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Application of the new CDC surveillance criteria for Ventilator-Associated Events to a cohort of pediatric intensive care unit patients identifies different patients compared to the previous definition and physician diagnosis.

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Abstract

Objective—We sought to compare the performance of the 2008 CDC pediatric criteria for ventilator-associated pneumonia (VAP), the 2013 adult ventilator associated condition (VAC) criteria, the new Draft pediatric VAC criteria, and physician-diagnosed VAP in a cohort of pediatric intensive care unit (PICU) patients.

Design—Secondary analysis of a previously conducted prospective observational study.

Setting—PICU within a tertiary care children's hospital between April 1, 2010 and April 1, 2011.

Patients—Patients between 31 days and 18 years of age, mechanically ventilated via endotracheal tube for more than 72 hours and no limitations of care.

Interventions—None.

Measurements and Main Results—VAP criteria applied in real time and VAC criteria applied retrospectively. Outcomes assessed between cases and non-cases within criteria.

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Of the 133 eligible participants, 24 (18%) had VAP by 2008 Pediatric criteria, and 27 (20%) by physician diagnosis. Sixteen (12%) and 10 (8%) had VAC by 2013 Adult and Draft Pediatric criteria, respectively. We found significant overlap between cases identified with 2008 Pediatric criteria and Physician diagnosis ($p=0.549$), but comparisons between the other definitions revealed that the newer criteria identify different patients than previous CDC VAP criteria and Physician diagnosis ($p<0.01$). While 20 participants were diagnosed with VAP by 2008 Pediatric criteria and physician diagnosis, only 3 participants were identified by all 4 criteria. Three subjects uniquely identified by the Draft Pediatric criteria were non-infectious in etiology. Cases identified by all criteria except Draft Pediatric had higher ratios of actual ICU LOS to PRISM III-adjusted expected LOS compared to non-cases.

Conclusions—The Draft Pediatric criteria identify fewer and different patients than previous VAP criteria or physician diagnosis, potentially missing patients with preventable harms, but also identified patients with potentially preventable non-infectious respiratory deteriorations. Further investigations are required to maximize the identification of patients with preventable harms from mechanical ventilation.

Keywords

ventilator-associated pneumonia; mechanical ventilation; ventilator associated events; pediatric intensive care

Introduction

Ventilator associated pneumonia (VAP) is one of the most common healthcare associated infections among Pediatric Intensive Care Unit (PICU) patients, occurring in 3% to 10% of mechanically ventilated children (1–5). PICU patients with VAP experience longer lengths of mechanical ventilation, PICU and hospital stay compared to patients without VAP (3–6). While pediatric VAP rates have appeared to decline from 2006 to 2013, the subjective complexities in diagnostic criteria have made comparisons across hospitals difficult (7, 8).

Historically, surveillance of pediatric VAP has been conducted using the Center for Disease Control and Prevention (CDC) 2002 algorithm, and its subsequent revisions (3). The CDC definition utilized radiographic and clinical signs and symptoms which were not clearly defined and were highly subjective in nature (9). The lack of clarity created a potential bias in the application of the definition, which likely contributed to wide variations in VAP rates across institutions. The incidence of VAP declined among PICUs reporting data to the CDC's National Healthcare Safety Network from 2007 to 2012 (10), however other prospective studies in the United States have not observed this decline (11). Such observed differences suggest that subjective VAP diagnostic criteria may lead to different classifications of VAP (12). Further, the increasing attention and negative financial impact to institutions related to hospital acquired conditions may contribute to underreporting of actual VAP cases.

A working group was established to aid the CDC in developing a new method of surveillance for VAP that was more objective and easier to apply, yet building upon existing knowledge (12–14). New adult criteria were released in 2013, focusing on ventilator

associated conditions (VAC) as the primary surveillance metric, as opposed to focusing solely on VAP, acknowledging that some preventable complications of mechanical ventilation are likely not infectious. Three classifications of Ventilator Associated Events (VAE) were developed: ventilator associated condition (VAC), infection-related ventilator associated condition (IVAC), and possible and probable VAP. Definitions of each classification have been provided elsewhere (15, 16), and comparisons are included in Supplemental Table 1.

