การพัฒนาเครื่องมือวัดผลลัพธ์ด้านความปลอดภัย งานการพยาบาลผู้ป่วยห้องผ่าตัด โรงพยาบาลทั่วไปสังกัดกระทรวงสาธารณสุข

A Scale Development of Safety Outcome Instruments for Operating Rooms in General Hospitals under the Ministry of Public Health

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บทคัดย่อ

การวิจัยเชิงปริมาณนี้มีวัตถุประสงค์เพื่อพัฒนาเครื่องมือวัดผลลัพธ์ด้านความปลอดภัยงานการพยาบาลผู้ป่วยห้องผ่าตัด โรงพยาบาลทั่วไปสังกัดกระทรวงสาธารณสุข ตามแนวคิดของโดนาบีเดียน มีขั้นตอนการสร้างเครื่องมือตามกรอบการสร้างเครื่องมือวัดของเดเวลลิส ผ่านการตรวจสอบความตรงเชิงเนื้อหาจากผู้ทรงคุณวุฒิ 7 คน มีค่าดัชนีความตรงตามเนื้อหา (CVI) เท่ากับ .90 และค่าสัมประสิทธิ์อัลฟาของครอนบาคเท่ากับ .98 กลุ่มตัวอย่างเป็นพยาบาลวิชาชีพห้องผ่าตัดจำนวน 326 คน จำนวน 21 แห่ง ใช้สถิติการวิเคราะห์ปัจจัยเชิงสำรวจ (EFA)

การวิจัยครั้งนี้พบว่าผลลัพธ์ด้านความปลอดภัยของงานการพยาบาลผู้ป่วยห้องผ่าตัด มีองค์ประกอบ 3 ด้าน ประกอบด้วย 29 ข้อคำถาม ดังนี้ 1) ด้านการดูแลที่ยึดผู้ป่วยเป็นศูนย์กลางประกอบด้วย 11 ข้อคำถาม 2) ด้านผลลัพธ์ที่ต้องการ ประกอบด้วย 12 ข้อคำถาม และ 3) ด้านประสิทธิภาพและประสิทธิผล ประกอบด้วย 6 ข้อคำถาม มีค่าน้ำหนักองค์ประกอบ (Factor loading) อยู่ระหว่าง 0.55-0.83 ที่นัยสำคัญทางสถิติที่ระดับ .001 และสอดคล้องกับข้อมูลเชิงประจักษ์ (KMO = 0.96, df = 406, $\chi 2$ = 8577.305 และ p <.001) มีค่าความแปรปรวนในแต่ละองค์ประกอบดังนี้ 27.05%, 24.77% และ 16.28% ตามลำดับและมีค่าความแปรปรวนร่วมเท่ากับ 68.10% ดังนั้นหัวหน้ากลุ่มงานการพยาบาลผู้ป่วยห้องผ่าตัดควรนำเครื่องมือวัดนี้ไปใช้เป็นแนวทางวัดระดับผลลัพธ์ด้านความปลอดภัยของห้องผ่าตัดในโรงพยาบาลทั่วไปซึ่งจะนำไปสู่ความปลอดภัยของผู้ป่วย

คำสำคัญ: ผลลัพธ์ด้านความปลอดภัย, การพัฒนาเครื่องมือวัด, การพยาบาลผู้ป่วยห้องผ่าตัด

Abstract

This quantitative study aimed to develop a measurement scale for the safety outcomes of operating rooms in general hospitals. The study used a quantitative research to develop the safety outcome scale based on the safety outcome concept of Donabedian. This study used of Devellis method for scale development. Descriptive statistics and exploratory factor analysis (EFA) were used to determine the validity of the instrument.

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The examination of the content validity by 7 experts revealed a content validity index = 0.90. The internal consistency reliability with Cronbach's alpha coefficient was .98. The construct validity was performed by using EFA with 326 operating room nurses at 21 general hospitals.

The safety outcome instrument consisted of three components with 29 indicators: 1) patient-centeredness composed of 11 indicators; 2) desired outcomes composed of 12 indicators and 3) effectiveness and efficacy composed of 6 indicators. The EFA showed that the factor loading of the indicators was between 0.55-0.83, all of which were statistically significant at .001. The developed instrument was congruent with empirical data (KMO = 0.96, df = 406, $\chi 2$ = 8577.305 and p <.001). The three components of the safety outcome measurement were explained by 27.05%, 24.77% and 16.28% with total of variance at 68.10%, respectively. The division head nurses should use the safety outcome measurement to measure the level of safety outcomes of operating rooms, thereby leading to patient safety.

