# CHAPTER 3

# Research design and methodology

## 3.1 INTRODUCTION

This chapter describes the research design and methodology used in the study, including population, data collection, validity and reliability, and ethical considerations.

The overall aim of this study is to explore and identify the delays experienced by the patient suffering from AMI from the time of arrival up to the time thrombolytic therapy is administered in the accident and emergency department of the Al Ain Hospital. The research methodology facilitates the attainment of the following research objectives:

- determine the extent of the delays facing the AMI patient at this hospital from the time of arrival till thrombolysis time
- identify the specific areas where the delays occur
- identify the reasons for the delays
- determine whether thrombolytic therapy is administered as recommended by NHAAP (1994:314), for example, within 30 minutes of arrival at the hospital
- establish ways for health care providers to reduce the “door to needle” time

## 3.2 RESEARCH DESIGN AND METHODOLOGY

To undertake a scientific study, all the components should fit together in a meaningful whole. To achieve this goal, the researcher needs to draw up a design, the strategy for conducting the study or the plan to obtain answers to the research questions. Burns and Grove (2001:223) describe the research design as a “blueprint for conducting a study that maximises control over factors” that could interfere with the validity of the findings. Polit et al (2001:465) describe the research design as the “research investigation in a logical and systematic way”. It spells out the strategy the

researcher plans to adopt to develop information that is accurate and interpretable. The research design guides the researcher in planning and implementing the study to achieve the intended goal. The control provided by the design increases the probability that the study results are accurate reflections of the real situations.

Polit et al (2001:223) state that research methodology refers to the techniques used to structure a study and gather and analyze the data in the course of the research investigation and consists of a set of orderly, disciplined procedures to acquire information.

In this study, the researcher selected to conduct a non-experimental, descriptive and quantitative study in the category of applied research, as the knowledge generated can directly affect or improve the practices of door to needle time in thrombolytic therapy for patients with AMI. According to Polit et al (2001:38), the purpose of applied research is to "solve problems, make decisions or control outcomes in real-life situations". The research methodology facilitates the "attainment of the research aims", which in this case is whether there are delays facing AMI patients and specific areas where the delays present with a view to improving the quality of care provided for patients with AMI by reducing the time to deliver thrombolytic therapy timeously.

### 3.2.1 Definitions of terms used in the research design and methodology

In this study, the following terms are described namely non-experimental, descriptive, quantitative, retrospective study and cross sectional design.

#### *3.2.1.1 Non-experimental*

Polit and Hungler (1999:194) describe a non-experimental study as one in which there is no manipulation of the variable. The researcher chose a non-experimental approach in this study as it is not morally acceptable nor her intent to harm or endanger the life of the subjects under study and manipulation is neither attempted nor considered desirable. This approach was best suited to the aim and objectives of the study in order to capture the phenomenon as it occurred without any manipulation. This was a vital requirement of the study design. The delays in terms of time were captured without manipulation of the independent variable.

#### *3.2.1.2 Descriptive*

Burns and Grove (2001:248) state that descriptive designs help to identify problems in current practice with a view to improve practice outcomes.

The purpose of descriptive research is the "exploration and description of real-life situations" and to provide information of the elements as they occur. The study attempts to describe the time delays in AMI as they occur from the onset of symptoms to the time of thrombolysis and examines the "door to needle time" delays.

#### *3.2.1.3 Quantitative*

According to Burns and Grove (2001:26), quantitative research is the "formal, objective, systematic process in which numerical data are used to obtain information about the world". The authors add that this method is used to describe variables, examine relationships among variables and determine cause-effect interactions between variables. This is currently the method of choice for scientific investigations in nursing practice and requires rigorous control to identify and limit the effects of extraneous variables not under study (Burns & Grove 2001:26). The extent of the control is to provide precise information on the study under investigation and is suited to this particular study as the researcher aims to limit extraneous factors not under study that may influence the results. Furthermore, control decreases the possibility of error and increases the probability that the study's findings are an accurate reflection of reality. This was the method for data collection and analysis and presentation of the findings of this study.

#### *3.2.1.4 Retrospective study (ex-post facto)*

Burns and Grove (2001:249) state that in a retrospective study, "the information about the phenomenon is collected as it occurred and focuses on the presently occurring outcome, then tries to ascertain antecedent factors that may have caused it". In this study, the researcher had no control over the independent variable as the presumed causative factor in the study (independent variable) had already occurred. The independent variable was the time factor which had already occurred.

Polit and Hungler (1999:714) define a retrospective study as “a study that begins with the manifestations of the dependant variable in the present and then limits this effect to some presumed outcome occurring in the past”.

