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Application of Hazard Vulnerability Analysis Based on Kaiser Model in Neonatal Breast Milk Management

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Abstract: *Objective:* To analyze the existing risks in breast milk management at the neonatal department and provide corresponding countermeasures. *Methods:* 22 risk events were identified in 7 risk links in the process of bottle-feeding of breast milk. Hazard Vulnerability Analysis based on the Kaiser model was applied to investigate and evaluate the risk events. *Results:* High-risk events include breast milk quality inspection, hand hygiene during collection, disinfection of collectors, cold chain management, hand hygiene during the reception, breast milk closed-loop management, and post-collection disposal. Root cause analysis of high-risk events was conducted and breast milk management strategies outside the hospital and within the neonatal department were proposed. *Conclusion:* Hazard Vulnerability Analysis based on the Kaiser model can identify and assess neonatal breast milk management risks effectively, which helps improve the management of neonatal breast milk. It is conducive to the safe development and promotion of bottle feeding of breast milk for neonates, ensuring the quality of medical services and the safety of children.

Keywords: Breast milk management; The Kaiser model; Hazard vulnerability analysis risk assessment

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1. Introduction

Breast milk is the best source of nutrients for newborns [1]. Organizations such as the World Health Organization (WHO) and the United Nations International Children's Emergency Fund (UNICEF) advocate breastfeeding [2-4]. Breast milk is also the primary choice of nutritional support for children hospitalized in neonatology departments [5]. However, most domestic neonatology departments adopt a closed management model and carry out bottle feeding of breast milk when the mother and baby are separated. Breast milk management is crucial. The operation links of breast milk collection, transportation, reception, storage, processing, and feeding can all affect breast milk's nutritional value and the safety of feeding [6-12]. Therefore, breast milk management for hospitalized newborns comes with many challenges.

Hazard Vulnerability Analysis (HVA) serves as a valuable tool in medical institutions by identifying

potential emergencies. It proactively assesses risks within medical work, pinpointing vulnerabilities and weak links. Through a systematic risk assessment and ranking process, HVA helps clarify risk management priorities. Subsequently, it enables the formulation of strategic countermeasures to enhance the emergency response capabilities of medical institutions [13–16]. As an evaluation tool that can quantify risks, the Kaiser model has been widely used in the HVA of many medical institutions [14–18]. Therefore, in this study, the HVA risk assessment method based on the Kaiser model was applied to evaluate risk events of breast milk management in the neonatology department. Countermeasures are then proposed for the weakest links in breast milk management to ensure the quality and safety of breast milk feeding.

2. Materials and methods

2.1. General information

The Neonatology Department of the 1st Affiliated Hospital of Wenzhou Medical University is a regional critical neonatal treatment center with 27 nursing staff. More than 1,500 newborns are treated in this department annually. Additionally, the collective duration of breastfeeding for all infants in the department amounts to 2,000 days annually. The age of the nursing staff ranges from 25 to 39 years (mean: 31.07 ± 3.931 years), with working experience ranging from 3 to 17 years (mean: 8.67 ± 4.16 years).

2.2. Research methods

2.2.1. Establishment of the research team

The Nursing Department established a neonatal HVA research team that comprised 10 members: 2 deputy senior professional nurses, 4 supervisor nurses, and 4 nurse practitioners. All team members had a bachelor's degree or above and had worked for 7 to 26 years. The members were divided into a strategy development team and an implementation team. (1) The strategy development team consisted of 4 members: 2 deputy senior professional nurses and 2 nurses in charge; among these nurses, there was 1 general surgery head nurse, 1 deputy head nurse, 1 teaching secretary, and 1 specialist nurse, who all have undergone risk assessment tool-related training. This team was responsible for building and analyzing risk event systems and guiding the development of strategies for breast milk management in the Neonatal Departments. (2) The strategy implementation team consisted of 6 members: 2 supervisory nurses and 4 nurse practitioners. This team was responsible for data and information collection, nurse training, strategy implementation, and feedback.

2.2.2. Risk event identification

The brainstorming method was employed to analyze each link, taking into account relevant literature and incorporating the practical clinical context of breast milk management in the neonatology department. This comprehensive approach covered the entire process, from the collection of breast milk to clinical feeding. All factors influencing the safety of bottle feeding with breast milk were identified and listed. A total of 22 risk events were identified in 7 major risk links, including breast milk storage outside the hospital, breast milk transportation, breast milk reception, breast milk storage in the ward, breast milk processing in the ward, and bottle feeding in the ward. A risk event system for breast milk management was then established for the Neonatal Department (**Table 1**).

