Department of Laboratory Medicine & Pathology, Faculty of Health Sciences

Research Methodology Syllabus

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PREFACE

The Research Methodology Syllabus (1st edition) is intended specifically for postgraduate students in Health Sciences and healthcare professionals. Its main purpose is to provide information about the scientific enquiry able to guide novice researchers through the research process.

Despite being comprehensive, this syllabus is not intended to replace research methodology text books that are in-depth sources able to provide all the answers related to the conduct of research. Unlike other sciences, research in medicine uses methods and practices that are evolving at a rapid rate. Hence, we introduce students to the fundamental principles of what it is like to think like a clinical scientist.

Research is an intellectually and professionally rewarding field, and that developing research skills is critical. With every step of the way, the research process in health sciences is fraught with decisions, trade-offs, and uncertainty. It is not an easy route to traverse, but we hope this syllabus will be a road map that can inspire the direction if not give absolute instructions.

As always, we listen to feedback from students and readers in order to make further improvements. We strive however to maintain the balance between clarity and conciseness, and continue to provide sufficient depth for those aiming at distinction.

We wish you all the best for your future careers!

Dr Teke Apalata

April 2019.
CHAPTER 1 RESEARCH PHILOSOPHIES, METHODS AND DESIGNS

1.1. Introduction

There are numerous philosophical assumptions defining what can be called a “valid” research. These assumptions are grounded in well-founded research methods in order to consider as appropriate, any knowledge produced after the conduct of a particular study. It is therefore crucial to understand and also clearly discuss in this section the underlying philosophical assumptions governing a research project, hence the choice of the used study design and methods (Figure 1).

Figure 1 Research "Onion" (Source: Saunders, Lewis, Thornhill, 2012).
1.2. Research Philosophies

A research philosophy is the belief about the ways in which data about a phenomenon should be collected, analyzed and used (Winit-Watjana, 2016:428; Corry, Porter, McKenna, 2019: 230). The adopted research philosophy contains critical assumptions about the way the researcher views the world. These assumptions are the basis for the researcher’s chosen methods as part of his/her research strategy. There are different types of research philosophies as depicted in Table 1.1 below (Winit-Watjana, 2016:428; Corry, Porter, McKenna, 2019: 230).

The research philosophy is viewed in two main ways: whilst Epistemology is concerned about what constitutes acceptable knowledge, Ontology deals with the nature of reality – meaning an interpretation by a researcher about what constitutes a fact (Winit-Watjana, 2016:428; Corry, Porter, McKenna, 2019: 230).

Table 1.1. Types of research philosophies

<table>
<thead>
<tr>
<th>Research philosophy</th>
<th>Researcher’s view and choices</th>
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<tbody>
<tr>
<td><strong>Epistemology</strong></td>
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<tr>
<td>Positivism</td>
<td>Only “factual” knowledge obtained through observation of phenomena, including measurement is trustworthy. Positivist studies use a deductive approach. Researcher’s role is restricted to data collection and analysis in an objective way. Findings are generally observable and quantifiable; hence the research strategy chosen is quantitative in nature.</td>
</tr>
<tr>
<td>Interpretivism</td>
<td>Researchers have to interpret elements of the study, hence integrate human interest into a study. It is necessary for the researchers to understand differences between humans in their roles as social actors. Interpretivism comes from phenomenology, hermeneutics and symbolic interactionism. Phenomenology is the way in which humans make sense of the world around them while hermeneutics refers to the philosophy of interpretation and</td>
</tr>
</tbody>
</table>

Understanding; and symbolic interactionism accepts symbols as culturally derived social objects having common meanings. Researcher’s approach is inductive and the research strategy chosen is qualitative in nature.

| **Realism** | This epistemological position relates to scientific enquiry. The underlying assumption is that objects have an existence independent of human mind. Direct realism stipulates that what a researcher sees is what he/she gets. However, critical realism says that what a researcher experiences are sensations, meaning the images of the things in the real world, not the things directly. Methods chosen by the researcher can be either quantitative or qualitative. |
| **Pragmatism** | Researchers should view their research philosophy as a continuum rather than opposite positions between positivism and interpretivism philosophies. Therefore, mixed research designs combining quantitative and qualitative strategies are advocated. |

**Ontology**

| **Objectivism** | This is an ontological position asserting that social phenomena and their related meanings exist independently from social actors. Objectivism is equivalent to positivism, which is an objective epistemology. |
| **Subjectivism** | This is an ontological position asserting that social phenomena are created from perceptions and consequent actions of social actors. Subjectivism is equivalent to interpretivism, which is a subjective epistemology. |

**Axiology**

| This is a social enquiry that focuses on judgements about values, including values in the fields of aesthetics and ethics. For research findings to be credible, researchers own values throughout the research process are of primordial importance. |

Adapted from Winit-Watjana (2016:428) and Corry, Porter, McKenna (2019: 230).
1.3. Research Methods

After a researcher has clearly set his/her objectives and research questions, a detailed plan on how to achieve such objectives, hence respond to research questions, is known as research strategy (Hulley et al., 2007: 106). The latter is a methodical approach able to bridge the gap between the researcher’s philosophy and his/her subsequent collection and analysis of research data. It is generally agreed that the choice of a particular research method is a result of the investigator’s objectives and raised questions. This strategy should detail not only the approach to the project but also existing resources and timelines as well as all potential data sources (Saunders et al., 2012:263). Different types of research methods are summarised in Figure 2 below.