This study was an attempt to find solutions to the occurring problem. Such studies are almost always cross-sectional in nature and have inherent limitations. This method is well suited to this type of study as the information is captured as it occurred, providing accurate information on the phenomenon (problem) under investigation. Polit et al (2001:178) state that the “problem related to documentation is common to all retrospective studies”. However, meticulous care was taken while gathering data from the files of patients. This study was also cost-effective in terms of time and finance.

#### *3.2.1.5 Cross-sectional design*

A cross-sectional design is defined by Polit and Hungler (1999:699) as a “study based on observation of different age or development groups at a single point in time for the purpose of inferring trends over time”. According to Polit et al (2001:184), cross-sectional design “indicates that the phenomena under study are captured at a particular point in time during one-data collection period”.

The researcher considered this design and method suitable for this study as the data already existed and could be accessed at one time, which made it cost-effective and easy to manage. Polit et al (2001:185) is of opinion that the “independent and dependent variables are collected concurrently, but the independent variable usually captures events or behaviors occurring in the past”. In this research, after identifying the cases who fall under the eligible criteria as discussed in chapter 1, the researcher approached the hospital management (see Annexure A) as well as the file manager to access the files and gather the relevant data at a convenient time. The information was gathered as the researcher found it and verification obtained, where necessary, with the doctor or cardiologist concerned.

## 3.3 RESEARCH METHODOLOGY

Polit et al (2001:465) state that research methodology refers to the techniques used to structure a study, gather and analyze the data in the course of the research investigation. In addition, it consists of a set of orderly disciplined procedures, steps and strategies to acquire and analyze information.

The population and sampling, sampling criteria, eligibility criteria, sampling of cases, validity and reliability, and the ethical consideration will be discussed next.

### 3.3.1 Population and sampling

Population is defined by Polit et al (2001:233) as "the entire aggregation of cases that meet a specified set of criteria". The target population in this study represents the patients who were selected with a diagnosis of AMI from January 2002 to December 2003. The files were closely scrutinized for all the relevant documentation necessary to complete the study.

Polit et al (2001:234) add that "sampling involves selecting a group of people, events, behaviors or other elements with which to conduct a study. When elements are persons, they are known as subjects and the subjects are selected from the delineated target population in a way that the individuals in the sample represent as nearly as possible the entire population. This decision has a major impact on the meaning and generalisability of findings".

### 3.3.2 Sampling criteria

Burns and Grove (2001:366) describe sampling criteria as "the characteristics essential for membership in the target population". According to Polit et al (2001:325), criteria are developed from the research problem, the purpose of the study, the conceptual and operational definitions of study variables and design. The sample for this study consisted of 351 patients who were treated from January 2002 to December 2003 with thrombolytic therapy for AMI as their primary therapy and selected according to the eligibility criteria for thrombolytic therapy described below (see 3.3.3).

### 3.3.3 Eligibility criteria

The AHA/ACC criteria (Antman et al 2004a:679-680) are intended to select patients eligible for thrombolysis and should be followed closely for successful outcomes, minimize risks and increase the benefit of treatment. To be eligible, a patient must present with two or more of the following criteria:

- continuing chest pain lasting more than thirty minutes
- arrive at hospital for treatment within twelve hours after the onset of symptoms
- evidence of relevant changes on a 12-lead ECG (see chapter 2, figure 2.4)

#### *3.3.3.1 Chest pain lasting more than thirty minutes*

The pain associated with AMI usually lasts for more than thirty minutes and is continuous and, in most cases, the prescribed dose of sublingual nitrates is insufficient to relieve the pain. Patients are advised by cardiologists or physicians to take up to three doses of 5 mg Isordil (nitrates) before seeking medical assistance. This advice is given to all patients who suffer from angina or chest pain.

#### *3.3.3.2 Time of presentation*

Patients arriving at the hospital for treatment prior to twelve hours after symptom onset derive maximum benefit from thrombolytic therapy, but patients' eligibility decreases as more time passes. This is due to myocardial tissue necrosis and thrombolysis after that is dangerous as it can cause free wall rupture of the heart (Nakatani et al 2003:785). Although the best time to thrombolyse is within the first two hours after the onset of symptoms, some doctor's thrombolyse patients up to twenty-four hours and later if the benefit is greater than the risk to patient.

#### *3.3.3.3 ECG recording*

The ECG recording must have the following:

- ST elevation present in 1mm in 2 limb leads
- ST elevation 2mm in 2 contiguous chest leads
- New Left Bundle Branch Block
- Posterior MI with tall T waves V2 and V 3 (see Figure 2.4)

In this study, patients were carefully evaluated for risks using the established relative and absolute contraindications for selection of patients for thrombolysis (see Table 2.5).

