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Pain assessment and management in the critically ill unconscious patient in the adult intensive care units

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CHAPTER 3

RESEARCH DESIGN AND RESEARCH METHOD

3.1 INTRODUCTION

This chapter focuses on the research design, research method which involves the research setting, sample and sampling method, data collection process, instruments used in the study, method of data analysis, pilot study, ethical considerations and validity and reliability of the study.

3.2 RESEARCH DESIGN

A non-experimental descriptive, prospective and comparative two part design was used for this study.

A non-experimental design is a type of design in which control groups are not used as in this study and there is no manipulation of variables and no attempt to establish casualty (Burns & Grove, 2001).

A descriptive design is designed to gain more information about a particular characteristic within a particular field of study (Burns & Grove, 2001) It may be used to develop theory, identify problems with current practice, justify current practice, make judgements or identify what others in similar situations may be doing (Waltz & Bausell, 1981). No manipulation of variables is involved. Descriptive studies are also a way of

discovering new meaning, describing what exists, determining the frequency with which something occurs and categorizing information (Burns & Grove, 2001). According to Burns and Grove (2001), interviews, unstructured observation, structured observations (observations guided by a checklist), and questionnaires to describe the phenomenon used in a descriptive research. In this study, the descriptive design was used to gain more information about how unconscious patients' pain is managed by ICU nurses in the adult intensive care units.

A prospective design allows the researcher to measure variables that are occurring during the study. (Brink, Van der Walt, Rensburg, 2006). This design was ideal for this study as it allowed the researcher to collect current information from the charts as recorded by the ICU nurses for the first 48 hours of admission.

A comparative design is a scientific comparison of different phenomenon in an effort to understand their origins of relationship (Burns & Grove, 2001). This was used to compare intensive care nurses' answers to the Likert-type questionnaire about parameters that can be used to assess unconscious patients' pain to a prospective record review of critically ill unconscious patients ICU chart to see if their responses reflect in their pain management strategies.

Part One of this study involved the description of the ICU nurses' demographic data and responses to the Likert-type questionnaire and part two involved the description of the unconscious patients' demographic data and a prospective patient's record review and a comparison was undertaken between the two parts.

3.3 RESEARCH METHOD

Research method refers to the methodical perspectives of the study which includes the research setting, methods of data collection, procedure, population, sample and sampling methods and data analysis (Polit & Beck, 2004).

3.3.1 Research Setting

Data was collected in four (n = 4) adult ICUs at a tertiary academic hospital. These consisted of Trauma ICU (which admits severely injured patients), Neurosurgical ICU (which admits patients' with severe head and spinal cord injuries), Cardiothoracic ICU (which admits mostly patients before and after major cardiac and thoracic surgeries) and General ICU (which admits major non-specific medical and surgical patients).

In the ICUs, nurses give pain medication according to the physician's prescription. This also enables them to give or repeat the medication when necessary (PRN) based on their clinical assessment. However, the accountability for this action is the responsibility of the nurse (SANC 1984). This also requires the nurses to keep the doctor informed regarding the condition of the patient. Each nurse is allocated to a patient for a 12-hour shift.

3.3.2 Target population

The target population in this study comprised of nurses who have worked in the adult ICU for at least six months and unconscious patients admitted to the ICU for the first 48 hours.

- Part One (Nurses)

Registered nurses with or without additional intensive care training that have worked in the adult intensive care units on day or night shifts for at least six months. The nurses surveyed had nursed the same patient for two consecutive 12 hour shifts. Thus the nurse has nursed the same patient for at least 24 hours. Nurses in the ICU were allocated mostly to patients on one on one basis and one nurse can nurse the same patient on more than one shift. Sampling nurses that have nursed the patient for at least 24 hours was done to give enough time to adequately assess an individual nurse's attitude towards pain.

Nurses on both day and night duty were included so as to get a wide range of opinions about the parameters used in assessing unconscious patients' pain. The six month period is to ensure that nurses have adequate knowledge and experience about pain assessment and management in the ICU.

Furthermore, hospital statistics obtained from hospital records from 2001-2002 showed that a total of approximately 96 registered nurses worked in the adult intensive care units.

- Part Two (Patients)

Patient population in the study comprised of unconscious patients admitted to the adult intensive care units for the first 48 hours. These patients were sampled because of the severity of pain during this acute phase of illness which is normally associated with pain.

