hr/>
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4	Measurement and			
5	valuation of preference	12	If applicable, describe the population and methods used to elicit preferences for outcomes.	<hr/>
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8	Estimating resources	13a	<i>Single study-based economic evaluation:</i> 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.	<hr/>
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15		13b	<i>Model-based economic evaluation:</i> 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.	<hr/>
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22	Currency, price date,	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.	<hr/>
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28	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.	<hr/>
29				
30				
31	Assumptions	16	Describe all structural or other assumptions underpinning the decision-analytical model.	<hr/>
32				
33				
34	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.	<hr/>
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41				
42	Results			
43	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.	<hr/>
44				
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48				
49	Incremental costs and	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.	<hr/>
50	outcomes			
51				
52				
53	Characterising	20a	<i>Single study-based economic evaluation:</i> Describe the effects of sampling uncertainty for the estimated incremental cost and incremental effectiveness parameters, together with the impact	<hr/>
54	uncertainty			
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1			of methodological assumptions (such as discount rate, study	
2			perspective).	
3		20b	<i>Model-based economic evaluation</i> : Describe the effects on the	
4			results of uncertainty for all input parameters, and uncertainty	
5			related to the structure of the model and assumptions.	
6				
7	Characterising	21	If applicable, report differences in costs, outcomes, or cost-	
8	heterogeneity		effectiveness that can be explained by variations between	
9			subgroups of patients with different baseline characteristics or	
10			other observed variability in effects that are not reducible by	
11			more information.	
12				
13	Discussion			
14	Study findings,	22	Summarise key study findings and describe how they support	
15	limitations,		the conclusions reached. Discuss limitations and the	
16	generalisability, and		generalisability of the findings and how the findings fit with	
17	current knowledge		current knowledge.	
18				
19	Other			
20	Source of funding	23	Describe how the study was funded and the role of the funder	
21			in the identification, design, conduct, and reporting of the	
22			analysis. Describe other non-monetary sources of support.	
23				
24	Conflicts of interest	24	Describe any potential for conflict of interest of study	
25			contributors in accordance with journal policy. In the absence	
26			of a journal policy, we recommend authors comply with	
27			International Committee of Medical Journal Editors	
28			recommendations.	
29				

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>

The citation for the CHEERS Task Force Report is:

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
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

1	Time horizon	#8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	4
2				
3				
4				
5				
6	Discount rate	#9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate	5
7				
8				
9				
10	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
11				
12				
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14				
15	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	4
16				
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22	Measurement of effectiveness	#11b	Synthesis-based estimates: Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data	5
23				
24				
25				
26				
27	Measurement and valuation of preference based outcomes	#12	If applicable, describe the population and methods used to elicit preferences for outcomes.	n/a
28				
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34	**Estimating resources and costs **			
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36				
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40		#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
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49				
50	Methods			
51				
52	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
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item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.

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4	Currency, price date,	#14	n/a
5	and conversion		
6		Report the dates of the estimated resource quantities	
7		and unit costs. Describe methods for adjusting estimated	
8		unit costs to the year of reported costs if necessary.	
9		Describe methods for converting costs into a common	
10		currency base and the exchange rate.	
11			
12	Choice of model	#15	6
13		Describe and give reasons for the specific type of	
14		decision analytical model used. Providing a figure to	
15		show model structure is strongly recommended.	
16			
17	Assumptions	#16	6
18		Describe all structural or other assumptions	
19		underpinning the decision-analytical model.	
20			
21	Analytical methods	#17	6
22		Describe all analytical methods supporting the	
23		evaluation. This could include methods for dealing with	
24		skewed, missing, or censored data; extrapolation	
25		methods; methods for pooling data; approaches to	
26		validate or make adjustments (such as half cycle	
27		corrections) to a model; and methods for handling	
28		population heterogeneity and uncertainty.	
29			
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33	Results		
34			
35	Study parameters	#18	6
36		Report the values, ranges, references, and, if used,	
37		probability distributions for all parameters. Report	
38		reasons or sources for distributions used to represent	
39		uncertainty where appropriate. Providing a table to show	
40		the input values is strongly recommended.	
41			
42			
43	Incremental costs and	#19	6-7
44	outcomes		
45		For each intervention, report mean values for the main	
46		categories of estimated costs and outcomes of interest,	
47		as well as mean differences between the comparator	
48		groups. If applicable, report incremental cost-	
49		effectiveness ratios.	
50			
51			
52	Characterising	#20a	n/a
53	uncertainty		
54		Single study-based economic evaluation: Describe the	
55		effects of sampling uncertainty for the estimated	
56		incremental cost and incremental effectiveness	
57		parameters, together with the impact of methodological	
58		assumptions (such as discount rate, study perspective).	
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1	Characterising	#20b	Model-based economic evaluation: Describe the effects	7
2	uncertainty		on the results of uncertainty for all input parameters, and	
3			uncertainty related to the structure of the model and	
4			assumptions.	
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8	Characterising	#21	If applicable, report differences in costs, outcomes, or	n/a
9	heterogeneity		cost effectiveness that can be explained by variations	
10			between subgroups of patients with different baseline	
11			characteristics or other observed variability in effects that	
12			are not reducible by more information.	
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16	Discussion			
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18	Study findings,	#22	Summarise key study findings and describe how they	11
19	limitations,		support the conclusions reached. Discuss limitations and	
20	generalisability, and		the generalisability of the findings and how the findings	
21	current knowledge		fit with current knowledge.	
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33				
34	Conflict of interest	#24	Describe any potential for conflict of interest of study	14
35			contributors in accordance with journal policy. In the	
36			absence of a journal policy, we recommend authors	
37			comply with International Committee of Medical Journal	
38			Editors recommendations	
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BMJ Open