Keywords: safety outcome, scale development, operating room nursing

Introduction

The World Health Organization (WHO) has set objectives prioritizing service quality and patient safety, while service systems are continuously developed.[1] However, gaps have always existed in the health care service system in regards to development in the patient safety system, particularly for patients who undergo surgery at numbers as high as 234 million surgeries per year on average worldwide.[1] Every surgery involves risk for complications, and 50% of these surgery complications are preventable.[1] Therefore, every medical facility recognizes the importance of revising surgery safety objectives to be in line with the WHO practice guidelines in order to ensure that the right surgeries are provided to the right sides or locations of the right patients and without leaving any foreign objects in patients' bodies, etc.[2] As for general hospitals (S-level), safety policies are implemented to achieve sustainability, with emphasis and importance given to nursing patients in operating rooms such that safety is ensured in patients and service providers.[2] Safety outcomes reflect the quality of safety management by organization managers.[3]

Operating room provide 24 hours surgery services for every category of surgical patients.[4] The aim is to accommodate injured and emergency patients or those in need of urgent and unexpected surgeries. The primary objective of this is to provide care with emphasis on the safety of patients receiving surgery.[4] Although the operating room prioritize patient safety and prevention of complications throughout surgeries as their primary objectives, up to 32.9% of patients died following required surgeries.[5] all hospitals that provides surgeries around the world today therefore should be realize the safety of the service recipients and prevent mistakes in patient care[6] Therefore, first-line nursing managers, and every operating room should focus on improving quality in service provision and safety outcomes of patients who receive surgery in order to consistently meet standards.[7]

Safety outcomes are the final outcomes desired for persons who undergo surgery, and this can be achieved by avoiding errors and complications that may occur as a result of care.[8] Although surgeries are aimed to save lives and prevent disability, unsafe surgical care can cause serious harm and impact safety outcomes and patient expectations,[9] safety outcome scales are available

for effectively measuring safety quality. In this study, the researcher used the safety outcome concept for frontline nursing managers of general hospitals based on Donabedian's concept[9] to ensure patient safety during surgery and prevent surgery complications, which were the primary objectives set.[10] However, current evaluations of safety outcomes in patients who receive surgeries in general hospitals are based on the practice guidelines of the WHO and patient and public health personnel safety policy of the Health Care Accreditation Institute,[2] and the evaluation forms in current use do not yet cover measurement of safety outcomes of operating rooms and are only in the form of surgery safety checklists for surgical patients. Therefore, it is necessary to develop a specific measurement form in the measurement of safety outcomes in order to provide safety management guidelines for the operating rooms of general hospitals and an important instrument for developing new and clearer knowledge on the safety outcomes of the operating room in general hospitals.

Research Objectives

To develop a safety outcome measurement scale of the operating room as perceived by nurses in general hospitals.

Methodology

Research design

This is a methodological study for developing and validating the Safety outcome for operating room. Scale development process the Safety outcome was developed based on the scale development guidelines by DeVellis[11] initial safety results were obtained from the Donabedian concept[9] integrated interviews with seven experts in nursing for operating room patients.

Population and samples

The population used in this research was 1,001 profession nurses of operating rooms in general hospitals under the Ministry of Public Health (Level S). who were ≥ 1 year of experience, currently working in an operating room nurse position and did not hold the position of the first-line nursing managers of the operating room by multi-stage random sampling technique.

Sample calculation

The sample size in this research was 326 profession nurses of operating rooms in general hospitals. The estimated sample size was calculated from the formula of Krejcie and Morgan[12], development confidence level and the tolerance level 0.05% to get complete information, data was collected to prevent loss of 20% of the sample. The researchers then adjusted the size of the group according to the formula of Gupta and the faculty by calculating a dropout rate of ten percent[13]. Data collection October to December 2020.

Indicators Development

On the development of the safety outcome measurement scale of the operating room nursing team in general hospitals (S level), after receiving permission from Donabedian[9], who owns the rights to the research instrument, the researcher applied the research instrument development procedures of Devellis[11] as follows:

1. Operational definitions of variables used in the research ensure that measurement capabilities are consistent with the concept of Donabedian with integration of analysis of content obtained from interviews of operating room nursing professionals. Components measured on the safety outcomes of first-line nursing managers of the operating room nursing work group in general hospitals (S-level) consisted of eight components as follows: 1) efficacy; 2) efficiency; 3) effectiveness; 4) optimality; 5) acceptability; 6) legitimacy;

7) equity; and 8) adverse outcomes.

