DEVELOPMENT AND PSYCHOMETRIC TESTING OF VENTILATOR BUNDLE QUESTIONNAIRE AND OBSERVATION SCHEDULE

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ABSTRACT

Background: There is a lack of valid and reliable instruments that can be used to examine critical care nurses' knowledge of ventilator bundles and their ability to adhere to them. The aim of the study was to develop and psychometrically test a Ventilator Bundle Questionnaire (VBQ) and Observation Schedule (VBOS).

Methods: The content of the VBQ and VBOS consisted of a list of pharmacological and non-pharmacological nurse-led interventions taken from the literature and supported by various degrees of evidence. After content validation, test-retest stability and inter-rater equivalence of the VBOS were established/determined/tested/evaluated with randomly selected critical care nurses in a single academic center in Finland.

Results: The final VBQ contained 49 multiple-choice questions while the final VBOS had 86 dichotomous items, whose overall content validity index ranged from 0.72 to 1.0. The test-retest stability estimates of the VBOS ranged from 0.89 to 1.0 while the inter-rater equivalence estimates ranged from 0.99 to 1.0.

Conclusions: The VBQ and VBOS were developed and shown to have acceptable psychometric properties. The VBQ and VBOS can provide objective method to measure whether evidence based guidelines are being used in clinical practice. However, further testing with diverse samples is needed to strengthen validity and reliability.

Key words: critical care, instrument development, psychometrics, ventilator-associated pneumonia, ventilator bundle

BACKGROUND

Ventilator-associated pneumonia (VAP) is the most frequent device-associated nosocomial infection encountered in critical care settings [1], causing substantial morbidity, a two-fold increase in mortality rate [2], excess costs [3], and prolonged lengths of ventilator days [2], as well as intensive care unit (ICU) and hospital stays [2, 4].

The Institute for Healthcare Improvement 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. Ventilator bundles (VBs) are considered as "package" of evidence-based guideline (EBGs), designed to reduce VAP and promote adherence to EBGs in order to improve clinical outcomes [5, 6]. These include combinations of daily "sedation vacations" and assessment of readiness to extubate [6–7], elevation of the head of the bed between 30° and 45° [7–8], daily oral care with chlorhexidine [6–8], adequate hand hygiene [6–8], and peptic ulcer disease and deep vein thrombosis prophylaxis [7].

According to previous literature, initiation of VBs has been an effective method for VAP reduction when the adherence is maintained. However, VBs are frequently inconsistently adopted, implemented, and evaluated [9–10]. There is a lack of validated instruments that can be used to examine critical care nurses' knowledge of VBs and their ability to adhere to them. Few evaluation instruments exist, but they are unpublished [11–18] and even fewer are validated [19].

Although majority of observational rating scales have been concentrated on daily "sedation vacations" and assessment of readiness to extubate [12–14, 16–18], semirecumbent positioning [11–18], daily oral care with chlorhexidine [11–12, 15, 17], and peptic ulcer disease and deep vein thrombosis prophylaxis [13–14, 16], they do not cover interventions related to adequate hand hygiene practices (e.g., alcohol-based handrub, hand hygiene technique, duration of hand rub, gloving) [6–8], appropriate enteral nutrition (e.g., body positioning, maintenance of optimal cuff pressure) [6, 8], daily oral care (e.g., oral decontamination with chlorhexidine, tooth brushing, swabbing, moistening) [6–8] or endotracheal suctioning (ETS) [20] practices, which are essential treatment-related risk factors in the pathogenesis of VAP [8, 20].

Therefore, the aim of the study was to develop and psychometrically test a Ventilator Bundle Questionnaire (VBQ) and Observation Schedule (VBOS) in order to examine critical care nurses' knowledge and skills in adhering to VBs in clinical practice. The knowledge of VBs was defined as a basic knowledge

required managing adult ICU patients with an artificial airway receiving continuous sedation, mechanical ventilation and enteral nutrition.

METHODS

A prospective psychometric instrument validation study was divided into two phases: 1) domain identification, item generation, and instruments formation, and 2) psychometric testing (Table 1).

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. Randomly selected critical care nurses were invited to participate via letters and electronic mails. Inclusion criteria were as follows: 1) participants had a degree of registered nurse, and 2) participants were direct care providers (bedside). Written informed consents of the participants were obtained prior to the inclusion in the study.

Phase 1: Domain identification, item generation, and instruments formation

The content of existing observational rating scales [11–18, 21–22] and multiple-choice questionnaire [19] were broaden to contain a list of pharmacological and non-pharmacological nurse-led interventions taken from the literature (e.g., MEDLINE Ovid®, the Cumulative Index to Nursing and Allied Health Literature, the Cochrane Library) and supported by various degrees of evidence (Table 1).

