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Development and pilot testing of a needs assessment scale for awake patients with tracheal intubation

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Awake intensive care unit (ICU) patients with endotracheal intubation are exposed to various physiological and psychological stressors due to their medical conditions. As they are unable to communicate verbally, these patients usually struggle to accurately express their needs, which can exacerbate their discomfort and hinder recovery. Our study aimed to develop a needs assessment tool specifically for patients who are awake while intubated to help identify unmet needs promptly. A preliminary needs assessment scale for awake and intubated patients was developed through a systematic literature review and panelist meetings. The scale was refined using two rounds of the Delphi method. A total of 17 and 16 experts participated in two rounds of expert consultation, respectively, during which we gathered their opinions and refined the indicators through a comprehensive literature review and expert panel meetings. This process culminated in developing a needs assessment scale comprising five primary dimensions and 37 secondary items. Subsequently, we conducted a pilot test involving 30 participants, and the results indicated that patients could accurately comprehend each item and independently complete the scale within approximately 10 min. The needs assessment scale developed in this study provides an accurate tool for assessing the needs of awake and intubated ICU patients, demonstrating strong scientific validity and feasibility, thereby providing healthcare professionals with guidance for implementing individualized interventions. Additional research is needed for multi-center, large-sample clinical validation.

Keywords Endotracheal intubation, Needs assessment, Delphi method, Awake

The intensive care unit (ICU) is a specialized environment that provides life support for acutely ill and injured patients within an appropriate time frame[1]. Endotracheal intubation is an essential life-saving intervention that can maintain patency of the respiratory tract, ensure adequate ventilation, improve oxygenation, and is necessary to rescue, treat, and stabilize critically ill patients in the ICU[2]. Previously, ICU patients requiring tracheal intubation were regularly administered high doses of sedative medications to alleviate associated pain and discomfort[3]. However, with the shift toward a patient-centered treatment approach, using light sedation or even no sedation during ongoing endotracheal intubation therapy has become increasingly prevalent[4,5]. As patients' consciousness levels improve and their awareness extends over time, their physiological and psychological needs become increasingly complex[6]. Nevertheless, due to the particular circumstances faced by ICU patients, including being in an unfamiliar environment without family presence, surrounded by medical devices, and subjected to adverse stimuli such as high-intensity invasive treatments, including endotracheal intubation, they exhibit distinct needs compared to those in general wards[7]. Furthermore, impeded communication capabilities hinder their ability to express feelings freely, exacerbating stress and frustration among these individuals[8,9]. Non-verbal communication has emerged as the primary means of expression for conscious intubated patients[10]; however, individual cognitive variations and cultural differences can lead to inefficiencies such as multiple interpretations or miscommunications inherent in non-verbal cues. This results in significant barriers between healthcare providers and patients along with diminished quality of doctor-patient interactions[11]. Consequently, this situation intensifies physical discomfort alongside psychological distress, including fearfulness, restlessness, anxiety, loneliness[12,13], and helplessness, which ultimately reduces patient satisfaction with nursing care services[14]. Such dynamics may exacerbate conflicts between doctors and patients, potentially triggering

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serious adverse events such as unplanned extubation. They may also adversely affect these individuals' survival outcomes or long-term quality of life[15,16]. A survey study reveals that ICU survivors consider the communication obstacles resulting from mechanical ventilation as one of their most distressing experiences[17]. The economic burden imposed on healthcare systems due to ineffective communication issues averages 2.2 million US dollars annually[18].

To further enhance communication efficiency between medical personnel and patients who are unable to speak, augmentation and alternative communication (AAC) tools have been developed, including options such as direct interaction with a tablet to select desired content, utilizing eye movement tracking for selection through gaze focus, and employing various simple or complex language devices[19]. However, despite the availability of these tools, communication difficulties persist in over one-third of interactions between medical staff and patients. Furthermore, the utilization rate of AAC tools remains below 25%, highlighting ongoing deficiencies in effective doctor-patient communication[19,20]. Understanding the genuine needs of patients with tracheal intubation is crucial to formulating individualized care plans. However, currently, there is a shortage of tools that can directly assess the needs of conscious patients with tracheal intubation. Therefore, our study aimed to assist healthcare professionals in promptly identifying patient needs and providing a reference for implementing personalized interventions.