Patients in this acute phase of illness are normally given analgesia to control their severe pain.

A preliminary record review of the 2001-2002 statistics revealed an average total number of 396 patients were admitted to the adult intensive care units over a period of three months. This is an average of 130 patients per month. Of these patients it was estimated that an average of 20-30 percent were unconscious.

3.3.3 Sample and Sampling Method

A sample is a subset of the population that is selected for a study (Burns & Grove, 2001). A sampling method is the process of selecting a group of people (ICU nurses and patients), events, behaviours or other elements that are representative of the population being studied (Burns & Grove, 2001).

- Part One (Nurses)

Simple random sampling method was used to sample nurses in this study. Random sampling ensures that every member of population has a probability higher than zero of being selected and thus more likely to be representative of the population ((Burns & Grove, 2001). ICU trained or non-trained nurses working in ICU who met the inclusion criteria (n = 40) were listed with their consent and co-operation. Each nurse surveyed was at the time of data collection nursing the unconscious patient whose record was reviewed and included in the study and must have nursed the same patient on the previous 12 hour

shift. Nurses that were nursing unconscious patients were identified and if they nurse the same patient on the next shift, and met all the other inclusion criteria they were sampled with their consent.

Inclusion criteria for nurses were as follows:

- Registered nurses.
- Working in ICU for > 6 months.
- Day/ Night shift.
- Must have nursed the same unconscious patient for at least 2 concurrent 12 hour shifts

- Part Two (Patients)

Simple random sampling method was used to sample unconscious patients in this study. A review of patients' records enabled the researcher to establish the patients who met the inclusion criteria. Patients who were admitted to the ICU for the first 48 hours were sampled. This was determined from the time of admission to the ICU. All patients (n = 40) who met the inclusion criteria and their ICU nurses met the criteria too, were included in the study with consent from their next-of-kin and retrospective consent from patients.

Inclusion criteria for patients were as follows:

- Age > 18 years.
- Glasgow Coma Scale (GCS) score < 7/15
- Admitted to ICU for the first 48 hours
- Must not be on a continuous infusion of analgesia

3.3.4 Data Collection

3.3.4.1 Procedure

- Part One (Nurses)

Registered nurses in all the adult intensive care units (n = 4) in the academic hospital used for the study who met the inclusion criteria and were willing to take part in the study, were asked to read an information sheet and sign a consent form. They were then asked to complete a form with their demographic data (refer **Annexure A).** Each registered nurse was allocated a research code to ensure anonymity, their professional qualification, shift worked (day/night), years of nursing experience and period working in ICU.

The ICU nurses then completed a self-administered Likert-type questionnaire **(**refer **Annexure A)** consisting of ten questions which were developed by the researcher related to parameters identified in literature that can be used to assess unconscious patients' pain. Rating on a five point Likert Scale ranging from strongly disagree (1) to strongly agree (5) was used in the following format, strongly disagree (1), disagree (2), uncertain (3), agree (4) and strongly agree(5). To facilitate the presentation of data, 1, 2 & 3 were collapsed to form the disagree group and 4 and 5 to form the agree group.

This formed the first part of the study. It was the researcher's intention to compare the participant's responses to the next part of the study.

- Part Two (Patients)

The second part of the study was a prospective record review of unconscious patients that met the inclusion criteria and consent obtained from their next-of-kin and an additional retrospective consent later from patients that were included in the study. Patients' demographic data included their research code, date and time of admission, gender, age, diagnosis on admission, type of analgesia prescribed, dosage of analgesia prescribed, amount of analgesia given in 24 hours and route of administration (refer **Annexure B**).

A record review of patients' ICU charts included heart rate, blood pressure; mean arterial pressure, temperature, respiratory rate, Glasgow Coma Scale, pupil size, mode of ventilation, type and dosage of analgesia given and sedatives or paralyzing agents given (refer **Annexure B**).

This was recorded for the first 48 hours of admission to the ICU. It was divided into the first 24 and second 24 hour periods. Time and dosage of analgesia given was noted and patients' parameters were reviewed by the researcher as recorded on the ICU chart.

