

**DEVELOP A MANUAL FOR SAFETY MEASURES IN INTENSIVE CARE
UNITS IN SELECTIVE HOSPITALS AT PORT SAID CITY**

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ABSTRACT

Background: The risks associated with the delivery of healthcare services are increased in Intensive Care Units (ICUs). **The aim** of this study was to develop a manual for safety measures in Intensive Care Units (ICUs) in selected hospitals at Port Said city. **This methodological** study involved 48 experts for validation of the manual, which was developed by the researcher based on assessment findings. **The data collection** tools included an opinionnaire for jury. The manual was validated through experts' opinions. The manual is valid by high percentages of jury agreement upon its face and content validity, reaching unanimous agreement in many of the items. **The study recommends** use of the developed manual in ICUs, with close supervision, and a system of rewards and punishment. The hospital administration must establish patient safety as a priority in its mission, and provide all needed equipment and supplies. Training courses in patient safety are strongly recommended. Further research is suggested to assess the impact of the use of the developed manual on nurses' performance of patient safety measures.

Key words: Patient safety, Manual, Intensive Care Units, Nurses

INTRODUCTION

Safety is defined as the control of recognized hazards to achieve an acceptable level of risk. This can take the form of being protected from the event or from exposure to something that causes health or economic losses (*Yoder-Wise, 2007*). Safety is about the focus on excluding unintended consequences of care delivery (*Barnsteiner, 2012*). Nowadays, the rapid changes in healthcare lead to greater attention to safety measures, which is essential for quality patient care, nurse welfare and morale (*Brous, 2008*). Common safety measures include implementation of standard protocols and procedures so that activities are conducted in a known way, with training of nurses, and availability of instruction manuals so that nurses know what is expected of them (*Laschinger, 2005*). The standards for practice can be a guide for unit specific standards, assist with the auditing of practice and guide professional practice (*American Association of Critical Care Nurses, 2012*).

Patient's safety is the reduction and mitigation of unsafe acts within the healthcare system, as well as use of best practices shown to lead to optimal patient outcomes (*Ellis, 2008*). However, for nursing it must mean more than that; it means being under the care of a professional healthcare provider who assists the patients to achieve an optimal level of health while ensuring that all necessary actions are taken to prevent or minimize harm (*Feng, Bobay, and Weiss, 2008*).

Patient's safety is a global issue affecting countries at all levels of development. The size of the problem is scarcely estimated, particularly in developing and transitional countries. It needs a great concern from healthcare leaders to be a top priority in all healthcare organizations. It is one of the nations' most pressing healthcare challenges. Adverse events in healthcare delivery cause many cases of illness, injury and death. Studies in a number of countries have shown a rate of adverse events rate of about 10% among hospital patients (*Mark and Natasha, 2008*). An average of one in every ten patients admitted to hospital suffers some form of preventable harm that can result in severe disability and even death (*World Health Organization [WHO], 2009*).

Intensive care unit represents heart beats of healthcare organizations; it focuses on intensive care and observation on the major system, including the cardiovascular system, the gastrointestinal tract, the central nervous system, and the respiratory tract. Intensive care providers try to keep these important bodily systems running smoothly

so that the patient remains stable. As the patient's underlying condition is treated, smoothly running bodily systems will greatly improve the patient's prognosis. For unstable patient, ICU care may require constant adjustment of medications and treatment programs, along with a very focused and dedicated staff, who must follow the safety measures for preserving patient's health (*Kahn., Goss., Heagerty., Kramer., O'Brien.,and Rubenfeld. 2006*). All ICUs must be separate and self-contained facilities in hospitals and conform to relevant guidelines (*Smith, 2013*). The ICU with correct structure will support proper processes, which in turn will result in a desired patient outcome (*Stockwell and Slonim, 2006; Johnson, 2012*).

The aim of this study was to develop a manual for safety measures in Intensive Care Units (ICUs) in selected hospitals at Port Said city.