The 2013 adult VAC criteria were not intended to be applied to pediatric populations (13,17–19). The CDC subsequently established a Pediatric and Neonatal Ventilator-Associated Events Surveillance Definition Working Group to develop a pediatric specific definition, modeled after the adult criteria. Notable differences from the adult definition are highlighted in Supplemental Table 1 (16). Because early data revealed that outcomes may be similar between VAC patients and those with IVAC, possible VAP, and VAP, initial application focused solely on VAC (20).

We compared four different criteria for identifying VAE in a prospective cohort of PICU patients: physician diagnosis of VAP, the 2008 CDC algorithm for clinically defined pneumonia for pediatric populations, the 2013 adult VAC criteria, and the newly proposed pediatric VAC criteria. Our objectives were: (1) to determine the number of VAP or VAC cases identified by each of the criteria, (2) determine the agreement of VAP and VAC diagnoses identified in each criteria, and (3) to determine the degree of association between each criteria and clinical outcomes.

Materials and Methods

Setting, Patients, and Ethics Review

Participants in this prospective cohort study were between 31 days and 18 years of age, admitted to the Pediatric Intensive Care Unit (PICU) at Children's Hospital Colorado between April 1, 2010 and April 1, 2011. This report reflects a secondary analysis of a parent study whose primary purpose was to evaluate microbiology characteristics that predispose patients to VAP, and the study design reflects that goal. To select a high-risk cohort, only patients intubated for more than 72 hours were eligible for inclusion in the study. Patients with tracheostomy or immediate plans to place one, limitations placed on care, previous episodes of intubation during current admission, and previous enrollment in the study were excluded. Patients were evaluated for VAP/VAC through the period of the first intubation or 21 days, whichever came first as defined by the study protocol. If a patient was intentionally extubated within the first 3 days of intubation and subsequently re-intubated, they were not eligible. Self-extubations immediately followed by reintubation or changing the ETT size were not considered extubations. Re-intubations within 24 hours were counted as continuous ventilation for the purpose of tracking duration of ventilation. The study was approved by the Colorado Multiple Institutional Review Board; informed consent for each participant was obtained from parents or legal guardians.

Data Collection

Study data were collected and managed using REDCap electronic data capture tools hosted at the University of Colorado Denver (21). Patient characteristics, presence of comorbidities, infection status at time of admission, patient origin, intubation status at time of admission, and the Pediatric Risk of Mortality (PRISM) III score (22) upon admission were collected. Outcome data were extracted from the electronic medical record (EMR). The primary outcome was the ratio of actual PICU LOS to PRISM-adjusted Expected LOS. Secondary outcomes were: total ventilator free days (VFD) in the 28 days following intubation, duration of non-invasive ventilation use following extubation, length of oxygen requirement, need for re-intubation, total hospital length-of-stay, change in Pediatric Overall Performance Category (POPC) Score from admission to discharge, and mortality. PRISM-adjusted Expected LOS was calculated and provided using methods already defined by Virtual PICU Systems (VPS) (23). VFD were calculated based on the following rules: if patient was extubated for >24 hours, ventilator days were counted as any part of a day that a patient was on mechanical ventilation, with a day that no mechanical ventilation support was provided a ventilator free day. Any patient who died within the first 28 days of intubation were assigned 0 VFD.

Application of VAP/VAE Criteria

The 2008 Pediatric criteria were applied manually on a daily basis and in a blinded manner to the clinical care team as to not influence physician diagnosis of VAP. Prior to initiation of this study, a standard operating procedure for radiology review of chest X-rays of intubated patients was implemented. Radiologists were educated on the X-ray criteria for the 2008 CDC VAP criteria and a VAP criteria template was inserted into the clinical radiology report for mechanically ventilated patients at the institution. Thus, the radiologists' interpretation of whether 2008 CDC VAP X-ray criteria were satisfied was available to the providers in real time. These reports were abstracted and utilized by the research team to apply the CDC VAP criteria to the cohort. Chest X-ray findings were not required nor validated for physician diagnosis. The research team reviewed EMR data (fever and leukocytosis) and obtained daily questionnaires from the bedside nurses to document the signs and symptoms criteria. To determine physician VAP diagnosis, the research team asked the physician daily whether enrolled patients were diagnosed with VAP, supported by a decision to treat with antibiotics.