Table 1. Neonatology Department's breast milk management risk and vulnerability analysis system

Risk link	Risk event
A. Breast milk collection	A1. Hand hygiene during collection
	A2. Disinfection of collection equipment
	A3. Purchase of breast milk storage bags
	A4. Identification after collection
	A5. Post-collection disposal
B. Breast milk storage outside the hospital	B1. Stored materials
	B2. Cleaning and disinfection of containers
	B3. Requirements for placement in the refrigerator
C. Breast milk transportation	C1. Transportation cold chain management
	C2. Shipping time
D. Breast milk reception	D1. Hand hygiene during reception
	D2. Breast milk verification and registration
	D3. Breast milk quality inspection
	D4. Breast milk closed-loop management
F. Breast milk handling in the ward	F1. Breast milk delivery
	F2. Thawing of breast milk
	F3. Breast milk pasteurization
	F4. Breast milk heating
G. Breastfeeding in the ward	G1. Feeding check
	G2. Disposal of remaining breast milk

2.2.3. Risk event assessment

A breast milk management risk list was made based on the Kaiser model, and a questionnaire was created to evaluate 22 risk events. Each risk event was evaluated based on two aspects: likelihood and severity. Likelihood was evaluated based on the probability of occurrence and the severity was evaluated based on intensity and readiness. Intensity encompassed three aspects: (2) personal injury, (3) property damage, and (4) service impact. Readiness also encompassed three aspects: (1) emergency preparedness, (6) internal response, and (7) external support. Among them, there were 4 levels of evaluation indicators for items 1 to 4, namely "none/not applicable," "low," "medium," and "high," with corresponding scores of 0, 1, 2, and 3; there were also 4 levels of evaluation indicators for items 5 to 7, which were "unknown," "high," "medium," and "low or none," and the corresponding scores were 0, 1, 2, and 3 [15-19].

2.2.4. Risk value calculation

The likelihood and severity of risk events were calculated based on the Kaiser model, and then the hazard-specific relative risk value for each risk event was calculated [15-18].

$$Likelihood = Probabilityof\ occurrence$$

$$Intensity = (personnel\ injury + property\ loss + service\ impact)/9$$

$$Readiness = (emergency\ preparedness + internal\ response + external\ support)/9$$

$$Risk = likelihood \times (intensity + readiness)$$

The breast milk management risk events in the neonatal department were ranked based on the hazard risk values of all risk event indicators.

2.2.5. Data collection

A breast milk management hazard risk assessment questionnaire was created using Questionnaire Star, and the details of the Kaiser model scoring standards were described in the questionnaire. The head nurse shared the questionnaire on the WeChat group of the Neonatal Department. A total of 27 questionnaires were received, and none of them were invalid.

2.2.6. Statistical methods

The data was summarized, and SPSS25.0 statistical software was used for statistical analysis. The count data were described as frequencies and percentages. Measurement data that conform to a normal distribution and were expressed as mean ± standard deviation [8,9].

3. Results

3.1. Risk value of risk events

The risk value of each risk event in breast milk management was evaluated and ranked. The top 10 risk events were breast milk quality inspection (D3), hand hygiene during collection (A1), collector disinfection (A2), cold chain management (C1), hand hygiene during reception (D1), breast milk closed-loop management (D4), post-collection disposal (A5), breast milk verification and registration (D2), environmental requirements (E1), and placement in the refrigerator (B3). Further details are illustrated in **Table 2**.

Table 2. Risk assessment results of HVA indicators for breast milk management in the Neonatology Department

