



# Effects of staff training and electronic event monitoring on long-term adherence to lung-protective ventilation recommendations



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## ABSTRACT

**Purpose:** To investigate long-term effects of staff training and electronic clinical decision support (CDS) on adherence to lung-protective ventilation recommendations.

**Materials and methods:** In 2012, group instructions and workshops at two surgical intensive care units (ICUs) started, focusing on standardized protocols for mechanical ventilation and volutrauma prevention. Subsequently implemented CDS functions continuously monitor ventilation parameters, and from 2015 triggered graphical notifications when tidal volume ( $V_T$ ) violated individual thresholds. To estimate the effects of these educational and technical interventions, we retrospectively analyzed nine years of  $V_T$  records from routine care. As outcome measures, we calculated relative frequencies of settings that conform to recommendations, case-specific mean excess  $V_T$ , and total ICU survival.

**Results:** Assessing 571,478  $V_T$  records from 10,241 ICU cases indicated that adherence during pressure-controlled ventilation improved significantly after both interventions; the share of conforming  $V_T$  records increased from 61.6% to 83.0% and then 86.0%. Despite increasing case severity, ICU survival remained nearly constant over time.

**Conclusions:** Staff training effectively improves adherence to lung-protective ventilation strategies. The observed CDS effect seemed less pronounced, although it can easily be adapted to new recommendations. Both interventions, which futures studies could deploy in combination, promise to improve the precision of mechanical ventilation.

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## 1. Introduction

### 1.1. Scientific background

On Intensive Care Units (ICUs), respiratory dysfunction due to several causes ranks among the most important clinical problems. Acute respiratory distress syndrome (ARDS) remains frequent and still results in a high mortality [1]. One of the essential parameters in mechanical

ventilation is the tidal volume ( $V_T$ ), defined as the gas volume the ventilator moves into the lungs during each respiratory cycle. Over the years, different strategies of adjusting  $V_T$  have been discussed [2]. In 1963, Bendixen et al. proposed the use of high  $V_T$  settings above 10 ml per kg predicted body weight (PBW) in order to prevent acidosis and atelectasis, and to improve oxygenation [3].

In later studies, however, such high  $V_T$  turned out to be harmful and to increase mortality [4] by causing “ventilator induced lung injury” [5], which led to the concept of the “baby lung” [6]. Special lung-protective ventilation strategies advise a lower  $V_T$  setting (6–8 ml/kg PBW) to reduce pulmonary side effects of mechanical ventilation and thus mortality [2]. This recommendation seems to protect not only patients with severe lung injuries, but anyone in need of mechanical ventilation e.g. [7–12]. Integrating these concepts into ICU routines, however, can be difficult and information-intensive insofar as frequently updated  $V_T$  settings have to consider patient-specific threshold parameters. Taking the

**Abbreviations:** APACHE II, acute physiology and chronic health evaluation II; ARDS, acute respiratory distress syndrome; CDS, clinical decision support; PBW, predicted body weight; PDMS, patient data management system;  $V_T$ , tidal volume; gas volume moved into the patient by the ventilator with every breath.

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importance of this parameter into account during everyday care depends on intensive staff training, while reminders and electronic support generally promise to improve awareness.

### 1.2. Rationale for the study

Accurate lung-protective ventilation requires calculating patient-specific  $V_T$  recommendations from PBW, which in turn is estimated by a linear formula from patient sex and height [2,13]. In addition to potential side effects of low-volume ventilation, the “difficulty [of] calculating tidal volume” is seen as a potential obstacle for a systematic adherence in daily practice [14]. Moreover, the parameters of mechanical ventilation have to be closely monitored over time and if necessary adjusted, because dynamic factors such as supine or prone positioning, fluid balance and edema, neuromuscular blocking, and sedation can influence thoracic compliance and therefore  $V_T$  (depending on the ventilation mode used). These determinants certainly contribute to the observation that “the protective ventilation strategy is often under-utilized as a therapeutic option, even in ARDS” [7].

Some organizational and educational efforts have aimed to consistently implement these lung-protective strategies in routine intensive care, but have yet produced only moderate clinical effects [14,15,16,17]. In previous studies of clinical decision support (CDS) for mechanical ventilation, Eslami et al. had reported that providing individual  $V_T$  calculations as part of the order entry process led to a more consistent application of lung-protective protocols in patients who were ventilated for >24 h, although adherence appeared to depend on the implemented CDS communication style [18,19]. The authors interpret a presumed trade-off between workflow intrusiveness and clinical effectiveness, and conclude that alternative CDS designs should be examined [19].

In contrast to these published CDS functions that had been integrated with patient-specific data entry, clinical event monitoring is rather geared to ‘tirelessly’ watch over clinical databases, and if necessary to communicate notifications beyond the context of individual medical records [20]. A review of CDS features enlisted an automatic provision among the determinants of an improved clinical practice [21]. Therefore, and because a continuous supervision appears to resonate with therapeutic requirements, we hypothesized that event monitoring might likewise facilitate putting sustained lung-protective ventilation into practice.