The 2013 Adult and Draft Pediatric criteria were applied retrospectively using daily minimum FiO₂, MAP, and PEEP data electronically extracted from the EMR (Epic). Criteria were applied only to subjects who consented for participation in the original prospective study with the additional exclusion of patients who required extracorporeal membrane oxygenation (n= 4). Validation of SAS programs utilized for applying the criteria was performed in a subset of patients by the research team via manual chart review.

Statistical Analysis

Descriptive statistics were calculated for the cohort. Clinical outcomes were assessed for differences in VAP vs No VAP for 2008 Pediatric criteria and physician diagnosis, and VAC vs No VAC for 2013 Adult criteria and Draft Pediatric criteria. Chi-Square and Fisher's

Exact tests were performed for categorical variables, with t-tests and Wilcoxon Mann Whitney tests applied to continuous variables.

Comparisons of agreement with diagnostic categories between each of the criteria were performed with McNemar's test. Kappa statistics with 95% confidence intervals were calculated to provide a quantitative measurement of agreement. All analyses were performed using SAS version 9.4, SAS Institute, Cary, NC.

Results

Of the 483 children intubated in the PICU during the study period, 133 participants were found eligible and recruited into the study (Figure 1). The primary reason for exclusion was length-of-intubation <72 hours. Demographic characteristics are presented in Table 1. The majority of participants were admitted for medical reasons (73.7% medical, 9% surgical, 17.3% trauma) and 60.9% of PICU admissions were admitted through the emergency department (Table 1). Approximately half of participants had co-morbidities (48.1%), and most participants (71.4%) were intubated on the day of PICU admission. The median PRISM III score for participants was 6 (IQR 3-14).

After application of each criteria to the 133 participants (Table 1), 24 (18%) were identified as having VAP with the 2008 Pediatric criteria and 27 (20%) were identified by physician diagnosis. Only 16 (12%) and 10 (8%) participants were identified as VAC by the 2013 Adult criteria and the Draft Pediatric criteria, respectively. A Venn diagram (Figure 2) shows the overlap between patients identified by each of the criteria. No significant difference was observed between the 2008 Pediatric criteria and Physician diagnosis ($p=0.549$; $k=0.47$, 95% CI: 0.21 – 0.74). All other comparisons were significantly different ($p<0.01$; except 2008 CDC vs 2013 Adult where $p=0.185$) with poor agreement in the participants identified (Table 2). While 20 participants were identified as having VAP by both 2008 Pediatric criteria and physician diagnosis, only 3 participants were identified by all 4 criteria as having VAP or VAC. The 2013 Adult Criteria identified 5 participants and the Draft Pediatric Criteria identified 3 participants as VAC that no other criteria identified, and both the Adult VAC and Draft Pediatric criteria identified 4 participants that were not identified by the 2008 Pediatric criteria or physician diagnosis. The 3 subjects exclusively identified with Draft Pediatric Criteria were found to be non-infectious respiratory deteriorations (two with fluid overload and pulmonary edema, and one with increased ventilatory support to support work of breathing in the context of hemodynamic instability). Additionally, the Draft Pediatric and 2013 Adult criteria together did not identify 24 participants that were found by the 2008 Pediatric Criteria or physician diagnosis. (Figure 2)

Comparisons of clinical outcomes were made within each of the criteria (Supplemental Table 2 and Figure 3). All criteria, except the Draft Pediatric Criteria, resulted in higher actual ICU LOS to PRISM-adjusted expected LOS ratios among participants identified with VAP or VAC compared to those participants without VAP/VAC ($p < 0.05$ for all except Draft). For the secondary clinical outcomes, participants identified as VAP by both the 2008 Pediatric criteria and physician diagnosis had significantly longer PICU and hospital LOS, fewer VFD, longer length of oxygen support, and significant declines in POPC at discharge