SUBJECTS AND METHODS:

Research Design:

A methodological operations action-oriented research design was used in conducting this study to develop the manual according to its aim.

setting: This descriptive cross-sectional study was carried out in the Intensive Care Units (ICUs) at Port Fouad and Elzhohor General Hospitals, which are affiliated to Ministry of Health (MOH).

Subjects: Jury groups: This third group consisted of 48 experts to seek their opinions regarding the validity of the developed safety manual. It consisted of two subgroups: one nursing (16) and the other medical (32).

Opinionnaire for Jury

The researcher prepared this tool for the validation of the developed module. It consisted of the following parts:

- **Part I:** Socio-demographic data such as age, gender, qualification, job position, and experience years.
- **Part II:** Face validity: 9 items with sub-items such as “in good logical sequence” and “sound with no mistakes,” etc.
- **Part III:** Content validity: 14 items with sub-items asking about the clarity, comprehensiveness, relevance, and applicability of the module parts.

The responder had to check with “agree” or “disagree” and for any comments. The percentages of agreement were calculated.

Data collection tools: Opinionnaire for Jury The researcher prepared this tool for the validation of the developed module. It consisted of the following parts:

- **Part I:** Socio-demographic data such as age, gender, qualification, job position, and experience years.
- **Part II:** Face validity: 9 items with sub-items such as “in good logical sequence” and “sound with no mistakes,” etc.
- **Part III:** Content validity: 14 items with sub-items asking about the clarity, comprehensiveness, relevance, and applicability of the module parts.

The responder had to check with “agree” or “disagree” and for any comments. The percentages of agreement were calculated.

Pilot study:

A pilot study was carried out on five nurses who were working in the casualty unit to test the questionnaire of job hazards and safety measures of nursing personnel, and on five patients to test the observation checklist for patients' hazards and safety measures, and for the facilities. The tools were finalized according to the results of the pilot study. The pilot sample was not included in the study sample.

Fieldwork:

An official permission was obtained from the pertinent authorities in the identified settings to collect the necessary data. This was through official letters addressed from the Dean of Port-Said Faculty of Nursing to hospital directors explaining the aim of study and its procedures. Upon securing official permissions for data collection, the researcher visited the study settings and met with the directors of nursing and medical directors to inform them about the study aim and procedures. This was followed by recruitment of the nurses in the study sample. The researcher met with each nurse individually, explained to her the aim and procedures of the study and invited her to participate. Those who gave their consent were handed the self-administered questionnaire and instructed on how fill it. Upon completion of the questionnaire, it was collected by the researcher and revised for any missing data.

The process of observation of the nurses was then started. Each nurse was directly observed while providing care for patients to assess her compliance with safety

precautions in general and in specific procedures. This was done using the nurse observation checklists for safety in ICUs. The process of observation took more than one shift for each nurse to cover all the procedures specified.

Then, the researcher started the monitoring of patient safety using the designed checklist. It covered both general and specific hazards. All the patients present in the ICUs of the study setting during six consecutive cases were monitored daily for the application of the safety measures. The numbers of patients varied from day to day according to admission and discharge rates.

Ethical considerations:

The study protocol was approved by the Research and Ethics committee at the Faculty of Nursing, Port-Said University. The researcher explained the study aim and procedures in a clear manner to all participants and an informed oral consent was obtained before collecting any data. No harmful maneuvers were used, and no foreseen hazards were anticipated. Participants were informed about their right to withdraw from the study at any time without giving any reason. Data were considered confidential and not be used outside this study.

Statistical analysis:

Data entry and statistical analysis were done using SPSS 18.0 statistical software package. Data were presented using descriptive statistics in the form of frequencies and percentages for qualitative variables, and means and standard deviations and medians for quantitative variables.

RESULTS:

Table (1): describes the characteristics of the jury group of nursing. Their age ranged between 23 and 70 years with mean 41.9. Approximately two thirds were having a doctorate degree (62.5%), experience of 10 years or more (62.5%), and an academic job position (62.5%). The highest percentages were from Port-Said and Ain-Shams universities (25% each).