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

Journal:	<i>BMJ Open</i>
Manuscript ID	bmjopen-2020-045327.R1
Article Type:	Original research
Date Submitted by the Author:	05-Aug-2021
Complete List of Authors:	Zuber, Alexander; Charité Universitätsmedizin Berlin, Institute of Medical Informatics; Charité Universitätsmedizin Berlin, Department of Anesthesiology and Operative Intensive Care Medicine Kumpf, Oliver; Charité Universitätsmedizin Berlin, Department of Anesthesiology and Operative Intensive Care Medicine Spies, Claudia; Charité Universitätsmedizin Berlin, Department of Anesthesiology and Operative Intensive Care Medicine Höft, Moritz; Charité Universitätsmedizin Berlin, Department of Anesthesiology and Operative Intensive Care Medicine Deffland, Marc; Charité Universitätsmedizin Berlin, Department of Anesthesiology and Operative Intensive Care Medicine Ahlborn, Robert; Charité Universitätsmedizin Berlin, IT Department Kruppa, Jochen; Charité Universitätsmedizin Berlin, Institute of Medical Informatics Jochem, Roland; TU Berlin, Departments of Machine Tools and Factory Management Balzer, Felix; Charité Universitätsmedizin Berlin, Department of Anesthesiology and Operative Intensive Care Medicine; Charité Universitätsmedizin Berlin, Institute of Medical Informatics
Primary Subject Heading:	Health economics
Secondary Subject Heading:	Intensive care, Health policy
Keywords:	INTENSIVE & CRITICAL CARE, Quality in health care < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, HEALTH ECONOMICS

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4 1 **Title:**

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6 2 **Does adherence to a quality indicator regarding early weaning from invasive**
7 3 **ventilation improve economic outcome? A single-center retrospective study.**

8
9
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30 30 **Key Words:** Critical Care, Intensive Care Unit, Quality Indicator, Transparency, Health Economics

31 31 **Type:** Original Research

32 32 **Word Count:** 4,505

33 33 **Supplementary and raw data:** Dataset anonymized upon request
34

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

70 INTRODUCTION

71 In the last decades, the need for quality management (QM) in the hospital has been growing. On one
72 hand costs have been rising and on the other patients, health insurance and public pressure urge
73 hospitals to improve outcome and services by cutting or tying reimbursement to valid quality
74 indicators [1]. This is why in the medium and long run quality-oriented reimbursement (pay for
75 quality) might change the hospital landscape [2]. Economics of health have been established widely
76 in order to curb costs for the national health care system. Many countries introduced diagnosis
77 related groups (DRGs) in order to pay on averaged costs and on a generalized financial
78 reimbursement per case (fixed prices). Reimbursement for inpatients is linked to DRG accounting and
79 updated annually based on reported data from hospitals. The fee-for-service system induces
80 hospitals to improve internal processes as reimbursement is predefined and to work goal-oriented
81 towards therapeutic aims [3].

82 In modern medicine, a considerable part of hospital costs arises from intensive care. The cost
83 structure of a tertiary German hospital shows that ca. 20% of costs are generated in ICUs [4].
84 Especially, mechanical ventilation is the main cost driver in ICUs [5]. Approximately 6% of the
85 patients in intensive care are affected by prolonged mechanical ventilation and weaning from
86 mechanical ventilation represents an essential element in the treatment of critically ill patients as it
87 can take up to 50% of the ventilation time [6]. As a consequence, up to 37% of all ICU resources are
88 allocated to these patients [7]. This means that weaning patients from mechanical ventilation is not
89 only essential for clinical outcomes like duration of ventilation or LOS [8,9], but also a critical step
90 from an economic perspective as costs can be reduced. Therefore, this process is a critical phase in
91 intensive care. However, the ideal weaning process is still subject to debate [10]. About 40% of
92 patients receiving mechanical ventilation will experience a complicated weaning process [11].
93 Patients categorized in prolonged weaning, failing at least three spontaneous breathing trials or
94 receiving more than seven days of weaning after the first spontaneous breathing trials, have an
95 increased risk in developing hospital mortality, mainly through ventilator-associated pneumonia
96 (VAP) [6], but also through post intensive care syndrome (PICS) or chronic critical illness (CCI) [12].
97 Due to demographic changes and technological advances in intensive care, the number of older
98 patients with complex diseases or comorbidities needing ventilation is increasing [13,14]. This
99 generates growing costs, as the cohort of patients requiring respiratory support accounts for a
100 disproportionate percentage of the resources available in intensive care [15].