Methods

Design

This study was conducted by a multidisciplinary research team comprising medical experts, nursing administrators, graduate nursing students, and clinical nurses, all of whom possessed extensive clinical and research experience. Using Maslow's Hierarchy of Needs as the theoretical framework, the needs of awake ICU patients with endotracheal intubation were categorized into the following dimensions: physiological, safety, love and belonging, esteem, and self-actualization.

Research team developed a preliminary needs assessment scale for awake ICU patients with endotracheal intubation through expert meetings and a systematic literature review. The Delphi method was then employed to refine the scale through iterative expert consultation and feedback. This study obtained ethical approval from the Ethics Committee of Sichuan Cancer Hospital(SCCHEC-02-2024-022).

The study design was developed by a research team comprising nursing managers, physicians, clinical nurses, and graduate students. Utilizing an electronic Delphi process, two rounds of electronic surveys were conducted between January 1, 2024, to April 1, 2024 to identify the genuine needs of conscious patients with endotracheal intubation. The Delphi method is a structured process that records the opinions of the panelist group and summarizes their feedback in subsequent inquiries to achieve consensus through iterative consultations[21]. The Delphi technique is mainly used to build consensus or explore areas beyond existing knowledge within current conceptual frameworks[22].

Research team

The research team comprised eight members, including one physician and seven nurses; three were advanced professionals, two were graduate nursing students, and the remaining were clinical nurses with substantial ICU experience. Their roles and responsibilities included the following:

(1) Conducting comprehensive literature searches, followed by synthesis and systematic analysis of relevant studies; (2) organizing panel meetings to develop a preliminary needs assessment scale tailored for awake ICU patients with endotracheal intubation based on the literature review findings and clinical insights; (3) facilitating consultations using the Delphi method to systematically gather, analyze, and incorporate expert opinions for assessment scale refinement.

Literature review and panelist meetings

The theoretical framework guiding this study was Maslow's Hierarchy of Needs[23]. A systematic literature search was conducted across major databases, including China National Knowledge Infrastructure(CNKI), Wanfang, China Science and Technology Journal Database, China Biology Medicine(SinoMed), PubMed, Embase, Web of Science, Cumulative Index to Nursing and Allied Health Literature(CINAHL), and Cochrane Library. The search aimed to identify studies focusing on the unmet needs of awake ICU patients with endotracheal intubation. Therefore, all literature that involved the assessment and analysis of the needs of ICU patients with tracheal intubation was included in the review. The search covered the timeframe from the inception of each database to March 31, 2023.

Two graduate-level nursing students independently screened and synthesized the relevant literature to construct a pool of items for the needs assessment scale. The results of the literature search and the PRISMA flowchart are provided in Online Resource 1. Subsequently, panel meetings were convened to critically evaluate and revise draft items. The outcomes of these discussions guided the development of the consultation questionnaire utilized in the Delphi process.

Delphi method

Following the principles of representativeness, professionalism, and voluntariness, the inclusion criteria for Delphi panel experts in this study were as follows: (1) Possession of a bachelor's degree or higher; (2) experience in intensive care nursing or nursing management for at least five years; (3) holding an intermediate professional title or above; (4) demonstrating enthusiasm for the research through their willingness to complete the panelist questionnaire and participate in subsequent rounds of surveys.

A total of 17 experts, aged 30 to 55 years, from Sichuan, Guangdong, Chongqing, Shanghai, Tianjin, and Harbin Provinces were invited through purposive sampling based on the needs of the study. Their fields include

intensive care medicine, radiotherapy nursing, surgical nursing, psychological clinics, nursing education, and nursing research.