- **Qualitative research**: During a qualitative research, investigators explore but most importantly find meanings that study participants ascribe to a problem of research interest. The process consists of raising probing questions to get participants express themselves with respect to the subject. During such interviews, that can be either individual or in small groups, researchers may record the discussion or make field notes. Interviews are thereafter transcribed, common themes generated and meanings are finally assigned. Generally, it is of the opinion that final write-ups of research findings benefit from a flexible structure. In addition, this approach in research is considered as that of an inductive style with a focus on individual meaning to the subject of interest. Qualitative research is exploratory in nature, and uses words. It uses open-ended questions to identify underlying reasons, opinions and motivations in order to generate working hypotheses. Examples of qualitative methods include focus group discussion and in-depth individual interviews. Whilst quantitative studies are conclusive, qualitative approaches are exploratory and help to define a specific problem (Saunders et al., 2012: 134).
Figure 2 Different types of research methods


- **Quantitative survey**: During a quantitative research, it is understood that investigators objectively test hypotheses by measuring relationships between dependent and independent variables. These variables are often measured by means of specific research instruments and analysed using different statistical methods. The latter are able to protect against any bias, hence control explanations and are also able to make findings more generalizable. Final write-ups of reports from quantitative studies follow a more stringent structure, and researchers are of the opinion that their tested assumptions and theories have been done much more deductively as opposed to the inductive style of qualitative studies. Quantitative research relies on measurable data to uncover a topic of interest in order to generate facts. Quantitative studies correlate with the positivism philosophy (Saunders *et al.*, 2012:161). The latter, often used in
social sciences, focusses on observable data and experiences, which are analysed to gain facts, hence considered to be a superior research method (Saunders et al., 2012: 134).

- **Mixed methods research**: Mixed methods are when quantitative and qualitative data are collected as part of a research inquiry combining philosophical assumptions with hypothetical frameworks. This approach aims at integrating the two forms of data; and it is thought to provide a more complete understanding of the research problem than either research method alone (Hulley et al., 2007: 106; Saunders et al., 2012: 134).

- **Case study**: this is an in-depth investigation of either a single case or a small number of cases. Information can be obtained from different sources using mixed methods including surveys, interviews and document reviews (Hulley et al., 2007: 106; Saunders et al., 2012: 134).

- **Action-oriented research**: this refers to a practical research directed towards a change or the production of recommendations leading to a change. It uses a participatory process combining theory and practice with action and reflection (Hulley et al., 2007: 106; Saunders et al., 2012: 134).

1.4. Research Design & Strategies

The research design refers to the overall strategy used by a researcher or an investigator in order to effectively address a research problem (Cohen, 2007:01; Gall and Borg, 2009:01). In order to obtain accurate and evidence-based findings, scientific studies rely on a chosen appropriate study design. The latter is the basis for a quality research project. It sets the scene on how an overall research plan will be executed, what data are likely to be required and what methods will assist in appropriately answering the research questions.
There are different types of research design as summarised in the Table 1.2 below. Each approach is used to answer a different research question, hence serves a different purpose and helps to achieve a different end result (Wright et al., 2016:97; Kroetze, 2013:1; Hulley et al., 2007: 106).

1.4.1. Quantitative designs

Quantitative designs include experimental and non-experimental designs (Wright et al., 2016:97; Kroetze, 2013:1; Hulley et al., 2007: 106). These two types of quantitative designs differ primarily in that during experimental designs:

- The researcher can control the action of the specific variables studied;
- The researcher manipulates the action of the independent or causal variables;
- The researcher observes and measures the action or outcome on the dependent variables.

In contrary, the purpose of non-experimental designs is to describe phenomena, and explore and explain the relationships between variables. There is no manipulation of the independent variables during non-experimental designs; hence no intervention is being carried out. The study is conducted in a natural setting and phenomena of interest are observed as they occur (Wright et al., 2016:97; Kroetze, 2013:1; Hulley et al., 2007: 106). Non-experimental designs are observational in nature, and can be either descriptive or analytical. Whilst the purpose of a descriptive study is to generate hypotheses, analytical studies test hypotheses. As a result, analytical studies, despite of being observational studies, they can also use experimental designs (Wright et al., 2016:97; Kroetze, 2013:1; Hulley et al., 2007: 106).
### Table 1.2 Different types of research designs

