

Construction of a quality-sensitive index system for managing wet packs after steam sterilization based on evidence

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ABSTRACT: Objective The present study establishes a quality-sensitive index (QSI) system for managing wet packs after steam sterilization. **Methods** The “structure, process, and outcome” model was adopted as the theoretical framework. The manuscript of the QSI system was drawn up after the literature review. The calculation formula was determined and data was collected by group discussion. After two rounds of Delphi expert consultation, the final draft was formed. **Results** The questionnaire response rates of the two rounds of expert consultation were 100%, the expert authority coefficient (Cr) was 0.905 and 0.925, and Kendall’s coefficient of concordance (Kendall’s W) was 0.159 and 0.161 ($P < 0.01$), respectively. Finally, the QSI system consisted of 3 first-, 9 second-, and 22 third-level indexes. **Conclusion** The QSI system established in this study is highly professional, scientific, and reliable, providing a reference for the quality control of wet pack management.

KEY WORDS: Steam sterilization; Wet pack; Quality-sensitive index system; Evidence-based nursing

Introduction

Steam sterilization is a preferred sterilization method for medical devices that are resistant to heat and humidity. However, if wet packs occur in the sterilized devices, the sterilization is considered to be unqualified and a repackaging and re-sterilization is required, increasing in workload and cost of the central sterile supply department (CSSD), reducing work efficiency, consuming excessive manpower, and posing an invisible risk on infection^[1]. LI et al.^[2] detected 122,000 sterilized packs and found that the wet pack rate reached 1.30%. WANG^[3] tested 53,615 packs with 1 031 pot times of sterilization and found that the wet pack rate was 1.01%. Since the 1950s, sterilization of wet packs has been the key link of quality and control in CSSD^[4]. Nevertheless, high-quality studies on sensitive indexes for managing wet packs are unavailable in China. This study in-

tends to take the “structure, process, and outcome” model proposed by Avedis Donabedian as the theoretical framework, and apply the methods of literature review, expert consultation, and group discussion to develop a scientific and practical quality-sensitive index (QSI) system for managing wet packs after steam sterilization, so as to standardize wet pack management, reduce the incidence of wet pack, and provide reference for the quality evaluation of specialized nursing care in CSSD.

1 Methods

1.1 Initial exploration of QSI system

1.1.1 Establishment of a research group

The research group consists of ten members in Shanghai Pulmonary Hospital, Shanghai, China, including one head nurse, one infection control specialist in the Department of Prevention and Control of Nosocomial Infection, and eight nurse special-

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ists. Among them, one has a primary title and nine have middle titles; one has a master's degree and nine have bachelor's degrees. Their tasks include reviewing literature, compiling questionnaires, selecting experts, distributing and collecting questionnaires, sorting out expert opinions, analyzing statistical data, and controlling quality during the process.

1.1.2 Literature review strategy

The databases used in this study include Chinese biomedical literature service system (SinoMed), China National Knowledge Infrastructure (CNKI), Wanfang Database, China Academic Journals Full-text Database (CJFD), UpToDate, Cochrane Library, Joanna Briggs Institute Evidence-Based Practice database (JBI EBP Database), Ovid, PubMed, EBSCO, Medline, Embase, and Web of Science. We carefully read all papers collected and rigorously analyzed them.

The keywords searched in Chinese included wet pack / wet load / sterilization / nursing quality / nursing management, index / index system / evaluation index, quality evaluation / quality control, and Delphi method / Delphi / expert consultation method.. The keywords in English included wet load / wet pack / failed sterilization, nursing quality / nursing management, index / indicators, evaluation / quality evaluation / quality control, and Delphi technique / Delphi method. The retrieval period was from the establishment of the database to January 2024.

1.1.3 Literature selection and quality evaluation

Criteria for inclusion of literature include (1) The study objects were wet packs after steam sterilization and (2) The literature type was a guideline, evidence summary, expert consensus, systematic review, or primary study. The exclusion criteria are (1) Full text is unavailable and (2) Duplicate publications. The quality of the literature was evaluated independently by two postgraduates receiving evidence-based training. They referred to the inclusion and exclusion criteria of the literature. Differences were resolved through discussion, and the third researcher engaged in discussion if necessary.

1.2 Screening of QSIs

1.2.1 Selection of experts

Criteria for inclusion of experts include (1) With more than 10 years' of work experience related to CSSD; (2) Bachelor's degree or above; (3) Voluntary participation in the study. A total of 15 nursing experts engaged in the field of disinfection supply, aged 38 to 54 years old were selected. Their working years ranged from 17 to 36 years; 5 of them are masters and 10 are bachelors; 2 have senior titles, 10 have associate senior titles, and 3 have middle titles; and 2 are tutors of postgraduates.