Two rounds of questionnaires were delivered via email or WeChat between January and April 2024. The two rounds were separated by two to four weeks to ensure sufficient time for the advisory group to summarize and analyze feedback from expert opinions. Each round provided panelists two weeks to respond. The questionnaire comprised three sections: (1) Introduction, which included background information regarding the study purpose and significance, along with instructions; (2) content of the scale, which assessed the importance of first-level indicators and reasonableness of second-level indicators using a five-point Likert scale, where a score of five indicated extreme significance or reasonableness and a score of one indicated no significance. The space was provided after each indicator for panelists to give comments on revisions or suggestions for additions or deletions; (3) demographic information about panelists, including their judgment basis and their familiarity with the research content and items.

After collecting data from the first-round questionnaire responses, the research team thoroughly collated and analyzed the opinions of panelists. Indicators with mean values > 3.5 and coefficients of variation (CV) < 0.25 were thoroughly discussed by team members based on these ratings and adjusted as needed before launching the second-round consultation process. Indicators meeting these criteria—reflecting the importance and low variability in opinions—were included in the subsequent phase. Otherwise, additional literature reviews and further meetings with panelists were conducted to validate scientific accuracy.

Content validity analysis of the scale

Content validity refers to the extent to which the content assessed by a scale aligns with its intended evaluative purpose[24,25]. Sixteen experts who actively participated in the second round of the Delphi process were invited to evaluate the relevance of each scale item within a predefined content domain. The Content Validity Index (CVI) was used to quantify content validity, including both the item-level CVI (I-CVI) and average scale-level CVI (S-CVI). An S-CVI of 0.8 or higher and I-CVI of 0.9 or higher indicate excellent content validity, thereby providing a comprehensive assessment of the scale[26].

Pilot survey

Convenience sampling was employed in a pilot survey involving 30 conscious patients with tracheal intubation at a tertiary hospital in Sichuan from June 1, 2024, to August 1, 2024. All participants provided written informed consent. The inclusion criteria were: (1) duration of tracheal intubation ≥ 12 h; (2) RASS score = 0; and (3) ability to understand and cooperate with the investigators to complete the questionnaire. The exclusion criterion was an inability to complete the questionnaire due to individual condition or severity of illness.

The questionnaire was administered through face-to-face oral interviews conducted by two designated research staff members. Both researchers received training and had reached consensus on the instructions and explanations provided to participants for any items that were unclear.

Additional assessment of patients' understanding of the scale items was conducted by the research staff after extubation, through follow-up questioning and by recording the time required to complete the assessment.

A summary of the demographic characteristics of subjects in the pilot study—including gender, age, educational level, disease diagnosis, and ventilation duration—is presented in Online Resource 2.

Statistical analysis

Data analysis was conducted using the Statistical Package for the Social Sciences software (version 25.0). Descriptive statistics, including means and standard deviations, are used to summarize continuous data, while categorical data are presented as frequencies and percentages. Consensus in the Delphi process was defined as achieving a rating of ≥ 4 for both the importance of first-level indicators and the reasonableness of second-level indicators by over 67% of experts[27]. The effectiveness of expert participation was evaluated through the effective response rate of the questionnaire, whereas expert authority was quantified using average judgment and familiarity coefficients. The level of consensus across expert opinions was assessed using Kendall's coefficient of concordance. A $P < 0.05$ was considered statistically significant.

Handling of missing data: During the Delphi consultation process, if any experts were unable to respond in a timely manner, the expert panel would discuss whether to conduct additional rounds of consultation. During the pilot survey, any incomplete questionnaires were excluded from the analysis.

Results

Characteristics of experts

Seventeen experts from six provinces and cities participated in the Delphi process, including Sichuan, Guangdong, Chongqing, Shanghai, Tianjin, and Harbin. The panel comprised specialists from diverse fields, including critical care medicine, radiation therapy, surgical care, psychology, nursing management, and nursing education. The average age of experts was 44 years, with an average professional nursing experience of 26 years. All participants held positions in nursing management; 6 experts (35.29%) possessed a master's degree, while 12 (70.59%) held senior professional titles (associate professor or above) (Table 1). One expert did not respond on time during the second round of the Delphi survey.