<table>
<thead>
<tr>
<th>Quantitative designs</th>
<th>Experimental</th>
<th>Non-experimental</th>
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<td></td>
<td>True experimental designs</td>
<td>Descriptive designs:</td>
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<tr>
<td></td>
<td>Pre-test-post-test control group</td>
<td>Case report</td>
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<td></td>
<td>Post-test-only control group</td>
<td>Case series</td>
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<td></td>
<td>Factorial designs</td>
<td>Incidence / Longitudinal survey</td>
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<td></td>
<td>Time-series designs</td>
<td>Prevalence /Cross-sectional</td>
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<td>Ecologic</td>
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<td>Comparative descriptive</td>
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<td>Analytical designs:</td>
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<td></td>
<td></td>
<td>Correlational designs</td>
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<td></td>
<td></td>
<td>Comparative designs</td>
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<td></td>
<td>Retrospective cohort</td>
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<td></td>
<td>Prospective cohort</td>
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<td></td>
<td>Predictive study</td>
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<td></td>
<td></td>
<td>Case-control</td>
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<tr>
<td>Qualitative designs</td>
<td>Exploratory: Ethnographic and Phenomenological</td>
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<tr>
<td></td>
<td>Descriptive</td>
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<tr>
<td></td>
<td>Correlational</td>
<td></td>
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<td></td>
<td>Explanatory studies</td>
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<td></td>
<td>Grounded theory</td>
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<td></td>
<td>Case study</td>
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<tr>
<td></td>
<td>Philosophical enquiry</td>
<td></td>
</tr>
</tbody>
</table>

Adapted from Kothari (2012: 37) and Saunders et al. (2012:171).
The following study designs are described:

- **Descriptive studies:** Saunders *et al.* (2012:171) stated that the primary objective of a descriptive research design is to describe patterns or trends in a population, situation or phenomenon of interest. It provides an accurate description of the characteristics and factors pertaining to a phenomenon as well as description of distribution of variables and outcomes of interest. As such, it appears to be more structured than an exploratory design.

According to Kothari (2012:37), the first step in conducting a descriptive study is to come out with well-formulated and measurable specific objectives assuring relevance of data to be collected. Failure to comply with this initial step will result in undesirable description of events regarding the subject matter. Examples of descriptive studies are case reports, case series, incidence or longitudinal designs, cross-sectional and ecologic designs.

- **Analytical studies:** The primary aim of analytical research is to test hypotheses about exposure-outcome relationships (Hulley *et al*., 2007: 106). In addition, according to Saunders *et al.* (2012:172), causal relationships among variables can be identified. The association between outcome of interest and exposures are measured. Examples of analytical observational studies are cohort studies (prospective and retrospective), case-control designs, and correlational, comparative and predictive studies. The most commonly used analytical experimental design includes clinical trials.

Quantitative research relies on measurable data to uncover a topic of interest in order to generate facts. As a result, it is seen by many as matching the positivism philosophy (Saunders *et al*., 2012:161). The latter, often used in social sciences, focusses on observable data and experiences,
which are analysed to gain facts, hence considered to be a superior research method (Saunders et al., 2012: 134).

1.4.2. **Qualitative designs**

The commonest types of qualitative designs include exploratory designs (phenomenology and ethnography), Grounded theory, and Philosophical enquiry (Hulley et al., 2007: 106).

- **Exploratory studies:** The primary objective of an exploratory research design is either to formulate a problem for further investigation or to generate a working hypothesis for an operational research (Hulley et al., 2007: 106). An exploratory study is often indicated when very little is known about the subject matter to research on, or if there is a paucity of data regarding the topic of interest. This approach is valuable mainly when there is either uncertainty or ignorance, and according to Saunders et al. (2012:171), it consists of asking open questions in order to generate valuable data and insights regarding a specific topic. The authors highlight that this approach improves understanding, particularly if the subject matter or the research question addresses something uncertain whose precise nature is unsure. Moreover, the exploratory design is characterized by high degree of flexibility and sometimes, its structure might not be formal. Exploratory studies include phenomenology and ethnography (Brink, van der Walt, van Rensburg, 2012: 120-129).

The purpose of phenomenological research is to describe what people experience in regard to certain phenomena, as well as how they interpret these experiences or what meaning the experiences hold for them. However, the focus of ethnography is the social and cultural values of the study population, meaning that ethnographic studies believe that people’s behavior can only be understood within the cultural context in which it occurs. Ethnography differs from phenomenology by the fact that phenomenology focuses on the meaning of an experience rather than on the role of culture in shaping the experience (Brink, van der Walt, van Rensburg, 2012: 120-129).
• **Grounded theory:** this study design identifies concepts and the relationship between them in an inductive manner. The purpose is to build theory that is faithful to and illuminates the area under study (Brink, van der Walt, van Rensburg, 2012: 124; Hulley et al., 2007: 106).

• **Philosophical enquiry:** the purpose of this approach is to perform research using intellectual analysis to clarify meaning, make values manifest, identify ethics and study the nature of knowledge (Burns & Grove, 2011).
CHAPTER 2 RESEARCH INSTRUMENTS, VALIDITY AND RELIABILITY

2.1. Research instruments

Data collection is critical when conducting a scientific research. This allows for collection of information about the problem under investigation. Depending on the type of the study, researchers can choose one or a combination of the following data collection methods: document reviews, observation, interviews (questioning), or measuring. Questionnaire and interviews are the commonest types of research instruments used for the purpose of data collection as summarised in Table 2.1 below.