Conceptually, three categories were distinguished: the first category covered demographic data (e.g., age, gender, certification degree, and years of ICU experience) as well as questions about the phenomenon of interest (e.g., etiology, epidemiology, and pathogenesis of VAP). The second category (intubation and mechanical ventilation) covered interventions aimed to reduce the duration of mechanical ventilation (e.g., daily "sedation vacations" and assessment of readiness to extubate, facilitate accelerated weaning) while the third category (prevention of airway colonization) covered interventions aimed to reduce the microbiological colonization of the lower airways (e.g., respiratory therapy equipment, appropriate enteral nutrition, adequate hand hygiene practices, daily oral care and updated ETS recommendations including practices prior to, during and post ETS event).

Thirty-six questions were included in to the original version of the VBQ, of which nine questions based on Labeau et al.'s [19] pre-validated multiple-choice questionnaire (difficulty 0.1–0.9; discrimination 0.10–0.65). Similarity to Labeau et al. [19], the VBQ was formatted as a highly structured multiple-choice questionnaire, which contained questions with four response alternatives including one correct answer, two

distractors, and the option "I don't know" to discourage guessing. Contrary to Labeau et al. [19], one open-ended question was included in the final VBQ to explore critical care nurses' knowledge of the pathogenesis of VAP.

Moreover, seventy-six dichotomous items were included in the original version of the VBOS, of which seventeen items based on Kelleher and Andrews's [21] previously pilot-tested observation schedules. Modified 20-item observational schedule [21] based on McKillop's [22] previously validated survey tool, which was designed to reflect observable behaviors associated with best-practice suctioning of adults with an artificial airway [23]. Similarity to existing observational rating scales [21–22], the VBOS was formatted as a highly structured checklist with a rating scale ("yes" or "no") to reduce observers' subjectivity and enhance objectivity and reliability [24–25]. If participants adhered to an item in the recommended procedure, they were assigned one point. Similar to McKillop [22], the VBOS included space for notes.

After domain identification, item generation**,** and instruments formation, the previously validated [19] and pilot-tested instruments [21–22] were translated independently of one another to ensure the validity of the translation process (Table 1). The permission to translate, modify and use previously published instruments was obtained from the copyright holders [19, 21–22].

Phase 2: Psychometric testing

The face and content validities of the developed instruments were established/determined/tested/evaluated using a structured procedure by an expert panel (Table 1), which consisted of a purposive sample of methodological and content experts, who were selected based on their methodological or clinical ICU expertise [26–27]. Following Lynn [26], the participants rated independently the relevance of each item using a four-point rating scale (1 = not relevant, 2 = somewhat relevant, 3 = quite relevant and 4 = very relevant). In addition, participants were asked to rate each item, question and answer for appropriateness, accuracy, clarity and readability (e.g., grammar and syntax) on a dichotomous rating scale. Finally, they were asked to evaluate the comprehensiveness of the instruments and identify whether any important issues were lacking [28].

Stability reliability testing of the VBOS was carried out twice in a simulation environment between January and May 2012 with a total of 65 critical care nurses using test-retest procedure (Table 1): a corresponding author observed critical care nurses' skills twice while managing adult ICU patients with an artificial airway receiving continuous sedation, mechanical ventilation and enteral nutrition using a direct,

structured, non-participatory method of observation [27]. The tests were repeated after two weeks of primary testing [27] via video records [25, 29].

Equivalence reliability testing of the VBOS was carried out in clinical practice between August and October 2012 with a total of 23 critical care nurses using inter-rater procedure (Table 1): the corresponding author and a second, trained observer observed the critical care nurses' skills managing adult, ICU patients with an artificial airway receiving continuous sedation, mechanical ventilation and enteral nutrition during morning shift (07:00–15:00), independently recording the data according to prescribed instructions [27].

Data analysis

The content validity was established/determined/tested/evaluated by calculating content validity index (CVI) of the relevancy of each item, which reflects the level of agreement seen across the members of the expert panel ratings. CVI above 0.80 was considered good [27]. The test-retest stability and inter-rater equivalence reliabilities were tested by calculating intraclass correlation coefficient (ICC), including confidence intervals (95% CI), and Cohen's kappa coefficient (κ) of each item and the average scale score, which indicates the degree of correlation between repeated measurements (test-retest procedure) or agreement between two observer's ratings (inter-rater procedure). An ICC above 0.80 was considered satisfactory [27]. The results of the kappa analysis were defined as showing fair (0.21–0.4), moderate (0.41–0.60), and substantial (0.61–0.8) or almost perfect (0.81–1.0) agreement [30]. SPSS 18.0 for Windows was used for data analysis (SPSS Inc., Chicago, Illinois, USA).

