

Development and Reliability-Validity Testing of the Patient Safety Care Competence Questionnaire for Health Care Assistant (HCA)

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Abstract

Objective

To develop the Patient Safety Care Competence Questionnaire for Health care assistant (HCA) and test its reliability and validity, thereby providing a standardized assessment tool for evaluating their patient safety care competence.

Methods

Based on the Iceberg Model, the questionnaire was constructed using literature review, semi-structured interviews, the Delphi method, correlation coefficient analysis, Cronbach's α coefficient, and exploratory factor analysis. A cluster sampling method was adopted to recruit 502 Health care assistant (HCA) for a survey to verify the questionnaire's reliability and validity.

Results

Exploratory factor analysis extracted 5 common factors (Knowledge and Skills, Motivation, Self-concept, Social Role, Personal Traits), with a cumulative variance contribution rate of 72.200%. The Cronbach's α coefficient of the total scale was 0.921, and the α coefficients of each dimension ranged from 0.824 to 0.928. The item-level content validity index (I-CVI) was 0.889–1.000, and the scale-level content validity index (S-CVI) was 0.938.

Conclusion

The Patient Safety Care Competence Questionnaire for Health care assistant (HCA) developed based on the Iceberg Model has good reliability and validity, and can be used to evaluate the patient safety care competence of HCA.

1. Introduction

With the increasingly severe aging of China's population, the rising incidence of chronic diseases, and the popularization of the "421" family structure^[1], the demand for comprehensive and multi-level care has grown^[2], leading to an annual increase in the demand for health care assistant (HCA) ^[3]. Health care assistant (HCA) refer to non-health technical personnel who provide accompanying care and daily living nursing services to patients in medical institutions^[4]. Their main responsibilities are to assist nurses in non-technical patient care, meet patients' basic living needs, and protect patients' safety. As an important supplementary human resource in the medical service industry, their core competence is directly related to patients' safety and quality of life^[5]. Currently, research on competence in the medical

and health field mainly focuses on doctors, nurses, and other groups, with few studies reporting on the patient safety care competence of HCA^[6]. Therefore, based on the characteristics of HCA' patient safety care competence and the Iceberg Model, this study developed a Patient Safety Care Competence Questionnaire for HCA, aiming to provide a reference for the selection and training of HCA.

2. Materials and Methods

2.1 Establishment of the Research Team

A 5-member research team was established, including 1 chief nurse (responsible for coordinating consulting experts and formulating the competence evaluation scale), 1 associate chief nurse (responsible for coordinating interviewees), 2 senior nurses (responsible for conducting interviews and organizing interview data), and 1 postgraduate nursing student (responsible for literature review, data collection, and formulating/modifying the Delphi questionnaire).

2.2 Construction of the Item Pool

2.2.1 Determination of Questionnaire Structure

The Competency Model refers to a set of gradable and measurable characteristics or combinations related to high performance required for specific jobs in an organization^[7]. Currently, the "Iceberg Model" proposed by McClelland^[8] and the "Onion Model" proposed by Boyatzis^[9] are two universally recognized general competency models in academia. The "Iceberg Model" vividly describes competence as an iceberg: the above-water part (directly observable) includes knowledge and skills; the underwater part includes motivation, self-concept, social role, and personal traits. Based on McClelland's "Iceberg Model", combined with the relevant literature analysis, this study developed the Patient Safety Care Competence Questionnaire for HCA^[10].

2.2.2 Establishment of the Item Pool

The research team searched databases including CNKI, CBMdisc, Wanfang Data, VIP, Web of Science, PubMed, and CINAHL using keywords such as "health care assistant/nursing assistant", "patient safety care/safety care", "competence", "knowledge", "skills", "role", "Health Care Assistant (HCA)", "Patient Safety Care/Safety Care", "Competence", "Knowledge", "Skills", and "Role" to provide data for interviews and item pool construction. Semi-structured interviews were conducted to guide interviewees to recall key experiences of success or frustration related to patient safety in their work. The interview outline included: ☐ From a personal perspective, what is your understanding of the HCA profession? What do you think is the most important responsibility of an HCA? ☐ Please recall the adverse events involving patients in your work and describe the situation at that time; ☐ What was your work task at that time? How did you handle such adverse events? ☐ What was the final outcome of the incident? What impact did it have on you? How do you view this incident? ☐ In terms of providing quality patient safety care, what knowledge and skills should be possessed? What qualities do you think are necessary to better

complete patient safety care work? Guided by the Iceberg Model, integrating literature analysis and qualitative research results, and based on the characteristics of HCA' patient safety care competence, the research team conducted in-depth discussions to form a pool of 62 questionnaire items.