Enthusiasm of experts

The positive coefficient of the experts reflects their enthusiasm for the research. Seventeen questionnaires were distributed to experts across two rounds, with 17 and 16 completed responses returned, resulting in effective response rates of 100% and 94.12%, respectively, indicating strong engagement from the panelists. Following the first round of Delphi consultations, 8 out of the 17 experts provided recommendations, while 5 out of 16

Items	Groups	*N* (%)
Age(years)	30–39	4 (23.53)
	40–49	11 (64.71)
	50–55	2 (11.76)
Work experience(years)	< 10	1 (5.88)
	10–19	4 (23.53)
	20–29	9 (52.94)
	≥ 30	3 (17.65)
Educational background	Master	11 (64.71)
	Bachelor	6 (35.29)
Professional title	Intermediate	5 (29.41)
	Deputy senior	8 (47.06)
	Senior	4 (23.53)
Research field	Critical care medicine	9 (52.9)
	Radiation care	1 (5.9)
	Surgical care	2 (11.8)
	Psychology	1 (5.9)
	Nursing management	2 (11.8)
	Nursing education	2 (11.8)

Table 1. Characteristics of the experts, provides an overview of the demographic and professional characteristics of the experts involved in the Delphi method, including their age, work experience, educational background, professional title, and research field.

experts contributed additional suggestions in the second round. This trend suggests growing consistency in expert opinions.

Authority of experts

The level of expert authority was assessed through a self-evaluation measure known as the expert authority coefficient (Cr). Cr is calculated as the average of two components: The expert's familiarity with the issues being consulted (Cs) and the basis for their judgment regarding questionnaire evaluations (Ca). The formula used is $Cr = (Ca + Cs)/2$ [28]. The degree of expert authority is critical to determine the reliability of Delphi consultation results.

In this study, the Cs and Ca values during the first round of Delphi consultations were 0.93 and 0.96, respectively. These values increased to 0.94 and 0.98, respectively, in the second round. The expert authority coefficients for both rounds were 0.947 and 0.956, respectively, indicating that the results can be considered reliable.

Degree of coordination among experts

The degree of coordination among expert opinions was assessed using the CV and the coefficient of coordination (W). The CV reflects the degree of fluctuation in the weight values assigned to each indicator by the expert group; a smaller value indicates better coordination among expert predictions or evaluation opinions, with a general threshold set below 0.25. W measures the level of agreement among all experts across all indicators, where a value < 0.05 is considered statistically significant[29].

In the first round, the mean scores for all first-level indicators exceeded 4.5 points, with CVs less than 0.2, and no experts recommended any modifications. Following deliberation, the project team concluded that additional ratings and adjustments for first-level items would not be necessary in the subsequent stages of the Delphi process.

In the second round, the mean scores for the secondary items ranged from 4.33 to 5 (with all scores exceeding 4). The standard deviations ranged from 0 to 0.64. The CVs for 36 s-level items (94.74%) ranged from 0.07 to 0.24; CVs for two items exceeded 0.25 and were initially candidates for deletion; however, they were revised based on literature reviews and group discussions. Conversely, during the second round, CV values for all 37 items are < 0.15, indicating high expert agreement (Online Resource 3). The coordination coefficients for both rounds of questionnaires were recorded at 0.169 and 0.160, respectively, with $P < 0.05$ signifying a high level of consensus among experts (Online Resource 4).

Content validity analysis of the scale

The I-CVI ranged from 0.82 to 1.0, and the S-CVI was 0.903, both exceeding the reference values[30]. These findings indicated the excellent content validity of the scale, reflecting the representativeness of the indicators in the needs assessment scale for awake patients with tracheal intubation.