Table 2.1. Types of research instruments

<table>
<thead>
<tr>
<th>Research instrument types</th>
<th>Characteristics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Questionnaires</td>
<td></td>
</tr>
<tr>
<td>Structured questionnaires</td>
<td>If the formats of questions used are closed-ended, allowing researchers to generate quantitative data able to provide patterns and trends during study analysis. These types of questionnaires provide little flexibility to study participants when answering, and the investigators usually have set pre-defined answers. A closed-ended questionnaire is made of questions without a predetermined set of responses allowing the respondent to choose from.</td>
</tr>
<tr>
<td>Unstructured questionnaires</td>
<td>If the formats of questions are open-ended questions providing respondents with the freedom to respond with great flexibility despite the fact that sequences are pre-determined by the investigators. Respondents use their own words and expressions to answer questionnaires, and the analysis is often more qualitative that quantitative. Open-ended questionnaire is made of questions can sometimes take the form of a multiple-choice question allowing the respondent to select from.</td>
</tr>
<tr>
<td>Semi-structured questionnaires</td>
<td>If mixed formats combining structured and unstructured questionnaires are used.</td>
</tr>
<tr>
<td>Interviews</td>
<td>Structured interview</td>
</tr>
<tr>
<td>-----------</td>
<td>---------------------</td>
</tr>
<tr>
<td></td>
<td>Semi-structured interview</td>
</tr>
<tr>
<td></td>
<td>In-depth interview</td>
</tr>
<tr>
<td></td>
<td>Focus group discussion</td>
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</table>

Adapted from Jansen et al. (2014:1-13) and Kroetze (2013:1).

Generally speaking, when using questionnaires, the following strengths are sought by this data collection approach (Jansen et al., 2014:1-13; Lopez-Lopez, Hinojosa-Pareja, 2016: 503):

(i) Data are collected much faster by means of questionnaires;

(ii) Feedbacks can be easily obtained from each respondent;

(iii) Since obtained feedbacks are often anonymous, they allow for honesty and openness;

(iv) Numerous statistical software such as SPSS, Epi-Info, Stata, etc. are available for analyzing quantitative data generated from structured questionnaires.

Alongside the above advantages, there are some limitations when using questionnaires (Jansen et al., 2014:1-13; Lopez-Lopez, Hinojosa-Pareja, 2016: 503). They are as follow:

(i) There are cases where some study participants can misinterpret some questions in a questionnaire. Although investigators are encouraged to pilot their questionnaires to minimize this effect during a study, sometimes this remains a challenge.

(ii) To process and analyse data obtained from a large sample of participants can be time
consuming;

(iii) There are instances where it is extremely difficult to enroll participants who are willing to fill in the questionnaires themselves.

2.1.1. Questionnaire construction

The construction of a research questionnaire refers to the design process of that questionnaire in order to be used during a study for the purpose of collecting useful information about the topic under investigation (Jansen et al., 2014:1-13; Lopez-Lopez, Hinojosa-Pareja, 2016: 503). When appropriately constructed, a questionnaire can provide much valuable information regarding the subject of interest (Jansen et al., 2014:1-13; Lopez-Lopez, Hinojosa-Pareja, 2016: 503). However, constructing a questionnaire involves many decisions pertaining but not limited to:

- Specific objectives of the research project;
- Wording and ordering of questions;
- Selection and wording of response categories; and
- Mode of administration of the questionnaire.

2.1.2. Administration of questionnaires

There are different ways for administering questionnaires during a research project. They differ in several ways including the method of contacting the study participants, the medium used for delivering these questionnaires, and the actual process for administration of questions (Jansen et al., 2014:1-13; Lopez-Lopez, Hinojosa-Pareja, 2016: 503). Table 2.2 below displays methods of the administration of questionnaires.
Table 2.2. Methods of the administration of questionnaires

<table>
<thead>
<tr>
<th>Methods for administration of questionnaires</th>
<th>Actual process of the administration of questions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Interview modes</strong></td>
<td></td>
</tr>
<tr>
<td>Verbal: face-to-face interviews using traditional paper and pencil /pen interview (PAPI)</td>
<td></td>
</tr>
<tr>
<td>Verbal: face-to-face interviews using computer assisted personal interviewing (CAPI) methods via personal computer</td>
<td></td>
</tr>
<tr>
<td>Verbal: telephonic interviews using paper or electronic computer assisted questionnaires (CATI)</td>
<td></td>
</tr>
<tr>
<td><strong>Self-administered questionnaires</strong></td>
<td></td>
</tr>
<tr>
<td>Traditional paper and pencil /pen self-administration (PAPI) methods sent by post or handing paper questionnaires</td>
<td></td>
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<tr>
<td>Computer-assisted (electronic) self-administration (CASI) methods – by automated electronic, including audio</td>
<td></td>
</tr>
<tr>
<td>Self-administration via interactive voice response methods with automated computer-assisted telephone programmes (ACASI)</td>
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</tbody>
</table>

Adapted from Jansen et al. (2014:1-13).