than participants not meeting the respective criteria for VAP. There was no difference in mortality between VAP and non-VAP patients for these groups. Participants identified as VAC by the 2013 Adult criteria had significantly longer PICU LOS (14.5 vs 8 days, $p=0.006$), and fewer VFD (15.5 vs 22 days, $p=0.004$) compared to participants not identified as VAC, however, this was not observed in participants identified by the Draft Pediatric criteria (Table 2). Significant differences in hospital LOS were observed for both the 2008 Pediatric criteria ($p=0.029$) and physician diagnosis ($p=0.003$), but not for 2013 Adult ($p=0.252$) and Draft Pediatric ($p=0.514$) criteria (Figure 3). Median day of diagnosis was similar across all four criteria ([median (IQR)] 2008 Pediatric: 5 (3.5-7); Physician: 5 (3-11); 2013 Adult: 5.5 (4.5-8); Draft: 5 (4-7)), with most diagnoses occurring around Day 5 of mechanical ventilation. On average, patients identified 2008 Pediatric, Physician diagnosis, and 2013 Adult criteria were ventilated for 7 days after diagnosis. Patients identified by Draft criteria were ventilated on average 3 days after diagnosis. For patients identified by more than one criteria, we observed earlier detection by both 2008 Pediatric Criteria and Physician Diagnosis by a mean of two days. There were no differences observed in diagnosis days for patients identified by both 2008 Pediatric and Physician, as well as in patients identified by both 2013 Adult and Draft criteria.

Discussion

The search for the most appropriate metric to define preventable ventilator-associated complications, including VAP in children remains elusive. A new definition for pediatric VAC has recently been put forth by the CDC, which differs from the adult definition and previous definitions of VAP. We compared the application of these definitions in a high-risk cohort of critically ill children in an effort to determine the overlap of patients identified by the different definitions and identify the definition most closely associated with poor outcomes. Among 133 prospectively enrolled children mechanically ventilated for more than 72 hours, Physician diagnosis and the 2008 Pediatric criteria identified the most VAP cases, (18% and 20%, respectively). Far fewer participants met the 2013 Adult (12%), and Draft Pediatric (8%) VAC criteria. All children diagnosed with VAP or VAC, demonstrated worse outcomes compared to those not diagnosed, however these differences were not statistically significant within the Draft criteria. Each definition identified different cohorts of children with substantial overlap between the 2008 CDC VAP and Physician diagnosis, but very little overlap between the other criteria. Only 3 (2%) participants were identified by all 4 criteria.

The minimal overlap among the four criteria for VAP/VAC surveillance is consistent with previous studies comparing the 2008 Pediatric criteria to 2013 Adult criteria (24, 25, 26), as well as those comparing clinical diagnosis to Draft criteria (27). Similarly, a reduction in the number of cases identified using the 2013 Adult criteria (17, 19, and 28) and the Draft Pediatric criteria (28) has also been observed. These data suggest that most patients diagnosed with VAP by both 2008 criteria and physician fail to meet the criteria for declines in oxygenation set forth by the newer VAC definitions. Yet, despite the lack of substantial declines in oxygenation, these patients are experiencing worse outcomes compared to patients without VAP. While an objective approach to VAP/VAC surveillance enables more reliable comparisons across institutions, these proposed definitions may reduce the sensitivity of the criteria, missing patients who would likely benefit from VAP/VAC

prevention efforts. Further, the newer VAC criteria are not at all aligned with physician assessments, suggesting that major changes to physician approach would be needed to impact the undesirable outcomes associated with VAC. Some of the difference may be attributed to non-infectious respiratory deteriorations identified by the VAC criteria, which are not identified by surveillance criteria exclusive for VAP, but may be preventable.

All 4 definitions identified patients with worse clinical outcomes compared to undiagnosed patients. However, no statistically significant association was observed in any of the clinical outcomes among those identified as VAC via the Draft Pediatric criteria compared to non-VACs. The Draft Pediatric criteria seemingly identified patients with higher severity of illness on presentation, based on PRISM III scores, than the previously used criteria. Thus, there is the possibility that the Draft Pediatric Criteria may identify patients with higher severity of illness or with diseases refractory to conventional therapies. Of the 3 subjects with Pediatric VAC and no 2008 CDC or physician diagnoses, 2 episodes of VAC appeared related to fluid overload and pulmonary edema. The other episode was a result of increased ventilator support to better support the work of breathing in a patient who was hemodynamically unstable. These data provide evidence that VAC also identifies noninfectious causes of respiratory deterioration that may or may not be preventable. Restricting surveillance definitions to those with stricter thresholds could result in missing children who could benefit from prevention strategies or intervention at earlier points in time.