3.3.4.2 Instrument

Two instruments were used to inform the study (refer **Annexure A** and **Annexure B**). These were developed by the researcher based on literature and the work of Blenkharn et al., (2002) and Gelinas et al., (2004). The items on the instruments were subjected to scrutiny by clinical experts working in the ICU which included nurses and doctors. Their

suggestions and recommendations were incorporated to make it more practical to record the information.

The first instrument **(**refer **Annexure A)** had two sections. Section one comprised of the nurses' demographic data.

Section two comprised of ten items to elicit nurses' response using a Likert-type scale. The nurse respondents completed the instrument once. The items on the questionnaire include raised blood pressure, pyrexia, increased respiratory rate, sedation, dilated pupils, increased heart rate, analgesia, Glasgow coma scale, pain management in haemodynamically unstable patients and assessment of pain. Three negative questions were used in the questionnaire to avoid inserting bias into the responses. These included questions 2.4, 2.8 and 2.9 (refer **Annexure A).**

The Likert Scale is a device designed to assign a numerical score to individuals to place them on a continuum with respect to the attribute being measured. Declarative statements expressing a viewpoint on the topic are developed and participants are asked to indicate the degree to which they agree or disagree (Polit & Hungler, 1997). Numbers are allocated to the responses and quantitatively analysed to elicit group opinions. Response choices on a Likert Scale most commonly address agreement, evaluation and frequency (Burns & Grove, 2001). The categories on the Likert Scale ranged from strongly disagree (1) to strongly agree (5) with a value of one given to the most negative answer and five to the most positive answer.

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The second instrument comprised of two sections (refer **Annexure B**). Section one comprised of the patient's demographic data and included a summary of analgesia given in 24 hours.

Section two for patient's record review was done over the first 48 hours of admission into ICU. This was divided into the first 24 hours and second 24 hours. It included: Haemodynamic parameters (heart rate, blood pressure, mean arterial pressure and temperature), Neurological parameters (Glasgow coma scale, pupil size), Respiratory parameters (respiratory rate, mode of ventilation), dosage and type of analgesia given and other types of medication (sedation, paralysis).

3.3.4.3 Pilot study

A pilot study is a smaller version of a proposed study conducted to refine the methodology (Van Ort, 1981). It is defined much like the proposed study using similar subjects, same setting, same treatment and the same data collection and analysis techniques. However, a pilot study could be conducted to develop and refine a research treatment, a data collection tool or the data collection process (Prescott & Soeken, 1989). Thus the pilot study could be used to develop a research plan rather than to test an already developed plan.

The research questionnaire was given to four intensive care nurses (n = 4) to answer and four unconscious patients (n = 4) ICU records were also reviewed. Data was analysed by comparing the responses to the questionnaire to the prospective patient's record review to

see if they reflect in the management of unconscious patients pain and to see if the results of the data analysed answered the research questions.

The ICU nurses included in the pilot study were also asked to comment on whether the questionnaire was easy to understand to which they responded in the affirmative. lt was thus affirmed that the questionnaire was comprehensible and no changes were made since the pilot study was used to test the response by ICU nurses to the questionnaire.

Statistical assistance was obtained from a statistician from MRC who suggested reducing the number of items on the patient's record review to make statistical analysis possible. This was done by reducing the initial patients' record review which included all the patients' records as seen on their ICU chart to include only the parameters in **Annexure B.** The results of the pilot study were not included in the main study.

3.3.5 Data Analysis

In part one of the study, the ICU nurses' demographic data and responses to the Likert-type questionnaire by intensive care nurses was descriptively analysed. Percentages were allocated to the answers to determine the parameters intensive care nurses identified that could be indicative of pain in unconscious patients. Answers on the Likert-Scale were collapsed to two groups of disagree and agree to make statistical analysis possible.

A record review of unconscious patients' records which formed part two of the study was then descriptively analysed. The patient's demographic data was analysed and percentages

were allocated. The patients' parameters, time and dosage of analgesia given were also analysed descriptively.

A comparison was then undertaken between the two parts (part one and part two) to see if the parameters identified by intensive care nurses in part one of the study were considered in their pain management. This was done by identifying sudden significant increases in the patient's heart rate, blood pressure, temperature, pupil size and respiratory rate on their ICU charts which were referred to as events. It was then determined if the nurses that agreed that increases in this parameters could be indicative of pain in the unconscious patient gave pain medication in the hour of the events.

