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Validation of the simplified therapeutic intervention scoring system in the intensive care units of a public sector hospital in Johannesburg

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CHAPTER 3

RESEARCH DESIGN AND RESEARCH METHODS

3.1 INTRODUCTION

This chapter describes the research methodology used in this study including the research design. The research methods are described with reference to the research setting, target population, sample, sampling, data collection procedure as well as instruments used in data collection. Methods of data analysis and ethical considerations are also described.

3.2 PURPOSE AND OBJECTIVES

For consistency, the purpose and objectives of this study are repeated here.

The purpose of this study was to introduce the simplified therapeutic intervention scoring system (TISS-28), the original therapeutic intervention scoring system (TISS-76) and simplified acute physiological score (SAPS) version II in critically ill adult patients, in order to describe the validity and reliability of the simplified therapeutic intervention scoring system (TISS-28) as a suitable measure of quantifying nursing workload in the intensive care units of a public sector hospital in Johannesburg.

In order to meet this purpose, the following objectives were set:

- To describe the profile of patient admissions to the intensive care units.
- To investigate the impact of the patients' profile on the requirements for nursing workload.

- To validate the use of TISS-28 as a measure of quantifying nursing workload in this setting.

3.3 RESEARCH DESIGN

A non-experimental, comparative descriptive, correlational and prospective two-staged design was used to determine the validity of the TISS-28 as an objective measure of quantifying nursing workload in the ICU.

Non-experimental design: In non-experimental research, the study is carried out in a natural setting and the phenomena are observed as they occur without manipulation of the variables (Brink, Van Der Walt & Rensburg, 2006). A non-experimental design was suitable for this study as it took place in a natural setting (ICUs in selected hospital) and there was no treatment or intervention administered.

Comparative descriptive design: Comparative descriptive design is used to describe variables and to examine differences in variables in two or more groups that occur naturally in a setting (Burns & Grove, 2003:203). This study was comparative in nature as it examined the difference between the TISS-28 scores for ICU patients and those in the ward including the data collected by the researcher and experienced assistant researcher. This study was also descriptive in nature as it aimed at describing the validity of TISS-28 as an objective measure of nursing workload in the ICU.

Correlational design: Correlational design is used to examine the relationship between or among two or more variables in a single group (Burns & Grove, 2003:208). Correlational

design was selected for this study so as to describe the relationship between the scores obtained from ICU patients using the TISS-28, TISS-76 and SAPS II in order to allow assessment of concurrent criterion-related validity.

Prospective design: A prospective study according to Brink et al. (2006:10) allows the researcher to measure variables that are occurring during the study. A prospective study was selected for this study as it would enable the researcher to collect current patients' information from the patients' charts which reflected the total score of therapeutic interventions that were rendered hence, this could allow quantification of nursing workload.

Two-stage design: A two-staged design is considered an important aspect for testing instruments and to allow valid comparison of the relationship between the patients' scores. Stage I involved testing the instrument for face and content validity using a panel of expert members following a method described by Lynn (1986). Stage II established the psychometric properties of TISS-28 using a sample of patient participants in the ICUs following a method described by Kwok et al. (2005) for examining concurrent and construct validity as well as inter-rater reliability.

3.4 RESEARCH METHOD

A research method refers to the methodological perspectives of the study which includes methods of data collection, procedure, population, sample and sampling methods and strategies for gathering and analyzing the data in the research investigation (Burns & Grove, 2003:51; Polit & Beck, 2004).

3.4.1 Research Setting

The research was conducted in three adult ICUs at a public sector tertiary level hospital in Johannesburg. The three adult ICUs of the selected institution were considered by the researcher to be homogenous and that they represented highly specialized ICUs that accept critically ill patients from both medical and surgical disciplines. The three units accept patients in the trauma, cardiothoracic and multi-disciplinary respectively. These units were selected because patients admitted here were level three patients i.e. critically ill patients admitted to ICU located in a major tertiary referral hospital (Bersten, et al., 2003).