2.3 Delphi Method Consultation

Inclusion Criteria for Experts

☐ Engaged in nursing education or clinical nursing with more than 5 years of work experience; ☐ Bachelor's degree or above; ☐ Intermediate or above professional and technical title; ☐ High enthusiasm for this research; ☐ Voluntary participation and ability to continue participating in multiple rounds of consultation.

Consultation Process

An expert consultation questionnaire was compiled, including research background, consultation content, expert information, familiarity with the content, basis for judgment, and importance of questionnaire items (scored using a 5-point Likert scale ^[11], from "very unimportant" to "very important", assigned 1–5 points), with a column for revision suggestions. The questionnaire was sent to experts via email, reminding them to return it within 2 weeks. Based on expert opinions and in-depth discussions by the research team, items were added, deleted, modified, or merged to form the questionnaire for the next round until expert opinions tended to be consistent. The item selection criteria were: importance mean ≥ 4.00 , full-score rate $\geq 20\%$, and coefficient of variation ≤ 0.25 ^[12, 13].

2.4 Pre-survey

A convenient sample of 23 in-service clinical nurses was selected for a pre-survey to assess whether questionnaire items were ambiguous. The research team collected, analyzed, and modified problems identified in the pre-survey to form the initial version of the Patient Safety Care Competence Assessment Questionnaire for HCA.

2.5 Reliability and Validity Testing of the Questionnaire

2.5.1 Study Participants

The initial questionnaire contained 43 items. The sample size for exploratory factor analysis is typically 5–10 times the number of variables ^[14], with a 20% allowance for invalid questionnaires, requiring 269–538 participants. This study recruited 502 HCA, meeting the sample size requirement.

Inclusion Criteria ☐ Holding a valid HCA certificate; ☐ Agreeing to participate in the study and cooperating with data collection.

Exclusion Criteria ☐ Probationary HCA.

From November to December 2025, cluster sampling was used to survey 502 in-service HCA from 4 tertiary general hospitals in Luzhou (2), Zigong (1), and Yibin (1) using the initial questionnaire and a general information questionnaire.

2.5.2 Research Instruments

(1) General Information Questionnaire: Including gender, age, educational background, professional title, and other basic information.

(2) Patient Safety Care Competence Assessment Questionnaire for HCA: The formal version included 5 dimensions: Knowledge and Skills (10 items), Motivation (7 items), Self-concept (6 items), Social Role (5 items), and Personal Traits (4 items). A 5-point Likert scale was used, with scores ranging from 1 ("very inconsistent") to 5 ("very consistent"). HCA scored each item based on their actual situation. Scores for each dimension and the total scale were calculated to evaluate their competence in various aspects and overall patient safety care; higher scores indicated stronger competence (shown in Table 1).

Table 1
Patient Safety Care Competence Assessment Questionnaire for HCA

Dimension	Item Name	Importance Rating					Revision Comments
		5	4	3	2	1	
Knowledge and Skills	1.I am familiar with the relevant regulations and rules for healthcare assistants' work						
	2.I know my job responsibilities and work content.						
	3.I can identify environmental hazards that may endanger patients (e.g., uneven floors, dim lighting, obstacles, etc.)						
	4.I know how to guide patients to use safety aids (e.g., bedside call bell, bed rails, handrails, emergency call device, etc.)						
	5.I can understand bedside safety warning labels (e.g., fall prevention, bed fall prevention, pressure injury prevention, nil by mouth, etc.)						
	6.I know how to use assistive devices (e.g., wheelchairs, crutches, stretchers, etc.)						
	7.I know how to monitor patients when using restraint straps						
	8.I know how to prevent patients from falling.						
	9.I know how to prevent patients from falling out of bed.						
	10.I know how to prevent patients from developing pressure injuries (commonly known as bedsores).						
	11.I know how to prevent patients from experiencing tube dislodgement.						
	12.I know how to prevent patients from choking or aspiration during eating.						
	13.I know that preventing cross-infection is crucial for ensuring patient safety						
	14.I have the ability to communicate with patients						
	15.I have the ability to communicate with patients' family members						
	16.I have the ability to communicate with medical staff						