101 With the purpose of managing quality throughout the difficult framework conditions of hospital care,
102 a proactive and structured QM is essential [16]. In general, QM focuses on securing and improving
103 clinical services economically, performed by physicians or nurses according to the patient's needs
104 [17]. In Germany, in the context of European and national QM initiatives, consensus-based
105 standardized QIs were developed for intensive care medicine since 2010 – third version in 2017 – by
106 the German interdisciplinary society for intensive and emergency care (DIVI) in order to simplify the
107 measurement of relevant quality data, to record timely and to allow transparent comparisons of
108 patient data. The according quantification of QM helps measuring effectiveness and efficiency of
109 ICUs [18,19]. QIs enable a descriptive picture of the actual condition and are an indispensable
110 instrument for comparisons between different states of quality [18]. Potentially, widely-accepted QIs
111 can progress hospital economics and support the reduction of the national budget for health care,
112 even though a recent study has shown that cost-quality relationships are difficult to generate [20].

113 QIs empower advances in intensive care medicine to be measured and evaluated on a regular basis
114 [19]. QIs can be defined as representative figures for quality of structure, processes or outcome
115 within the medical care process. Thus, indicators are useful for measuring improvement in the

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4 116 context of quality management and should be developed in line with evidence-based literature [21].
5 117 Ideally, measures for QIs can be extracted from routine patient data to avoid excess documentation
6 118 work. Therefore, patient data management systems (PDMS) are pivotal for measuring complex
7 119 quality figures [18]. The economic aspects for the whole hospital of the introduction of QIs are not
8 120 well investigated. However, there is evidence that the application of QIs is a value-creating instrument
9 121 [12].

11 122 The objective of this study was, to determine the economic impact of adherence to a single quality
12 123 indicator evaluating the weaning process from invasive ventilation. We analyzed this by comparing
13 124 economic results per case and clinical outcome parameters like LOS between two groups of either
14 125 high or low quality adherence. Additionally, we sought to determine factors that would influence a
15 126 potential interaction between economic and outcome parameters.

18 127 **METHODS**

20 128 This original research is in accordance with the Consolidated Health Economic Evaluation Research
21 129 Standards (CHEERS).

23 130 **Patient and public involvement**

25 131 Patients and the public were not directly involved in this observational study.

27 132 **Study Center**

29 133 We conducted this single study-center in a university hospital (Charité - Universitätsmedizin Berlin).
30 134 This observational analysis was performed at a 14-bed ICU (reference center), specialized in
31 135 treatment of acute respiratory distress syndrome in adult patients. All patients at our ICU were
32 136 treated according to guidelines and internal standard operating procedures for clinical practice [22].

34 137 **Study Design**

36 138 This was a retrospective descriptive study, using data from multiple electronic databases used in
37 139 routine patient care and for routine administrative purposes. All patients admitted to and discharged
38 140 from the ICU between 1 January 2012 and 31 December 2017 who received invasive ventilation
39 141 during their stay were eligible to be included in this study. Furthermore, duration of ventilation <95
40 142 hours, receiving no invasive ventilation, terminal status, incomplete patient record or missing
41 143 readiness to be weaned were defined as exclusion criteria (see figure 1).

44 144 The study was approved by the Ethics Commission of Charité – Universitätsmedizin Berlin
45 145 (EA2/139/20). The need for patient's consent was waived due to the retrospective nature of the
46 146 study. Confidentiality was guaranteed, no interventions were performed and only clinical routine
47 147 data were collected. Data were retrieved from a PDMS called COPRA (Computer Organized Patient
48 148 Report Assistant; COPRA System GmbH, Berlin, Germany). Data are recorded both automatically by
49 149 patient monitors and manually by caregivers. The ICU staff validates all information manually.
50 150 However, the design of the PDMS prevents manual alterations to the data, for example adding
51 151 missing values after discharge from the ICU. PDMS data are also transferred to the clinical
52 152 information and accounting system (SAP, Walldorf, Germany). Based on this administrative system,
53 153 cost unit accounting is performed annually. In addition to basic demographic data, we assessed
54 154 clinical and administrative parameters of in-patient cases (e.g. LOS). Data were retrieved using a
55 155 structured query. No patient identifiers were extracted in order to secure anonymity of patients'
56 156 data. Data related to diagnoses were not retrieved from the administrative systems.

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4 157 PDMS data of patients included in the study were transferred to the study database, where we also
5 158 collected the administrative and cost accounting data respectively. We contrasted patient, intensive
6 159 care and economic parameters of the two adherence groups (see table 1). Then, we calculated the
7 160 profits per case by subtracting costs of reimbursement per case. In order to generate an economic
8 161 outcome per case for the dependent variable in multivariate linear regression. Besides administrative
9 162 data, we used different scores for assessing the QI for eligibility. Selection criteria were: (i) no
11 163 additional workload required for documentation, (ii) the availability within the PDMS system, (iii)
12 164 standardized values for all patients and the existence of standard operating procedures for each
13 165 indicator and (iv) the relevance of the indicator for clinical decision-making [19,23].