3.4.2 Target Population

3.4.2.1 Stage I: (face and content validation of TISS-28)

According to Lynn (1986:382), face validity includes validity by assumption (a non statistical assessment of the logical tie between the items of an instrument and its purpose) and validity by definition (the determination by one or more content experts that the elements / items of an instrument represent the content domain being assessed). On the other hand, she refers to content validity as the determination of the content representativeness or content relevance of the elements or items of an instrument. The judgement of content validity of an instrument involves the assertion by a specific number of experts that the items are content valid and that the entire instrument is content valid, and this can only be quantified using Content Validity Index (CVI) (Lynn, 1986:383).

Burns and Grove (2003:233) describe the target population as the entire set of individuals who meet the sampling criteria whereas an accessible population is the portion of the target population to which the researcher has reasonable access to. The population from which

the ICU experts for the discussion were selected consisted of ICU nurses considered to be experts in the ICU. These experts consisted of:

- Nurses who were currently working in the ICUs and had extensive experience on daily nursing activities performed in the ICUs.
- Specialists in nursing education were also included in the panel of experts.

3.4.2.2 Stage II: (testing concurrent and construct validity and inter-rater reliability of the TISS-28)

Concurrent criterion-related validity is the ability to detect a positive or negative statistical relationship between two instruments simultaneously measuring the same concept at the same time (Higgins & Straub, 2006:25; De Von, Block & Moyle-Wright, et al., 2007:159). This was accomplished by comparing the relationship between the patients' scores obtained from the TISS-28 and TISS-76 as well as TISS-28 and SAPS II. In this case, Pearson product moment correlation coefficient test which is both descriptive and inferential statistic, and it is used to summarise the magnitude and direction of a relationship between two variables as well as to test hypotheses about population correlations respectively (Polit, Hungler & Beck, 2001) was used to determine the strength of the relationship between TISS-28 and TISS-76 as well as TISS-28 and SAPS II in order to determine the concurrent criterion-related validity of TISS-28.

Construct validity as outlined by De Von et al. (2007:156) is the degree to which an instrument measures the construct it is supposed to measure. This was tested by comparing the patients' TISS-28 scores obtained in ICU and the scores obtained in the ward after discharge. A Paired t-test used when the researcher wishes to compare the means of two groups in order to determine whether the differences between the means are significant or

caused by chance (Brink, et al., 2006) was used to test for the difference between TISS-28 mean score of ICU patients and ward patients in order to determine construct validity of TISS-28.

Polit and Beck, (2004:420) state that inter-rater reliability is the degree of agreement among raters, it gives a score of how much homogeneity, or consensus, there is in the ratings given by different raters. This, as advised by the statistician, was accomplished by collection of data by the researcher and an experienced assistant researcher, from 15 participants at the same time. The scores obtained were thereafter compared for its consistency. An intra-class correlation used to demonstrate the strength of the relationship between one observer's ratings and another's (Polit & Beck, 2004) was used to assess the reliability of TISS-28 in the hands of two raters.

The target population in this stage comprised of all critically ill patients admitted to the trauma, cardiothoracic, and multi-disciplinary ICUs at the public sector hospital in Johannesburg. A preliminary record review undertaken in August 2007 indicated that approximately 315 patients were admitted to the ICUs (n=3) during the period 1.03.2007 to 31.05.2007. This was an average of 105 patients per month.

3.4.3 Sample and Sampling Method

3.4.3.1 Stage I

A non probability purposive sampling method was used to select experts to asses the face and content validity of TISS-28 to ensure applicability of the items for the South African context. Six nurses specializing in ICU and/ or nursing education were invited to

participate in the validation process. This number was chosen, as the process is similar to that of a focus group and between six and ten participants has been described as being suitable for focus groups (Burns & Grove, 2003:287).

Inclusion criteria for the expert group were:

- Registered with an additional qualification in ICU nursing.
- More than 5 years of experience in speciality practice and or education.
- Working in either trauma, cardiothoracic or multidisciplinary ICU.
- Provided written consent to participate was obtained.