2.1.3. Collection of questionnaires

There are many ways for collection of questionnaires following their administration (Jansen et al., 2014:1-13; Lopez-Lopez, Hinojosa-Pareja, 2016: 503):

- Manually handing over paper questionnaires to the researcher;
- Automated electronic return (including audio or computer assisted) of questionnaires to the researcher;
- Handing over paper questionnaires by post.
2.2. **Validity and Reliability**

Validity and reliability of a test or data collection tools must be measured. Their values provide objective criteria to investigators for judging the quality of their research methods (Taylor *et al.*, 2011:2).

2.2.1. **Reliability testing**

Reliability is whether investigators are able to generate consistent findings on different occasions after using the same data collection tools or procedures Saunders *et al.* (2012:192). A reliability coefficient measures the correlation, which measures the intensity and direction of different variables.

**a) Test-Retest Reliability:** this is when reliability coefficients obtained after administering the same test on different occasions remain consistent. In order to determine a coefficient of test-retest reliability, the same test must be administered on two or more different occasions to the same group of participants (Taylor *et al.*, 2011:2). A test is said to be reliable when a score obtained by each participant during the initial administration remains similar to subsequent obtained scores. In such case, researchers expect a positive correlation between the first and second coefficients.

A major drawback when using test-retest reliability is called “memory effect”. This is obtained particularly when the same test is administered on two occasions, which are closer to each other in time. Suppose that an investigator administers to a group of study participants a short 5-question test on vocabulary, and that the same test is repeated 10 minutes later to the same participants. It is highly likely that the vast majority of participants will tend to answer questions the same way that they initially did, and will probably not pay enough attention to read questions more appropriately.
This will certainly generate an artificially high coefficient of reliability due to participants’ memory effect.

The memory effect plays a major role mainly when a pre-test is exactly the same as a post-test (Taylor et al., 2011:2). To prevent this effect from impacting on reliability test result, investigators are encouraged to use a post-test that is different from a pre-test while the two tests remain parallel, means equal to what they measure. In order to ascertain that two tests are parallel, reliability coefficients of the two experiments are computed, and their correlation determined. In the presence of a high and positive correlation, pre- and post-test are confirmed to be parallel.

b) **Internal Consistency:** this is obtained by splitting a set of questions into two or more separate questionnaires measuring the same subject or topic of interest. After study participants have responded to these two or more questionnaires, a correlation is calculated between the two or more sets of questions using Cronbach’s Alpha (Taylor et al., 2011:2). The closer is the value of Cronbach’s Alpha to one, the higher is the reliability of the test instrument. As compared to test-retest reliability technique, the measure of internal consistency by means of Cronbach’s Alpha is a less conservative approach (Taylor et al., 2011:2). Whilst test-retest technique measures reliability of a test instrument by administering the same instrument on two separate occasions to the same group of participants, the technique of internal consistency uses at least two sets of different questions within a test instrument measuring the same topic and administered once to a group of study participants.

C) **Inter-rater reliability:** this measures relative consistency. It relates to observations or judgements that different interviewers can make about respondents when collecting observational
These judgements are recorded on scale ranging between 0 and 10 on how interested respondents were during interviews (Taylor et al., 2011:2).

2.2.2. Validity testing

Validity is a degree by which a test instrument or any other measurement device is capable of measuring what it truly intended to measure. There are four types of validity of data collection instruments (Taylor et al., 2011:2):

a) **Criterion-related validity**: This technique allows investigators to test the validity of their measurement instrument by comparing it with another instrument already known to be valid (“criterion measure”). If data collected from the instrument that is newly constructed closely match results obtained from the instrument know to be valid, then the researcher may conclude that the new instrument is also valid (Taylor et al., 2011:2). It is recommended that the two sets of data be collected from the same study population. There are two types of criterion-related validity: predictive validity and concurrent validity. Whilst predictive validity deals with future outcomes (comparing results from a specific population using the new construct to an event or criterion measure that is expected to occur in that population in the future), concurrent validity deals with the fact that results of the new data collection instrument are compared to those of a criterion measure at the same point in time.

b) **Content validity** is when the measurement ability of a test instrument is determined by its capacity to include all relevant contents of a construct of interest (Taylor et al., 2011:2).

For example, the method of content validity to assess the validity of the new study questionnaire can be used as follow: the study questionnaire is presented to the group of participants during a pilot study. They evaluate each item on the instrument with regard to the degree to which the
variables to be tested are represented, as well as the instrument’s overall suitability for use. Ambiguous questions are reformulated and experts also found that essential aspects of the relevant variables are contained in the instrument to allow measurement of what the investigator intended to measure.

C) **Face validity:** this is based on an intuitive judgement made by experts in the field. The instrument is mainly assessed with regard to determining its readability and clarity of contents. This method is perceived to be the weakest method for measuring instrument validity (Taylor *et al.*, 2011:2).

d) **Construct validity:** this method is used to explore the relationship of the instrument’s results to measures of the underlying theoretical concepts of the instrument. It is useful particularly when the study instrument intends to measure traits or feelings (Taylor *et al.*, 2011:2).