Table (2): indicates that their age ranged between 34 and 60 years with mean 48.7. Approximately two thirds or more were having a master degree (62.5%), experience

of 10 years or more (71.9%), and a specialist job position (53.1%). The highest percentages were from cardiology department (62.5%).

Table (3): points to high percentages of agreement upon all the items of face validity of the developed manual among the two jury group members. The percent of agreement ranged between 68.8% and 100% in the nursing group. As for the medical group, it was mostly 100%. The lowest percent of agreement for both groups was upon the manual general introduction, 68.8% and 53.1% respectively.

Table (4): indicates very high percentages of agreement upon all the of items among the two jury group members, reaching 100% in most items. The lowest percentages of agreement were 93.8% in the nursing group and 96.9% in the medical group.

Table (5): indicates 100% agreement upon all the items among the medical jury group members. For the nursing group, the agreement reached 100% in most items. The lowest percentage of agreement in this group was for the item of safety aspects of housekeeping services (87.5%).

Table (6): demonstrates a unanimous (100%) agreement upon all the items of content validity concerning the relevance of the developed model among the medical jury group members. As for the nursing group, the agreement reached 100% in most items, and 93.8% in the remaining ones.

Table (7): demonstrates generally high percentages of agreement upon all the items among the two jury group members, reaching 100% in many items in the medical group. The lowest percentages of agreement in both groups were for OSHA inspection and OSHA record keeping, 62.5% in the nursing group and 40.6% in the medical group. Additionally, the agreement upon the item of emergency action plan was only 53.1% in the medical group.

Table 1: Personal characteristics of the nursing group of juries (n=16)

	Frequency	Percent
Age:		
<45	6	37.5
45+	10	62.5
Range	23.0-70.0	
Mean±SD	41.9±11.1	
Median	44.0	
Qualification:		
Bachelor	6	37.5
Doctorate	10	62.5
Experience (years):		
<10	6	37.5
10+	10	62.5
Range	3.0-40.0	
Mean±SD	12.8±9.5	
Median	12.0	
Hospital:		
Port-Fouad	3	18.8
Al-zohour	3	18.8
Suez Canal University	1	6.3
Port-Said University	4	25.0
Ain-Shams University	4	25.0
Cairo University	1	6.3
Job site:		
Service	6	37.5
Academic	10	62.5
Job position:		
Assistant professor	10	62.5
Director/assistant	2	12.5
Supervisor	2	12.5
Head nurse	2	12.5
Specialty:		
Medical	5	31.3
Administration	5	31.3
Infection control	1	6.3
Medical-surgical	5	31.3

Table 2: Personal characteristics of the medical group of juries (n=32)

	Frequency	Percent
Gender:		
Male	20	62.5
Female	12	37.5
Age:		
<45	10	31.3
45+	22	68.8
Range	34.0-60.0	
Mean±SD	48.7±6.7	
Median	50.0	
Qualification:		
Master	20	62.5
Doctorate	12	37.5
Experience (years):		
<10	9	28.1
10+	23	71.9
Range	4.0-30.0	
Mean±SD	16.7±7.6	
Median	17.5	
Hospital:		
Port-Fouad	16	50.0
Al-zohour	16	50.0
Job:		
Specialist	17	53.1
Consultant	15	46.9
Specialty:		
Medical	6	18.8
Surgical	6	18.8
Cardiology	20	62.5

Table 3: Agreement upon the face validity of the developed manual among the nursing and medical groups of juries

	Group			
	Nursing (n=16)		Medical (n=32)	
	No.	%	No.	%
The proposed manual looks structurally like a safety manual	15	93.8	32	100.0
The size (number of pages) is suitable	12	75.0	31	96.9
It has a clear outline	16	100.0	32	100.0
It has a general introduction	11	68.8	17	53.1
It is divided into parts which look:				
In good logical sequence	15	93.8	31	96.9
Having no gaps	13	81.3	32	100.0
Having no overlaps (repetitions)	14	87.5	31	96.9
The wording (writing) of the proposed manual is:				
Clear (easily understandable)	15	93.8	31	96.9
Interesting	15	93.8	32	100.0
Sound (no mistakes)	13	81.3	32	100.0
With no redundancy (repetitions)	15	93.8	32	100.0
The manual has suitable illustrations	12	75.0	32	100.0
The manual has a list of references that is:				
Updated	15	93.8	32	100.0
Comprehensive	14	87.5	30	93.8
Relevant	15	93.8	32	100.0
The manual can be used:				
In orienting new staff	16	100.0	32	100.0
As a reference book for working staff	16	100.0	32	100.0
As a benchmark for quality control/improvement	15	93.8	32	100.0