3.4.3.2 Stage II

Following a discussion with the statistician a sample size of 105 patients (n=105) was decided upon to provide a good representation of the population from which the sample is drawn. A larger sample is needed to obtain a confidence interval of 95% (Burns & Grove, 2003). A simple random sampling method was used to select the sample of patients. In order to ensure that each patient had an equal opportunity of being selected, the ICU register was used as the sampling frame.

Inclusion criteria for the patient sample were:

- Critically ill patients on admission to either trauma, cardiothoracic or multidisciplinary ICU, who were 18 years and older.
- Had an anticipated admission period > 24 hours.
- Provided written consent to participate was obtained.

3.4.4 Data Collection

3.4.4.1 Procedure Stage I

ICU experts who met the inclusion criteria were invited to participate in the study. Lynn (1986:383) states that a structured procedure for the evaluation of the face and content validity of the instrument as well as instructions by which to determine the content relevance of the items and also of the instrument as a whole must be given to the experts. Prior to the expert group meeting, all those who agreed to participate in the study were sent the following documentations: a letter outlining the study and its procedures (refer **Appendix A**), a consent form (refer **Appendix B**) and a checklist consisting of the simplified therapeutic intervention scoring system (TISS-28) by Miranda et al. (1996) for review (refer **Appendix C**).

The expert group discussion was held in the Department of Nursing Education of the University of the Witwatersrand, Faculty of Health Sciences on 29th May, 2008 at 14.00 hours. Prior to the commencement of the group discussion, the researcher gave a brief Power Point presentation to orientate the participants to the study and as to what was expected of them during the discussion session. Chairs were arranged in a manner whereby all group members could see each other so as to facilitate good communication. Refreshments were also provided to the group members as this promotes conversation and communication within the group (De Vos, Strydom & Fouche, et al., 2005:309). All participants were assured of anonymity and confidentiality. All data was handled confidentially as only the researcher and her supervisor had access to the raw data.

Face validity was assessed by asking each expert whether they found the items in the TISS-28 relevant and if they really represent the area/domain being assessed. Content

validity was assessed by asking each panel member to identify and comment on the daily nursing activities performed in the ICU using a rating form (refer **Appendix C**) to ensure that the items represented critical attributes of issues of nursing workload in ICUs.

Content Validity Index (CVI) was derived from rating the content relevance of items using a 4-point Likert Scale, where 1 connoted not relevant; 2, unable to assess relevance without item revision or item is in need of such revision that it would no longer be relevant; 3, relevant but needs minor alteration; and 4, very relevant and succinct (Lynn, 1986). Space was also provided for additional comments by the panel members for all the items. The CVI for each item was determined by the proportion of experts who rated it as content valid (a rating of 3 or 4); whereas the CVI for the entire instrument was the proportion of total items judged content valid (Lynn, 1986).

3.4.4.2 Procedure Stage II

Permission was sought from the Chief Executive Officer (CEO) of the hospital being requested to participate in the study (refer **Appendix K**). Once permission had been obtained from the institution, the permission from the nursing services manager was sought and thereafter the unit managers were approached for permission. The researcher visited the ICUs (n=3) and observed the respective admission register for selection of patient participants.

Those patients who agreed to participate in the study were given an information letter outlining the study and its procedures (refer **Appendix F**). A consent form was also given to the patient (refer **Appendix G**). In the event that the patient was unable to provide consent due to his or her critical nature of illness, the family members were given an

information letter outlining the study and its procedures (refer **Appendix D**) including a consent form to sign (refer **Appendix E**) until the patient was able to consent. A retrospective consent was thereafter obtained from the patient during the recovery period in the ward (refer **Appendix G**) after reading the information letter with understanding (**Appendix F**).

Data was collected by means of a checklist (refer **Appendix H**) comprising four sections, namely patient data and items derived from three instruments (SAPS II, TISS-28 and TISS-76). Regular intervals for measurement were determined by published studies, which was within the first 24 hours of admission for SAPS II score and after the first 24-hour period of admission for both the TISS-28 and TISS-76 scores. One measurement of the SAPS II score was obtained, followed by two measurements of the TISS-28 and TISS-76 scores over a 24 and 48-hour admission period, thus data was collected at the same time i.e. 1800 hours at a 24-hour interval to optimize consistency in the demonstration of concurrent validity and inter-rater reliability.

