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## Major article

## Development and psychometric testing of ventilator bundle questionnaire and observation schedule

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## Key Words:

Instrument development

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**Background:** There is a current lack of valid and reliable instruments that can be used to examine critical care nurses' knowledge and skills in adhering to ventilator bundles. The aim of this study was to develop and psychometrically test a ventilator bundle questionnaire (VBQ) and ventilator bundle observation schedule (VBOS).

**Methods:** The VBQ and VBOS consisted of a list of pharmacologic and nonpharmacologic nurse-led interventions taken from the literature and supported by various levels of evidence. After content validation, stability and equivalence reliabilities of the VBOS were determined in a randomly selected sample of critical care nurses from a single academic center in Finland.

**Results:** The final VBQ contained 49 multiple-choice questions, and the VBOS had 86 dichotomous items, whose overall content validity ranged from 0.99 to 1.0. The overall intraclass correlation coefficient of the VBOS ranged from 0.93 to 1.0.

**Conclusions:** The VBQ and VBOS have acceptable psychometric properties and could be used to objectively assess whether evidence-based guidelines regarding ventilator bundles are being used in clinical practice. Further testing with diverse samples is needed to strengthen the validity and reliability of these instruments.

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Ventilator-associated pneumonia (VAP) is the most frequent device-associated nosocomial infection encountered in critical care settings,<sup>1</sup> causing substantial morbidity, a 2-fold increase in mortality rate,<sup>1,2</sup> excess costs,<sup>3</sup> and prolonged duration of ventilator use<sup>2</sup> and intensive care unit (ICU) and hospital stays.<sup>2,4</sup> The Institute for Healthcare Improvement has developed the concept of “bundles” to help health care providers more reliably deliver the best possible care for patients undergoing particular treatments with inherent risks. A ventilator bundle comprises a group of evidence-based guidelines designed to reduce VAP and improve clinical outcomes.<sup>5,6</sup> These include combinations of daily “sedation vacations” and assessment of readiness for extubation,<sup>6,7</sup> elevation of

the head of the bed between 30 and 45 degrees,<sup>7,8</sup> daily oral care with chlorhexidine,<sup>6-8</sup> adequate hand hygiene,<sup>6-8</sup> and prophylaxis for peptic ulcer disease and deep vein thrombosis.<sup>7</sup>

According to the literature, the use of ventilator bundles may reduce VAP provided that adherence is maintained; however, ventilator bundles are frequently inconsistently adopted, implemented, and evaluated.<sup>9,10</sup> In addition, there is a lack of valid and reliable instruments that can be used to examine critical care nurses' knowledge and skills in adhering to bundle guidelines. Numerous evaluation instruments have been developed but remain unpublished,<sup>11-18</sup> and even fewer have been validated.<sup>19,20</sup> In addition, these instruments generally do not cover interventions related to adequate hand hygiene (eg, alcohol-based handrub, hand hygiene technique, duration of handrub),<sup>6-8</sup> appropriate enteral nutrition (eg, body positioning and maintenance of optimal cuff pressure),<sup>6,8</sup> daily oral care (eg, oral decontamination with chlorhexidine, tooth brushing, moisturizing, subglottic suctioning),<sup>6-8</sup> or updated endotracheal suctioning recommendations,<sup>20</sup> all of which are essential treatment-related risk factors in the pathogenesis of VAP.<sup>8,21</sup>

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The aim of the present study was to develop and psychometrically test a ventilator bundle questionnaire (VBQ) and ventilator bundle observation schedule (VBOS) to evaluate the care of patients receiving mechanical ventilation, with a focus on critical care nurses' knowledge and skills in adhering to ventilator bundles.

## METHODS

This prospective psychometric instrument validation study was conducted in 2 phases: (1) domain identification, item generation, and instrument formation and (2) psychometric testing.

### Sample

The study was conducted in a single academic center in an 8-bed adult coronary care unit and a 22-bed adult mixed medical-surgical ICU in Finland during 2011–2012 (Table 1). Randomly selected critical care nurses were invited to participate via letter and e-mail. Inclusion criteria were a registered nurse (RN) degree and direct care provider (bedside) experience. Written informed consent was obtained from the participants before study enrollment.

### Phase 1: Domain identification, item generation, and instrument formation

The content of existing observational rating scales<sup>11–18,20,22</sup> and multiple-choice questionnaires<sup>19</sup> was broadened to include a list of pharmacologic and nonpharmacologic nurse-led interventions aimed at preventing VAP, which were taken from the literature and supported by various degrees of evidence.