	17.I know how to respond to sudden power outages.
	18.I know the safety hazards that may cause fires.
	19.I know how to respond to sudden fires.
	20.I know how to use fire hydrants and fire extinguishers.
	21.I know how to respond to sudden earthquakes.
	22.When a patient falls or falls out of bed, I know how to handle it.
	23.When a patient develops a pressure injury, I know how to handle it.
	24.When a patient experiences tube dislodgement, I know how to handle it.
	25.When a patient chokes or aspirates during eating, I know how to handle it.
	26.When a patient gets scalded, I know how to handle it.
	27.I have mastered basic methods to prevent cross-infection (e.g., hand hygiene, mask-wearing)
	28.I have the ability to communicate with patients, their families, and medical staff
	29.I have the ability to communicate with patients, their families, and medical staff
	30.I can communicate effectively with colleagues to avoid misunderstanding or omission of safety care information and complete handover smoothly
	31.When I find unsafe behaviors in the ward (e.g., smoking, drinking, noise, etc.), I will stop them promptly
	32.I am proficient in cardiopulmonary resuscitation (CPR)
	33.I am proficient in the Heimlich maneuver
Motivation	34.I regard ensuring patient safety as my top priority
	35.I feel satisfied to be able to ensure patient safety

	36.I feel a sense of accomplishment when I identify and (assist in) eliminating safety hazards promptly
	37.When a patient experiences an adverse event, I feel sad.
	38.I hope to improve my safety care ability and take on more challenging work
	39.I hope to minimize adverse events and continuously improve job satisfaction
	40.I hope to gain recognition from superiors and get more promotion opportunities
	41.I aspire to be an excellent healthcare assistant
Self-concept	42.I am clear about my professional positioning
	43.I am kind, friendly, and honest
	44.I will take the initiative to communicate with patients, their families, and medical staff about safety care matters
	45.I treat patients as family members at work
	46.I am clear about my strengths and weaknesses at work
	47.I can make good use of my strengths at work
	48.I am a person who loves learning, practices diligently, and actively pursues progress
Social Role	49.I believe healthcare assistants are an important supplementary human resource for maintaining nursing safety
	50.I will not pass on uncertain information to patients.
	51.I believe healthcare assistants play a vital role in patient safety care
	52.I believe healthcare assistants have the responsibility to provide safety care to patients
	53.When family members behave incorrectly, I will point it out (performing a supervisory role).

	54.I can protect patients' privacy
	55.I still complete my work carefully even when there is no supervision
Personal Traits	56.I can stay calm when a patient experiences a safety incident
	57.At work, I can maintain an optimistic attitude.
	58.I can regulate myself well when work pressure is high
	59.I still have confidence in completing work smoothly when it is busy
	60.I am a person who loves learning, practices diligently, and actively pursues progress
	61.I will regularly reflect on loopholes and shortcomings in my work
	62.I have compassion, patience, love, and a sense of responsibility, and treat all patients equally

2.5.3 Data Collection and Quality Control

Electronic questionnaires were distributed via the Wenjuanxing platform. The research purpose and filling instructions were explained at the beginning of the questionnaire, and informed consent was obtained from HCA. Investigators were trained before questionnaire distribution to ensure consistency in the process. The questionnaire was set to allow only one submission per user/IP address, and only complete questionnaires could be submitted. After data collection, two researchers independently verified the data, excluding questionnaires with obvious response patterns or contradictory answers to ensure the authenticity, accuracy, and reliability of the data.

2.6 Methods for Reliability and Validity Evaluation

2.6.1 Item Analysis

(1) Critical Ratio Method: Participants' total scores were ranked from high to low; the top 27% were classified as the high-score group, and the bottom 27% as the low-score group. Independent samples t-tests were used to compare the mean scores of each item between the two groups. Items with no statistically significant differences were considered for deletion [14].

(2) Correlation Coefficient Method: Pearson correlation analysis was performed between each item score and the total score. A higher correlation coefficient indicated a closer relationship between the item and the total scale. Items with a correlation coefficient < 0.4 were considered for deletion [15].

2.6.2 Reliability Testing

Cronbach's α coefficient and test-retest reliability were used to assess questionnaire reliability, with values ranging from 0 to 1; higher values indicated better questionnaire stability^[16].

2.6.3 Validity Testing

(1) Content Validity: Expert consultation and relevance scoring were used to test the appropriateness and representativeness of the questionnaire content and items.

(2) Construct Validity: Bartlett's sphericity test and kaiser-meyer-olkin(KMO) value were first used to determine whether the data were suitable for exploratory factor analysis. A KMO value ≥ 0.6 and Bartlett's sphericity test $P < 0.001$ indicated suitability for exploratory factor analysis. Principal component analysis and maximum variance orthogonal rotation were used, with an initial limit of 5 common factors (Knowledge and Skills, Motivation, Self-concept, Social Role, Personal Traits).

2.7 Statistical Methods

SPSS 26.0 and AMOS 22.0 software were used for data analysis. Expert enthusiasm, authority, opinion concentration, and coordination were represented by questionnaire recovery rate, authority coefficient (Cr), mean value, standard deviation, full-score rate, coefficient of variation (CV), and Kendall's harmony coefficient (W value). Cronbach's α coefficient was used for internal consistency testing; exploratory factor analysis was performed using SPSS 26.0.