An additional final measurement of the TISS-28 score was obtained from the same participants during the recovery period i.e. within 24 - 48 hours of discharge from ICU to the ward. According to Kwok et al. (2005), patients in the ward are not expected to demonstrate high TISS-28 scores as the instrument was specifically designed for use in the ICUs, these scores were used to demonstrate construct validity.

The data was obtained from the ICU charts, medical and nursing notes, laboratory test results, admission records and ward discharge notes, thus this study is described as a record

review. Polit and Hungler (1997) describe records as an economical and convenient source of data.

3.4.5 Instruments

The following three (3) instruments identified in the literature and previously published studies were used to achieve the study objectives.

The Simplified Therapeutic Intervention Scoring System (TISS-28) by Miranda et al. (1996) comprises 28 therapeutic items and each item is awarded from one to eight points depending on the degree of nursing time and nursing effort required. The total score ranges from 0 to 70. A total TISS-28 score is calculated by summing the scores for selected activities and this reflects the provided level of care for the past 24-hour period after admission. The higher the score, the more the nursing time and effort is required to care for the patient, and vice versa (Hariharan, Chen & Merritt-Charles, et al., 2007).

The Therapeutic Intervention Scoring System (TISS-76) by Keene and Cullen (1983) comprises 76 therapeutic items and each item is awarded from one to four points depending on the degree of nursing time and nursing effort required. The scores range from 0 to 174. Similarly to the TISS-28, a total TISS-76 score is calculated by summing the scores for selected activities and this reflects the level of care for the past 24-hour period after admission. The higher the score, the more the nursing time and effort is required to look after the patient, and vice versa (Hariharan, et al., 2007).

The Simplified Acute Physiological Score (SAPS) version II by Le Gall et al. (1993) comprises 15 items and each item is awarded between 0 to 26 points. The SAPS II score

will record the worst value of the selected items during the first 24 hours of admission. The range of scores is 0 to 160 and the higher the score obtained, the greater the patients severity of illness and vice versa.

3.4.6 Data Analysis

According to Burns and Grove (2007), data analysis is conducted to reduce, organize and give meaning to the data that has been collected. The raw data for both stage I and II was transferred to excel spreadsheet and was doubled checked for accuracy. The biostatistician was consulted for assistance with analyzing the study data.

3.4.6.1 Stage I

The content validity of each item is determined by the proportion of the experts who rate that item as content valid by scoring it as either a 3 or a 4 on the rating scale (Lynn, 1986:384). A table published by Lynn (1986:384) was used to determine the number of experts needed to rate a question as being content valid. Content validity of each item was assessed by the panel of ICU nursing experts by rating the content relevance of the items of the instrument using a 4-point ordinal rating scale, where 1 connotes an irrelevant item and 4 an extremely relevant item. According to Lynn (1986) and Polit and Beck (2006), the acceptable item CVI with 3-5 experts is 1.00 and a minimum of 0.78 for 6-10 experts.

On the other hand, CVI of the entire instrument is the percentage or proportion of items judged as content valid by experts. Content validity of the entire instrument was determined as the percentage of items rated as either 3 or 4 using the CVI. Polit and Beck (2006) state that the acceptable instrument content validity is 0.9

3.4.6.2 Stage II

Demographic data was analyzed using descriptive statistics to describe the characteristics of the sample group. Inferential statistics were used to assess the psychometric properties of the TISS-28 as a measure of nursing workload and staffing requirements in the ICU.

Following statistical consultation, the following statistical tests were used during analysis in order to meet the study's objectives. A Pearson product moment correlation coefficient was used to determine the strength of the relationship between the TISS-28 and the TISS-76 scores as well as TISS-28 and SAPS II scores. A paired t-test was also used to test for the difference between the mean TISS-28 scores of the participants in the ICU and ward. The intra-class correlation coefficient was also determined so as to assess the repeatability and internal consistency of TISS-28.

