Analysis of the Implementation of an Antiretroviral Treatment Programme in KwaZulu- Natal Province

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Submitted fulfilment of the requirements for the Degree of Doctor of Philosophy,

Faculty of Community and Health Sciences, University of the Western Cape

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Analysis of the Implementation of an Antiretroviral Treatment Programme

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by

Manyeke Sengwana

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KEY WORDS

Human immunodeficiency virus (HIV)

Acquired immunodeficiency syndrome (AIDS)

Implementation

Analysis

Antiretroviral therapy (ART) programme

KwaZulu-Natal (KZN)

Systematic literature review

Delphi technique

Model development

Home-based ART model

DECLARATION

I declare sole ownership of this dissertation *"Analysis of the Implementation of an Antiretroviral Treatment Programme in KwaZulu- Natal province"* is my own work, that it has not been submitted for a degree or examination in any other University, and that all the sources I have used or quoted have been indicated and acknowledged by complete reference.

Manyeke Sengwana December 2018

Signed: ....

DEDICATION

I dedicate my thesis to:

- *my children – ntandoyesizwe, bacebile, zamaobi and zophiwa*
- *my sister – cebile, your spirit kept me focused throughout*
- *all my family members, relatives, friends and colleagues who lost their lives from HIV related illnesses*

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The Provincial Departments of Health, KwaZulu-Natal: Special thanks for allowing me to use data from the facilities in your jurisdiction for the purpose of this study.

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My Loving Family: To my mother Johanna and my sister Gogo. Thank you for your love, warmth, support and kind wishes. Loads of love to my daughters Ntandoyesizwe, Bacebile and Zamaobi and my son Zophiwa for loving me even when I was constantly not available for them.

ABSTRACT

The rapid expansion of the ART programme in South Africa has placed an additional service demand on an already stretched public health infrastructure. The main aim of this study was therefore to analyse the implementation of the ART programme in KwaZulu-Natal province using the Donabedian Model of structure, process and outcome in order to develop an ART delivery model. Ethical approval to conduct this research was issued by the University's Senate Research Committee. The first phase of the study used a descriptive quantitative approach to review existing data from government departments to analyse the ART programme. A checklist with the list of indicators for the three elements of the study; the structure, process and outcome were used to collect data. A pilot study was conducted and the Cronbach Alpha test was used to determine the rigour of the study. In the second phase, a systematic review of studies on implementation of the existing models of ART programme was conducted using quantitative descriptive approach. The Quality Appraisal Tool was used to determine the validity of the research findings from the literature. In phase 3, both qualitative and quantitative approaches were used to conduct the Delphi study which included a group of experts in the field of HIV and ART programme. Responses from the participants were modified to determine the reliability of the study. The study found that there were structural problems such as shortages of antiretroviral drugs and delays in the return of laboratory results. The systematic literature review found that there were only two community-based ART models in South Africa, namely; the adherence clubs and community-based adherence clubs. These two models of ART delivery were implemented only in Cape Town. Some of

the ART programme outcomes indicators in KwaZulu-Natal were poor compared to national outcomes. The findings from all three phases led to the development of the home-based ART model. The conclusion from the study is that there is a need to expand community-based ART delivery models such as the home-based model.

LIST OF ABBREVIATIONS

ART	Antiretroviral Treatment
AIDS	Acquired Immune Deficiency Syndrome
DoH	Department of Health
HB	Home-based
HIV	Human Immunodeficiency Virus
KZN	KwaZulu-Natal Province
NDoH	National Department of Health
PHC	Primary Health Care
PMTCT	Prevention of Mother to Child Transmission
SA	South Africa
SANAC	South African National AIDS Council
UNAIDS	United Nations Joint Program on HIV & AIDS
WHO	World Health Organisation
TB	Tuberculosis

CHAPTER 1: OVERVIEW OF THE STUDY

1.1 INTRODUCTION

This chapter introduces the reader to the background and rationale for conducting this study on the implementation of the antiretroviral treatment (ART) programme in KwaZulu-Natal (KZN) province, South Africa (SA). The study analysed the ART programme in the province using the Donabedian (1980) model as a guide; reviewed studies that implemented the differentiated ART delivery models; and developed a model that can be used to strengthen the national ART response to HIV using the Delphi technique. A further discussion on the research problem, research question, research aim and objectives and the significance of the study is provided. Lastly, ethical considerations and measures that were applied to ensure rigour are also discussed. A layout of the thesis is provided at the end of the chapter.