3. Results

3.1 Results of Delphi Expert Consultation

3.1.1 Expert Characteristics

A total of 21 experts engaged in clinical nursing, nursing education, and nursing management from 6 provinces/municipalities (Jiangsu, Anhui, Xinjiang, Chongqing, Liaoning, Sichuan) participated in 2 rounds of consultation. Among them, 38.09% were aged ≥ 50 years, and 42.96% had work experience ≥ 20 years. The general characteristics of the experts are shown in Table 2.

Table 2
Demographic Characteristics of Experts (n = 21)

Item	Subcategory	Number	Percentage (%)
Gender	Male	1	4.76
	Female	20	95.24
Age (years)	30–39	10	47.62
	40–49	3	14.29
	50 and above	8	38.09
Educational background	Bachelor's degree	11	52.38
	Master's degree	5	23.81
	Doctoral degree	5	23.81
Position	Head nurse	11	52.38
	Others	3	14.29
Work experience (years)	5–10	6	28.57
	11–20	6	28.57
	20 and above	9	42.96
Professional title	Intermediate	11	52.38
	Associate senior	5	23.81
	Senior	5	23.81
Expert work field	Nursing education	2	9.52
	Nursing management	14	66.67
	Clinical nursing	5	23.81
Whether in leadership position	Yes	3	14.29
	No	18	85.71
Region (Province)	Jiangsu	2	9.52
	Anhui	1	4.76
	Xinjiang	4	19.05
	Chongqing	3	14.29
	Liaoning	1	4.76

Item	Subcategory	Number	Percentage (%)
	Sichuan	10	47.62

3.1.2 Consultation Results

Two rounds of consultation were conducted, with a 100% recovery rate (RR) for both rounds, indicating high expert enthusiasm. The expert authority coefficient of this study was 0.88. In the second round of expert consultation, the importance score was (4.82 ± 0.29), and the coefficient of variation was 0–0.20, indicating concentrated expert opinions. Kendall's harmony coefficients for the two rounds of consultation were 0.659 and 0.502 (both $P < 0.001$), indicating high consistency of expert opinions. Combining the opinions of the two rounds of experts: 6 items (e.g., "cardiopulmonary resuscitation, Heimlich maneuver", "catheter displacement") that were not within the operational scope of HCA were deleted; 2 items ("I can understand hospital safety warning signs (e.g., fire safety exits, radiation protection signs, hazard obstacle signs, etc.)", "When adverse events occur to patients (e.g., falls, bed falls, choking, pressure injuries, catheter displacement, scalds, etc.), I will promptly report to the on-duty nurse") were added and adopted after group discussion; 27 items (e.g., "occupational positioning", "assistive devices") were merged and modified.

Based on the results of two rounds of expert consultations, a total of 6 items were deleted and 2 items were added. After revision and integration, an initial scale consisting of 5 dimensions and 43 items was finally developed, including Knowledge and Skills (20 items), Motivation (7 items), Self-concept (6 items), Social Role (5 items), and Personal Traits (5 items). The second round results of consultation by experts are shown in Table 3.

Table 3
Second Round results of Consultation by Experts

Item Name	Importance Rating ($\bar{x} \pm s$)	Full-Score Rate (%)	Coefficient of Variation (CV)
1. I am familiar with the relevant regulations and rules for healthcare assistants' work	4.57 $\pm$ 0.51	57.14	0.11
2. I know my job responsibilities and work content.	4.86 $\pm$ 0.36	85.71	0.07
3. I can identify environmental hazards that may endanger patients (e.g., uneven floors, dim lighting, obstacles, etc.)	4.67 $\pm$ 0.66	76.19	0.14
4. I know how to guide patients to use safety aids (e.g., bedside call bell, bed rails, handrails, emergency call device, etc.)	5.00 $\pm$ 0.00	100.00	0.00
5. I can understand bedside safety warning labels (e.g., fall prevention, bed fall prevention, pressure injury prevention, nil by mouth, etc.)	4.86 $\pm$ 0.36	85.71	0.07
6. I know how to prevent adverse events (e.g., falls, bed falls, choking, pressure injuries, tube dislodgement, scalds, etc.)	4.90 $\pm$ 0.30	90.48	0.06
7. When a patient experiences an adverse event (e.g., fall, bed fall, choking, pressure injury, tube dislodgement, scald, etc.), I will promptly report it to the on-duty nurse	4.95 $\pm$ 0.22	95.24	0.04
8. I know how to use assistive devices (e.g., wheelchairs, crutches, stretchers, etc.)	4.81 $\pm$ 0.40	80.95	0.08
9. I know how to monitor patients when using restraint straps	4.62 $\pm$ 0.74	76.19	0.16
10. I can understand hospital signs (e.g., fire hydrants, fire escape routes, hazard obstacle signs, etc.)	4.76 $\pm$ 0.54	80.95	0.11
11. I know how to assist in handling emergency incidents (e.g., power outage, fire, earthquake)	4.62 $\pm$ 0.67	71.43	0.14
12. I know that preventing cross-infection is crucial for ensuring patient safety	4.95 $\pm$ 0.22	95.24	0.04
13. I have mastered basic methods to prevent cross-infection (e.g., hand hygiene, mask-wearing)	4.90 $\pm$ 0.30	90.48	0.06
14. I have the ability to communicate with patients, their families, and medical staff	4.71 $\pm$ 0.56	76.19	0.12
15. I will take the initiative to communicate with patients, their families, and medical staff about safety care matters	4.33 $\pm$ 0.86	57.14	0.20