To comparatively estimate long-term effects of staff training and CDS-based graphical notifications, we retrospectively analyzed adherence to lung-protective ventilation recommendations at two surgical ICUs.

## 2. Material and methods

### 2.1. Setting

Erlangen University Hospital is a tertiary care facility in southern Germany with approximately 1370 beds. This study took place on two surgical ICUs with collectively 35 beds, which in 2015 treated 2400 adult patients and in total administered approximately 87,000 ventilator hours. At the end of 2006, both ICUs were equipped with a commercial patient data management system (PDMS, Integrated Care Manager®, Dräger Medical, Lübeck, Germany), which is used to document various patient attributes, such as vital signs, medication data, nursing activities, laboratory results, and blood gas analysis [22].

This application has already been used for studying ICU documentation [23], workflows [24] and finances [25], and served as the basis for implementing a CDS platform whose technical characteristics have been reported previously [26,27,28]. This CDS infrastructure builds on Arden Syntax, which has been purposefully designed to facilitate a modular and shareable definition of automated reasoning in support of particular clinical decisions [29]. The PDMS supports diverse data processing tasks, such as automated calculations of Acute Physiology and

Chronic Health Evaluation II (APACHE II) scores. All ventilators have interfaces with the PDMS, enabling the automatic storage of ventilation settings and associated measurements.

### 2.2. Conventional training intervention

In response to formerly published recommendations on mechanical ventilation, ICU nurses and a senior physician convened earlier to standardize locally adapted protocols concerning lung-protective ventilation. Based on the developed documents, a series of training sessions for ICU staff was initiated at the beginning of 2012. These consisted of one-hour instructions in groups of approximately 20 persons, which in sum were attended by around 109 nurses and physicians, from a total of approximately 150. These courses were held again in August 2012, and then reached 52 staff members from 150. Tuition was augmented with several four-hour workshops, where another 52 workers participated, with yearly lessons (each reaching approximately 80 people) among other things dedicated to  $V_T$  settings, as well as with online manuals provided to instruct employees when they rotated to either of the two ICUs.

These educational interventions addressed standard operating procedures for mechanical ventilation, essential settings such as limited peak pressure, continuous positive airway pressure,  $V_T$ , respiratory rate, and inspired oxygen fraction. Training repeatedly focused on clinical benefits of avoiding high- $V_T$  ventilation, and explained how to calculate individually recommended  $V_T$  maxima according to 8 ml/kg PBW, while weight was to be estimated as a linear function of height and sex, in conformance with applicable guidelines [2].

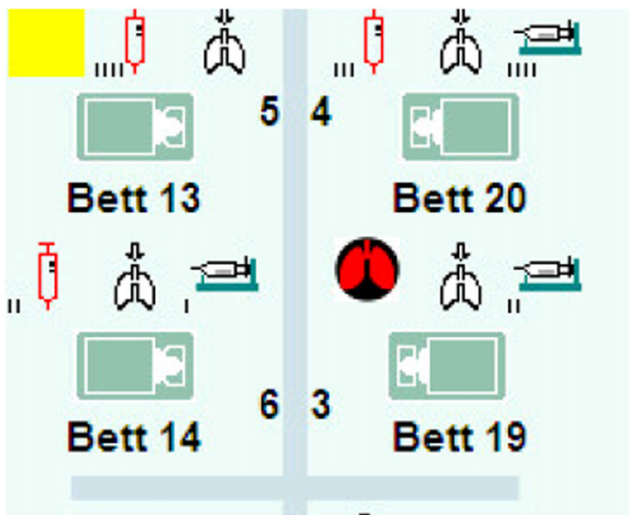
### 2.3. CDS intervention

Even after the training intervention, daily experience suggested that  $V_T$  settings might often remain too high. This circumstantial evidence prompted the alternative consideration and prototypical implementation of an Arden-based CDS module for monitoring and if necessary notifying staff about potential non-adherence. Like previous applications [18,19], we assumed that individual  $V_T$  targets should follow PBW-dependent ventilation requirements. The developed triggering mechanism thus implements the established linear functions in order to automatically personalize  $V_T$  thresholds from PDMS records.

Insofar as unspecific CDS messages can entail that nurses and physicians begin to ignore or override notifications in practice [30], we aimed to minimize such ‘alert fatigue’ by deliberately restricting criteria to situations where the benefits of lowering  $V_T$  seemed relatively unambiguous. This was realized by relaxing recommended thresholds by 10%, so that only  $V_T$  settings in excess of 8.8 ml/kg PBW could effectively trigger alerts.