1.2 BACKGROUND AND RATIONALE FOR THE STUDY

The background and rationale provide relevant arguments regarding specific issues that were identified from the literature. Each identified issue is analysed to show the current status of the ART programme, how the situation should be ideally, and lastly what measures are necessary to address the issues that were identified.

With an estimated population of 56 million by June 2018, it is estimated that 7,9 million people are living with HIV in SA in 2018 (Stats SA, 2018). Over 60% or an estimated 4.4 million people living with HIV (PLHIV) were on antiretroviral treatment (ART) in 2017 [SA National HIV Prevalence, Incidence and Behaviour Survey for 2017 (SABSSM V, 2017)].

The UNAIDS 90-90-90 targets of 2020 (UNAIDS, 2014) aim to ensure that 90% of all people living with HIV know their HIV status, 90% of people with diagnosed HIV infection receive sustained ART and 90% of all people receiving ART have viral suppression. In line with this SA adopted the WHO guidelines on Universal Test and Treat (WHO, 2016) which recommend universal ART for all people living with HIV regardless of CD4 count as soon as possible after diagnosis. Since the adoption of the guidelines, there has been a need to scale-up ART coverage in the best possible way. Models of care for ART delivery have evolved considerably in resource-limited settings. Services have been decentralised from hospitals to primary care facilities and tasks shifted from doctors to nurses and community health workers (CHWs) (Ford, Chu & Mills, 2012). To support the ambitious targets and accelerate ART provision to reduce congestion at busy health facilities, further adaptations and health systems changes are needed (Deeks, Lewin & Havir, 2013; UNAIDS, 2014).

Community-based models of decentralised care for stable patients have been implemented, designed to make ART delivery more efficient for the health system and provide appropriate support to encourage long-term retention of patients (WHO, March

2014). However, the evidence base for community-based models of care, where treatment, care and support is located outside of health facilities, is limited (Grimsrud, Sharp, Kalombo et al. 2015).

1.3 PROBLEM STATEMENT

South Africa has aggressively scaled up access to ART for HIV in recent years with an estimated 4.4-million people receiving HIV treatment in 2017 (SABSSM V, 2017). This equates to 61% of the people living with HIV in the country (UNAIDS, 2018). As a result, SA now has the largest ART programme in the world. With this successful implementation of one of its largest public health programmes, SA faces several fiscal, logistic and operational challenges as the treatment programme continues to expand. Several problems have been identified in the literature regarding the implementation of the ART programme. These include increasing detection within communities, linkage and retention in care, and at the same time strengthening operational support functions such as consistent drug supply, health staffing and infrastructure, diagnostic services, programme monitoring and sustainable financing (WHO, 2013).

Although SA has implemented the largest treatment programme in the world, close analysis of the programme has not kept pace with this expansion. While the problems have been identified in different ways, no study has organized them in such a way as to allow proper understanding as well as capture the depth of the problems. This study,

therefore, aimed at looking at these problems more closely and gaining a broader understanding of the implementation of ART programme. This was achieved by analysing the ART programme using the Donabedian model (1980). Donabedian's approach is to properly understand the depth of problems associated with implementing a public health programme, it is necessary to look at the structure, process and outcome of the programme. A holistic view of these three elements was needed to better understand the overall implementation process of the ART programme. This approach also aided in the identification of programme components that are most problematic in delivering this complex health care intervention especially to areas with limited resources.

In addition, continued expansion of the ART programme prompted SA to adopt the evidence-based WHO guidelines of Universal Test and Treat (UTT) in 2016 (NDoH, 2016). In order for SA to realise implementation of UTT, there was a need for all high-volume facilities to free up space and human resources at facilities through implementation of differentiated care models. However, a literature search found that there was lack of implementation models aimed at solving context specific problems identified in ART programmes in SA and KZN in particular, which has maintained the highest prevalence rate in the country at 12.2% (KZN AIDS Council, 2017). Hence, this study was conceptualised as it aimed to develop a model that will address the identified challenges within the study context and could be rolled out to another similar context in SA and the world.