Table 4: Agreement upon the content validity regarding the clarity of the developed manual among the nursing and medical groups of juries

	Group			
	Nursing (n=16)		Medical (n=32)	
	No.	%	No.	%
Introduction	16	100.0	32	100.0
General policy	16	100.0	32	100.0
General safety rules	15	93.8	32	100.0
Safety committee	16	100.0	32	100.0
Hazard prevention and control	16	100.0	32	100.0
Safe operating procedures:				
Proper body mechanics and lifting techniques	15	93.8	31	96.9
Endotracheal or tracheostomy tube suctioning	15	93.8	31	96.9
Inhalation therapy by nebulizer	15	93.8	31	96.9
Enteral nutrition	16	100.0	31	96.9
Arterial puncture	15	93.8	31	96.9
O2 saturation monitoring by pulse oximetry	15	93.8	32	100.0
Twelve lead electrocardiogram	16	100.0	32	100.0
Total parenteral nutrition	16	100.0	32	100.0
Compressed-gas cylinders	16	100.0	32	100.0
Handling and storage of nonflammable gases	16	100.0	32	100.0
Handling and storage of flammable gases and liquid	15	93.8	32	100.0
Patient and personnel safety measures	15	93.8	32	100.0
Security personnel safety	16	100.0	32	100.0
General plant safety and health rules:				
Ventilation heating and other mechanical systems	16	100.0	32	100.0
General storage areas	15	93.8	32	100.0
Waste disposal	16	100.0	32	100.0
Safety aspect for housekeeping services	15	93.8	32	100.0
Personal protective equipment	16	100.0	32	100.0
Blood borne pathogens	15	93.8	32	100.0
Electrical safety	15	93.8	32	100.0
Accident investigation	16	100.0	32	100.0
Emergency action plan	16	100.0	32	100.0
OSHA inspection	15	93.8	32	100.0
OSHA record keeping	16	100.0	32	100.0

Table 5: Agreement upon the content validity regarding the comprehensiveness of the developed manual among the nursing and medical groups of juries

	Group			
	Nursing (n=16)		Medical (n=32)	
	No.	%	No.	%
Introduction	15	93.8	32	100.0
General policy	15	93.8	32	100.0
General safety rules	16	100.0	32	100.0
Safety committee	15	93.8	32	100.0
Hazard prevention and control	15	93.8	32	100.0
Safe operating procedures:				
Proper body mechanics and lifting techniques	15	93.8	32	100.0
Endotracheal or tracheostomy tube suctioning	16	100.0	32	100.0
Inhalation therapy by nebulizer	15	93.8	32	100.0
Enteral nutrition	15	93.8	32	100.0
Arterial puncture	15	93.8	32	100.0
O2 saturation monitoring by pulse oximetry	15	93.8	32	100.0
Twelve lead electrocardiogram	15	93.8	32	100.0
Total parenteral nutrition	15	93.8	32	100.0
Compressed-gas cylinders	15	93.8	32	100.0
Handling and storage of nonflammable gases	15	93.8	32	100.0
Handling and storage of flammable gases and liquid	16	100.0	32	100.0
Patient and personnel safety measures	16	100.0	32	100.0
Security personnel safety	15	93.8	32	100.0
General plant safety and health rules:				
Ventilation heating and other mechanical systems	15	93.8	32	100.0
General storage areas	16	100.0	32	100.0
Waste disposal	15	93.8	32	100.0
Safety aspect for housekeeping services	14	87.5	32	100.0
Personal protective equipment	15	93.8	32	100.0
Blood borne pathogens	16	100.0	32	100.0
Electrical safety	16	100.0	32	100.0
Accident investigation	15	93.8	32	100.0
Emergency action plan	15	93.8	32	100.0
OSHA inspection	16	100.0	32	100.0
OSHA record keeping	16	100.0	32	100.0