Due to the large amount of data collected, nurses were put into four management categories (Categories A-D as discussed in chapter four). These categories were derived during the comparison of Part One and Part Two of the study which indicated how nurses actually managed the unconscious patient's pain. Statistical help was sought from a statistician from the Medical Research Council (MRC).

3.4 ETHICAL CONSIDERATIONS

- The research proposal was presented to the Department of Nursing Education for peer review and to ascertain the feasibility of the study.
- The research proposal was presented to the Postgraduate Committee of the University of the Witwatersrand, Faculty of Health Sciences for their approval to conduct the study.

- Ethical clearance was obtained from the Committee for Research on Human Subjects (Medical) of the University of the Witwatersrand for their permission to conduct the study. The committee issued a clearance certificate (refer **Annexure G**)
- Permission to conduct the study and assess information from patients' records was obtained from the Chief Executive Officer and Deputy Director of Nursing Services from the academic hospital **(**refer **Annexure H)**.
- Informed consent was obtained in writing from nurses **(**refer **Annexure C).**
- Informed consent was obtained in writing from patients' next of kin on the patients' behalf and a retrospective consent was obtained from the patient during the recovery period **(** refer **Annexure D)**.
- Patients were allowed to voluntarily withdraw from the study and assured that that will not affect their treatment or admission to the institution.
- An information sheet outlining the procedure of the study and researchers contact number was given to the nurse, the patient's next-of- kin and later to the patient to keep **(**refer **Annexures C and D)**.
- Patients' and nurses' names were not used to ensure anonymity and confidentiality. Research codes were used

3.5 VALIDITY AND RELIABILITY OF THE STUDY

Validity

The validity is a determination of the extent to which an instrument actually reflects the abstract construct being examined. Validity has to do with truth, strength and value (Burns and Grove 2001).

- Content related validity examines the extent to which the method of measurement includes major elements relevant to the construct being measured (Burns & Grove, 2001). This was maintained in this study by ensuring that parameters in the study were obtained from relevant literature on pain assessment and management in critically ill patients.
- Face validity basically verifies that the instrument looked like or gave the appearance of measuring the content (Burns and Grove 2001). This was achieved in the study by ensuring that all the parameters are related to pain assessment and management in unconscious patients and verified by clinical experts to establish whether the instrument was comprehensive in seeking the proper range of responses
- Content and face validity of the data collection instruments were assessed by experts in the field of intensive care nursing which included ICU nurses with more than ten years of nursing experience, intensive care educators, managers and doctors.
- The prospective patient record review measured all the relevant parameters in the questionnaire as recorded on the patient's ICU chart to ensure content validity.

- All the patients included in the study were unconscious. Only the data on the ICU charts were recorded and all the data recorded was relevant to pain assessment and management in the unconscious patient.
- Validity of the study was also maintained by sampling any nurse that met the inclusion criteria and was willing to participate in the study to avoid bias.
- The data collection included nurses on both day and night shifts so as to solicit a wide range of opinions.
- Participation in the study was voluntary and patients were assured that withdrawal will not affect their treatment. Nurses and patients were both assured that their identity will be withheld.
- Statistical assistance was sought from an expect statistician during the data analysis and his recommendations complied with.

Reliability

The reliability of a measure denotes the consistency of measures obtained in the use of a particular instrument and is an indication of the extent of random error in the measurement method (Burns & Grove, 2001). The same measurement scale if administered to the same individuals at two different times is reliable if the individuals' responses to the items remain the same (Burns & Grove, 2001).

- This was maintained in the study by ensuring that the same method of data collection and instrument was used throughout the study.
- All the data was collected by the researcher alone and was collected independently without influence from anyone.

- An expert statistician verified data collected for accuracy and helped in the analysis of the data to ensure accuracy.
- The scale used for the data collection (Likert Scale) is the most widely used scale to determine opinions or attitudes of subjects and contains a number of declarative statements (Burns & Grove, 2001). This scale was the most appropriate scale for the type of questionnaire used in the study.

3.6 SUMMARY

Chapter three outlined the research design and research method including the research setting, population, sample and sampling method as well as the process of data collection, analysis, pilot study, ethical considerations and the validity and reliability of the study.

The next chapter will discuss the data analysis and discussion of the results.