Item Name	Importance Rating ($\bar{x} \pm s$)	Full-Score Rate (%)	Coefficient of Variation (CV)
16. I can communicate effectively with colleagues to avoid misunderstanding or omission of safety care information and complete handover smoothly	5.00 $\pm$ 0.00	100.00	0.00
17. When I find unsafe behaviors in the ward (e.g., smoking, drinking, noise, etc.), I will stop them promptly	5.00 $\pm$ 0.00	100.00	0.00
18. When a life-threatening situation occurs to a patient, I know how to call for help and assist in handling it	4.95 $\pm$ 0.22	95.24	0.04
19. I am proficient in cardiopulmonary resuscitation (CPR)	4.90 $\pm$ 0.30	90.48	0.06
20. I am proficient in the Heimlich maneuver	5.00 $\pm$ 0.00	100.00	0.00
21. I regard ensuring patient safety as my top priority	5.00 $\pm$ 0.00	100.00	0.00
22. I feel satisfied to be able to ensure patient safety	4.67 $\pm$ 0.00	66.67	0.10
23. I feel a sense of accomplishment when I identify and (assist in) eliminating safety hazards promptly	4.67 $\pm$ 0.48	66.67	0.10
24. I hope to improve my safety care ability and take on more challenging work	4.57 $\pm$ 0.51	57.14	0.11
25. I hope to minimize adverse events and continuously improve job satisfaction	4.29 $\pm$ 0.78	47.62	0.18
26. I hope to gain recognition from superiors and get more promotion opportunities	4.76 $\pm$ 0.54	80.95	0.11
27. I aspire to be an excellent healthcare assistant	4.38 $\pm$ 0.74	52.38	0.17
28. I am clear about my professional positioning	4.57 $\pm$ 0.68	66.67	0.15
29. I am kind, friendly, and honest	4.67 $\pm$ 0.58	71.43	0.12
30. I treat patients as family members at work	4.62 $\pm$ 0.59	66.67	0.13
31. I am clear about my strengths and weaknesses at work	4.33 $\pm$ 0.80	52.38	0.18
32. I can make good use of my strengths at work	4.71 $\pm$ 0.64	80.95	0.14
33. I am a person who loves learning, practices diligently, and actively pursues progress	4.76 $\pm$ 0.62	85.71	0.13
34. I believe healthcare assistants are an important supplementary human resource for maintaining nursing safety	4.71 $\pm$ 0.64	80.95	0.14

Item Name	Importance Rating ($\bar{x} \pm s$)	Full-Score Rate (%)	Coefficient of Variation (CV)
35. I believe healthcare assistants play a vital role in patient safety care	4.86 $\pm$ 0.48	90.48	0.10
36. I believe healthcare assistants have the responsibility to provide safety care to patients	4.57 $\pm$ 0.81	76.19	0.18
37. I can protect patients' privacy	4.95 $\pm$ 0.81	95.24	0.04
38. I still complete my work carefully even when there is no supervision	4.52 $\pm$ 0.75	66.67	0.17
39. I can stay calm when a patient experiences a safety incident	4.81 $\pm$ 0.40	85.71	0.08
40. I can regulate myself well when work pressure is high	4.62 $\pm$ 0.74	76.19	0.16
41. I still have confidence in completing work smoothly when it is busy	4.67 $\pm$ 0.58	71.43	0.12
42. I will regularly reflect on loopholes and shortcomings in my work	4.57 $\pm$ 0.68	66.67	0.15
43. I have compassion, patience, love, and a sense of responsibility, and treat all patients equally	4.95 $\pm$ 0.22	95.24	0.04

3.2 Results of Item Analysis

There were statistically significant differences in the scores of each item between the high-score group and the low-score group (all $P < 0.001$), with critical ratios ranging from 9.639 to 17.917. Pearson correlation analysis between each item and the total scale showed correlation coefficients ranging from 0.503 to 0.727. As shown in Table 4.