2. Generation of an item pool, by which the researcher created questions consistently with the operational definitions of the safety outcome variables for use as the questions of the safety outcome form of the operating room nursing team in eight components consisting of a total of 34 questions to cover meanings of minor characteristics and maintain consistency with the element analysis principle of Hair et al.[14]

3. Designing of the scale, by which 5-level Likert scales were used with answer and scoring of perceived values as follows: 1 indicated perceived least accuracy while 5 indicated perceived highest accuracy.

4. Content validity testing by experts: Content validity testing was performed by 7 individuals, namely, 3 people who were nursing professors with management expertise and/or nurses with experience or academic work related to safety outcomes and 4 people were first-line nursing managers of the operating room nursing team in general hospitals (S-level).[15]

5. Instrument reliability testing in a sample group representative of the population: Testing was performed in 30 operating room professional nurses with identical attributes to the studied sample but who were not included as part of that group.[16]

6. Evaluation of the question items by administering the items to development samples. The researcher administered the constructed measurement form in at least 326 samples and performed analysis to produce Cronbach's α values ranging from 0.00 to 1.00. Values below 0.60 were not acceptable. Values ranging from 0.60 to 0.65 were acceptable but not desired. Values ranging from 0.65 to 0.70 were somewhat acceptable. Values from 0.70 to 0.80 were acceptable. Values ranging from 0.80 to 0.90 were very good values. However, values greater than 0.90 indicated that question items were to closely connected, and duplicates might exist, thereby making it appropriate to consider whether to eliminate or retain certain items.

7. Construct validity testing by exploratory factor analysis (EFA).

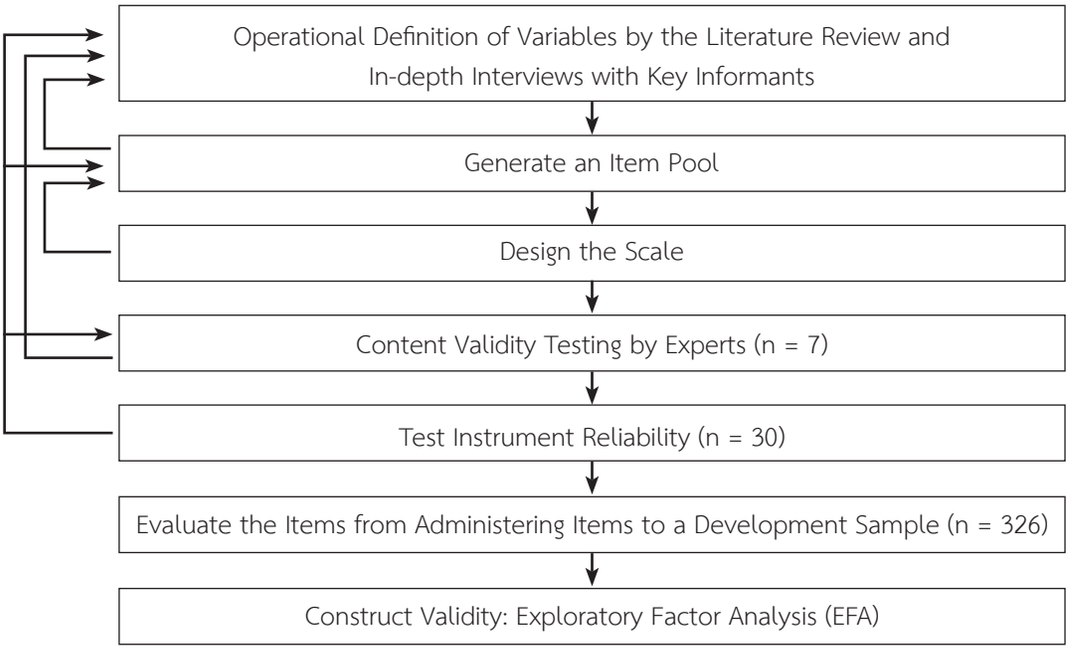

Figure 1: Steps of DeVellis's method of scale development application for safety outcomes.

Ethical Considerations

This study was approved by the institutional review board (IRB) at Christian University of Thailand (IRB No: N.03/2563) before data collection. The participants were obtained as personal information and ethical concerns, which included informed consent and maintaining confidentiality. The participants had the right to cancel participation in the study at any time without any impact.

Data Analysis

The data were analyzed by using the following statistical methods:

1) Descriptive statistics were used to determine means and standard deviations for safety outcome measurement with a software package.

2) In depth interview using content analysis.

3) Exploratory factor analysis was used to analyze the components of safety outcome measurement with a software package.