1.2.2 Implementation of expert consultation

We consulted experts by email and WeChat. The questionnaire consists of the main body and annex to the survey of experts. The main body includes a description, the importance of index items, the rationality of the calculation formula, the operability of data collection for scoring, and an opinion column for modification or improvement. The researchers sorted out and summarized the opinions and data collected in time, discussed and revised items, and carried out the next round of expert consultation. Two consultations were conducted in this study.

1.3 Statistical analysis

All data were collected and verified by two persons and recorded in Excel 2017. SPSS Statistics 22.0 was used for statistical analysis.

2 Results

2.1 Results of literature search and quality evaluation

A total of 1136 papers were retrieved. We removed duplicate and unqualified papers and supplemented new papers by snowball reading titles, abstracts, and full texts. Finally, 18 papers related to the quality of wet pack management, 5 in Chinese and 13 in English were included. The research team integrated the literature evidence and summarized the content, calculation formula, and collection method of each index. Then, ten nurses with more than five years of work experience in CSSD conducted face-to-face discussions three times. The manuscript of the QSI system was formed, where 3 first-, 9 second-, and 29 third-level indexes were included.

2.2 Motivation, authority, and opinion coordination of experts

The questionnaire response rate of the two rounds of expert consultation was both 100%, indicating that the experts were highly willing to participate in this study. The expert authority coefficient (Cr) were 0.905 and 0.925, respectively, revealing that the experts were highly authoritative. The Kendall's coefficient of concordance (Kendall's W) is

high, as shown in Table 1.

2.3 Contents of QSI system

A total of 12 opinions were received in Round 1. The team discussed and made revisions as follows. The results of Round 2 expert consultation on third-level indexes are shown in Table 2. After two rounds of consultation, the QSI system was finally formed, including 3 first-, 9 second-, and 22 third-level indexes, as shown in Table 3.

Table 1 Coordination degree of expert opinions

Rounds	Item	Importance of Index			Rationality of Calculation Formula			Operability of Evaluation Method		
		<i>W</i>	χ^2	<i>P</i>	<i>W</i>	χ^2	<i>P</i> value	<i>W</i>	χ^2	<i>P</i>
Round 1	29	0.159	66.724	<0.001	0.128	53.757	<0.001	0.195	81.828	<0.001
Round 2	22	0.161	50.754	<0.001	0.138	43.389	<0.001	0.126	53.549	<0.001

Table 2 Results of Round 2 of expert consultation on third-level indexes

Index Title	Importance of Index		Rationality of Calculation Formula		Operability of Collection Method	
	$(\bar{x}\pm s)$	CV	$(\bar{x}\pm s)$	CV	$(\bar{x}\pm s)$	CV
	Improvement rate of wet pack management rules and regulations	5.00	0	4.533±0.516	0.114	4.667±0.488
Proportion of nurse specialists in CSSD	4.800±0.414	0.086	5	0	4.867±0.352	0.072
Pass rate of wet pack management training	4.733±0.458	0.097	4.733±0.594	0.126	4.800±0.561	0.117
Pass rate of monitoring drain valve	5.00	0	4.467±0.640	0.143	4.600±0.507	0.110
Pass rate of monitoring condenser	5.00	0	4.600±0.507	0.110	4.800±0.414	0.086
Pass rate of monitoring vacuum in vacuum pump	5.00	0	4.533±0.516	0.114	4.733±0.458	0.096
Pass rate of monitoring leakage of components	5.00	0	4.733±0.457	0.096	4.667±0.488	0.105
Pass rate of monitoring sterilizer drainage system	5.00	0	4.800±0.414	0.086	4.733±0.458	0.097
Pass rate of equipment drying	5.00	0	4.600±0.632	0.137	4.800±0.414	0.086
Pass rate of equipment drying	5.00	0	4.800±0.414	0.086	4.733±0.458	0.097
Pass rate of equipment pack weight	4.867±0.352	0.072	4.667±0.617	0.132	4.533±0.516	0.114
Pass rate of equipment pack volume	4.933±0.258	0.052	4.733±0.457	0.097	4.800±0.414	0.086
Pass rate of dressing loading	4.800±0.414	0.086	4.667±0.617	0.132	4.733±0.458	0.097
Pass rate of equipment loading	4.867±0.352	0.072	4.667±0.617	0.132	4.733±0.458	0.097
Pass rate of placing mixed sterilization packs	5.00	0	4.600±0.632	0.137	4.533±0.516	0.114
Case-time of sterilization procedure errors times	5.00	0	4.467±0.640	0.143	4.533±0.516	0.114
Drying time in the sterilization chamber	5.00	0	4.334±0.716	0.165	4.267±0.594	0.139
Microclimate compliance in the offloading area	5.00	0	4.533±0.516	0.114	4.533±0.516	0.114
Time for sterilized packs to cool to room temperature ≥30 min	5.00	0	4.467±0.640	0.143	4.333±0.617	0.039
Pass rate of monitoring BD	5.00	0	5	0	4.800±0.561	0.117
Pass rate of sterilization monitoring results	5.00	0	5	0	4.933±0.258	0.052
Wet pack incidence	5.00	0	4.800±0.414	0.086	4.733±0.458	0.097