1.4 OVERVIEW OF THE RESEARCH METHODOLOGY

Research methodology forms an integral part of the research process and is one of the most fundamental aspects of any scientific study (Polit & Beck 2011; Mouton & Marais 2012). The study was conducted in three phases: 1) Analysis of the ART programme in relation to structure, process and outcome, 2) Systematic literature review aimed to critically appraise individual studies in order to identify valid and applicable evidence and 3) Model development using the Delphi technique based on data from Phases 1 and 2.

1.4.1 Overview of the Research Design

According to Kirumbi (2018), a research design is a set of methods and procedures used in collecting and analysing measures of the variables specified in the research problem. Burns and Grove (2009) further defines the research design as the overall plan for obtaining answers to the research question guiding the study. Brink (2006) indicated that the best design is always the one that is most appropriate to examine the research problem and purpose.

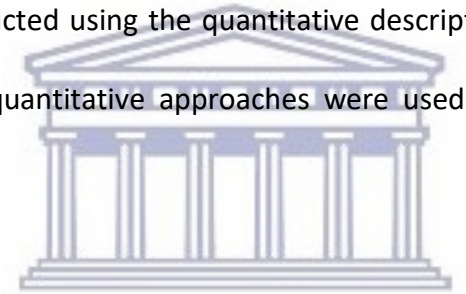
Based on these definitions, a variety of issues were considered when selecting the design as a means of obtaining answers to the research problem raised in 1.3 above. Decision on the choice of the design by the researcher was made by considering the following dimensions: 1) the purpose of the research; 2) the theoretical paradigm informing the

research; 3) the context in which the research was conducted and 4) the research techniques that would be employed to collect and analyse data (Leedy & Ormrod 2013).

Considering the dimensions stated above, a multiple research approaches was adopted by the researcher as appropriate and as a means of generating data about the ART programme in KZN. The multiple research approach included the use of more than one method of data collection to build from one phase of research to another (Teddie & Tashakkori, 2009). The approaches involved quantitative and qualitative research and each piece of research was completed on its own and then used together to form the essential components of the research as a whole. This implied that each research component was planned and conducted to answer a sub-question of the study and the results of the research were triangulated to form a comprehensive whole (Teddlie & Tashakkori, 2009).

The reason for this design was that the use of both quantitative and qualitative research provided a better understanding of a research problem than either research approach alone (Halcomb & Hickman 2015; Teddlie & Tashakkori 2009). It provided a holistic focus through acquisition of objective and subjective data in the same context (Halcomb & Hickman 2015; Teddlie & Tashakkori 2009) from analysis of the ART programme using documents review, the systematic literature review of studies implementing ART delivery models in SA, and the development of the new ART model using the Delphi technique to evaluate and explore the implementation of the ART programme.

The study used the elements in Donabedian's model (1980), commonly used for evaluation of programmes from a systems perspective. These include (1) the structure (2) process and (3) outcome. The study had three phases: In phase 1, a descriptive quantitative approach was used to review existing data from government departments to analyse the ART programme. A checklist with the list of indicators for the three elements of the study (the structure, process and outcome) was used to collect data. In phase 2, a systematic review of studies on implementation of the existing models of the ART programme was conducted using the quantitative descriptive approach; and in phase 3, both qualitative and quantitative approaches were used for the Delphi technique for model development.



A mix of quantitative and qualitative approaches is suggested in the literature (Halcomb & Hickman 2015; Teddlie & Tashakkori 2009) as adding value to offset the weakness of one by another (Halcomb & Hickman 2015). Additionally, the design was useful for application in this study on the basis of different types of data that were collected (Teddlie & Tashakkori 2009) as some aspects of data could not be calculated statistically and were therefore analysed using mixed methods of analysis.