15 166 **Procedures**

17 167 In this study, we used present KPIs in order to examine the adherence to the quality indicator “Early
18 168 Weaning from Invasive Ventilation” until ICU discharge [8]. A small set of evidence-based key
19 169 performance indicators (KPIs) was established in 2009, providing indicators that were already
20 170 available within the PDMS. The KPIs in intensive care medicine proved helpful for practical use and
21 171 compliance with standard operating procedures. A description of the KPI is provided in the
22 172 supplementary material. Within the weaning therapy, fast visual feedback for “readiness to wean”
23 173 and “weaning protocol compliance” were implemented. If both KPIs were positive, the according
24 174 result of the “spontaneous breathing trial” (SBT) was recorded [23]. Once the patient was assessed to
25 175 be ready to wean since the primary disease showed clinical improvement, the standard weaning
26 176 protocol activities were conducted on a daily basis according to standard operating procedures.
27 177 Congruent with clinical guidelines in place, weaning protocols were adapted to evaluate the progress
28 178 of respirator therapy [22]. The subsequent result was recorded in the weaning protocol. For each
29 179 patient, we monitored the daily weaning protocol compliance between readiness to wean and ICU-
30 180 discharge in order to evaluate the percentage of adherence. Within the weaning process, the SBT
31 181 represents the major diagnostic test to evaluate if the patient can be extubated successfully [10]. The
32 182 SBT is successful if the patient succeeded the trial and does not have to be re-intubated within 48
33 183 hours [24]. This process is directly linked to a specific QI for weaning derived from the DIVI-QI [19]. A
34 184 definition of the indicator is presented in the supplementary material.

39 185 **Outcome Parameters**

41 186 In this study, we investigated for economic results, clinical outcome parameters per case and the
42 187 respective adherence to quality. Economic results were defined as the profit or loss per case, by
43 188 subtracting all assigned costs from the reimbursement on a case level. Clinical outcomes as a
44 189 representative for clinical effectiveness were measured in order to set economic outcomes in
45 190 relation to the purpose of medicine. Adherence to quality was calculated on a per case level in order
46 191 to categorize the patients into groups.

49 192 We used the adherence level of the examined quality indicator in order to create two quality groups.
50 193 We calculated the final quality level by averaging the daily indicator results for the duration with
51 194 equal weights per day. In order to set the optimal cutoff point for dichotomously distinguishing
52 195 between high-adherence and low-adherence of weaning quality, we combined recommendations
53 196 from literature with our institutional standards. A cutoff value of 70% deemed as a suitable
54 197 fulfillment-threshold for quality indicators [25]. However, due to partially high workload under
55 198 certain circumstances in intensive care, we decided to lower the cutoff for 5% tolerance in order to
56 199 account for missing values in documentation. Therefore, we inserted a cutoff for weaning protocol
57 200 compliance at 65% adherence. The LAG was defined as adherence to QI of less than 65%. The HAG
58 201 was defined as adherence to QI of equal or more than 65%. Once this threshold was reached, the QI
59 202 was characterized as high-adherence.

203 Statistical Analyses

204 Descriptive analyses and statistical testing were performed using SPSS, version 14.0 (SPSS Inc.,
205 Chicago, IL, USA) for Windows. Results are expressed as median (interquartile range) or frequency
206 (%). We controlled data for risk and severity by exclusion as patients and therapies in intensive care
207 are heterogenic, as studies have shown [18]. Differences between the adherence groups in terms of
208 outcome parameters were tested using the univariate unpaired t-test and chi-squared statistics for
209 independent variables as appropriate with a *P*-value below 0.05 regarded as significant.

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

218 RESULTS

219 All patients with complete electronic patient records (n=3,063 patients) were screened for eligibility.
220 After selection regarding inclusion and exclusion criteria, 583 patients were included in the final
221 analysis (Figure 1). Of these patients, 378 showed low-adherence if the indicator was below 65% and
222 205 showed high-adherence. The median age of admitted patients was 57 [40;70] years; 64.7 % of
223 patients were male. There were significantly (*P* = 0.038) more male patients within the HAG (70.2%)
224 than in the LAG (61.6%). As reflected by a median APACHE II admission score of 21 [14;27], a SAPS II
225 admission score of 47 [34;61] and a SOFA admission score of 9 [7;12], the study population was
226 characterized by severe medical conditions. Patient demographics are displayed in Table 1. Along the
227 line, at discharge patients generated an average daily SOFA score of 8.2 [6.6;10.3] indicating
228 resource-intensive monitoring and treatment of the patient.