Risk event	Possibility	Severity	Severity		Risk value	Risk rank	Level of risk
			Intensity	Readiness			
A1. Hand hygiene during collection	0.7436	0.5000	0.4359	0.5641	0.3718	2	High risk
A2. Disinfection of collectors	0.7436	0.4615	0.5128	0.4102	0.3432	3	High risk
A3. Purchase of breast milk storage bags	0.5641	0.3590	0.3846	0.3333	0.2025	15	Low risk
A4. Identification after collection	0.4359	0.3974	0.3590	0.4359	0.1732	19	Low risk
A5. Post-collection disposal	0.6410	0.4487	0.4872	0.4103	0.2876	7	High risk
B1. Storage	0.5641	0.3462	0.3333	0.3590	0.1953	16	Low risk
B2. Cleaning and disinfection of containers	0.4872	0.3718	0.3590	0.3846	0.1811	18	Low risk
B3. Placement in the refrigerator	0.6410	0.3974	0.3846	0.4103	0.2548	10	Medium risk
C1. Cold chain management	0.6410	0.5128	0.5128	0.5128	0.3287	4	High risk
C2. Shipping time	0.5385	0.4615	0.4359	0.4872	0.2485	12	Medium risk
D1. Hand hygiene during reception	0.6410	0.5128	0.4359	0.5897	0.3287	5	High risk
D2. Breast milk verification and registration	0.7179	0.3974	0.3590	0.4359	0.2853	8	Medium risk
D3. Breast milk quality inspection	0.8205	0.4615	0.5385	0.3846	0.3787	1	High risk
D4. Breast milk closed-loop management	0.6923	0.4487	0.4615	0.4359	0.3106	6	High risk
E1. Environmental requirements	0.5385	0.5128	0.4359	0.5897	0.2761	9	Medium risk
E2. Refrigerator management	0.5128	0.4872	0.4102	0.5641	0.2498	11	Medium risk

Table 2 (Continue)

Risk event	Possibility	Severity	Severity		Risk value	Risk rank	Level of risk
			Intensity	Readiness			
F1. Breast milk delivery	0.4359	0.3718	0.3333	0.4103	0.1621	22	Low risk
F2. Thawing of breast milk	0.5385	0.4103	0.3846	0.4359	0.2209	14	Low risk
F3. Breast milk pasteurization	0.6154	0.3653	0.3846	0.3459	0.2248	13	Medium risk
F4. Breast milk heating	0.5385	0.3462	0.3590	0.3333	0.1864	17	Low risk
G1. Feeding inspection	0.4872	0.3333	0.2821	0.3846	0.1624	20	Low risk
G2. Disposal of remaining breast milk	0.3846	0.2692	0.1538	0.3846	0.1035	22	Low risk

3.2. Risk distribution results

The risk level was determined by calculating the likelihood and severity of potential risk events. The top 10 rankings of these calculated values were used as the criteria for differentiation. High-risk areas were identified as those ranking in the top 10 for both likelihood and severity. Medium-risk areas were designated as those ranking in the top 10 for either likelihood or severity, but not both. Low-risk areas were defined as those not ranking in the top 10 for either likelihood or severity. High-risk areas include breast milk quality inspection (D3), hand hygiene during collection (A1), disinfection of collectors (A2), cold chain management (C1), hand hygiene upon reception (D2), breast milk closed-loop management (D4), post-collection disposal (A5). Medium-risk areas include breast milk verification and registration (D2), environmental requirements (E1), Refrigerator placement requirements (B3), refrigerator management (E2), transport time (C2), breast milk pasteurization (F3); the remaining risk events are all low-risk.

4. Discussion

Many studies have been carried out at home and abroad on encouraging breastfeeding. However, much of the research emphasizes the management of breast milk in the hospital without considering the management outside the hospital. HVA under the Kaiser model has been carried out by medical institutions and has shown good results. However, there have been no domestic reports on HVA of breast milk management, especially out-of-hospital breast milk management. HVA based on the Kaiser model is a valuable tool in neonatal breast milk management. It can identify potential risk events and weak links in neonatal breast milk management, standardize breast milk operations outside the hospital, and promote the development of standardized management inside and outside the Neonatal Department.

The results of this study showed that high-risk events were primarily concentrated in the out-of-hospital management of breast milk and the reception of breast milk. This highlights deficiencies in personnel training for breast milk management in the neonatal department, health education, supervision and feedback mechanisms in out-of-hospital management, breast milk reception and verification processes, and closed-loop breast milk management. Hence, despite the routine implementation of breast milk management, out-of-hospital breast milk management and the reception of breast milk are identified as the primary risk points based on relevant risk values. Consequently, key enhancements and improvements should be focused on these specific areas. Therefore, addressing risk events such as poor hand hygiene during collection, incorrect disinfection methods of collectors, poor cold chain management, and improper post-collection disposal is crucial. To achieve this, there should be a focus on enhancing health education, including training for nursing staff and educating

family members. Additionally, we propose implementing a supervision and feedback mechanism for breast milk processing outside the hospital to ensure its safety. Furthermore, a well-defined workflow for breast milk reception should be developed to address risk events like poor breast milk quality inspection and hand hygiene during the reception process. Standardizing the management of nursing staff involved in receiving breast milk is essential. To achieve these objectives, key control points should be identified through hazard analysis and specific control measures should be established for each key point. This systematic approach aims to enhance work efficiency, ensure feeding safety, and establish a comprehensive strategy for out-of-hospital breast milk management and breast milk reception in the Neonatal Department.