1.4.2 Research Question

In line with the problem as presented above, the study attempted to answer the following research questions which were formulated to obtain information that could provide relevant solutions to the research problem. The main research question was "*How is the ART programme for the provision of HIV services to people living with HIV being implemented in KwaZulu-Natal*?"

To answer the research question, the following sub-questions were presented:

1.4.2.1 What are the implementation structures, processes and outcomes of the ART programme in place in KwaZulu-Natal?

1.4.2.2 What are the existing ART delivery models in South Africa and how are they being implemented?

1.4.2.3 What do ART experts believe will be better support to patient adherence and retention in the ART programme in KZN?

1.4.3 Research Aim and Objectives

Based on the research problem and questions posed above, the main aim of this study was to analyse the implementation of the ART programme in KwaZulu-Natal province using the Donabedian Model (1980) of structure, process and outcome in order to develop an ART delivery model.

From this aim the following objectives were extrapolated:

Phase 1: ART Programme Analysis

1.4.3.1 To assess the structure in the form of physical infrastructure, human and material resource composition and availability of programme related policies.

1.4.3.2 To assess the processes involved in evaluation and treatment of patients who utilise services in the facilities.

1.4.3.3 To assess the outcome of the programme in relation to the prevention, care and treatment outcomes.

Phase 2: Systematic Literature Review

1.4.3.4 To conduct a systematic literature review of studies that assessed existing models of the ART programme.

Phase 3: Model Development

1.4.3.5 To develop a model that will be used to improve ART programmes in KwaZulu-Natal using the Delphi technique.

	POPULATION, SAMPLE AND SAMPLING	DATA COLLECTION	DATA ANALYSIS	RIGOUR
PHASE 1: ANALYSIS OF THE ART PROGRAMME USING THE DONABEDIAN MODEL (1980)				
OBJECTIVES: 1.4.3.1 To assess the physical infrastructure; human and material resource composition and availability of programme related policies. 1.4.3.2 To assess the processes involved in evaluation and treatment of patients who utilise services in the facilities. 1.4.3.3 To assess the outcome of the programme in relation to the prevention, care and treatment outcomes				
CHAPTERS 3,4 & 5	**Population:** All reviewed documents **Sample:** ➢ Health districts (*n*=4): 1) Ethekwini 2) Umkhanyakude 3) Uthungulu 4) Ugu ➢ Facilities with ART programmes (*n*=15) ➢ 11 Documents generated from government websites • Structure (*n*=2) • Process (*n*=6) • Outcomes (*n*=3) **Sampling:** ➢ Purposive sampling of health districts: ➢ Sampling frame for ART facilities ➢ Purposive sampling of documents	• Document Review • Checklist	SPSS 25 Statistics computer software	Reliability: ➢ Pilot test ➢ Cronbach Alpha test

PHASE 2: SYSTEMATIC LITERATURE REVIEW				
OBJECTIVE: 1.4.3.4 To conduct a systematic literature review of studies that implemented existing models of ART programme				
CHAPTER 6	**Population:** ➢ Studies implementing ART model in SA **Sample:** ➢ Nine (9) Studies included for critical appraisal **Sampling:** PICO strategy (Squires et al., 2013): ➢ People living with HIV (PLWHIV) ➢ Implementation of different models ➢ Effectiveness of the ART model	Data about study characteristics and findings were extracted from each study using a data extraction form.	Narrative synthesis	Quality Appraisal Tool for Descriptive Studies designed by Spencer et al., (2003)
PHASE 3: MODEL DEVELOPMENT				
OBJECTIVE: 1.4.3.5 To develop a model that will be used to improve ART programmes in KwaZulu-Natal using the Delphi technique				
CHAPTER 7	**Population:** ➢ Experts in HIV care services and ART programme **Sample:** ➢ Ten (10) Delphi participants **Sampling:** ➢ A nomination process	**Round 1:** ➢ Concept classification from conclusion statements derived from phases 1 & 2. **Round 2:** ➢ Five-point Likert-type scale ratings **Round 2:** ➢ Five-point Likert-type scale ratings	• Content analysis • SPSS 25 Statistics computer software.	• Validity and reliability of the questionnaires • Reliability ➢ Modification of responses