To keep temporary violations from provoking inconsequential notifications, the CDS function analyzes recent case-specific records in order to ensure that either the preceding  $V_T$  record or the previous 6-h average also breached 8.8 ml/kg. To further prevent false positive messages, the trigger mechanism automatically monitors whether current settings belong to a previously defined selection of pressure-controlled ventilation modes (technically encoded as a list of trademarked mode notations).

Since the intrusiveness of generated warnings may hamper effective clinical responses [30], we specifically designed messages to avoid workflow interruptions as far as possible. Notifications were therefore communicated via warning icons, which the CDS mechanism superimposed as necessary on a patient-specific graphical representation of the central ward overview (see Fig. 1). This rather subtle communication style does not require that staff members occupy themselves with active data entry into patient-specific PDMS records, but still promises that those who are present on the ward may become aware relatively fast.



**Fig. 1.** PDMS detail of a ward overview. The round “red lung” overlay signals that the event monitor detected a violation of recommended  $V_T$  maxima for the patient in bed 19. The other displayed icons are configured to graphically summarize various patient features with a general relevance for clinical management.

When the developed alerting function was activated on two surgical ICUs in February 2015, nurses and physicians were briefed via handouts, via email, and via brief demonstrations; this introductory information explained the motivation for the intervention, the developed functionality, suitable interpretations of the warning symbols, as well as the background of the accompanying observational study.

#### 2.4. Study design and participants

To retrospectively investigate potential effects of the described educational and technical lung-protective interventions on clinical practice, we exported and analyzed basic patient features and ventilator parameters from the PDMS. Among surgical ICU patients who had been treated between January 2007 and February 2016, case-specific datasets

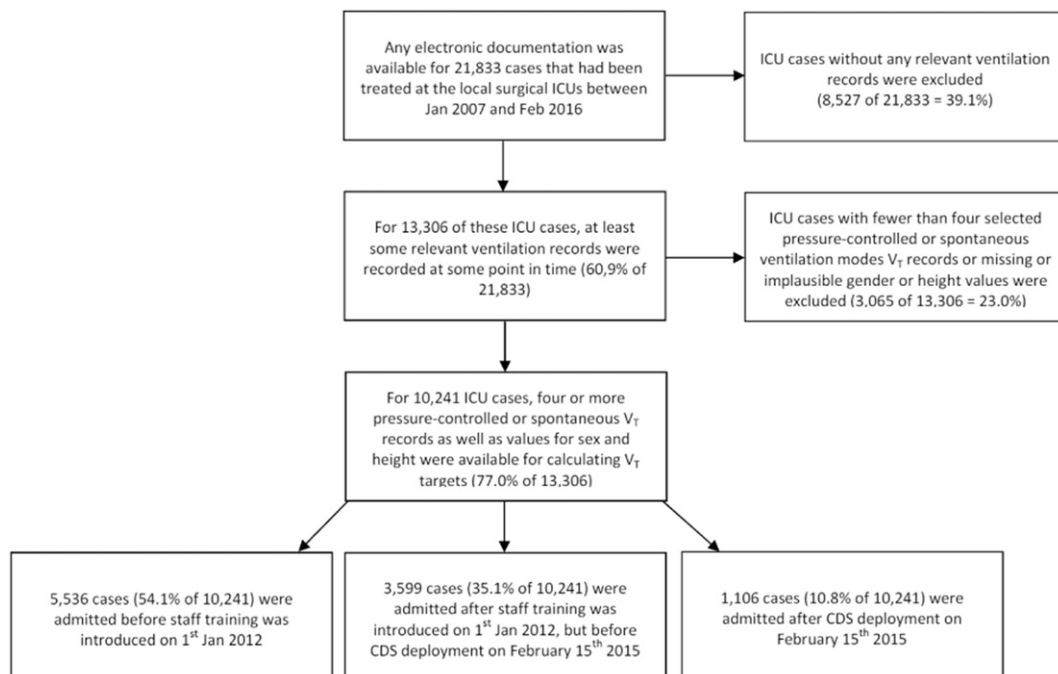
were included in the analysis if certain ventilation modes as well as simultaneous  $V_T$  records had been documented on at least four different points in time, and if PBW could be recalculated from available height and sex attributes. In addition to a selection of pressure-controlled ventilation modes (which potentially triggered notifications), we also analyzed the development of tidal volumes that were recorded during spontaneous assisted modes (which could not trigger alerts), where the relationship between ventilator parametrization and measurable  $V_T$  is more indirect.

The selected ICU cases were then subdivided according to both lung-protective interventions that had been introduced at the time of individual ICU admissions. We interpret the initial five-year phase after PDMS deployment as baseline (Jan 2007–Dec 2011). During the following three-year interval, the educational intervention has been introduced, but the CDS function was not yet implemented (Jan 2012–Feb 2015). Between the middle of February 2015 and February 2016, staff training as well as automated  $V_T$  event monitoring was activated. Fig. 2 summarizes the selection of PDMS cases and their distribution across these three phases.