Table 4
Project analysis status

Item	CR(t)	<i>P</i>	Item-Total Correlation Coefficient (r)	Item	CR(t)	<i>P</i>	Item-Total Correlation Coefficient (r)
T1	9.939	0.000	0.615	T23	11.763	0.000	0.685
T2	13.339	0.000	0.681	T24	17.423	0.000	0.707
T3	12.061	0.000	0.596	T25	12.706	0.000	0.692
T4	9.939	0.000	0.667	T26	12.987	0.000	0.639
T5	11.539	0.000	0.684	T27	10.858	0.000	0.674
T6	11.092	0.000	0.527	T28	16.146	0.000	0.676
T7	10.378	0.000	0.667	T29	13.291	0.000	0.657
T8	11.102	0.000	0.607	T30	13.824	0.000	0.654
T9	12.526	0.000	0.687	T31	12.566	0.000	0.646
T10	13.676	0.000	0.702	T32	13.75	0.000	0.680
T11	13.133	0.000	0.727	T33	16.207	0.000	0.683
T12	9.996	0.000	0.618	T34	13.097	0.000	0.672
T13	9.639	0.000	0.547	T35	10.688	0.000	0.643
T14	12.512	0.000	0.692	T36	12.008	0.000	0.663
T15	11.587	0.000	0.720	T37	11.177	0.000	0.641
T16	9.891	0.000	0.679	T38	10.887	0.000	0.630
T17	13.177	0.000	0.703	T39	13.074	0.000	0.678
T18	13.339	0.000	0.638	T40	14.768	0.000	0.645
T19	17.917	0.000	0.591	T41	17.333	0.000	0.660
T20	16.166	0.000	0.503	T42	13.132	0.000	0.598
T21	11.53	0.000	0.699	T43	10.887	0.000	0.636
T22	13.233	0.000	0.708				

3.3 Results of Reliability and Validity Analysis

3.3.1 General Information of Participants

A total of 502 HCA were surveyed, and 475 valid questionnaires were recovered, with an effective recovery rate of 94.62%. Among them, 37 were male and 438 were female; 10 were aged 20–29 years, 41 were 30–39 years, 230 were 40–49 years, and 194 were 50–59 years. This study was approved by the Hospital Ethics Committee.As shown in Table 5.

Table 5
Patient Safety Care Competency Assessment Scale for Health Care Assistant

Subscale	Number of Items	Score ($\bar{x} \pm s$)	Score Range
Knowledge and Skills	20	87.60 $\pm$ 9.17	20 ~ 100
Motivation	7	30.89 $\pm$ 3.82	7 ~ 35
Self-concept	6	26.51 $\pm$ 3.25	6 ~ 30
Social Role	5	22.44 $\pm$ 2.75	5 ~ 25
Personal Traits	5	22.06 $\pm$ 2.48	5 ~ 25

(first draft) Score status(n = 475)

3.3.2 Validity Analysis

(1) Content Validity: Nine experts were invited, including 3 experts with scale development experience, 4 clinical nursing experts, and 2 nursing management experts. The average age of the experts was 41.56 years, with an average work experience of 17.89 years. There were 3 doctoral degree holders, 3 master's degree holders, and 3 bachelor's degree holders; 3 with senior titles, 2 with associate senior titles, and 4 with intermediate titles. The expert authority coefficient (Cr) was 0.87. Based on the opinions of 9 experts, the relevance of each item to the corresponding dimension was evaluated. The content validity of each item was 0.889–1.000, and the content validity of the questionnaire was 0.938.As shown in Table 6.

Table 6

Authority of experts (2)Construct Validity: The KMO value of the questionnaire was 0.921, and Bartlett's sphericity test $\chi^2=9545.330$, $df = 496$ ($P < 0.001$), indicating suitability for exploratory factor analysis. Exploratory factor analysis of the 43 items was performed, and 5 common factors were extracted after maximum variance orthogonal rotation, with a cumulative variance contribution rate of 72.200%. According to the factor analysis results, all items were included in the designed factors, consistent with the theoretical framework of the Patient Safety Care Competence Questionnaire for HCA.As shown in Table 7.

	Expert 1	Expert 2	Expert 3	Expert 4	Expert 5	Expert 6	Expert 7	Expert 8	Expert 9
Judgment Coefficient	1.0	0.9	1.0	1.0	1.0	0.8	0.7	0.7	1.0
Familiarity Degree	1.0	0.8	1.0	1.0	0.8	0.8	0.6	0.6	1.0
Authority Degree	1.0	0.85	1.0	1.0	0.9	0.8	0.65	0.65	1.0

Table 7

KMO and Bartlett test results Five factors were extracted based on the criterion of eigenvalues greater than 1, with the total variance explained by the common factors reaching 72.200%, which was above the 60% threshold.As shown in Table 8.