229 In order to account for the remaining clinical patient outcomes after grouping, we analyzed the
230 ventilation parameters. Overall in the median, patients were ventilated for 431 [250;709] hours on
231 the ICU and 578 [338;924] throughout their hospital stay. Following the division into two adherence
232 groups, there was a significant reduction in duration of ventilation on ICU from 476 to 389 hours (*P* <
233 0.001). Overall in-hospital duration of ventilation was decreased from 597 to 535 hours (*P* = 0.017).
234 Concerning the number of SBTs and reintubations, there was no significant finding (*P* = 0.456 and *P* =
235 0.531). In addition to the significant decrease in ventilation parameters seen between the differences
236 in adherence, the LOS was decreased by 5 days from 21 to 16 (*P* < 0.001) and overall in-hospital LOS
237 decreased from 36 to 26 days per patient (*P* = 0.001) in the median, indicating strong arguments for
238 quality indicator adherence. With regard to economic outcome, the overall median economic results
239 (loss) per case was -2,999€. There was an increase in profitability from a median loss of 3,696€ to
240 1,030€ (*P* < 0.001).

241 Considering the discharge of the patients, there was a highly significant difference (*P* < 0.001)
242 between both groups. Most patients were discharged to intermediate care (44.6%), other ICUs
243 (27.6%) or rehabilitation (18.9%). Within the LAG, 50 (13.2%) patients died on the ICU compared to 2
244 (1.0%) in the HAG. This gives room to assume a certain impact of weaning quality on mortality.
245 However, since we didn't include diagnosis data, we cannot exclude an influence from this fact.

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

	All Patients	LAG	HAG	P-Value
	n = 583	QI < 65%	QI ≥ 65%	
		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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248 **Multiple Linear Regression**

249 The results of the multivariate linear regression analysis of the complete study population of 583
250 patients are given in table 2. The parameters were not adjusted for severity of illness. The fixed
251 variables age, sex and percentage of quality indicator adherence examined did not show significant
252 effects on profitability.

253 In the linear regression analysis, the LOS on the study-ICU ($P < 0.001$), the LOS in the hospital ($P <$
254 0.001), the averaged daily SOFA score ($P < 0.001$) and the averaged daily costs per patient ($P < 0.001$)
255 were shown to have significant effects on the profitability (table 2). Strong effects were found for the
256 averaged daily SOFA score, which increased profits per case by 1,608€ [CI: 892€, 2,323€] for each
257 SOFA point. Furthermore, the LOS on the ICU decreased profits per case for 529€ for every day
258 longer on the ICU. To the best of our knowledge, multivariate regression for economic outcome has
259 not yet been conducted for these factors. The regression model was performed without the
260 admission scores for SAPSII, SOFA and APACHEII. When these scores were included, the statistical
261 significances remained unchanged for the remaining variables that were analyzed (s. table 2).

262 Comparing the cumulative parameters of weaning patients along the years (see table 3), a higher
263 number of patients weaned as well as a higher average SOFA-score can be associated with a higher
264 number of median economic result. The observation over time supports the outcome parameters of
265 table 1. Considering the development since 2012, there is an increase in the number of patients
266 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]

¹Case-Mix Index, Averaged case-mix per case according to German DRG-System

²Averaged financial result per case

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272 DISCUSSION

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

287 Highly specialized ICUs are resource- and cost-intensive and not universally available. By
288 implementing QM as a method to constantly eliminating the factors of chance, hospitals are trying to
289 reduce complexity in defining, measuring and learning from QIs. Furthermore, QM is associated as a
290 necessity for certification processes and therefore incremental part of critical care concepts [1]. The
291 importance of weaning protocols and according adherence is based on studies that have proven
292 between 70-80% of all patients receiving >24h invasive ventilation could already be weaned after the
293 first SBT [8,27,28]. This is why in 2011, a study at our institution investigated that the support of fast
294 visual feedback for adherence to standard operating procedures within the PDMS led to decreased
295 duration of mechanical ventilation and higher documentation compliance, supporting our findings
296 [29]. The approach of measuring and steering quality with indicators carries several direct and
297 indirect economic incentives. First, less loss per patient due to better clinical outcome has positive
298 effects on the general economic results of the department. Second, decreased LOS on the ICU gives
299 room to available beds earlier and therefore other patients to fill in the existing resource [30]. Third,
300 because of public reporting and potential pay for quality structures, indicators are important
301 methods for measuring quality and safety in health care, resulting in better outcome [31]. In
302 particular, transparent quality indicators allow department leaders to identify weak spots and initiate
303 improvement in a structured and measurable way [2]. Our matched with a study performed in 2008,
304 showing positive clinical outcome effects of ventilator weaning protocol measures [32]. Patients
305 spent less time on mechanical ventilation, and thus less time in intensive care and in the hospital. We
306 found that the more patients that could be weaned per year, the less time they spent on the
307 ventilator and better the economic results followed, since more patients generating contribution
308 margins covered fixed costs. This effect shows that redundant capacities can be used for new
309 admissions and thus higher throughput, similar to a former study at our institution [33].