#### 2.5. Outcome measures and statistical analyses

To estimate effects on adherence to lung-protective ventilation, we calculated relative frequencies of ventilator settings that would conform to individual recommendations, case-specific mean excess  $V_T$  (i.e., above individual thresholds), as well as total ICU survival (regardless of length of stay) in electronic PDMS exports. Quantifying adherence within various patterns of individual  $V_T$  readings should obviously take into account that we would feasibly expect both the duration as well as the severity of any threshold violation to negatively affect clinical outcomes.

To avoid the loss of information that would originate from simplifying individual  $V_T$  time series into ‘how many’ readings should be considered ‘too high’, we quantified non-adherence along the lines of the ‘hyperglycaemic index’, which Vogelzang et al. [31] had proposed as the average area of the blood glucose curve above a presumed upper threshold. By analogy, we summarized excess  $V_T$  as the average area of each case-specific  $V_T$  time series above a presumed personalized upper threshold of 8.8 ml/kg PBW. This method yields the advantage



**Fig. 2.** Overview of the selection of ICU cases for retrospective analysis and subdivision into three cohorts.

of monotonically reflecting the duration as well as the severity of any  $V_T$  elevation; when none of the  $V_T$  readings oversteps case-specific limits, this metric assumes a value of zero, which is consistent with our intuition that in such situations no  $V_T$  excess is present.

All statistical analyses based on PDMS exports were performed in R 3.3. Exact temporal calculations were achieved by converting timestamp-representing character sequences via `strptime()`. Potential associations in frequency tables were evaluated with `fisher.test()` or with `chisq.test()`, depending on the number of observations. We compared sets of sortable (i.e., ordinal) or metric observations using `quantile()`, `mean()`, `boxplot()` and `wilcox.test()`. Multivariate linear models of the ranks of excess  $V_T$  estimates were fitted with `lm()`.

### 3. Results

#### 3.1. Patient data overview

A total of 10,241 patients who were treated at both local surgical ICUs between January 2007 and February 2016 fulfilled our described inclusion criteria concerning data completeness and minimum ventilation records. Based on admission dates, 5536 case records were assigned to the first study phase 1 (baseline), 3599 to phase 2 (after the educational intervention), and 1106 to phase 3 (after the CDS function was activated). Table 1 summarizes the basic characteristics of these patient groups.

Approximately two thirds of cases were male, with moderate fluctuations. About one quarter of cases was on admission younger than 59 years, while another 25% were older than 76 years. The distribution of the length of ICU stays was strongly asymmetric around a median of around 44 h, insofar as a dense left tail concentrated a high number of short postoperative stays, while a few cases experienced rather protracted recoveries.

Average patient height appeared to increase slightly between phase 1 and phase 2, which may be attributable to a growing proportion of male patients. Case severity as measured by APACHE II scores increased moderately over time. During the last study phase, a somewhat higher fraction of patients under mechanical ventilation appeared to require it for longer than 24 h.

#### 3.2. Development of outcome parameters

In total, we included 571,478  $V_T$  observations in the analysis, which amount to an average of 55.8  $V_T$  values per case. Timestamp differences between the earliest and the latest patient-specific  $V_T$  records suggest that the analyzed cohort collectively accumulated 875,570 ventilation hours, although their distribution across the 10,241 cases was quite skewed. Mean ventilation as measured by the difference between the earliest and latest case-specific  $V_T$  record lasted for around 85.5 h (3.6 days), with the correspondingly estimated measurement intervals between successive  $V_T$  records averaging approximately 92 min.

Logfile analysis indicated that the event monitor was technically available 95.2% of the time after activation. Warning icons were displayed in 1782 situations, and were thus triggered for 354 of those 1059 cases in question (33%) who received pressure-controlled ventilation between February 2015 and February 2016.

As is shown in Table 2, the proportion of 'conforming'  $V_T$  measurements (i.e., those <8.8 ml/kg PBW that could not trigger CDS alerts) during pressure-controlled ventilation increased from 61.6% before the educational intervention to 83.0%, followed by a further modest improvement after CDS activation to 86.0%. Likewise, the corresponding percentage of  $V_T$  settings that exceeded 150% of individual maxima decreased twice. When spontaneous assisted modes were applied, the development was more heterogeneous insofar as the share of conforming  $V_T$  settings first increased and then decreased moderately.

According to case-specific quantitative summaries of ventilation settings, excess  $V_T$  during pressure-controlled ventilation decreased markedly after the educational intervention (see Fig. 3). When the event monitor was subsequently switched on, the distribution of case-specific excess  $V_T$  displayed no comparable further improvement. Fig. 3 also illustrates that any changes concerning spontaneous modes were much smaller than the relatively pronounced improvement after the educational intervention during pressure-controlled ventilation. Another analysis of  $V_T$  settings that differentiated the case-specific time that has elapsed after the initiation of mechanical ventilation indicated that high-volume  $V_T$  settings were less frequent during long-term ventilation (see supplement).