Cocoros and colleagues observed longer ICU LOS, longer mechanical ventilation, longer total hospital LOS and higher mortality in cases identified using the Draft Pediatric criteria compared to matched controls in a more inclusive cohort of ventilated children in the neonatal, cardiac, and pediatric ICUs. These differences were observed in our study, however, no statistically significant associations were found (20). While fewer patients were identified among the new criteria tested in their study, the authors argue that a MAP 4 and FiO₂ 25% still identifies a reasonable number of events. While this may have been observed compared to other cutoffs in their study, a MAP of 4 was the least stringent cut-off studied. Unlike our study, they compared the incidence in their population to reported rates of the 2013 Adult VAC, offering no comparisons to the event rates of 2008 Pediatric VAP, Physician Diagnosis, or even 2013 Adult VAC in the same population. While we did not match cases and controls, our study provided a direct comparison of all 4 of these criteria to the same population, and in comparison, the Draft Pediatric criteria did not have a comparable event rate to any of the other three.

Provided that our study was performed in a single PICU with a small sample size which required consent, we are limited in the generalizability and comparability of our results to other studies. The Draft Pediatric criteria were devised to apply to children cared for in the neonatal, cardiac, and pediatric intensive care units, however our study applied definitions only in the PICU population. Thus, the findings in this study may not hold true for patients cared for in the other intensive care units or for patients chronically ventilated through tracheostomy tubes. Inclusion/exclusion criteria successfully identified patients of high risk for VAP as evidence by the relatively high rates we reported. Strengths of our study are the use of a high risk PICU cohort (patients intubated for at least 72 hours), greatly increasing

the probability of VAC or VAP events within our sample, as well as the ability to demonstrate differences across four different criteria that have been proposed for the surveillance of ventilator associated events. Physician diagnosis and 2008 CDC criteria were assessed in real time, the latter through strict application of the signs and symptoms criteria with the bedside nurse. Our study is the first to provide rigorous comparisons across all four criteria in the same population.

Conclusions

Each of the studied VAP/VAC criteria identified cases with worse clinical outcomes. However, the newly proposed Draft Pediatric criteria identified far fewer PICU patients as well as a different set of patients than previous criteria or physician diagnosis, potentially missing substantial numbers of patients with preventable harms. Conversely, the Draft Pediatric criteria may identify non-infectious causes of respiratory deterioration that may be preventable. With the hopes of prevention and reduction in the future, further research with variations of these criteria prior to their implementation in the pediatric population is needed to maximize the identification of patients with preventable harms from mechanical ventilation.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Figure 1.

Study Recruitment Diagram. A total of 483 patients admitted to the PICU were screened for study recruitment. One hundred forty subjects were consented, with 7 subjects determined to be ineligible for participation due to study protocol. A total of 133 patients were included in this study.

Figure 2.

Different Cohorts of Patients are Identified by Each Diagnostic Criteria. *No significant difference was observed between the 2008 Pediatric criteria and Physician diagnosis ($p=0.549$; $k=0.47$, 95% CI: 0.21-0.74). All other comparisons were significantly different ($p<0.01$; except 2008 Pediatric and 2013 Adult $p=0.185$) with poor agreement in the patients identified.*

Figure 3. Differences in Clinical Outcomes by Diagnostic Criteria: VAP/VAC vs. No VAP/VAC. (A) Significantly larger PICU length-of-stay ratios, defined as the ratio of actual ICU length-of-stay to PRISM-adjusted expected length of stay, were observed in VAP/VAC cases versus non-cases in all criteria tested *except Draft criteria*. (B) Significantly longer hospital lengths of stay among VAP/VAC cases versus non-cases were only observed by the 2008 Pediatric VAP and Physician Diagnosis criteria. (C) Significantly fewer ventilator free days were observed in VAP/VAC cases versus non-cases in all =criteria tested *except Draft Criteria*.