Generally, reliability and validity of a test instrument can be related since a test lacking reliability will hardly provide valid outcomes. Unfortunately, not all reliable techniques are necessary valid techniques as suggested by Taylor *et al.* (2011:3).
CHAPTER 3 STUDY POPULATION, SAMPLING TECHNIQUES AND DATA SOURCES

3.1. Target population

A group of subjects to whom investigators have interest in is called target population. The latter has varying characteristics allowing researchers to draw generalizable conclusions at the end of the study (Hulley et al., 2007: 106; Saunders et al., 2012: 134).

However, an accessible population, also known as the study population, is a subset of the target population that actually took part in the study allowing investigators to draw their final conclusions. Individuals from the study population are enrolled until a pre-defined sample size is reached (Hulley et al., 2007: 106; Saunders et al., 2012: 134).

3.2. Sampling techniques

Sampling technique is a process by which researchers select participants for their studies until they achieve a required sample size (Wright et al., 2016:97; Kroetze, 2013:1; Hulley et al., 2007: 106). This process is crucial since it helps in preventing selection bias and also in supporting generalization of the study findings. Participants’ selection criteria should be part of the research planning. Prior to that, a representative sample size should be calculated because researchers cannot enrol the entire population of interest due to challenges associated with limited time and resources. Hence, the sample is chosen from a population of interest and should be representative of that population. This process aims at not only minimizing costs but at maximizing generalisability. In selecting study participants to represent the required sample size, investigators rely on predefined
techniques, called sampling techniques. Although there are a variety of sampling techniques, they are often divided in two categories:

- **Probability sampling:** this technique is based on the assumption that every individual belonging into a particular population is known, hence has an even chance or probability of being chosen (Wright *et al*., 2016:97; Kroetze, 2013:1; Hulley *et al*., 2007: 106). A random process is often used when selecting participants based on each individual’s probability for being part of the required study sample.

- **Nonprobability sampling:** this technique however, is based on the assumption that every member of the population of interest is not known, hence individual probabilities for being selected as part of the study cannot be predicted. (Wright *et al*., 2016:97; Kroetze, 2013:1; Hulley *et al*., 2007: 106). Although common sense is used here when selecting participants, efforts should be made to avoid bias and maintaining a representative sample.

### 3.2.1. Kinds of sampling

a) **Kinds of probability sampling:**

- **Simple random sampling:** This technique is when an investigator creates a list with all individual members of the population of interest, and then starts selecting each participant by random selection. This approach guarantees that all individuals on the created list have an equal chance of being selected (Wright *et al*., 2016:97; Kroetze, 2013:1; Hulley *et al*., 2007: 106). It is a fair approach in addition of it being unbiased and high likely easy to be carried out. Unfortunately, one key drawback of this method is the fact that there is no assurance of having a sample that will be completely representative of the population.
• **Clustered sampling:** This consists of obtaining the study sample by randomly selecting pre-existing groups of individuals called “clusters” from a created list of members of the population of interest. (Wright *et al.*, 2016:97; Kroetze, 2013:1; Hulley *et al.*, 2007: 106). Although this method of selection is known to lack independence, it is however easy to obtain a large and relatively random selection of individuals.

• **Systematic Sampling:** This sampling technique is mainly indicated when performing a process-based research, with data collected real time when a process of interest is taking place. In addition, sampling frequency should be pre-defined to prevent any selection bias. For example, if the investigators decide to collect samples every third unit per hour. This predefined frequency is known as a systematic rule for that particular study. (Wright *et al.*, 2016:97; Kroetze, 2013:1; Hulley *et al.*, 2007: 106). In some cases, systematic sampling can be used during a population-based study only if investigators are able to control frequency for sampling to avoid any bias being introduced. The only drawback when using systematic sampling technique is when the systematic rule matches an underlying structure or condition leading into a sampling bias.

• **Rational Subgrouping or stratified sampling:** This sampling technique is also indicated during a process-based study with real time collection of samples when process operations are taking place. The technique consists of classifying meaningful measurements in order to understand major sources of variations among them. (Wright *et al.*, 2016:97; Kroetze, 2013:1; Hulley *et al.*, 2007: 106). In practical terms, measurements that are produced under similar conditions are classified into same groups, allowing for determination of short-term variation. Over time, this grouping strategy will allow researchers to better understand sources of variations between various sub-groups, and this is defined as long-term variation. This type
of subgrouping over time is the commonest used approach aiming at minimizing the chance of special causes of variation within a subgroup while maximizing the chance of special causes in variation between subgroups.

b) **Kinds of non-probability sampling:**

- **Convenience sampling:** This is often composed with study participants who are easy to enrol. Unfortunately, the drawback is the high likelihood of obtaining a biased sample (Wright *et al.*, 2016:97; Kroetze, 2013:1; Hulley *et al.*, 2007: 106).

- **Quota sampling:** In this approach, study participants are selected via convenience from pre-identified various population subgroups. (Wright *et al.*, 2016:97; Kroetze, 2013:1; Hulley *et al.*, 2007: 106). For example, quota sampling can be the appropriate method if an investigator selects a convenient sample of college students but prefers to enrol an equal number of boys and girls in the study. Although this approach is better in controlling a convenience sampling technique, it might however create a biased sample that is unable to be representative of the population of interest.