RESULTS

The face and content validities of the developed instruments were established/determined/tested/evaluated with the purposive sample of methodological (n = 6) and content (n = 10) experts. After content validation, test-retest stability and inter-rater equivalence were established/determined/tested/evaluated among randomly selected critical care nurses in a single academic center in Finland during 2012 (Table 2).

Validity of the VBQ and VBOS

After content validation, minor revisions to the wording and content of the final VBQ and VBOS were performed. Fifteen questions were included to the VBQ, while four questions were combined into two questions. Only one question was considered not relevant according to the four-point scale and thus was eliminated from the VBQ. The final VBQ contained 49 questions, whose overall CVI ranged from 0.91 to 1.0. The total score of the VBQ ranged from 0 to 41 while the higher scores indicated higher knowledge.

Twenty-two items were included to the final VBOS, while two questions were combined into one question. Eleven items related to the prevention of airway colonization were considered impossible to assess, and thus were eliminated from the final VBOS. The final VBOS contained 86 dichotomous items, whose overall CVI ranged from 0.72 to 1.0. The total score of the VBOS ranged from 0 to 70 while higher scores indicated higher skills.

The reliability of the VBOS

The degree of correlation between repeated measurements (test-retest stability) ranged from 0.89 to 1.0, while the 95% of CIs for the ICCs ranged from 0.80 to 1.0 (Table 3). The Cohen's κ values ranged from 0.24 to 1.0 (Table 3). The lowest Cohen's κ values were associated with adequate hand hygiene technique (κ = 0.48–1.0) and duration of handrub (κ = 0.24–1.0).

The degree of agreement between two observer's ratings (inter-rater equivalence) ranged from 0.99 to 1.0, while the 95% of CIs for the ICCs ranged from 0.97 to 1.0 (Table 3). The Cohen's κ values ranged from 0.25 to 1.0 (Table 3). The lowest Cohen's κ value (κ = 0.25) was associated with the length of time suction applied to airway.

DISCUSSION

Psychometric instrument validation study was adopted due to the lack of existing instruments that can be can be used to examine critical care nurses' knowledge and skills in adhering to VBs. These newly developed instruments shown to have acceptable psychometric properties and can be used to measure the extent to which EBGs are being translated into clinical practice.

The content of existing observational rating scales [11-18, 21–22] and multiple-choice questionnaire [19] were broaden to contain adequate hand hygiene practices [6–8], appropriate enteral nutrition [6, 8], daily oral care [6–8] and updated ETS practices [20] while the content of existing instruments have included combinations of three to six evidence-based interventions that have been shown to improve clinical outcomes. Contrary to existing observational rating scales [13–14, 16], the pharmacological prevention strategies such as peptic ulcer disease and deep vein thrombosis prophylaxis were eliminated because they are intended to prevent other complications of mechanical ventilation [9].

Nowadays a CVI value of 0.9 or higher is suggested as a standard for establishing excellence in a scales' content validity [27]. The content of instruments was considered very or quite relevant by the expert panel. However, one item related to the spontaneous breathing test was considered somewhat relevant (CVI 0.72), demonstrating a lack of knowledge of protocols for weaning, which may be a barrier to adherence. In addition, the response options related to the frequency of suction systems and humidifier changes [19] were considered unclear, and therefore need to be modified in order to obtain a higher validity.

The test-retest stability and inter-rater equivalence reliabilities were established/determined, which provided complementary information to that given by the internal consistency reliability. Almost perfect agreement (ICC 0.89–1.0) was obtained between two observer's ratings [27, 30]. The lowest κ values (17.6% of the total average scale score) were related to adequate hand hygiene, which might be due to the situational contaminants or administration variations (e.g., the location of the data gathering and other environmental factors) in spite of using a homogenous sample and trained observers [27, 31].

However, in some situations a lower reliability coefficient can be acceptable even the use of a small number of items would reduce the risk of the situational contaminants [27]. The items related to adequate hand hygiene (e.g., adequate hand hygiene technique and duration of handrub) were not eliminated because adequate hand hygiene plays an essential role in the prevention of VAP [32] and elimination would have jeopardized the content validity of the instruments. However, ambiguities related to hand hygiene technique

were modified by stating criteria for adequate behaviour [31] in order to obtain a higher validity. In the future, emerging technologies, such as wireless locating systems and electronic sensors, may provide alternative or additional solutions for monitoring hand hygiene practices among health care practioners [33].