### 3.3.4 Selection of cases

Polit et al (2001:234) define sample as "the subset of the population". In this study "selection of cases" is more appropriate than "sample" as the entire set of patients who had thrombolytic therapy from January 2002 to December 2003 were selected. The subjects were chosen if they met the criteria outlined above.

Patients diagnosed with AMI and treated with thrombolytic therapy were selected for the study in an effort to identify the time delays in the treatment of AMI patients receiving thrombolytic therapy.

### 3.3.5 Number of cases

A total of 457 patients were selected for the study but the eligible criteria applied to 351 patients only (see description under 4.2: Data Collection). The names and file numbers were accessed from the coronary care and intensive care unit logbook which contained the full demographic data and other relevant details of the patients admitted to the unit. Prior to collection of the relevant data the files were cross-checked and verified in the file section.

### 3.3.6 Sampling method

Burns and Grove (2001:376) define purposive sampling as "judgmental sampling that makes the conscious selection by the researcher of certain subjects or elements to include in the study". This method was appropriate for this study as the cases were consciously and deliberately included because they had been diagnosed with AMI and fulfilled the eligibility criteria for thrombolysis.

### 3.3.7 Context

According to Polit et al (2001:44), the context refers to "the setting within the site where the data collection will occur". This study was conducted at the Al Ain Hospital in the United Arab Emirates.

Prior permission was obtained through the appropriate channels from the Nursing and Medical Directors and the Manager of the Filing Section (see annexure A: Permission to conduct research). The personal files are stored under secure conditions and only accessed if permission has been granted through proper channels. The information was collected in the filing section at time convenient to the researcher. The filing section operates on a 24-hour basis.

### 3.3.8 Data collection

Burns and Grove (2001:49), define data collection as "the precise systematic gathering of information relevant to specific research objectives or questions". According to Burns and Grove (2001:50), data can be collected in several ways depending on the study and can include a variety of methods; however, the research objectives must be accomplished with the instrument used.

The data for this study was gathered retrospectively, with the use of a questionnaire list which was developed to achieve the research aim and objectives.

## 3.4 CHOICE OF INSTRUMENT

In this study the data was collected by the researcher with the help of a structured questionnaire with the input from a qualified statistician, developed to elicit responses relevant to achieve the aims. According to Burns and Grove (2001:426), a questionnaire is a "printed self-report form designed to elicit information" and is developed with specific items to assist with the data collection. The development of the questionnaire involved deciding on the type of questions, compiling the questions, and refining the questionnaire.

### 3.4.1 Development

Burns and Grove (2001:49) describe measurement as "the process of assigning numbers to objects or events to situations in accord with some rule". According to the authors, a component of measurement is instrumentation, which is the application of specific rules to the development of a measurement device or instrument and the instrument is selected to examine a specific variable in the study. Selection of the instrument requires extensive examination of its reliability and validity (Burns & Grove 2001:49). The purpose is to produce trustworthy evidence that can be used in evaluating the outcomes of the research study. The literature was searched to identify critical points in the study and thereafter the researcher developed a set of specific questions, based on Lambrew, Bowlby, Rogers, Chandra and Douglas (1997:2577) USA study on factors influencing the time to thrombolysis in AMI, which ranged from the "door to needle time" and included the "door, data, decision-making and drug" time.

### 3.4.2 Types of items in the questionnaire

Although based on Lambrew et al's (1997:2577-2582) study, the researcher developed a structured questionnaire to elicit the specific responses required for this study to enable control over the extraneous factors affecting the study. The questionnaire was evaluated for construct validity by cardiologists from the ethics committee and the hospital. Closed-ended questions were formulated so that the responses were specific to the research objectives.

### 3.4.3 Compilation of the questions

The demographic details did not require the identity of the patient, thereby maintaining confidentiality. The questionnaire was structured and guided by the study problem, purpose and objectives.

Closed-ended questions were formulated with the aim of achieving the objectives and to maintain control over extraneous variables. The questions were ordered in a logical sequence to allow for meticulous documentation of events.

The language of communication was English and the same tool was used for all the subjects. The researcher had the relevant Arabic information contained in the files translated into English by an Arabic speaking professional when needed.