KMO	Measure of Sampling Adequacy (MSA)	0.921
	Approx. Chi-Square	9545.330
Bartlett's Test of Sphericity	df (Degrees of Freedom)	496
	Sig. (Significance)	0.000

Table 8

Results of the second exploratory factor analysis Items 9, 15 and 43 loaded on two common factors simultaneously, but the difference in their factor loadings was greater than 0.2. Therefore, these items were retained and assigned to the common factor with the higher factor loading value. After item screening was performed using the above-mentioned methods, combined with the research team's discussion on the statistical analysis results, items 3, 6, 11, 12, 13, 14, 16, 18, 19, 20 and 42 were finally deleted. The formal version of the scale was thus developed. As shown in Table 9.

Item	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
T1	0.595				
T2	0.644				
T4	0.798				
T5	0.787				
T7	0.712				
T8	0.643				
T9	0.644	0.403			
T10	0.617				
T15	0.640	0.433			
T17	0.622				
T21		0.698			
T22		0.733			
T23		0.776			
T24		0.669			
T25		0.640			
T26		0.735			
T27		0.666			
T28			0.798		
T29			0.833		
T30			0.800		
T31			0.743		
T32			0.758		

Item	Factor 1	Factor 2	Factor 3	Factor 4	Factor 5
T33			0.828		
T34				0.667	
T35				0.822	
T36				0.818	
T37				0.849	
T38				0.856	
T39					0.709
T40					0.765
T41					0.774
T43				0.421	0.626

Table 9

Evaluation Scale for Patient Safety Care Competence of Health care Assistants (HCA) (Formal Scale)

Serial No.	Items (To what extent do the following items match your own situation?)	Strongly Disagree	Disagree	Sometimes Agree	Agree	Strongly Agree
1	I am familiar with the relevant regulations and rules for healthcare assistants' work					
2	I know my job responsibilities and work content.					
3	I know how to guide patients to use safety aids (e.g., bedside call bell, bed rails, handrails, emergency call device, etc.)					
4	I can understand bedside safety warning labels (e.g., fall prevention, bed fall prevention, pressure injury prevention, nil by mouth, etc.)					
5	When a patient experiences an adverse event (e.g., fall, bed fall, choking, pressure injury, tube dislodgement, scald, etc.), I will promptly report it to the on-duty nurse					
6	I know how to use assistive devices (e.g., wheelchairs, crutches, stretchers, etc.)					
7	I know how to monitor patients when using restraint straps					
8	I can understand hospital signs (e.g., fire hydrants, fire escape routes, hazard obstacle signs, etc.)					
9	I will take the initiative to communicate with patients, their families, and medical staff about safety care matters					
10	When I find unsafe behaviors in the ward (e.g., smoking, drinking, noise, etc.), I will stop them promptly					

Serial No.	Items (To what extent do the following items match your own situation?)	Strongly Disagree	Disagree	Sometimes Agree	Agree	Strongly Agree
11	I regard ensuring patient safety as my top priority					
12	I feel satisfied to be able to ensure patient safety					
13	I feel a sense of accomplishment when I identify and (assist in) eliminating safety hazards promptly					
14	I hope to improve my safety care ability and take on more challenging work					
15	I hope to minimize adverse events and continuously improve job satisfaction					
16	I hope to gain recognition from superiors and get more promotion opportunities					
17	27. I aspire to be an excellent healthcare assistant					
18	I am clear about my professional positioning					
19	I am kind, friendly, and honest					
20	30. I treat patients as family members at work					
21	I am clear about my strengths and weaknesses at work					
22	I can make good use of my strengths at work					
23	I am a person who loves learning, practices diligently, and actively pursues progress					
24	I believe healthcare assistants are an important supplementary human resource for maintaining nursing safety					

Serial No.	Items (To what extent do the following items match your own situation?)	Strongly Disagree	Disagree	Sometimes Agree	Agree	Strongly Agree
25	I believe healthcare assistants play a vital role in patient safety care					
26	I believe healthcare assistants have the responsibility to provide safety care to patients					
27	I can protect patients' privacy					
28	I still complete my work carefully even when there is no supervision					
29	I can stay calm when a patient experiences a safety incident					
30	I can regulate myself well when work pressure is high					
31	I still have confidence in completing work smoothly when it is busy					
32	I have compassion, patience, love, and a sense of responsibility, and treat all patients equally					

3.3.3 Reliability Analysis

Cronbach's α coefficient was used to evaluate the internal consistency of the scale. The Cronbach's α coefficient of the total scale was 0.921 (> 0.7), indicating good reliability of the scale. The Cronbach's α coefficients of the five dimensions (Knowledge and Skills, Motivation, Self-concept, Social Role, Personal Traits) were 0.923, 0.928, 0.885, 0.852, and 0.824, respectively. As shown in Table 10.