Primary dimensions	Secondary items
Physiological needs	I wish to have the endotracheal tube removed
	I want to know the expected extubation time
	I wish to talk
	I want to rinse my mouth
	I want to remove the restraints
	I want to move my trunk and limbs
	I want to change my position
	I wish to cough
	I wish to spit out mucus
	I want to relieve the pain
	I wish to drink
	I wish to eat
	I wish to have the catheter removed
	I need to have a bowel movement
	I want to sleep
	I need to keep warm
	I need to cool down
	I need to reduce the noise
	I need to adjust the lighting
Safety needs	I know I am safe
	I know my treatment is effective
	I know what is happening with my health
	I hope the doctors and nurses will inform me before my treatment
	I know what time it is right now
	I know I'm in the ICU right now
	I want to know about my ICU costs
	I hope to get timely responses to my questions
Love and belongingness needs	I want to know my family's current situation
	I want to have my relatives around for some company
	I received care and support from the medical staff
Esteem needs	I received respect from the medical staff
	I need some personal space
	I need to ensure that I am protected before undergoing any invasive or privacy-exposing actions
Self-actualization needs	I want to have some fun (for instance, writing, reading, listening to music, using my phone, and others)
	I want to be involved in the treatment decision-making
	I want to know when my condition will improve
	My faith is respected

Table 2. Needs assessment scale for awake patients with tracheal Intubation, outlines the final needs assessment framework developed in this study, which comprises five primary dimensions—physiological needs, safety, love and belonging, esteem and self-respect, and self-actualization—along with 37 secondary items.

Results of the panelist consultation

In the first round of the panelist consultation, two experts recommended the removal of Item 1; two experts proposed the removal of Item 13; three experts recommended the removal of Item 38; and one expert advocated moving Item 30 from the first-level indicator "Love and Belonging" to the first-level indicator "Safety Needs".

Based on these expert opinions, along with the literature review and group discussions, the following modifications were made: (1) The primary dimensions for Item 30 was altered; (2) Item 1 was retained while Items 13 and 38 were revised; (3) the expressions of Items 4, 20, 21, 25, 33, and 36 were refined; (4) Items 34 and 35 were merged. The specifics of these modifications are presented in Online Resource 5, followed by the second round of panelist consultation.

In the second round, three experts indicated that the expression of Item 33 was inadequate and required revision, and one expert each suggested improvements to the expressions for items 23, 27, and 29. Modifications were made in response to feedback from experts following a panel discussion and literature review. The details of these revisions are presented in Online Resource 6, leading to a needs assessment scale for awake patients with tracheal intubation, comprising five primary dimensions and 37 secondary items, which are presented in Table 2.

Results of the pilot survey

In the pilot study, all participants completed the questionnaire and reported that the language of the items was clear and that they could accurately comprehend the intended meaning. Furthermore, all participants completed the scale within 10 min, indicating that the scale has good readability and ease of use.

Discussion

The imperative of scaling development

Currently, ICU patients with endotracheal intubation encounter multiple needs due to their incapacity to communicate verbally[31]. These needs encompass five crucial domains: Physiological needs, verbal and physical expressions, restraint and mobility, aspiration for family companionship, and dissatisfaction with the ICU environment. Nevertheless, a comprehensive instrument for evaluating the needs of these patients is absent. This study endeavored to bridge this gap by developing a needs assessment scale for awake and intubated ICU patients. Utilizing Maslow's Hierarchy of Needs as a theoretical framework, the scale was formulated through an evidence-based literature review and the Delphi method. It encompasses five dimensions: physiological needs, safety, love and belonging, esteem and self-respect, and self-actualization, comprising 37 items. This scale provides a comprehensive and precise identification of unmet patient needs, allowing healthcare professionals to formulate individualized care plans. This facilitates personalized care without significantly augmenting the workload of medical staff, alleviates patient discomfort, promotes recovery, and enhances patient comfort and satisfaction.

Scientific validity and reliability of our study

This study comprised a research team encompassing medical specialists and nursing staff with rich clinical experience. The team adopted a patient-centered approach during the scale development process, taking Maslow's Hierarchy of Needs as a theoretical framework. Through a systematic literature review and panel discussion, a pool of items was developed to assess the needs of awake and intubated patients and construct a panel consultation questionnaire. During the Delphi process, 17 experts from six provinces with backgrounds in critical care medicine, surgery, psychology, and nursing management were invited to participate. All experts held a bachelor's degree or higher and had an average of 26 years of professional experience, bringing substantial theoretical and practical panelists to the research.