Results

Respondent Characteristics

Three hundred and twenty-six nursing administrators responded in this study. The majority of respondents were female (91.4%), middle aged with an average age of 33.4 years Most of respondents had earned a bachelor degree (94.2%).

Instrument quality

As for the results on the testing of the attributes of the original measurement form by content validity analysis by calculating the content validity index of the entire form (S-CVI), the CVI score was 0.90. In addition, testing of the form's validity after testing in a group of 30 samples produced an overall Cronbach's alpha coefficient of the form of 0.98.

Construct validity

The mean score of each item was 4.15-4.63, with a standard deviation of .55-.84. The correlation coefficient for each item with the total score was .70-.84. (Table 1.)

Exploratory factor analysis (EFA)

For the development of the safety outcome measurement form by exploratory factor analysis, the researcher tested the sufficiency of the sample size by using the Kaiser-Meyer Olkin (KMO) method, which relied on index comparison with the size of the correlation coefficient observed, and the partial correlation size between each variable pair. After eliminating variance from other variables, the value equaled 0.96. Then the Bartlett's test was performed with statistical significance with $\chi 2 = 8577.305$ and $p < .001$, and principle component analysis was performed to extract components to reduce the number of variables to the lowest possible number. Subsequently, orthogonal axis rotation was performed by using the Varimax method, which caused the sum of the variance of the component weights between components to have the highest value. Then safety outcome components were arranged with three components with Eigen values of 16.05, 2.40, and 1.30, respectively. Ultimately, 29 questions remained (out of the original 34). All three components were able to jointly describe the variance that occurred by 68.10% with component weights valuing shown in Table 1.

Table 1: Rotated Component Matrix of Items

Items		Mean	S.D.	Factors		
				1	2	3
Patient-centeredness		4.42	.64			
q1	Patients can refuse surgery if they need another treatment after receiving an explanation.	4.45	.65	0.83		
q2	Patients demonstrate understanding after receiving positive and negative postoperative outcomes.	4.37	.65	0.81		
q3	Patients have the right to lodge a complaint if they receive poor quality of care.	4.40	.66	0.81		
q4	Patients undergoing surgery have the right to change to a health professional.	4.26	.84	0.74		
q5	Patients receive equitable services in operating room nursing care.	4.47	.57	0.73		
q6	Patients are respected for their individuality.	4.53	.55	0.72		
q7	Patients feel they have access to surgical services according to their health problems without differences.	4.39	.62	0.70		
q8	Patients receive nursing care consistent with treatment plans.	4.43	.59	0.66		
q9	Patients agree to receive diagnosis or treatment for surgery after receiving advice.	4.41	.61	0.65		
q10	Patients' information about their illness is kept confidential.	4.55	.58	0.64		
q11	Patients understand welfare and benefits after receiving advice and information.	4.31	.68	0.63		
q12	Patients do not experience compression of the nerves or injury of tissues during or after surgery.	4.58	.61	0.82		
q13	Patients are not harmed by the use of tourniquets during surgery.	4.57	.59	0.80		
q14	Patients are not harmed by the use of electrosurgical devices after surgery.	4.56	.61	0.77		
q15	Patients do not have an incidence of surgical errors caused by the carelessness of the surgical nursing staff.	4.53	.65	0.76		
q16	Patients have no objects remaining in their bodies.	4.58	.70	0.73		
q17	Patients do not have symptoms of drug allergy or chemical allergy and various agents.	4.48	.66	0.71		
q18	Patients are safely transported with appropriate equipment according to patients' conditions.	4.63	.55	0.69		
q19	Patients are safe from every surgical procedure.	4.51	.61	0.65		
q20	Patients do not get infections from readiness instruments and examination according to the aseptic technique steps.	4.54	.61	0.64		
q21	Patients do not get infections from skin preparation at the surgical site according to the infection prevention standards.	4.44	.63	0.62		
q22	Patients receive safe surgery services before, during and after surgery according to the operating room nursing standards.	4.57	.57	0.56		
q23	Patients in emergency situations receive surgery with timeliness, safety and no complications within 30 minutes.	4.50	.60	0.55		