- **Judgment sampling:** this is arguably the most common used non-probability sampling technique. Sample selection is purely based on the researcher’s personal judgement. This approach is considered as an extension of a convenience sampling. (Wright *et al.*, 2016:97; Kroetze, 2013:1; Hulley *et al.*, 2007: 106). For example, an investigator may decide to include the entire sample obtained only from one city that he/she judges as representative for all the cities in a particular region. This approach is acceptable only when the researcher is certain and confident enough about the representativeness of the judged sample.
• **Snowball sampling:** this non-probability sampling technique is indicated when the desired sample of interest is very rare to be found. This is either because study respondents can be located with a lot of difficulties or when it’s highly costly to locate them. (Wright et al., 2016:97; Kroetze, 2013:1; Hulley et al., 2007: 106). In practical terms, investigators rely on referral obtained from the initial respondents in order to reach subsequent respondents, and so on. Although investigators will find this approach to be cost-effective but it is highly evident that the obtained sample will not be representative of the target population.

3.3. **Data sources**

When conducting a research, investigators rely on two types of data sources: primary and secondary. Whilst the primary data source refers to an original data source collected first-hand by the investigator in order to resolve a specific research question, the secondary data source however, is comprised of data acquired from optional published sources such as books, articles, and newspapers (Brink, van der Walt, van Rensburg, 2014: 147-152).

Examples of primary data sources are:

i. Medical and nursing charts: providing data about patients’ demographics and hospitalization unit. The primary diagnosis, use of invasive devices (mechanical ventilator, central venous catheter, Swan-Ganz catheter, Foley catheter, arterial catheter, and/or a wound drainage tube), receipt of hemodialysis, history of antibiotic therapy at the time of hospital admission, and hospital discharge status (ie, dead or alive) were provided. Data related to each nosocomial infection, including the dates and sites of infection, isolated pathogens, and antibiotic susceptibility profiles.

ii. Laboratory and imaging reports: test values for all patients with nosocomial infections.
iii. Management report regarding costs (cost for diagnosing a case of HAI; cost for laboratory and imaging investigation; cost for antimicrobial treatment; cost for additional tests; cost for additional procedures and devices; loss of revenue due to prolonged admission).

iv. Management report regarding investment costs for implementing IPC strategies (budget for annual salary of an IPC coordinator; office suppliers and administrative costs; cost for developing educational guidelines and surveillance tools; and cost for IPC materials and supplies).
CHAPTER 4  PILOT STUDY, CONTROL BIAS AND ETHICAL CONSIDERATIONS

4.1. Pilot Study

The use of a pilot study in research can have two separate meanings. First, a pilot study can be considered as a small version, also called trial run, of an upcoming major study (Polit et al., 2001: 467). Second, a pilot study aims to pre-test a newly designed research instrument such as a questionnaire (Baker 1994: 182-3). When a pilot study is conducted as a trial version in preparation of a major study, its advantage is particularly the fact that it is able to warn investigators of potential failure of their study, probably due to the use of inappropriate or complex research methods. However, when a pilot study is used to test a new research instrument, its key advantage is the fact that it will help in determining the validity and the reliability of the tested instrument, allowing for subsequent improvements. As suggested by De Vaus (1993: 54), investigators are encouraged to avoid unnecessary risks of embarking into major studies by conducting pilot studies first. The other reason for conducting a pilot study is that researchers can use the obtained preliminary findings from their pilot research in order to convince funding agencies that their study is worth funding.

The pilot survey can also focus on finding clarity, appropriateness and adequacy of questions regarding the identification of variables of interest containing in a survey instrument.

4.2. Control bias

Any predisposition to prevent unfair sampling or consideration of a question of interest is considered as bias. The latter is generally introduced as a result of either a random or a systematic error either during the application of a particular sampling technique or when testing a hypothesis
by over selecting or encouraging one outcome over the others. However, bias can take place during any phase of research (Pannucci and Wilkins, 2010: 126(2): 619–625). A random error occurs by chance and is particularly due to disturbances in performance of the measure. This type of error is always unpredictable. However, a systematic error is a type of error that consistently affects the measurement of the variable in the same way each time that the measurement is done. This type of error usually impacts on the reliability of a measure.

Researchers can control bias in different ways, depending on the research stage as follow [Pannucci and Wilkins, 2010: 126(2): 619–625]:

A. Pre-trial phase:

a) Plan a blind collection of data as well as the use of standardized data collection methods after carefully defining the study objectives, expected outcomes and risk factors.

b) Plan the rigorous use of pre-defined inclusion criteria in the selection of study participants in order to prevent the occurrence of confounders. For example, the use of a well-designed prospective study helps in avoiding the introduction of selection bias.

c) Define rigorous criteria for assigning study participants in separate cohorts.