310 This study is the first to find that high-adherence to the quality indicator “Early weaning from
311 invasive ventilation” above a proven threshold of 65% showed higher economic returns (or less
312 losses) than low-adherence. Furthermore, the study is unique in using a case defined data set to
313 examine the economic effect of a single quality indicator. Current economic prediction models in
314 intensive care usually describe interventions of entire quality management programs [30] or changes
315 in staffing [33]. Overall, we found that the median financial return for a hospital is negative when
316 focusing on weaning from ventilation. This is independent of their QI adherence results. In Germany,
317 insurance companies reimburse hospitals using the G-DRG System (German Diagnosis Related
318 Groups System) based on a performance-oriented compensation for inpatients. Within DRG-Systems

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4 319 [30], the case-mix of weaning patients does not provide adequate economic incentives for quality
5 320 based critical care since the reimbursement is mainly focused on procedures, e.g. duration of
6 321 ventilation. This is consistent with other studies that found higher process quality led to decreased
7 322 ventilator dependence and reduced reimbursement [25,26,34]. To avoid wrong incentives,
8 323 reimbursement should potentially be tied to patient-centered outcomes. For example, the
9 324 prevention of ventilator-associated pneumonia, post intensive care syndrome and chronic critical
10 325 illness. In this study, we used comprehensive per-patient cost data, based exclusively on the DRG-
11 326 system. At our institution, a case-related cost calculation is well established and highly accurate for
12 327 reimbursement per case and costs since we have been substantial cost-accounting reference center
13 328 since the beginning of the G-DRG-system. Therefore, we used this administrative data to calculate
14 329 the economic outcome per case [35]. In Germany, a representative mix of hospitals gather case-
15 330 related treatment costs on a yearly basis in order to report them to the Institute for the Hospital
16 331 Reimbursement System for continuous development [36]. On an annual basis, cost weights are
17 332 adjusted for each DRG, potentially leading to higher reimbursement per case. Hospitals can also
18 333 benefit from economies of scale, considering more cases per year with fixed reimbursement values.
19 334 This may explain why in 2015 and 2016 profits per case were higher.

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24 335 The results of this study can inform policy makers on the following points: In Germany, the
25 336 application of quality indicators in critical care is so far not mandatory [12]. Since positive effects of
26 337 clinical and economic parameters can be found measuring the adherence to only one indicator of the
27 338 DIVI set (n=10), it is recommended to establish QIs widely and combine patient-centered outcomes
28 339 with economic outcomes systematically. Over the years examined, we found that weaning and the
29 340 according QI have developed positively as the number of patients receiving weaning increased while
30 341 the duration of ventilation per patient decreased. The relation between these two parameters shows
31 342 that the quality of care increased and the organization for the volume effect became more efficient,
32 343 which is a dominant economic factor according to Nguyen et al. [37]. However, in order to evolve
33 344 further in this direction, intensive care needs adequate reimbursement. Higher assessment scores as
34 345 SAPS II or SOFA play an important role in ICU reimbursement and might induce higher DRG
35 346 reimbursement. Considering QM, contrary to the majority of ward care, which benefits from shorter
36 347 LOS within the flat-compensation system, a decrease in LOS in intensive care is not rewarded with
37 348 higher reimbursement. Literature confirms our analyses [36]. This is why we recommend that efforts
38 349 for quality should be shifted in the center of reimbursement in intensive care for better clinical
39 350 outcomes, following the approach of valued-based payment (pay for quality), where ICUs are
40 351 checked upon costs and quality of service [38]. Furthermore, because keeping patients on the ICU
41 352 and on mechanical ventilation economically-incentivized is proven to be dangerous for the patient
42 353 [8] and inefficient for the organization [30]. This structural change can ensure the incentives for
43 354 intensivists to adhere to quality standards instead of collecting ventilation hours. Our argument is
44 355 supported by a recent publication of a group of experts in intensive care. They argue in favor for a
45 356 reform in hospital reimbursement, away from flat-compensation towards progressive levels of
46 357 intensive care. Moreover, they suggest a central planning of all system relevant intensive care
47 358 infrastructures and according criteria for quality standards [39]. In the end, hospitals benefit from
48 359 investments in quality, as clinical quality has subsequent effects on economic returns. Thus, not only
49 360 hospitals, insurance companies and policy makers profit from adherence to quality indicators, also
50 361 the patient who should be in the center of healthcare does.

51 362 **Unanswered questions and future research**

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53 363 As noted previously, the study was conducted in a tertiary university hospital, which is characterized
54 364 by specific and well-established medical processes and structures. A transfer of our observations to
55 365 other ICUs or reimbursement systems is not feasible. The current study is subject to its retrospective