### 3.4.4 Refinement of questions

A panel of three experts in emergency cardiology and a cardiologist representing the ethics committee reviewed the questions and refined them. The experts evaluated each item. Two key issues were searched for relevancy and appropriateness in terms of construct and whether the items measured all dimensions of the construct identified. The cardiologists rated the items on Burns and Grove's (2001:401) 4-point scale to assess the relevance and content validity of the questions as follows:

1 Not relevant
2 Unable to assess relevance or item is in need of revision
3 Relevant but needs minor alteration
4 Very relevant and succinct

### 3.4.5 Structure of questionnaire

The questionnaire was divided into the following sections:

Section A: Demographic data
Section B: Medical history
Section C: Current illness
Section D: Assessment, data collection, diagnosis, decision making and drug administration
Section E: Prognosis

## 3.5 VALIDITY AND RELIABILITY

In the following section the validity and reliability as applied to this research is discussed.

### 3.5.1 Validity

Polit et al (2001:308) define validity as "the degree to which an instrument measures what it is supposed to measure". According to Polit et al (2001:309), three aspects of validity are important namely: content, criterion-referenced and construct validity.

Content-related validity is defined by Burns and Grove (2001:400) as "the extent to which the method of measurement includes all the major elements relevant to the concept being measured". These authors add that the researcher may cite sources from literature to seek feedback for understanding the phenomenon under study. In this study, the four cardiologists consulted evaluated and documented the content validity of the instrument and the content validity index was computed to assess the relevance of the items on a 4-point scale (Burns & Grove 2001:401). The cardiologists further identified important items not included in the questionnaire which were subsequently added.

### 3.5.2 Reliability

Polit et al (2001:305) describe reliability as "the consistency with which an instrument measures the attribute". An instrument is said to be reliable if its measures accurately reflect the true score of the attribute under investigation. To reinforce and assess the reliability of the instrument in this research, evaluating test-retest reliability assessed stability. The same questionnaire was used twice and a comparison of scores obtained. The comparison procedure was performed objectively by computing the reliability coefficient. In this research, Cronbach's alpha coefficient, Kuder-Richardson formula 20 and Spearmen's Brown prophecy formula were used to test the internal consistency or homogenity or reliability of the study (Polit & Hungler 1999:415).

## 3.6 DATA COLLECTION

Permission was obtained from the Nursing and Medical Directors to conduct a study at the Al Ain Hospital (see Annexure A). In addition the Medical Director requested the Ethics Committee at the Faculty of Medicine at Tawam Hospital to review the proposal.

The recommendations of the Ethics Committee were considered and items added as deemed necessary. Access to patient files is a strictly controlled procedure at Al Ain Hospital. Unauthorized persons are not allowed access to the file section. Prior permission and authorization was essential for the collection of confidential information, thereafter the Manager of File Section was approached with the letter of authorization to gather the relevant information. The files were not allowed to leave the department so the data was collected in the filing section and the files returned immediately after use, so the researcher gathered the data when off-duty and over weekends, over a period of 9 days.

## 3.7 ETHICAL CONSIDERATIONS

Conducting research ethically begins with identification of the topic and continues through to the publication of the study therefore the conduct of research requires not only expertise and diligence but honesty and integrity (Burns & Grove 2001:191; De Vos 2001:24; Polit & Hungler 1999:90). Ethical considerations are vital to any study because of the influence on the researcher's ability to acquire and retain participants (Polit & Hungler 1999:13). In this study, the ethical consideration of confidentiality was strictly upheld. Confidentiality was maintained through protection of the privacy of the patients selected by not revealing their identity. Although informed consent was not necessary from the patients, permission to undertake the study was sought from the Ethics Committee, Medical Director and Nursing Director. The research proposal was further subject to approval by the Department of Health Studies at the University of South Africa (Unisa). The information accessed was kept in the possession of the researcher in a safe place and kept confidential. The data stored in the computer was linked to a secret password to which only the researcher had access.

## 3.8 SCOPE AND LIMITATIONS OF THE STUDY

Every precaution was taken to ensure that the documentation was verified and proofread by content experts or the original authors were approached for verification.

The number of patient's thrombolysed in the Accident Unit was insufficient, so the patients in the Intensive Care and Coronary Care Units were included.

## 3.9 CONTROL OF EXTERNAL VARIABLES

Researchers strive to control external variables to determine the true nature of the relationship between the independent and dependent. The structured questionnaire enabled control over extraneous factors and the questions were developed to elicit only those responses relevant for the study under investigation.

## 3.10 DATA ANALYSIS

The Statistical Analysis System, Version 9.1 (SAS 9.1) computer program was used for data analysis. The program covers frequency tables, graphs, diagrams, statistical pies and representative characteristics or values, such as averages and percentages. A statistician assisted with the statistical analysis.

## 3.11 CONCLUSION

This chapter described the research design and methodology in detail. The researcher developed a structured questionnaire as the data-collection instrument designed to elicit those responses relevant and essential to the research problem. The researcher collected all the information in person and confidentiality was maintained throughout the study.

Chapter 4 discusses the results of this research.