Table 3 QSI system for managing wet packs after steam sterilization

First-level index	Second-level index	Third-level index			
		Importance of Index Title	Rationality of Calculation Formula	Operability of Collection Method	
1. Structure indexes	1. 1 Organizational Management	1. 1. 1 Improvement rate of wet pack management rules and regulations	Number of wet pack management rules and regulations / Number of management systems established by departments $\times 100\%$	By collecting archival records	
		1. 2. 1 Proportion of nurse specialists in CSSD	Total number of CSSD nurse specialists/ department nurses $\times 100\%$	By collecting archival records	
	1. 2 Human Resources	1. 2. 2 Pass rate of wet pack management training	Number of qualified wet pack management training/Total number of annual wet pack management training $\times 100\%$	By collecting archival records	
		1. 3. 1 Pass rate of monitoring drain valve	1. 3. 1 Pass rate of monitoring drain valve	Qualified number of drain valve performance monitoring/Total number of drain valve performance monitoring in the working area this month $\times 100\%$	By collecting archival records
	1. 3. 2 Pass rate of monitoring condenser		1. 3. 2 Pass rate of monitoring condenser	Condenser performance monitoring qualified number/The total number of condenser performance monitoring in the working area this month $\times 100\%$	By collecting archival records
		1. 3. 3 Pass rate of monitoring vacuum in vacuum pump	1. 3. 3 Pass rate of monitoring vacuum in vacuum pump	Qualified number of vacuum pump performance monitoring/The total number of vacuum pump performance monitoring in the working area this month $\times 100\%$	By collecting archival records
	1. 3 Sterilizer		1. 3. 4 Pass rate of monitoring leakage of components (Including safety valve, evacuation valve, drain valve connection, platinum thermal resistance, copper pipe)	1. 3. 4 Pass rate of monitoring leakage of components (Including safety valve, evacuation valve, drain valve connection, platinum thermal resistance, copper pipe)	Qualified number of leakage accessories performance monitoring/Total number of leakage accessories performance monitoring in the work area this month $\times 100\%$
		1. 3. 5 Pass rate of monitoring sterilizer drainage system		Qualified number of sterilizer drainage system performance monitoring/Total number of sterilizer drainage system performance monitoring in the work area this month $\times 100\%$	By collecting archival records
		1. 4 Steam Quality	1. 4. 1 Pass rate of steam dryness	Qualified number of steam dryness monitoring/Total number of steam monitoring this month $\times 100\%$	By collecting archival records
	2. Process indexes	2. 1 Packaging	2. 1. 2 Pass rate of equipment drying	Number of qualified drying packages/Total number of reused equipment packages processed this month $\times 100\%$	By site observation
2. 1. 3 Pass rate of equipment pack weight			Number of qualified packages of equipment packaging weight checked/the total number of reused equipment packages processed this month $\times 100\%$	By site observation	
2. 1. 4 Pass rate of equipment pack volume			2. 1. 4 Pass rate of equipment pack volume	The number of qualified packages of the checked packaging volume/the total number of reused equipment packages processed in this month $\times 100\%$	By site observation

continued

First-level index	Second-level index	Third-level index			
		Importance of Index Title	Rationality of Calculation Formula	Operability of Collection Method	
3. Outcome indexes	2. 2 Loading	2. 2. 1 Pass rate of dressing loading	The number of qualified dressing packages/the total number of dressing packages this month $\times 100\%$	By site observation	
		2. 2. 2 Pass rate of equipment loading	Number of qualified equipment loading packages checked/Total number of reused equipment packages processed this month $\times 100\%$	By site observation	
		2. 2. 3 Pass rate of placing mixed sterilization packs	The number of qualified mixed sterilization bags checked/the total number of mixed sterilization bags this month $\times 100\%$	By site observation	
		2. 3 Sterilization	2. 3. 1 Case-time of sterilization procedure errors	Fill in the report according to the actual occurrence cases	By site observation
			2. 3. 2 Drying time in the sterilization chamber	Drying time shall comply with the requirements of the manufacturer's manual	By site observation
		2. 4 Environment	2. 4. 1 Microclimate compliance in the offloading area	Monitoring (temperature, humidity) coincidence number $/2 \times 100\%$	By collecting archival records
	2. 4. 2 Time for sterilized packs to cool to room temperature ≥ 30 min		Fill in the report according to the actual occurrence cases	By collecting archival records	
	3. 1 Sterilization Quality	3. 1. 1 Pass rate of monitoring BD	BD monitoring qualified quantity/BD monitoring quantity of this month $\times 100\%$	By collecting archival records	
		3. 1. 2 Pass rate of sterilization monitoring results	The number of qualified sterilized packs for sterilization monitoring/the total number of sterilized packs this month $\times 100\%$	By collecting archival records	
		3. 1. 4 Wet packet incidence	Number of sterilized packets with wet packs/Total number of sterilized packets this month $\times 100\%$	By collecting archival records	