In conclusion, the VBQ and VBOS were developed and shown to have acceptable psychometric properties. These newly validated and updated instruments can provide an objective method to measure whether EBGs are being used in clinical practice. It might be possible to apply these instruments in nursing education (e.g., pre- and post-baccalaureate education) and research to identify deficiencies and misconceptions regarding the prevention of VAP in order to understand, inform and develop current practices for VAP prevention, especially in Scandinavia, where the topic has largely been undiscussed in the contrast of the USA [11, 14, 16, 18] and majority of European countries [12, 15, 17].

However, a single-center study with a limited sample size cannot be used to make generalizations. On the other hand, no exact criteria exist regarding the sample size needed for psychometric instrument validation study. Further testing with diverse samples is needed to strengthen validity and reliability. In addition, modification and reevaluation of the instruments will be needed each time new evidence-based interventions for preventing VAP are discovered.

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Table 2 Phases and steps of the development process of the VBQ and VBOS

Phases and steps	Purpose	Method	Members
Phase 1: Domain identification, item generation, and instruments formation			
Step I	To identify existing instruments to examine critical care nurses' knowledge of ventilator bundles and their ability to adhere to them	Literature review during April and June 2011	Researcher
Step II	To identify the content of instruments in order to determine the items, concepts and elements to be included in the newly developed instruments	Literature review during August and September 2011	Researcher
Step III	To develop instruments based on the previously published formats		Researcher
Step IV	To translate previously published instruments into Finnish	Double-blind, forward-back-forward translation process during October 2011	Researcher
	To translate Finnish version back into English		Translator
	To translate English version back into Finnish		First bilingual expert
	To evaluate similarity of the items and response format regarding wording, sentence structure, meaning and relevance	Critical review and comparison of the original and translated versions	Researcher and second bilingual expert
Phase 2: Psychometric testing			
Step I	To established/determined/tested/evaluated instruments' face and content validity and test the instruments' format and instructions	CVI calculation during November 2011	Expert panel (n = 16)*
Step II	To established/determined/tested/evaluated observation schedule's stability reliability	Test-retest procedure in the simulation environment: researcher conducted the measurement to a sample twice	Researcher

Phases and steps	Purpose	Method	Members
		and then compare the scores	
		1th measurement: January 2012	Critical care nurses (n = 40)
		2nd measurement: May 2012	Critical care nurses (n = 25)
	To established/determined/tested/evaluated observation schedule's equivalence reliability	Inter-rater procedure in clinical practice during August and October 2012: researcher and a second observer observed the participants independently recording the data according to prescribed instructions	Researcher and a second observer Critical care nurses (n = 23)

CVI, Content validity index.

Table 2 Characteristics of the participants involved in the 1st measurement in the simulation environment and in the expert panel

Characteristics	n (%)
The expert panel (n = 16)	
Education	
Physicians	2 (12.5)
Critical care nurses (RN)	3 (18.6)
Research nurses (RN)	1 (6.3)
Infection control nurses (RN)	4 (25.0)
Biostatisticians	1 (6.3)
Methodological experts/researchers	5 (31.3)
Years' experience	
< 10 years	1 (12.5)
≥ 10 years	7 (87.5)
Critical care nurses (n = 40)	
Gender	
Female	30 (75.0)
Age	
< 35 years	21 (52.5)
≥ 35 years	19 (47.5)
Education	
Master's degree	1 (2.5)
Bachelor's degree	39 (97.5)
Employment	
Permanent	29 (72.5)
Years ICU experience*	
< 10 years	25 (65.8)
≥ 10 years	13 (34.2)

RN, registered nurse.

T**able 4** Stability and equivalence reliability of the VBOS

Content	Cohen's κ Min–Max	ICC	95 % CI for the ICC
Stability reliability of the VBOS			
Intubation and mechanical ventilation			
Simulation environment: 1st measurement (n = 40)	0.94–1.0	0.93	0.88–0.96
Simulation environment: 2nd measurement (n = 25)	0.75–1.0	0.97	0.93–0.99
Prevention of airway colonization			
Simulation environment: 1st measurement (n = 40)	0.48–1.0	0.89–1.0	0.80–1.0
Simulation environment: 2nd measurement (n = 25)	0.24–1.0	0.93–1.0	0.84–1.0
Equivalence reliability of the VBOS			
Intubation and mechanical ventilation			
Clinical practice (n = 23)	1.0	1.0	1.0
Prevention of airway colonization			
Clinical practice (n = 23)	0.25–1.0	0.99	0.97–1.0

ICC, Intraclass correlation coefficient; CI, Confidence intervals