4.1. Health education

4.1.1. Nursing staff training

Health education plays an important role in breastfeeding. The "Evidence-Based Guidelines for Breastfeeding of Hospitalized Newborns" constructed by the School of Nursing of Fudan University in 2017 provides a basis for breastfeeding standards. Many scholars have also pointed out the importance of systematic breastfeeding training for nurses [6-11,20]. Besides, the prerequisite for standardizing breast milk management outside the hospital is effective breastfeeding education, which also highlights the importance of the level of knowledge of the educators. Our research team trained the nurses through teaching theories, online and offline assessments, and case studies. The theories were taught based on the "Evidence-Based Guidelines for Breastfeeding for Hospitalized Neonates," which covered breastfeeding advocacy, measures to promote breastfeeding, breast milk screening, breast milk collection, breast milk storage at home, and breast milk transportation; breast milk reception, ward breast milk storage, breast milk processing and feeding in the ward; and other related knowledge. The nursing staff were also required to master the key points of breast milk quality management. Furthermore, the content of breastfeeding education for nursing staff was standardized, which improved the quality of education. (2) Online and offline assessment: The exam papers were generated using Questionnaire Star. The nursing staff were required to score at least 90 points to pass the exam. Those who fail the exam will be questioned on the spot by the trainer after a period of self-study. Mock tests were also given from time to time based on real cases and all staff were required to pass the tests. Case studies: Retrospective studies of breast milk-related adverse events were carried out, and discussions were held to identify the high-risk links in breast milk management in and out of the hospital. The nursing staff were encouraged to provide ideas for effective health education to avoid risks and reduce the occurrence of breast milk-related adverse events.

4.1.2. Propaganda of breastfeeding knowledge to newborn family members

The families of newborns were provided with a multi-faceted, systematic, and standardized breastfeeding education. (1) Development of education content: The education content was established based on the "Evidence-based Guidelines for Breastfeeding of Hospitalized Neonates," which covered breastfeeding advocacy, breastfeeding taboos, the timing and frequency of breast milk collection, preparation before collection, hand hygiene, breast pump selection, labeling, sterilization of collectors, home storage, cold chain management, etc. (2) Diversified publicity and education methods: The "Information on Breastfeeding of Hospitalized Newborns" was distributed. In addition to oral publicity, posters based on the "Evidence-based Guidelines for Bottle Feeding of Breast Milk for Hospitalized Newborns" were also produced and distributed. Electronic education manuals and videos were created and distributed daily to the WeChat group consisting of families of hospitalized newborns. Online education took place through Internet+ Q&A, online classes, webcasts, and other online platforms. Personalized education programs were developed to guide the families of newborns in performing correct breastfeeding practices outside the hospital.

4.2. Feedback on breast milk management and supervision outside the hospital

Supervision of the breast milk collection process is essential to ensure the quality and safety of breast milk [5-6,9,20]. The "Breast Milk Management Self-Checklist" was designed based on the "Evidence-Based Guidelines for Breastfeeding of Hospitalized Neonates," requiring family members to conduct self-evaluation of breast milk management after completing breastfeeding-related training. The nursing staff could participate in breast milk management only after passing the assessment. When receiving breast milk for the first time, the nursing staff conducted a one-to-one assessment of the knowledge of bottle-feeding of breast milk on the family members who were delivering the breast milk. Their "Breast Milk Management Self-Check Formed" were checked and each link breast milk handling outside the hospital was evaluated. Mistakes in the handling and feeding of breast milk were rectified upon the evaluation.

4.3. Breast milk reception workflow

A "Neonatology Department Breast Milk Receipt Checklist" was established. The verification process involved maintaining good hand hygiene during breast milk collection, following operational procedures for handling breast milk outside the hospital, ensuring breast milk quality and good cold chain management, and accurately labeling the breast milk. Once the verification was complete, both nursing staff and family members signed off. The nursing staff adhered strictly to hand hygiene protocols while receiving the breast milk. They discarded the outer packaging and cleaned and disinfected the surface of the breast milk collection bag using quaternary ammonium salt disposable disinfection wipes. The breast milk was then placed into a disposable storage bag and stored in a freezer.

Any breast milk that did not meet the quality standards underwent rejection, and any errors were promptly corrected to ensure the quality and safety of the breast milk.