Table 1-1: Summary of the research process

1.5 SIGNIFICANCE OF THE STUDY

- The study contributed to knowledge, by analysing the ART programme in KwaZulu-Natal, the province with the highest HIV prevalence in SA.
- The study provided clarity on how the ART programme was implemented, giving a wholistic perspective on the structure of the programme, the processes to implement the programme and the outcomes of the programme.
- The study contributed to the increasing need for research findings and reports on the implementation of ART programmes as the programme continues to expand.
- The study made a significant contribution in understanding the ART programme delivery gaps and constraints that might impact on future resource planning by policy-makers and implementers of the programme.
- The findings, conclusions and recommendations from this wholistic study may be generalised to other similar settings around SA where the ART programme is being implemented.
- The development of the home-based ART model might influence the Department of Health not only to include home-based ART delivery in the national ART programme but to also develop guiding policies and procedures regarding implementation of the model.

1.6 DEFINITIONS AND EXPLANATIONS OF TERMS

For the purpose of this study, the following key concepts are defined and applied within the context in which they have been explained.

1.6.1 Antiretroviral Therapy (ART)

Antiretroviral therapy (ART) is the use of HIV medicines to treat HIV infection. People on ART take a two-drug or three-drug fixed dose combination of HIV medicines (called HIV regimen) every day. The HIV medicines are often called antiretrovirals or ARVs.

ART is defined as "a regimen containing at least three antiretroviral drugs, including a protease inhibitor, a nonnucleoside reverse-transcriptase inhibitor, or three nucleoside reverse-transcriptase inhibitors, including abacavir or tenofovir" (Thompson, Aberg, Cahn, et al. 2010). It does not cure the disease (Jamison, Breman, Measham et al., 2006); rather, it aims to increase life expectancy and reduce opportunistic infections (Li, Tubiana, Katlama et al., 1998) and may potentially reduce the likelihood that an infected individual transmits the virus to another (Jamison, et al. 2006). HIV medicines help people with HIV live longer and healthier lives.

ART is recommended for everyone who has HIV. ART prevents HIV from multiplying and reduces the amount of HIV in the body (also called the Viral Load). The main goal of ART is to reduce a person's viral load to an undetectable level. An undetectable viral load means that the level of HIV in the blood is too low to be detected by a viral load test. People with HIV

who maintain an undetectable viral load have effectively no risk of transmitting HIV to their HIV-negative partner through sex.

1.6.2 People Living with HIV (PLWHIV)

People living with HIV (PLWHIV) refers to a person(s) infected with the virus, HIV. HIV stands for human immunodeficiency virus, which is the virus that causes HIV infection. The abbreviation "HIV" can refer to the virus or to HIV infection. HIV attacks the body's immune system, specifically the CD4 cells (T cells), which help the immune system fight off infections. HIV reduces the number of CD4 cells in the body, making the person more likely to get other infections or infection-related cancers. Without treatment, these opportunistic infections or cancers take advantage of a very weak immune system and signal that the person has AIDS, the last stage of HIV infection. No effective cure currently exists, but with proper medical care, HIV can be controlled.

1.6.3 Antiretroviral Treatment (ART) programmes

ART programmes are those facilities and services where people living with HIV are recognised as a specific group needing special attention and are provided with HIV treatment; and as such structures and processes are put in place to address their needs. These programmes can be within the health care delivery services managed by government or the community.

1.6.4 Donabedian Model (1980)

The study adopted the Donabedian model as a framework through which the implementation of the ART programme is analysed by using the key elements in Donabedian's "Model for Quality Care" (1980) commonly used for evaluation of programmes from a system perspective. The choice of model was influenced by existing global models, concepts, theories, current trends and principles on HIV and PLWHIV's health. According to Donabedian (1980), programmes should be explored or evaluated on three key elements. These include (1) the structure (2) process and (3) outcome. Donabedian believed that structure measures have an effect on process measures, which in turn affect outcome measures. Each of the different types of measures has a different purpose in determining whether the programme has had the desired impact. In the context of this study they form the basis of what is required for an effective ART programme.