After domain identification, the content of the instruments was divided into 3 main categories. The first category covered factual data on demographics (eg, clinical characteristics) and the phenomenon of interest (eg, etiology, epidemiology, and pathogenesis of VAP). The second category (intubation and mechanical ventilation) covered interventions aimed at reducing the duration of mechanical ventilation (eg, daily “sedation vacations,” assessment of readiness for extubation, facilitation of accelerated weaning). The third category (prevention of airway colonization) covered interventions aimed at reducing microbiological colonization of the lower airways (eg, respiratory therapy equipment, appropriate enteral nutrition, adequate hand hygiene, daily oral care, updated endotracheal suctioning recommendations).

After item generation, 36 questions were included in the original version of the VBQ, 9 of which were based on the validated international multiple-choice questionnaire (difficulty, 0.1–0.9; discrimination, 0.10–0.65) of Labeau et al.<sup>19</sup> Similar to that questionnaire, the VBQ was formatted as a highly structured, self-administered, multiple-choice questionnaire with 4 response alternatives (ie, 1 correct answer, 2 distractors, and the option “I don't know” to discourage guessing).

Seventy-six dichotomous items were included in the original version of the VBOS, 20 of which were based on the previously validated observation schedule of Kelleher and Andrews.<sup>20</sup> Similar to existing observational rating scales,<sup>20,22</sup> the VBOS was formatted as a highly structured checklist with a rating scale (“yes” or “no”) to reduce observers' subjectivity and to enhance objectivity and reliability.<sup>23,24</sup> Participant adherence to an item in the recommended procedure earned 1 point.

After domain identification, item generation, and instrument formation, the principle of a double-blind, forward-back-forward translation process was adopted to translate previously published instruments into Finnish.<sup>19,20,22</sup> Permission to translate, modify, and use previously published instruments was obtained from the respective authors.

**Table 1**

Characteristics of the participants involved in the first measurement in the simulation environment and expert panel

Characteristic	Value
Expert panel (n = 16), n (%)	
Education	
Physicians	2 (12.5)
Critical care nurses (RNs)	3 (18.6)
Research nurses (RNs)	1 (6.3)
Infection control nurses (RNs)	4 (25.0)
Biostatisticians	1 (6.3)
Methodological experts/researchers	5 (31.3)
Experience	
<10 years	1 (12.5)
≥10 years	7 (87.5)
Critical care nurses (n = 40)	
Sex, n (%)	
Female	30 (75.0)
Male	10 (25.0)
Age, years, median (range)	33 (23–60)
Age <35 years, n (%)	21 (52.5)
Age ≥35 years, n (%)	19 (47.5)
Education, n (%)	
Master's degree	1 (2.5)
Bachelor's degree	39 (97.5)
Employment, n (%)	
Permanent	21 (52.5)
ICU experience, years, median (range)*	6.5 (1–30)
<10 years experience, n (%)	27 (67.5)
≥10 years experience, n (%)	11 (27.5)

\*Missing values (n = 2).

### Phase 2: Psychometric testing

The face and content validities of the developed instruments were tested following a structured procedure by an expert panel comprising methodological experts (n = 6) and content experts (n = 10), who were selected for their methodological and/or clinical ICU expertise.<sup>23,25,26</sup> Following Lynn,<sup>25</sup> the experts independently rated the relevance of each item on a 4-point scale (1, not relevant; 2, somewhat relevant; 3, quite relevant; 4, very relevant). In addition, the experts were asked to rate each item, question and answer, for accuracy, clarity, and readability on a dichotomous scale (“clear” or “not clear”). Finally, they were asked to evaluate the comprehensiveness of the instruments (eg, format, instructions) and identify whether any important issues were lacking.<sup>23,27</sup>

Based on the experts' suggestions, minor revisions were made to the instructions, wording, and content of the final VBQ and VBOS. Fifteen additional questions were included in the VBQ, and 4 questions were combined into 2 questions. Only 1 question was considered not relevant according to the 4-point scale and was deleted from the VBQ. Twenty-two additional items were included in the final VBOS, and 2 questions were combined into 1 question. In addition, 11 items relating to the prevention of airway colonization were considered impossible to assess, and thus were deleted from the final VBOS.

After content validation, the stability reliability of the VBOS was tested twice in a simulation environment with a total of 65 critical care nurses using a test-retest procedure. The researcher observed the nurses' skills while managing adult ICU patients with an artificial airway receiving continuous sedation, mechanical ventilation, and enteral nutrition using a direct, structured, nonparticipatory observation approach.<sup>26</sup> The prospectively collected data were cross-checked retrospectively after 2 weeks of primary testing<sup>23</sup> via the use of 3 strategically placed video cameras to record video and audio evidence of the nurses' performance.<sup>24,28</sup>

Moreover, equivalence reliability of the VBOS was tested in clinical practice with 23 critical care nurses using an interrater procedure. The researcher and a second trained and validated observer independently observed the nurses' skills while managing

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