Table 6: Agreement upon the content validity regarding the relevance of the developed manual among the nursing and medical groups of juries

	Group			
	Nursing (n=16)		Medical (n=32)	
	No.	%	No.	%
Introduction	15	93.8	32	100.0
General policy	15	93.8	32	100.0
General safety rules	15	93.8	32	100.0
Safety committee	15	93.8	32	100.0
Hazard prevention and control	15	93.8	32	100.0
Safe operating procedures:				
Proper body mechanics and lifting techniques	15	93.8	32	100.0
Endotracheal or tracheostomy tube suctioning	15	93.8	32	100.0
Inhalation therapy by nebulizer	16	100.0	32	100.0
Enteral nutrition	15	93.8	32	100.0
Arterial puncture	16	100.0	32	100.0
O2 saturation monitoring by pulse oximetry	15	93.8	32	100.0
Twelve lead electrocardiogram	15	93.8	32	100.0
Total parenteral nutrition	15	93.8	32	100.0
Compressed-gas cylinders	15	93.8	32	100.0
Handling and storage of nonflammable gases	15	93.8	32	100.0
Handling and storage of flammable gases and liquid	15	93.8	32	100.0
Patient and personnel safety measures	15	93.8	32	100.0
Security personnel safety	15	93.8	32	100.0
General plant safety and health rules:				
Ventilation heating and other mechanical systems	15	93.8	32	100.0
General storage areas	15	93.8	32	100.0
Waste disposal	15	93.8	32	100.0
Safety aspect for housekeeping services	15	93.8	32	100.0
Personal protective equipment	16	100.0	32	100.0
Blood borne pathogens	16	100.0	32	100.0
Electrical safety	16	100.0	32	100.0
Accident investigation	16	100.0	32	100.0
Emergency action plan	16	100.0	32	100.0
OSHA inspection	16	100.0	32	100.0
OSHA record keeping	15	93.8	32	100.0

Table 7: Agreement upon the content validity regarding the applicability of the developed manual among the nursing and medical groups of juries

	Group			
	Nursing (n=16)		Medical (n=32)	
	No.	%	No.	%
Introduction	14	87.5	30	93.8
General policy	14	87.5	30	93.8
General safety rules	13	81.3	30	93.8
Safety committee	13	81.3	29	90.6
Hazard prevention and control	12	75.0	29	90.6
Safe operating procedures:				
Proper body mechanics and lifting techniques	14	87.5	31	96.9
Endotracheal or tracheostomy tube suctioning	14	87.5	31	96.9
Inhalation therapy by nebulizer	14	87.5	32	100.0
Enteral nutrition	15	93.8	32	100.0
Arterial puncture	15	93.8	32	100.0
O2 saturation monitoring by pulse oximetry	15	93.8	32	100.0
Twelve lead electrocardiogram	15	93.8	32	100.0
Total parenteral nutrition	13	81.3	30	93.8
Compressed-gas cylinders	14	87.5	29	90.6
Handling and storage of nonflammable gases	14	87.5	29	90.6
Handling and storage of flammable gases and liquid	14	87.5	30	93.8
Patient and personnel safety measures	14	87.5	31	96.9
Security personnel safety	14	87.5	31	96.9
General plant safety and health rules:				
Ventilation heating and other mechanical systems	14	87.5	31	96.9
General storage areas	14	87.5	31	96.9
Waste disposal	14	87.5	32	100.0
Safety aspect for housekeeping services	14	87.5	28	87.5
Personal protective equipment	15	93.8	28	87.5
Blood borne pathogens	15	93.8	31	96.9
Electrical safety	15	93.8	30	93.8
Accident investigation	13	81.3	26	81.3
Emergency action plan	12	75.0	17	53.1
OSHA inspection	10	62.5	13	40.6
OSHA record keeping	10	62.5	13	40.6