Table 1.

Descriptive Characteristics by Diagnostic Criteria

Variable	Total Cohort (N=133)	2008 Pediatric VAP (N=24)	Physician VAP (N=27)	2013 Adult VAC (N=16)	Draft Pediatric VAC (N=10)
Age, years, median (range)	4.6 (0.1-17.3)	5.7 (0.2-16.6)	6.0 (0.2-16.6)	5.5 (0.3-17.2)	4.0 (0.3-17.2)
Male Sex, n (%)	85 (63.9)	14 (58.3)	16 (59.3)	10 (62.5)	6 (60.0)
Race, n (%)					
Black or African American	10 (7.5)	0 (0.0)	0 (0.0)	1 (6.2)	1 (10.0)
White	97 (72.9)	18 (75.0)	21 (77.8)	13 (81.3)	8 (80.0)
Other	4 (3.1)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Unknown	22 (16.5)	6 (25.0)	6 (22.2)	2 (12.5)	1 (10.0)
Ethnicity, n (%)					
Hispanic/Latino	41 (30.8)	8 (33.3)	9 (33.3)	3 (18.7)	2 (20.0)
Non-Hispanic/Latino	86 (64.7)	14 (58.3)	17 (63.0)	13 (81.3)	8 (80.0)
Unknown	6 (4.5)	2 (8.4)	1 (3.7)	0 (0.0)	0 (0.0)
Admission category, n (%)					
Medical	98 (73.7)	14 (58.3)	16 (59.3)	14 (87.5)	8 (80.0)
Surgical	12 (9.0)	2 (8.4)	1 (3.7)	0 (0.0)	0 (0.0)
Trauma	23 (17.3)	8 (33.3)	10 (37.0)	2 (12.5)	2 (20.0)
Origin, n (%)					
Emergency Department	81 (60.9)	17 (70.8)	20 (74.1)	13 (81.3)	7 (70.0)
Operating Room	17 (12.8)	3 (12.5)	2 (7.4)	0 (0.0)	1 (10.0)
Inpatient Ward	23 (17.3)	3 (12.5)	3 (11.1)	1 (6.2)	0 (0.0)
Direct Admit/Clinic	12 (9.0)	1 (4.2)	2 (7.4)	2 (12.5)	2 (20.0)
Infectious Admitting Diagnosis, n (%)	50 (37.6)	6 (25.0)	6 (22.2)	10 (62.5)	4 (40.0)
Antibiotics prior to PICU admission, n (%) ^a	24 (18.2)	4 (16.7)	4 (14.8)	5 (31.3)	4 (40.0)
PRISM III Score, median (range)	6 (0-40)	7 (0-40)	7 (0-23)	7 (0-18)	13.5 (7-27)
Intubated on PICU Admission Day, n (%)	95 (71.4)	18 (75.0)	22 (81.5)	8 (50.0)	8 (80.0)
Comorbidities, n (%)	64 (48.1)	9 (37.5)	7 (25.9)	9 (56.3)	5 (50.0)
Immunosuppressed, n (%)	7 (5.3)	1 (4.2)	1 (3.7)	0 (0.0)	0 (0.0)

^a. Subject received antibiotics during the 7 days prior to PICU admission.

Table 2.

McNemar's Test and Kappa Values for each Criteria Comparison Group

Criteria Compared	Kappa Value	95% Confidence Limits	McNemar's Test Statistic	P-value
2008 Pediatric VAP vs Physician Diagnosis	0.47	0.21 – 0.74	0.82	0.549
2008 Pediatric VAP vs Draft Pediatric VAC	–0.23	–0.47 – 0.02	7.00	0.013
Physician Diagnosis vs Draft Pediatric VAC	–0.27	–0.51 – –0.02	9.32	0.003
2008 Pediatric VAP vs Adult VAC	–0.26	–0.54 – 0.01	2.29	0.185
Physician Diagnosis vs Adult VAC	–0.35	–0.62 – –0.08	3.9	0.071