1.6.5 Structure:

Structure describes the context in which care is delivered, including hospital buildings, staff, financing, and equipment (Donabedian, 1980). In this study, structure describes the organisation of the ART programme facility in which HIV care services are delivered. These include the availability of furniture and equipment; staff; drugs, medicines and supplies; laboratory results and national guidelines. The structure reflects the attributes of the service or facility such as staff to patient ratios and these are known as input measures.

1.6.6 Process

Process denotes the transactions between patients and providers throughout the delivery of healthcare (Donabedian, 1980). In this study, process refers to the availability of relevant information, guidelines, resources and services to indicate whether there are measures in place to evaluate and treat PLWHIV to enable implementation of the ART programme. It refers to the PLHIV seeking care and the provider making the diagnosis and providing treatment.

1.6.7 Outcome

Outcome refers to the effects of healthcare on the health status of patients and the improvement of knowledge and behaviour (Donabedian, 1980). In this study, the outcome demonstrates the end result of the activities carried out by ART programme facilities in the provision of HIV care services. The outcome refers only to the health care system variables, patient level data is not evaluated.

1.6.8 Systematic Literature Review

According to Hempel, Xenakis and Danz (2016), systematic review is an overview of existing evidence pertinent to a specific research question that uses systematic and explicit methods to identify, select and critically appraise relevant research and to collect, report and analyse data from the studies that are included in the review. A systematic review summarises the

results of available carefully designed healthcare studies and provides evidence on the effectiveness of healthcare interventions.

1.6.9 Delphi Technique

The Delphi technique is a systematic and interactive method which relies on a panel of experts who anonymously reply to questionnaires and subsequently receive feedback in the form of a representation of the group response, after which the process repeats itself.

Gould (2011) and Okoli (2004) define Delphi as a method for the "systematic solicitation and collation of judgments on a particular topic through a set of carefully designed sequential questionnaires interspersed with summarised information and feedback of opinions derived from earlier responses".

In a Delphi, rounds of questionnaires are sent out to the experts and anonymous responses are aggregated and shared with the group after each round. The experts can adjust their answers in subsequent rounds. Since multiple rounds of questions are asked and the panel is told what the group thinks as a whole, the Delphi method seeks to reach the correct response through consensus.

1.7 ETHICAL CONSIDERATIONS

Ethical consideration in research refers to a deliberate ethical stance that is taken by the researcher to ensure that the research is conducted ethically. It ensures that the research practice is free from unprofessional and harmful research practice. De Vos, Strydom, Fouche

et al., (2011) point to a need to handle ethical aspects in a manner that promotes good practice and research.

The proposal for this study was presented at the school for input from colleagues, after which it was submitted to the faculty's research committee for scrutiny so as to determine if it was written according to the ethical requirements and standards before it could be submitted to the Senate Research Committee of the university where the study was approved by issuing Research Certificate no. BM/17/1/1 (see Appendix 1-1).

Beauchamp's and Childress's (2009) ethical framework which is fundamental in social science was used. The ethical principles include: respect for autonomy, right to privacy, beneficence and non-maleficence and justice. The Code of Ethics as formulated by Beauchamp and Childress (2009) was followed in fulfilling the research ethics requirements including approval by ethical committees. The ethical aspects that were applied in this study are discussed below.

1.7.1 Approval by Ethical Committees

The University's faculty research committee scrutinised the proposal so as to determine if it was written according to the ethical requirements and standards before it could be submitted to the Senate Research Committee of the university where the study was approved by issuing Research Certificate No. BM/17/1/1 (see Appendix 1-1).

1.7.2 Principle of Respect for Autonomy

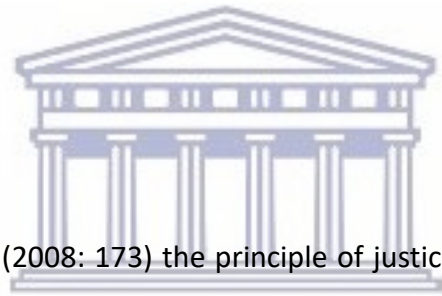
The principle of respect acknowledges a person's right to self-determination; right to making choices, to holding views, and to taking action based on personal values and beliefs. It entails acknowledging the participant's autonomy to decide to participate or not to participate in the study. Clarifications and explanations about the study were provided. The participants were free to ask the researcher questions for the purpose of clarity and decision-making on whether or not to participate; their questions were answered as per individual need(s). Furthermore, the participants were informed that they had the right to withdraw from the research at any stage, and that they would not be penalized or punished should they decide to withdraw from the study (Brink, 2006).