Table 1: Rotated Component Matrix of Items

Items		Mean	S.D.	Factors		
				1	2	3
Effectiveness and Efficiency		4.32	.67			
q24	Patients are prioritized before and after surgery in accordance with infection control standard precautions to prevent cancellation-postponement of surgery due to operating room availability.	4.31	.70	0.72		
q25	No incidence of cancelling or postponing surgery due to unavailability of the operating room schedules or designated surgical nursing staff.	4.15	.76	0.72		
q26	Patients receive effective surgical nursing care by applying research utilization or practical experiences.	4.34	.66	0.63		
q27	Scheduled patients are assessed and prepared before the surgery date according to the operating room nursing standard.	4.33	.70	0.65		
q28	Patients can correctly follow the operating room nurses' instructions before and after surgery.	4.35	.62	0.57		
q29	Patients are safe from using requiring special surgery instruments due to the surgical nurse specialists.	4.46	.59	0.55		

As the table shows, there were three components with 29 items: 1) patient-centeredness (11 items); 2) Adverse Outcomes (12 items) and 3) Effectiveness and Efficacy (6 items). The EFA showed that the factor loading of the indicators was between 0.55-0.83, all of which were statistically significant ($p < .001$).

Discussion

Testing of the operating room nursing work group safety outcome measurement scale revealed that the instrument has content validity with total content validity index (S-CVI) at 0.98 and by-item content validity index with acceptable value for the newly-developed instrument at 0.80. In other words, every expert shared the opinion that each question item was consistent with the research concept. Therefore, the measurement form had the content validity for use in measuring safety outcome in the operating room nursing team in general hospitals.

The reliability of the consistency in the safety outcome measurement scale as determined from a sample group of 30 people produced the Cronbach's alpha coefficient of 0.98 with the Cronbach's alpha coefficient of from 326 samples at 0.97 and internal consistency of the measurement form on individual items greater than 0.70 for every item. Therefore, the measurement form's reliability was acceptable, and the measurement form was valid based on repeated measurement.

Meanwhile, results of the exploratory factor analysis on safety outcomes revealed that the Kalser-Meyer-Olkin Measure of Sampling Adequacy (KMO) value was 0.96. A KMO value so closely approaching 1 indicated the suitability of all data and that the variables had a very high level of correlation and can be used in component analysis. In addition, the Bartlett's Test of Sphericity revealed that variables were correlated with statistical significance (Bartlett's Test of Sphericity Approx. $\chi 2 = 8577.305$, df = 406, and P-value < .001), thereby indicating the presence

of a matrix for the correlation of the variables.

As for the results of the analysis of the variables of the factor components following component axis rotation by using Varimax with Kaiser Normalization, three components were obtained. Evaluation of the Eigen values found that one factor had more than one factor loading value greater than 1 at 0.5 Hair. The components obtained in this study consisted of three components made up of a total of 29 question items (there originally eight components and 34 items). The elimination of five questions improved clarity in the categorization of the question items, and the factor loading values of the form after the axis rotation ranged from 0.55 to 0.83, which exceeded the criteria of 0.30 and indicated that the items were consistent as component members.

Finalized a scale development of safety outcome instruments after empirically establishing the validity of the scale via EFA, there were three components with 29 indicators: 1) patient-centeredness (11 items); 2) Adverse Outcomes (12 items) and 3) Effectiveness and Efficacy (6 items).

In the construction of the operating room safety outcome measurement scale, the instrument was constructed in the context of general hospitals with content validity testing performed by qualified experts and confirmed by samples composed of professional nurses. It was found that content components had an acceptable level of consistency with a high validity score in every component and consistency with empirical data. The quality of the measurement scale was tested item by item and by the entire form. The safety outcome content analysis resulted in three components with 29 question items. Every item met the safety standard of the Health Care Accreditation Institute and the WHO. However, the newly developed safety outcome measurement scale is suitable for the service quality of surgical patient nursing in general hospitals (S level) and is an important instrument for heart-based care according to the notion that the patient is a human being and that, for the desired outcomes, efficiency and effectiveness in measuring safety outcomes, if operating room nursing work group supervisors can use this instrument in operating room units in appropriate contexts, the best nursing outcomes can be achieved,[17] whether in terms of surgical patient safety, satisfaction, or self-care knowledge.[18]

Conclusions

The indicators of the safety outcome measurement scale had an accurate construct consistent with the safety outcomes three components with a total of 29 questions. The indicators developed are suitable for measuring outcomes on the safety of patients receiving surgical services in the operating rooms of general hospitals under Ministry of Public Health in the context of Thailand.

Recommendations

Because first-line nursing managers of operating room have to work with patients in complex and unpredictable environments, nursing department supervisors should take actions relating to safety outcome evaluations by using the currently developed safety outcome measurement. The study found that the safety outcome measurement can serve as a reliable and professional instrument for measuring safety outcomes in first-line nursing managers of operating room with quality and effectiveness improvements of the instrument after use in order to produce even clearer measurement results.

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