According to multivariate linear models of the ranks of excess  $V_T$ , adherence under pressure-controlled ventilation improved significantly between phases 1 and 2, while the corresponding difference between phases 2 and 3 was not significant (see supplement). When no interaction term for height and sex was included, excess  $V_T$  was unexpectedly lower for taller patients and for women; in a model that accounted for potential interaction between height and sex, women as well as smaller patients experienced significantly more  $V_T$  excess. These complex relationships might indicate that actual clinical requirements could be more intricate than PBW-based  $V_T$  targets that are estimated as linear functions of sex and height. During pressure-controlled ventilation neither age on admission, APACHE II scores, length of ICU stay, nor the duration of ventilation displayed notable associations with excess  $V_T$ . No study phases were associated with excess  $V_T$  under spontaneous modes, but patient sex and height were related in the same direction like under pressure-controlled modes.

During the three study phases, overall ICU survival remained relatively constant, including among patients who received ventilation for longer than 24 h, even though severity as measured by the distribution of APACHE II scores increased moderately over time. We could not identify any available PDMS data that would have been suitable for a selective subgroup analysis of pulmonary complications and ventilator-associated mortality.

**Table 1**

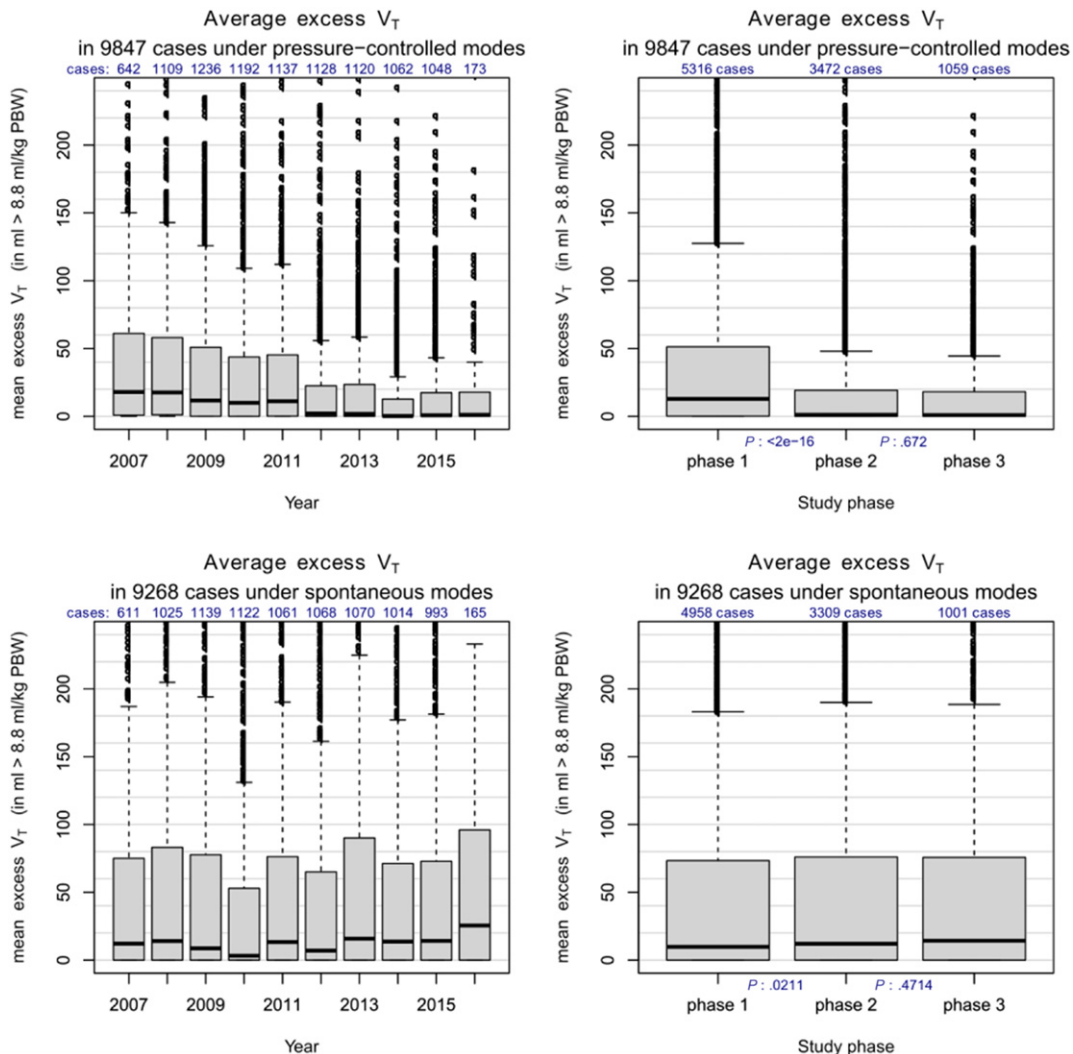
Basic characteristics of 10,241 analyzed cases. \* `fisher.test()`, median [interquartile range]  $\mu$  mean  $\pm$  standard deviation, § `wilcox.test()` phase 1 vs. phase 2 and phase 2 vs. phase 3.