2.3.1 Revision of nine items

15 experts suggested that “equipment management” and “water security”, the second-level indexes, should be changed to “sterilizer” and “steam quality” and “environment” should be added to comply with the operating process of steam sterilization; the order of third-level indexes should be rearranged into “Improvement rate of wet pack management rules and regulations”, “Pass rate of monitoring drain valve”, “Pass rate of monitoring condenser”, “Pass rate of monitoring vacuum in vacuum pump”, “Pass rate of monitoring leakage of components (Including safety valve, evacuation valve, drain valve connection, platinum thermal resistance, copper pipe)”, “Pass rate of monitoring sterilizer drainage system” and “Pass rate of steam dryness”.

2.3.2 Removal of two items

The third-level index “Disinfection operator certification rate” should be removed because staff who conduct steam sterilization must hold a certificate. The index of “unqualified rate of device placement” should be deleted because device placement is difficult to identify accurately.

2.3.3 Supplementation of one item

The index of “Pass rate of wet pack management training” should be added in view of the importance of continuing education and training.

3 Discussion

3.1 Scientificity and reliability of QSI system

In this study, the “structure, process, and outcome” model was applied as the theoretical framework. The QSIs initially formulated by reviewing

literature are highly scientific. Delphi expert consultation method was adopted to verify and revise the QSI system. Two rounds of expert consultation were carried out. The questionnaire response rate and valid rate were both 100%, revealing experts' positive participation. A total of twelve experts put forward twelve opinions in Round 1, indicating that they are familiar with the study details. After Round 2, experts' opinions on all indexes were consistent; Kendall's W reached 0.159 and 0.161, respectively, with statistically significant differences, suggesting high coordination in all indexes; the coefficient of variation ranged from 0.00 to 0.097 (both <0.25 in Rounds 1 and 2)^[5], demonstrating that the QSI system established in this study is scientific and reliable.

3.2 Content analysis of QSI system

Several studies^[6-8] have explored causes of wet packs, of which man-made faults account for 85%, issues related to steam account for 60%, and factors, such as malfunctioned pressure sensors, blocked drainage networks or incomplete door washers during sterilization, account for 30%. Thus, in this study, the structural indexes include four items, organizational management, human resources, sterilizers, and steam quality. Improvement rate of wet pack management rules and regulations, Pass rate of wet pack management training, Pass rate of monitoring sterilizer drainage system, and Pass rate of steam dryness fully reflect the experts' attention to the management, training of wet pack, and the monitoring and maintenance of sterilizer. The four process indexes of packaging, loading, sterilization and environment are closely related to the operation of employees. The monitoring quality is ensured and the clinical operation is accurate under the control of indexes such as Pass rate of equipment drying, Pass rate of equipment pack weight, Pass rate of equipment pack volume, Pass rate of dressing loading, Pass rate of equipment loading, Pass rate of placing mixed sterilization packs, Case-time of sterilization procedure errors, Drying time in the sterilization chamber, Microclimate compliance in the offloading area, and Time for sterilized packs to cool to room temperature ≥ 30 min. The outcome indexes of ster-

ilization quality is directly associated with instrument safety, nosocomial infection control, patient welfare, and effective evaluation of service quality in CSSD.

4 Conclusion

In this study, the QSI system constructed by literature review and expert consultation shows excellent specificity and operability, providing a reference for evaluating the quality of wet pack management and continuously improving the management quality. However, the sample size shall be expanded and the evaluation process shall be tracked to further verify the sensitivity of the indexes and improve the QSI system.

Author contributions

MAO Yanjun was the guarantor and the person who designed the study; FANG Xuee, ZHANG Guifen, ZHU Qiuping and CAI Yanni participated in the acquisition, analysis, and interpretation of the data, and drafted the manuscript; FANG Xuee revised the article critically for important intellectual content.

Conflict-of-interest statement

There are no conflicts of interest to declare.

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