4.4. Breast milk information closed-loop management process

Effective management and information support are essential for breastfeeding in hospitals. The closed-loop management of breastfeeding in the Neonatology Department should be digitalized to allow the monitoring of the entire breastfeeding process to ensure the safety of breastfeeding and improve nursing efficiency [5,21-24]. A breast milk information closed-loop management system was developed (see Figure 1), marking a departure from traditional manual operations and recording methods in the breastfeeding process. Information technology is employed to achieve monitoring and traceability at every stage, allowing for the comprehensive tracking of the entire process. The dynamic tracking of breast milk status contributes to standardized breastfeeding management.

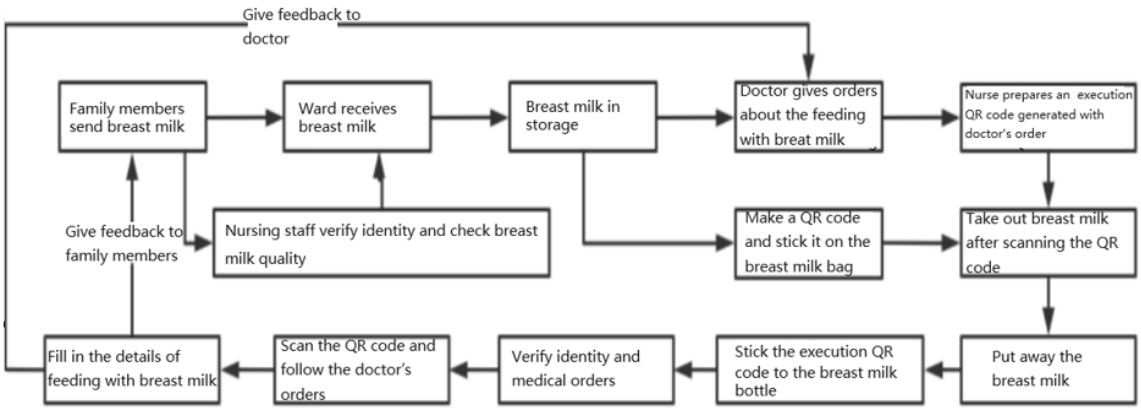

Figure 1. Breastfeeding closed-loop management process

4.4.1. Breast milk reception

The breast milk reception process involved screening the patient's family and child's personal information, examining the "Breast Milk Management Self-Check Form," assessing the quality of breast milk, verifying the breast milk label, and documenting details such as the neonatal ward, bed number, name, medical record number, type of breast milk, time of breast milk collection, and the quantity of breast milk collected. Qualified breast milk was then officially received and recorded.

4.4.2. Breast milk storage

A QR code containing information about the breast milk was generated and pasted on the corresponding bag. The barcode included details such as ward, bed number, medical record number, name, breast milk type, collection time, storage time, personnel responsible for registration, and milk volume. The breast milk was stored in the refrigerator, and the information management system encompassed the breast milk in the ward. This comprehensive approach allowed for the tracing of each breast milk bag's status throughout the entire hospital process.

4.4.3. Breastfeeding instructions

Doctors provided instructions on breastfeeding, and the nurse entered the orders, subsequently generating and printing the QR code for breastfeeding execution.

4.4.4. Breast milk delivery

Breast milk was scanned and taken out of the storage according to the doctor's orders. If the doctor did not prescribe feeding with breast milk, the breast milk could not be scanned or taken out from storage.

4.4.5. Breast milk processing

The breast milk was thawed, pasteurized, and fed according to the doctor's instructions. A QR code was also generated for the bottle feeding of breast milk.

4.4.6. Breastfeeding

The nurse executed the breastfeeding orders, checked the volume of milk upon identity verification, and fed the breast milk according to the instructions in the QR code. The newborn's feeding situation was also recorded.

4.4.7. Feedback

The data platform automatically provided feedback on the breastfeeding status to the attending physician's electronic medical record system. The doctor then promptly communicated the breastfeeding status to the family members and collaborated with them to develop a feeding plan.

5. Summary

This study retrospectively analyzed breastfeeding data in the department, utilizing the Hazard Vulnerability Analysis risk assessment method based on the Kaiser model. Risks in each stage of breast milk management were evaluated, and the risk values of the risk events were ranked. A regional distribution analysis was carried out to identify weak links. Upon the analyses, strategies for out-of-hospital breast milk management and neonatal department breast milk reception management were formulated. These strategies effectively improved breast milk management and the prevention of adverse events. As a result, the safety of breastfeeding in the

Neonatology Departments was ensured and the quality of medical services was improved.

Disclosure statement

The authors declare no conflict of interest.

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