	Phase 1	Phase 2	Phase 3	P-value
Admission period	Jan 2007–Dec 2011	Jan 2012–Jan 2015	Feb 2015–Feb 2016	
Number of cases under ventilation	5536 (54.1% of 10,241)	3599 (35.1% of 10,241)	1106 (10.8% of 10,241)	
Gender (% male)	3735 (67.5% of 5536)	2521 (70.0% of 3599)	758 (68.5% of 1106)	0.035 *
Age on admission (years)	69.2 [59.4–75.9] $\mu$ 66.7 $\pm$ 13.1	69.5 [59.0–76.2] $\mu$ 66.7 $\pm$ 13.6	68.1 [58.1–76.2] $\mu$ 66.2 $\pm$ 13.4	0.443 and 0.136 §
Height (cm)	170 [165–177] $\mu$ 170.2 $\pm$ 9.8	172 [165–178] $\mu$ 171.0 $\pm$ 9.2	172 [165–178] $\mu$ 171.0 $\pm$ 9.7	0.001 and 0.665 §
Length of ICU stay (hours)	44.2 [22.1–100.5] $\mu$ 120.4 $\pm$ 246.5	43.0 [21.7–115.4] $\mu$ 128.6 $\pm$ 263.6	44.7 [21.3–135.1] $\mu$ 138.9 $\pm$ 263.4	0.651 and 0.437 §
APACHE II scores (available for 5799 cases)	19 [16–24] $\mu$ 20.2 $\pm$ 6.9 (2882 cases)	23 [19–27] $\mu$ 23.6 $\pm$ 6.5 (2215 cases)	24 [20–28] $\mu$ 24.7 $\pm$ 6.5 (701 cases)	< 0.001 and < 0.001 §
Duration of ventilation (hours)	10.3 [5.2–47.7] $\mu$ 83.4 $\pm$ 229.6	8.6 [4.7–45.5] $\mu$ 86.5 $\pm$ 242.6	10.2 [4.9–66.1] $\mu$ 92.5 $\pm$ 228.1	< 0.001 and 0.012 §
Cases with >24 h ventilation (%)	1783 (32.2% of 5536)	1117 (31.0% of 3599)	392 (35.4% of 1106)	0.024 *

**Table 2**

Clinical outcomes and summaries of ventilation parameters calculated from 571,478  $V_T$  records. \* fisher.test(), median [interquartile range]  $\mu$  mean  $\pm$  standard deviation,  $\S$  wilcox.test() phase 1 vs. phase 2 and phase 2 vs. phase 3,  $\P$  available for subsets of cases,  $\ddagger$  chisq.test() phase 1 vs. phase 2 and phase 2 vs. phase 3.