Table 10
Results of the Cronbach's alpha coefficient

Dimension	Number of Items	Cronbach's Alpha Coefficient
Knowledge and Skills	10	0.923
Motivation	7	0.928
Self-concept	6	0.885
Social Role	5	0.852
Personal Traits	4	0.824

4. Discussion

4.1 Reliability of the Questionnaire

Both rounds of consultation questionnaires were fully recovered. The consulting experts covered nursing management, nursing education, and clinical nursing, with work experience ≥ 5 years and distribution across different regions of China, ensuring good expert representativeness. The expert authority coefficient of this study was 0.88, and the harmony coefficients of the two rounds of consultation were 0.659 and 0.502 (both $P < 0.001$), indicating that expert opinions tended to be consistent and the research results were highly reliable^[17].

4.2 Good Reliability and Validity of the Questionnaire

Item analysis results showed that the critical ratios of the high-score and low-score groups were > 9.0 , the correlation coefficients between each item and the total scale were > 0.5 , and the correlation coefficients between dimensions and the total scale were < 0.9 (all $P < 0.001$), indicating high item discrimination, significant correlation between items and the total scale, and reasonable dimension design. Evaluation by 9 experts showed that the content validity of each item was > 0.8 , and the content validity of the questionnaire was > 0.9 , indicating good content validity. The cumulative variance contribution rate using principal component analysis was 72.200%, and the factor loading of each item in the common factors was > 0.4 , indicating good construct validity.

4.3 Practicality and Necessity of the Questionnaire

Research on the core competence of HCA in China is still in its preliminary stage. Domestic researcher constructed a core competence evaluation index system for HCA caring for elderly patients based on expert interviews and literature research, including 3 first-level indicators (basic quality, theoretical knowledge, practical skills), 9 second-level indicators, and 39 third-level indicators^[18]. Yang L et al. initially developed a simple, feasible, and reliable core competence evaluation scale for elderly HCA^[19]. Currently, there is a lack of evaluation tools for the safety care competence of HCA in domestic research. Therefore, it is particularly necessary to construct a scientific and practical evaluation tool for the patient safety care competence of HCA^[20].

The applicability and practicality of the questionnaire are as follows: ☐ It can be used to guide the training of HCA; ☐ It can guide employers in the selection and training of HCA and the establishment of work assessment standards; ☐ HCA can identify their weaknesses and direction for improvement, continuously reflect on and deepen their learning; ☐ It helps to better protect patient safety and reduce medical accidents; ☐ It lays the foundation and points out the research direction for subsequent studies on patient safety care of HCA based on the competence model.

5. Limitations

This study designed a self-reported questionnaire with strong subjectivity, which has limitations in comprehensively evaluating the patient safety care competence of HCA. Due to the obvious regionality of the study participants, future studies can expand the sample size to further verify the practicality of the questionnaire.

Abbreviations

English-Chinese Glossary of Abbreviations	
English Abbreviation	English Full Form
HCA	Health Care Assistant
CVI	Content Validity Index
I-CVI	Item-level Content Validity Index
KMO	Kaiser-Meyer-Olkin
S-CVI	scale-level Content Validity Index

Declarations

Ethics approval and consent to participate

The entire study complies with the Helsinki Declaration (World Medical Association Declaration of Helsinki, 2013). The investigation process follows the principles of informed consent, confidentiality, and non harm, and an informed consent form is signed with the survey subjects to ensure that they understand the purpose and significance of the research. The survey will be conducted in a back-to-back anonymous manner, and the collected data will be absolutely anonymous to protect the privacy and rights of the subjects. All research data will not be made public, and the participants will decide whether to participate in this study. During the research period, if the research subjects have doubts or are unwilling to continue participating, they can suspend or withdraw from the study at any time without affecting any of their rights. With the consent of the subjects, the questionnaire-filling process will begin. This study has been approved by the Ethics Committee of the Affiliated Hospital of Southwest Medical University (KY2023348).

Consent for publication

Not applicable.

Availability of data and materials

The datasets used and analyzed during the current study are available from the first author upon reasonable request.

Competing interests

The authors declare that they have no competing interests

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Authors' contributions

J.R. wrote the main manuscript text; C.H., Y.H., S.Y., and Q.H. prepared the figures; H.S. provided overall guidance for the manuscript. All authors reviewed the manuscript.

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