B. During the trial phase:

a) The interaction between study participants and the researcher during interview processes must be standardized. For example, the investigator should be blinded to the exposure status of the participants.

b) The uses of a prospective study prevent the introduction of a chronology bias but also avoid the use of historic control groups.
c) Rely as much as possible on the use of objective rather than subjective data sources.

d) Investigators are encouraged to set up plans, in advance, for dealing and/or overcoming cases of loss to follow up among the study participants.

e) It is recommended that researchers define their list of exposures in advance and should refrain from using proxies.

f) The uses of gold standard diagnostic tools as well as validated measurement instruments are highly recommended.

g) In order to prevent variability in the used surgical techniques for example, cluster stratification is of a paramount importance.

h) Whilst known confounders can be prevented by using an appropriate study design or data analysis technique (i.e. regression models), unknown confounders can be controlled using randomization approaches.

C. During the post-trial phase:

Ensure that a trial is indeed registered, and double-check trial registries for similar trials whether in-progress or unpublished.

For the purpose of this study, selection bias and interviewer bias were likely to occur and were therefore well controlled by the researcher using appropriate control techniques as described above.
4.3. Ethical considerations

When performing a study involving human subjects, the following ethical requirements should be taken into consideration:

4.3.1. Ensuring participants have given informed consent

Informed consent is an ethical requirement when conducting a study involving human participants. The process is characterized by informing each potential participant about all aspects of the study, which are important for him/her to make a decision whether or not to voluntarily participate into the study. The concept is embedded in the principle of “Autonomy”, principle by which participants have the right to make decisions by themselves about their willingness to participate in a research project (Hulley et al., 2007: 106; Brink, van der Walt, van Rensburg, 2012: 120-129).

Written consent forms are generally required to document those discussions that took place between an investigator and a study participant. The investigator must disclose the following information to the potential participants: the nature of the research project; the procedures of the study; and risks and potential benefits of the study as well as possible alternatives to participating in the study (Hulley et al., 2007: 106; Brink, van der Walt, van Rensburg, 2012: 120-129).

Participating in a research project is not a straight problem. Firstly, researcher will seek informed consents from a group of participants. This is not a once-off situation since participants still require an assurance about the way researcher handles their confidential information. As a result, consenting to participate does not guarantee anything since participants can withdraw at any point in time according to Saunders et al. (2012:238).
4.3.2. Ensuring no harm comes to participants

The duty of every researcher is to avoid causing harm to his/her study participants through the adoption of risk mitigation strategies. This ethical principle is embedded into two other principles:

- **Nonmaleficence**: this principle states that investigators must act in ways that they have to avoid inflicting any harm to any participant. This is particularly critical for intentional or avoidable harms (Hulley et al., 2007: 106; Brink, van der Walt, van Rensburg, 2012: 120-129).

- **Beneficence**: this principle is when actions are taken to provide acceptable benefits to participants. Therefore, researchers are obliged to take beneficent measures in order to remove harms and promote benefits. Conducting a risk-benefit analysis in order to ensure an appropriate risk-benefit ratio when conducting a research project is an example of respecting the ethical principle of beneficence (Hulley et al., 2007: 106; Brink, van der Walt, van Rensburg, 2012: 120-129).

4.3.3. Ensuring confidentiality and anonymity

Confidentiality refers to the process by which an investigator, knowing the identity of the study participant, takes the necessary steps to protect that identity and other private information from being discovered by others (Hulley et al., 2007: 106; Brink, van der Walt, van Rensburg, 2012: 120-129). Since studies involving human participants require that participants sign informed consents, it makes it easier for the researcher to know their identities, hence confidentiality is key in ensuring the protection of private information. Methods used for protecting private information include but not limited to: keep all study records secure through the use of password-protected files; use encryption when sending the information via internet; use locked drawers to store the study files;
and report aggregate findings, not individual-level data, to the public (Hulley et al., 2007: 106; Brink, van der Walt, van Rensburg, 2012: 120-129).

Anonymity refers to a situation in which researchers do not know the identity of participants. It can be achieved by conferring each participant a study number and by preventing the use of any participants’ identifiers on the study files (Hulley et al., 2007: 106; Brink, van der Walt, van Rensburg, 2012: 120-129).

4.3.4. Ensuring that permission is obtained

Conducting a research requires that an investigator has access to either people or data. This means that a researcher needs cooperation of the “gatekeepers” to the data he/she has to access, or to the people he/she has to talk to. Obtaining permission is therefore the process by which an investigator secures approval from the organization or different professional bodies before he/she can go ahead with the study (Hulley et al., 2007: 106; Brink, van der Walt, van Rensburg, 2012: 120-129).

Gatekeepers when accessing the study sample

- When collecting data, researchers often face gatekeepers who are defined as any person standing between an investigator and his/her potential study participants. This might lead to various ethical challenges such as coercion, hence preventing a sample to be representative of the population. Gatekeepers often have a major influence on the study participants either because of their professional relationships or because they might be community representatives. The reliability and sample representativeness of both qualitative and quantitative study designs can be affected by gatekeepers unless participants are interacting with researchers freely and there is no one able to coerce individuals for taking part in the study, hence influencing the nature of data collected.
LIST OF REFERENCES