	Phase 1	Phase 2	Phase 3	P-Value
Total $V_T$ records during pressure-controlled modes	156,195 (60.3% of 259,017)	76,598 (29.6% of 259,017)	26,224 (10.1% of 259,017)	
Total $V_T$ records during spontaneous modes	147,793 (47.3% of 312,461)	123,272 (39.5% of 312,461)	41,396 (13.2% of 312,461)	
Conforming $V_T$ records (<8.8 ml/kg PBW) during pressure-controlled modes	96,212 (61.6% of 156,195)	63,562 (83.0% of 76,598)	22,558 (86.0% of 26,224)	< 0.001 and <0.001 $\ddagger$
$V_T$ records above 150% of individual thresholds during pressure-controlled modes	3118 (2.0% of 156,195)	602 (0.8% of 76,598)	168 (0.6% of 26,224)	< 0.001 and 0.021 $\ddagger$
Case-specific mean $V_T$ excess >8.8 ml/kg in ml during pressure-controlled modes $\P$	12.8 [0.2–51.3] $\mu$ 37.3 $\pm$ 60.5 (5316 cases)	1.2 [0.0–19.2] $\mu$ 20.6 $\pm$ 62.3 (3472 cases)	0.9 [0.0–18.1] $\mu$ 19.6 $\pm$ 48.5 (1059 cases)	< 0.001 and 0.672 $\S$
Case-specific mean $V_T$ excess >8.8 ml/kg in ml during pressure-controlled modes among cases with >24 h ventilation	15.6 [2.5–49.1] $\mu$ 34.5 $\pm$ 50.2 (1697 cases)	1.9 [0.0–14.1] $\mu$ 17.9 $\pm$ 82.6 (1056 cases)	2.0 [0.0–15.2] $\mu$ 16.5 $\pm$ 47.7 (373 cases)	< 0.001 and 0.975 $\S$
Conforming $V_T$ records (<8.8 ml/kg PBW) during spontaneous modes	96,749 (65.5% of 147,793)	85,348 (69.2% of 123,272)	27,365 (66.1% of 41,396)	< 0.001 and <0.001 $\ddagger$
$V_T$ records above 150% of individual thresholds during spontaneous modes	5946 (4.0% of 147,793)	4093 (3.3% of 123,272)	1643 (4.0% of 41,396)	< 0.001 and <0.001 $\ddagger$
Case-specific mean $V_T$ excess >8.8 ml/kg in ml during spontaneous modes	9.8 [0.0–73.3] $\mu$ 59.6 $\pm$ 116.8 (4958 cases)	12.1 [0.0–76.1] $\mu$ 63.2 $\pm$ 118.9 (3309 cases)	14.3 [0.0–75.7] $\mu$ 56.9 $\pm$ 96.4 (1001 cases)	0.021 and 0.471 $\S$
Case-specific mean $V_T$ excess >8.8 ml/kg in ml during spontaneous modes among cases with >24 h ventilation	18.0 [1.6–64.7] $\mu$ 52.1 $\pm$ 104.5 (1613 cases)	14.1 [0.9–55.6] $\mu$ 45.6 $\pm$ 80.4 (1056 cases)	18.2 [2.0–62.0] $\mu$ 44.8 $\pm$ 70.8 (369 cases)	0.057 and 0.204 $\S$
Total ICU nonsurvival of patients under mechanical ventilation (%)	486 (8.8% of 5536)	313 (8.7% of 3599)	99 (9.0% of 1106)	0.960 *
Total ICU nonsurvival among cases with >24 h ventilation (%)	390 (21.9% of 1783)	250 (22.4% of 1117)	75 (19.1% of 392)	0.397 *



**Fig. 3.** Development of excess  $V_T$  above 8.8 ml/kg PBW during pressure-controlled and spontaneous ventilation.

## 4. Discussion

It has been reported that adherence to the ARDSNetwork recommendations for lung-protective ventilation can be inconsistent, and that specific interventions should target an improved application in clinical practice [14,15,16,32,33]. We thus analyzed adherence at two surgical ICUs over the past years in order to judge whether two interim interventions – staff training and implementation of CDS-based event monitoring – had any effect on ventilation settings.

Our retrospective analysis had to confront the problem that putting the initial educational intervention into practice actually took some time because of the number of persons who had to be trained, a process which in fact continues to date. Nevertheless, for analytical purposes, we had to simplify this ongoing organizational procedure in order to delimit comparable periods of time before and after instructions commenced.

The need for repeated staff training and the associated expenditures in time and money [34] then originated the idea of an automatic electronic monitoring of  $V_T$  settings. Motivated by earlier comparable investigations [18,35], we subsequently developed a specific notification module based on the local CDS platform [26,27]. The deployment of this monitoring function took considerably less effort than the described staff training, and could be easily activated at a defined point in time.

### 4.1. Interpretation of main observations

We interpret that it is likely that the initial intervention – conventional training of medical staff – materially improved adherence to recommended  $V_T$  maxima during pressure-controlled ventilation. The necessity and effectiveness of repeated training, teaching and standardization of such procedures has been investigated before [14,15,16,32,33], so this finding may not be surprising.

Another interesting observation concerns a reduced median duration of ventilation in phase 2 (from 10.3 h down to 8.6 h, see Table 1), which seems more remarkable in light of increasing median APACHE II scores (from 19 to 23). This reduction of ventilation hours may in retrospect be attributable to other parts of the introduced training program, which aimed to accelerate weaning from mechanical ventilation. The observed relatively constant  $V_T$  settings under spontaneous assisted ventilation may be due to the fact that local staff training prioritized  $V_T$  settings under controlled ventilation, therefore a relevant change in other modes seems less likely.

The second phase after the institution of staff training simultaneously served as the comparison group for estimating the potential additional effect of the subsequently deployed alerting system – the primary innovation in this study. In relation to previous CDS functions for supporting lung-protective ventilation, our application was specifically geared to achieve a high degree of automation. This way, notifications can be triggered without the need of repeated user interactions with the PDMS, as long as patients' height and sex have been entered once as the basis for estimating individual  $V_T$  thresholds.

The advanced integration and automatization of our system targets a seamless  $V_T$  monitoring as well as a low number of alarms, thus allowing for mostly undisturbed ICU work routines. Several CDS functions have been described and investigated in practice [18,19,35,36,37,38], although we interpret that earlier applications involved relatively tighter integration with manual data entry tasks. Because of our careful embedding into work processes, in the run-up to the CDS activation we had actually expected to see some further improvements of  $V_T$  settings.