3.4.7 Pilot Study

A pilot study was conducted prior to the commencement of the main study. The data collection tool was used on ten patients in the ICU at the selected study site. A pilot study is a small scale trial run of all the aspects planned for use in the main study. Its purpose is to help the researcher fine-tune the study for the main inquiry and to determine whether the methodology, sampling, instruments and analysis are adequate and appropriate (De Vos, et al., 2005). There were no difficulties encountered during the pilot study. Results obtained from the pilot study were assessed by the biostatistician who then determined the sample size and the statistical tests used in this study. The results obtained from the pilot study were not used in the main study.

3.5 VALIDITY AND RELIABILITY OF INSTRUMENTS

According to Burns and Grove (2003:274), the validity of an instrument is a determination of how well the instrument reflects the construct being examined. Reliability is the degree to which the instrument can be depended upon to yield consistent results if used repeatedly over time on the same person or if used by two different investigators (Brink, et al., 2006:171). The researcher instituted the following so as to ensure validity and reliability of the instruments.

- Face and content validity of TISS-28 was assessed by panel of ICU nurse experts in order to determine content representativeness of the instrument
- The researcher was the sole data collector and compliance to the data collection instruments was highly maintained
- Researcher collected data from randomly selected participants (n=15) at the same time with the expert assistant researcher so as to assess the instruments' consistency

3.6 RELIABILITY AND VALIDITY OF DATA COLLECTION PROCESS

Reliability was maintained by:

- Ensuring consistency of data collection, which was achieved through compliance by the researcher with the data collection instrument
- The researcher collected data independently
- Data was also collected at a predetermined time
- Data was verified by the statistician for accuracy

Validity was maintained by:

- Face and content validity of TISS-28 was assessed by a panel of ICU nurse experts
- Random sampling method was used to prevent selection bias
- Non threatening environment was created by assuring the participants that participation in the study was voluntary and that anonymity would be ensured
- Expert statistical assistance was sought during data analysis

3.7 ETHICAL CONSIDERATIONS

According to Burns and Grove (2007), the goal of research is to generate sound scientific knowledge, which is possible only through the honest conduct, reporting and publication of quality research. In this regard, ethical review and clearance before conducting any research is necessary to ensure that the benefits of subjects outweigh the risks and that there is no research misconduct. Concerning this, the following ethical considerations were applied in the proposed study:

- The research proposal and the instruments were submitted to the postgraduate Committee (Faculty of Health Sciences) of the University of the Witwatersrand for permission to undertake the research. Permission was obtained. (refer **Appendix I**)
- The research proposal and instruments were submitted to the Committee for Research on Human Subjects of the University of the Witwatersrand to ensure compliance with the ethical standards. The committee issued a clearance certificate. (refer **Appendix J**)
- Permission to conduct the research was obtained from the participating Hospital management and the Department of Health, Gauteng. (refer **Appendix K**)

- A written informed consent was obtained from the group of ICU experts. (refer **Appendix A and B**)
- Before inclusion in the study, a written informed consent was obtained from the patients' relatives depending on the patients' capacity to consent (refer **Appendix D and E**) and thereafter, a retrospective informed consent was obtained in writing from the patient in the recovery period to use the information obtained (refer **Appendix F and G**)
- Anonymity of the participants was guaranteed in that names were not recorded. Consent forms and instruments were separated at time of data collection to maintain the anonymity of the participants
- Confidentiality was guaranteed in that the researcher and her supervisor were the only people with access to the raw data
- Participants were allowed to withdraw from the study at any time without penalty

3.8 SUMMARY

In this chapter the research methodology of the study has been described. The design, the research setting, target population, sample and sampling method including data collection and analysis were also described. In addition, instruments used for data collection, methods of ensuring validity and reliability related to this study including ethical considerations and pilot study were discussed.

The following chapter will present the data analysis and results of the study.