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4 366 design and potential selection bias, as some of the cases with incomplete data or special diagnoses
5 367 were not detected during the observation period. We could have used neurological and
6 368 neurosurgical diagnoses to exclude patients with low chances for weaning outcome, but in our
7 369 administrative system there is no time point matched to it accordingly as diagnoses are often added
8 370 just before discharge. For example: Patients developing specific neurological conditions after their
9 371 stay on the study-ICU. Some aspects of our analysis deserve comment on limitation. First, the
10 372 weaning process has constantly evolved during the years between 2012 and 2017. Since the
11 373 importance of the weaning protocol emerged throughout the years, the focus on measures hereof
12 374 and according documentation improved over the years as documentation became mandatory at our
13 375 institution [8]. Furthermore, it was not possible matching the qualifications of staffing as a
14 376 determinant of adherence to quality and curbing of costs. There is supposed to be a connection
15 377 between experience and cost awareness [40]. Second, even though indicators and our study-ICU can
16 378 be examined independently for research purposes, the QI and its progression are substantially
17 379 connected to other intensive care indicators [19]. For further research, the interactions between the
18 380 QIs and the progression on other ICUs need to be considered. Our results provide a robust
19 381 assessment of the impact of changes of the quality adherence and robust evaluation of their effects.

23 382 **CONCLUSION**

25 383 While the need for critical care increases constantly for various reasons (e.g. demographic change or
26 384 pandemic crisis), the challenge to provide high quality but cost-effective services will only become
27 385 more important. Available resources differ among the various hospital sizes and types. Although we
28 386 examined a single indicator for quality in a university reference center and found proof that high-
29 387 adherence to it lead to significantly better clinical outcome, we think patients and hospitals in
30 388 general benefit from high adherence to quality measures. Within the univariate analysis, major
31 389 clinical parameters were significantly better in the HAG. Furthermore, we showed that adherence for
32 390 65% or higher generated significantly higher median earnings within our univariate analysis.
33 391 However, we also showed that the investigated quality indicator does not significantly affect
34 392 economic results in our multivariate analysis. Instead, by using clinical parameters as proxies for
35 393 clinical outcome, they were found to be the main drivers for according economic success. The reason
36 394 for this is the increased number of patients who could be treated due to more total capacity, when
37 395 LOS decreased due to higher quality. This is why the focus of this study is not only on reimbursement
38 396 and on costs, but also on the direct effect of quality on the clinical outcome, which subsequently
39 397 influences economic results.

44 398 Overall, quality matters for reimbursement, but reimbursement is not adjusted to the costs of
45 399 providing quality. Since there is no central, structured and timely publication of comparable quality
46 400 data in Germany, it is difficult for politics and assurances to reimburse on a pay for quality model as
47 401 the basis for comparisons is missing as not mandatory. Still, as quality in treatment is decisive for the
48 402 patient's hospital choice and the results of the treatment, QIs will be essential for public information
49 403 and health economics as the patient decides where to be treated.

52 404

405 **Abbreviations**

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

413 **Author contributions:**

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

423 **Funding:** This research received no specific grant from any funding agency in the public, commercial
424 or not-for-profit sectors. This analysis is part of a quality improvement effort from the Department of
425 Anesthesiology and Operative Intensive Care Medicine of the Charité Universitätsmedizin – Berlin,
426 Campus Mitte and Virchow-Klinikum.

427 **Patient Consent:** Not required.

428 **Competing interests:** The authors declare that they have no competing interests related to this
429 article. ICJME forms have been submitted to the editorial office.

430 AZ has nothing to declare. Dr. Kumpf has nothing to disclose. CS reports grants from Aridis
431 Pharmaceutical Inc., grants from B. Braun Melsungen AG, grants from Drägerwerk AG & Co. KGaA,
432 grants from Deutsche Forschungsgemeinschaft / German Research Society, grants from Deutsches
433 Zentrum für Luft- und Raumfahrt e. V. (DLR) / German Aerospace Center, grants from Einstein
434 Stiftung Berlin / Einstein Foundation Berlin, grants from European Society of Anaesthesiology, grants
435 from Gemeinsamer Bundesausschuss / Federal Joint Committee (G-BA), grants from
436 Inneruniversitäre Forschungsförderung / Inner University Grants, grants from Projektträger im DLR /
437 Project Management Agency, grants from Stifterverband / Non-Profit Society Promoting Science and
438 Education, grants from WHOCC, grants from Baxter Deutschland GmbH, grants from Cytosorbents
439 Europe GmbH, grants from Edwards Lifesciences Germany GmbH, grants from Fresenius Medical
440 Care, grants from Grünenthal GmbH, grants from Masimo Europe Ltd., grants from Pfizer Pharma PFE
441 GmbH, personal fees from Georg Thieme Verlag, grants from Dr. F. Köhler Chemie GmbH, grants
442 from Sintetica GmbH, grants from European Commission, grants from Stifterverband für die deutsche
443 Wissenschaft e.V. / Philips, grants from Stiftung Charité, grants from AGUETTANT Deutschland
444 GmbH, grants from AbbVie Deutschland GmbH & Co. KG, grants from Amomed Pharma GmbH,
445 grants from InTouch Health, grants from Copra System GmbH, grants from Correvio GmbH, grants
446 from Max-Planck-Gesellschaft zur Förderung der Wissenschaften e.V., grants from Deutsche
447 Gesellschaft für Anästhesiologie & Intensivmedizin (DGAI), grants from Stifterverband für die
448 deutsche Wissenschaft e.V. / Medtronic, grants from Philips Electronics Nederland BV, grants from
449 BMH, outside the submitted work; In addition, Prof. Spies has a patent 10 2014 215 211.9 licensed, a