In fact, after event monitoring was switched on in February 2015, the quantitative outcome parameter of excess  $V_T$  during pressure-controlled ventilation displayed no further reduction that would compare in magnitude to the one that earlier followed on the educational intervention. The proportion of single  $V_T$  records that complied with case-specific thresholds, however, improved modestly (from 83.0% under 8.8 ml/kg PBW up to 86.0%), as did the proportion that at least fell

below 150% of these maxima (from 0.8% down to 0.6%). The clinical relevance of these rather subtle shifts seems difficult to gauge.

Among the potential explanations for the sobering observation that our carefully designed automated monitoring application admittedly produced no further substantial improvements of  $V_T$  parameters, one reason could be that the previous educational intervention has already largely exhausted clinically achievable improvements. Another interpretation would be that the graphical notifications – which automatically disappear after a period of 20 min unless new data prompt their reappearance – had been designed in a too reticent communications style, and in some situations could have been simply ignored in practice.

Another reason, supported by circumstantial observations, could be some staff members (despite repeated instructions) may not have been always fully aware of the meaning of and adequate responses to the graphical warning symbols. A different interpretation could be that since any CDS method will always build on formalized generalizations that cannot fully capture all information that may be relevant in every individual instance, clinicians at the bedside may in some situations also have consciously decided not to respond to graphical alerts due to particular clinical reasons, such as current hypercapnia or hypoxia.

### 4.2. Strengths and weaknesses of the study

Over the nine-year period that we retrospectively studied, various features of patient management and patient care may well have changed, so attribution of any shifts in outcomes to the described interventions should be inferred with caution. On the other hand, we were able to automatically analyze a large collective of patients with a substantial number of  $V_T$  measurements, which we see as potentially representative for various clinical settings.

The local general prerequisites, however, also differ from the ones reported 2012 by Eslami et al. insofar as our analyzed case sets consisted of surgical ICU populations, while a majority of previously investigated patients were predominantly medical cases; this fundamental difference between the studied populations has likely contributed to a relatively shorter distribution of ventilation hours at our local surgical ICUs, and may simultaneously undermine the general comparability between pulmonary risk profiles, complication frequencies, and CDS effects.

Our novel CDS-module which automatically monitors  $V_T$  settings – with a patient-individual calculation of  $V_T$  limits and graphical notifications that do not depend on active user actions – can be interpreted as unique feature. The automatic background computations were designed to produce only a reduced number of specific alarms – which can be seen as substantial potential advance in monitoring of mechanical ventilation.

On the one hand, the observation that ICU survival remained mostly unchanged over the years could also be seen as a failure to achieve relevant improvements. In light of an exacerbating case severity as measured by APACHE II scores between study phases, however, holding ICU outcomes relatively constant might also be consistent with gradual therapeutic improvements. In this retrospective analysis based on reutilized PDMS records from everyday care, adequate control of various potential confounders remains inherently difficult. On the other side, this retrospective single-center study design with three study phases with varying duration and case numbers was certainly oriented towards achieving a cost-effective study completion based on a relatively subtle workflow modification. In theory, more resources could be employed in order to examine such interventions more thoroughly, for example by widening clinical settings to several sites, or by simultaneously testing alternative CDS designs with alternative communication styles via crossover trials.

### 4.3. Outlook

The real effects of CDS functions on the quality of care of critically ill patients are known to be difficult to assess. We see it as plausible that

obtaining material clinical benefits via advanced CDS functions may increasingly depend on more complex underlying models. Since advanced automated analyses of vast PMDS data could in the future give rise to data-driven refinements of alerting criteria, and since triggered notifications could also feasibly be communicated in various other formats, such as via increasingly adopted wall-mounted displays or widespread handheld devices, the scope for promising alternative investigations in this context seems vast.

## 5. Conclusion

On ICUs adherence to recommended mechanical ventilation with low tidal volume can still be low. Staff training, protocols, standardization and other actions to improve this situation are highly effective but complex and need a repetitive effort. CDS promises to facilitate adherence, especially in larger teams where repeated staff training requires enormous resources. Once implemented, a CDS – can also be updated easily to new recommendations or to changing limits, thereby avoiding or at least reducing the need of repeated staff training. A seamless monitoring of ventilator parameters can thus help making mechanical ventilation more precise and its application safer for critically ill patients. Maybe the combination of both – education and electronic decision support – are the bundle of measures needed to achieve a lasting effect.

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## Ethics committee approval

The Research Ethics Committee of the Faculty of Medicine, Friedrich-Alexander University Erlangen-Nuremberg, approved this study.

## Conflicts of interest

No author reports a conflict of interest regarding the subject of this publication.

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## Appendix A. Supplementary data

Supplementary data to this article can be found online at <http://dx.doi.org/10.1016/j.jcrr.2017.06.027>.

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