DISCUSSION :

The ultimate goal of the present study was to develop and validate a safety manual for the nurses' working in ICUs. This was done through seeking the opinions of experts from the nursing and medical disciplines, both in academia and service. This variability in the experts group was intended to ensure different views from different aspects. This would increase the credibility in the scientific value of the manual, in addition to its applicability. This is a known approach to validation known as consensus validation as explained by (*Bellucci and Matsuda, 2012*).

The study findings revealed high percentages of experts' agreement upon the face validity of the developed safety manual. More than three-fourth of the two groups of jury, nursing and medical, expressed their agreement upon all the items of face validity. The only exception was related the manual general introduction, which was agreed upon by slightly more than half of them. This was modified according to their opinions and suggestions. Most importantly was the almost unanimous agreement that the manual can be used in orienting new staff, as a reference for working staff, and as a benchmark for quality control improvement. A similar approach to validation was used by *Toupin April et al (2016)* in Canada.

Concerning the validation of the content of the developed manual, the current study revealed very high percentages of agreement upon all items among the members of the two groups of jury, reaching full agreement in most items of clarity, comprehensiveness, relevance, and applicability. This validity of contents determines the representation of items expressing a given content based on the assessment of experts in each area of the manual or instrument under study (*Barbosa and Tronchin, 2015*). This type of validation determines whether the developed manual content will effectively cover the requirements toward the application of safety in the study setting.

The results also revealed low percentages of agreement in both groups, less than two-thirds, concerning the applicability of OSHA inspection and record keeping, and of the emergency action plan. This could be explained by the over-ambitiousness of these items, which may require more strict application of safety measures that need extra-resources. In agreement with this, *Sinclair and Cunningham (2014)*, in their study on safety in small

business in the United States, denoted that the lack of resources, greater time demands on managers, poorer manager attitudes about safety, and fewer employees to engage in activities such as safety committees underlie the deficient application of OSHA inspection and record-keeping guidelines.

CONCLUSION:

The study results lead to the conclusion that the nurses in the study settings lack knowledge about occupational diseases, and are not compliant to preventive measures to protect themselves. Their perception of job hazards is low. Moreover, their performance of patient safety measures is generally deficient in all areas, whether general, specific, or miscellaneous. It also declines throughout the patient stay in the ICU. Similar findings apply to the monitoring of the unit physical environment, facilities, and patient rooms, with the same decreasing trends throughout follow-up. The developed patient safety measures manual takes into consideration all these deficiencies and shortcomings in order to help nurses improve their performance to protect themselves and others and to provide safe quality care to their patients. The manual is valid by high percentages of jury agreement upon its face and content validity, reaching unanimous agreement in many of the items.

RECOMMENDATIONS:-

In view of the main study findings, the following recommendations are proposed.

- The developed manual should be made available to all nurses working in ICUs, with emphasis on its use and application of all its content.
- Close supervision of the nurses working in ICUs in their performance of patient safety measures is strongly recommended.
- A fair and clear system of rewards and punishment needs to be set in order to encourage nurses to comply with all patient safety measures.
- ***The hospital administration must:***
 - Establish patient safety as a priority in the organization's mission statement.
 - Provide all the equipment and supplies that are required for enabling the nurses to adhere to all patient safety measures.
 - Designate a patient safety officer and create an internal reporting system for patient safety measures.

- More consideration should be given by the hospital administration to the preventive measures needed to protect their staff, including nurses, such as the vaccination programs and the periodic medical examinations.
- Educational programs and practical hands-on training courses in patient safety are strongly recommended for the nurses working in ICUs.
- The nurses should encourage patients to actively participate in the patient safety process, and should empower them.
- Regular review and updating of the safety standards and/or best practices applicable to health care should be done by the hospital administration.
- Further research is suggested to assess the impact of the use of the developed manual on nurses' performance of patient safety measures.

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