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4 450 patent 10 2014 215 212.9 licensed, a patent 10 2018 114 364.8 licensed, and a patent 10 2018 110
5 451 275.5 licensed. MH has nothing to disclose. MD has nothing to disclose. RA has nothing to disclose. JK
6 452 has nothing to disclose. RJ has nothing to disclose. FB reports grants from Einstein Foundation,
7 453 personal fees from Axon Publishing, grants from Vifor Pharma, personal fees from Elsevier
8 454 Publishing, grants from Federal Ministry of Health, Germany, grants from Berlin Institute of Health,
9 455 outside the submitted work.

11 456 **Research Ethics Approval:** The study was approved by the Ethics Commission of Charité –
12 457 Universitätsmedizin Berlin (EA2/139/20). The need for patient’s consent was waived due to the
13 458 retrospective nature of the study.

15 459 **Data Availability Statement:** The datasets analyzed during the current study are available from the
16 460 corresponding author on reasonable request.

17 461 **Clinical Trial Registration:** Not applicable.
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567 **Figure Legend:**

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

For peer review only

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

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

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

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

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

1	Time horizon	#8	State the time horizon(s) over which costs and consequences are being evaluated and say why appropriate.	4
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6	Discount rate	#9	Report the choice of discount rate(s) used for costs and outcomes and say why appropriate	5
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10	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
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16	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	4
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23	Measurement of effectiveness	#11b	Synthesis-based estimates: Describe fully the methods used for identification of included studies and synthesis of clinical effectiveness data	5
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29	Measurement and valuation of preference based outcomes	#12	If applicable, describe the population and methods used to elicit preferences for outcomes.	n/a
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36	**Estimating resources and costs **			
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42		#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
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52	Methods			
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55	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
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secondary research methods for valuing each resource item in terms of its unit cost. Describe any adjustments made to approximate to opportunity costs.

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6	Currency, price date,	#14	n/a
7	and conversion	Report the dates of the estimated resource quantities	
8		and unit costs. Describe methods for adjusting estimated	
9		unit costs to the year of reported costs if necessary.	
10		Describe methods for converting costs into a common	
11		currency base and the exchange rate.	
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14	Choice of model	#15	6
15		Describe and give reasons for the specific type of	
16		decision analytical model used. Providing a figure to	
17		show model structure is strongly recommended.	
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20	Assumptions	#16	6
21		Describe all structural or other assumptions	
22		underpinning the decision-analytical model.	
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24	Analytical methods	#17	6
25		Describe all analytical methods supporting the	
26		evaluation. This could include methods for dealing with	
27		skewed, missing, or censored data; extrapolation	
28		methods; methods for pooling data; approaches to	
29		validate or make adjustments (such as half cycle	
30		corrections) to a model; and methods for handling	
31		population heterogeneity and uncertainty.	
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36	Results		
37			
38	Study parameters	#18	6
39		Report the values, ranges, references, and, if used,	
40		probability distributions for all parameters. Report	
41		reasons or sources for distributions used to represent	
42		uncertainty where appropriate. Providing a table to show	
43		the input values is strongly recommended.	
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47	Incremental costs and	#19	6-7
48	outcomes	For each intervention, report mean values for the main	
49		categories of estimated costs and outcomes of interest,	
50		as well as mean differences between the comparator	
51		groups. If applicable, report incremental cost-	
52		effectiveness ratios.	
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55	Characterising	#20a	n/a
56	uncertainty	Single study-based economic evaluation: Describe the	
57		effects of sampling uncertainty for the estimated	
58		incremental cost and incremental effectiveness	
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parameters, together with the impact of methodological assumptions (such as discount rate, study perspective).

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4	Characterising	#20b	Model-based economic evaluation: Describe the effects
5	uncertainty		on the results of uncertainty for all input parameters, and
6			uncertainty related to the structure of the model and
7			assumptions.
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11	Characterising	#21	If applicable, report differences in costs, outcomes, or
12	heterogeneity		cost effectiveness that can be explained by variations
13			between subgroups of patients with different baseline
14			characteristics or other observed variability in effects that
15			are not reducible by more information.
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20	Discussion		
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22	Study findings,	#22	Summarise key study findings and describe how they
23	limitations,		support the conclusions reached. Discuss limitations and
24	generalisability, and		the generalisability of the findings and how the findings
25	current knowledge		fit with current knowledge.
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29	Other		
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32	Source of funding	#23	Describe how the study was funded and the role of the
33			funder in the identification, design, conduct, and
34			reporting of the analysis. Describe other non-monetary
35			sources of support
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39	Conflict of interest	#24	Describe any potential for conflict of interest of study
40			contributors in accordance with journal policy. In the
41			absence of a journal policy, we recommend authors
42			comply with International Committee of Medical Journal
43			Editors recommendations
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