Two rounds of Delphi consultations were conducted, with expert response rates of 100% and 94.1%, respectively.The experts provided constructive feedback, which, combined with relevant literature and expert meetings, led to targeted revisions and improvements to the scale.

Both rounds showed expert authority coefficients greater than 0.94, indicating that the consulted experts were highly knowledgeable and representative in the fields. The results of Kendall's coefficient of concordance in both rounds demonstrated significant agreement among the experts ($P < 0.05$). In both rounds, the average importance rating of all items was ≥ 4 points, with 94.74% of the first-round items and all second-round items having a CV of less than 0.25, signifying a high degree of consensus and reliability in the Delphi results.

Additionally, a third-panel review was conducted to evaluate the relevance of the items, involving 16 experts. The results revealed that I-CVI was greater than 0.8 for all 37 items, while S-CVI was 0.903, indicating acceptable content validity. The understanding and responses of participants were well-aligned with the intended content of the scale, further confirming the enhanced reliability of the scale.

Feasibility of the scale

This study was guided by the needs of clinical patients in defining the research topic. The needs assessment scale was developed through a systematic literature review and the Delphi method, enabling a comprehensive assessment of patient needs. The results of the pilot test indicated that the scale items were readily understandable and the length was appropriate. Most patients were able to complete the scale independently within approximately 10 min, demonstrating its outstanding feasibility.However, the feasibility of the scale lacks quantitative supporting data, and a standardized quantitative assessment of comprehension was not conducted. Future studies will need to include more quantitative data to fully demonstrate the scale's feasibility and improve comprehension assessment.

Limitations and recommendations of our study

Our study developed a needs assessment scale for awake ICU patients with endotracheal intubation based on Maslow's Hierarchy of Needs. However, some needs may simultaneously align with the physiological, esteem, or safety dimensions, making strict categorization challenging. Additionally, safety needs remain the most important throughout ICU treatment. Although adjustments were made based on expert feedback from the Delphi method and relevant literature to ensure the scale's applicability within the local cultural context, there are still limitations in accurately capturing the dynamic changes in the needs of awake ICU patients with endotracheal intubation. Future research should further refine the scale through analysis of needs assessments from a larger sample of patients.

Although the results of the Delphi process demonstrated good overall consensus for the scale, items 34, 35, and 37 received the lowest ratings, suggesting areas for potential future refinement.

The scale developed in this study has only been piloted within the ICU of a single tertiary oncology hospital and has yet to undergo psychometric validation. In the future, we plan to validate the scale's psychometric properties by incorporating a larger sample within a single center. Furthermore, we aim to involve collaborations across different regions and various types of hospitals to assess the scale's accuracy and applicability. In the future, the scale is expected to be applicable in all hospital departments caring for patients with endotracheal

intubation. This process will allow for further refinement of the scale and promote its broader implementation, ultimately improving the identification of patient needs and enhancing healthcare quality.

Conclusion

In conclusion, the development of the needs assessment scale in this study followed standardized procedures and principles. A comprehensive set of items was constructed through a systematic literature review and panel discussions. Expert consultations were then conducted to gather feedback, enabling preliminary revisions to the content and language of the scale. Various methods were employed to refine the scaling terms, ensuring the validity and reliability of the needs assessment scale for families of ICU patients and demonstrating its scientific foundation and methodological rigor.

Data availability

The datasets used and/or analysed during the current study available from the corresponding author on reasonable request.

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Declarations

Competing interests

The authors declare no competing interests.

Institutional review board statement

The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Ethics Committee for Medical Research of Sichuan Cancer Hospital (protocol code SCCHEC-02-2024-022 and January 24, 2024 approval).

Additional information

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1038/s41598-025-22851-0.

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