1.7.3 The Right to Privacy, Anonymity and Confidentiality

Privacy, anonymity and confidentiality were ensured to prevent harm to participants (Brink, 2006: 40-42). Privacy of the participants was ensured at all levels in handling data. All study participants were kept anonymous throughout the data collection process, data analysis process and beyond. Participants' names never appeared on the study documents but only codes used as pseudonyms. Only the researcher knew the true identity of the participants. This was necessary for sound ethical practice where confidentiality ensured that no other person could detect any connection with the participants based on available information. All the documents containing information obtained from participants were kept under lock and key.

1.7.4 Principles of Beneficence and Non-maleficence

Several measures were applied to ensure that all potential forms of errors and negligence in relation to research activities were avoided. Respect for autonomy was enhanced through an information sheet (see Appendix 7-2) and informed consent (see Appendix 7-3) which were sent to participants to read. The information sheet contained the contact details of the researcher. A consent form was signed by all Delphi participants. Participants were informed and explained to about their expected role in the study. The contact details of the researcher were made available to all participants in case they needed to access the researcher for any study related questions.



1.7.5 Principle of Justice

According to Polit and Beck (2008: 173) the principle of justice refers to fairness and equity that is applied when handling humans. It entails participants' right to fair treatment and their right to privacy. Researchers have a responsibility to protect the rights and interests of participants and ensure that participants are not exploited for the advancement of knowledge. This means that participants should freely and willingly participate in the research. They should be treated in a non-prejudicial manner if they withdraw from participating even after having agreed to participate. The researcher must honour all promises made to the participants and provide courteous and tactful treatment to participants at all times (Polit & Beck, 2008: 173-174). In this study, the principle of justice

was applied through a fair selection and treatment of the participants. Participants were selected on the basis of their knowledge and experience of the study topic.

1.7.6 Scientific Honesty

Scientific honesty was maintained through abstinence from plagiarism by providing full citation and reference list of sources used. This was to observe copyright and intellectual property rights regarding other authors' work. This was not only exercising the fundamental ethical principles but also a sign of respect for authors of information sources and databases that were consulted (Brink, 2006: 40-43). Authors whose findings were used to support the arguments and conclusions of the study were acknowledged to ensure that no plagiarism was committed. The researcher adhered to this aspect by ensuring that all the information that was reported was accurate and that no data was falsified.

1.8 THESIS CHAPTERS

The following outline provides the structure and organisation of the thesis chapters. Each chapter is designed to specifically address an aspect relevant to the study process and the findings.

Chapter 1: Overview of the study.

Chapter 2: Literature **r**eview.

Chapter 3: Phase 1 – Research methodology on analysis of the ART programme.

Chapter 4: Phase 1 – Analysis and presentation of results from the analysis of the ART programme.

Chapter 5: Phase 1 – Discussions and conclusions on the analysis of the ART programme.

Chapter 6: Phase 2 – Systematic literature review on the existing ART models.

Chapter 7: Phase 3 – Model development using the Delphi technique.

Chapter 8: Overall discussion, conclusions, limitations and recommendations of the study.

1.9 CHAPTER SUMMARY

This chapter outlined the overview of the study in which the aim and objectives of the study and the problem statement were presented. Definitions of concepts were provided. The research design and methods as well as measures to maintain rigour and ethical considerations were also addressed.

CHAPTER 2: LITERATURE REVIEW

2.1 INTRODUCTION

There has been a massive research output in the field of HIV and Aids care, both in peer-reviewed publications and unpublished. This made it difficult to establish what work has been done in the implementation of the ART programme. In order to begin investigations into these concerns, a literature review was undertaken to explore and discuss key findings relating to the implementation of the ART programme in South Africa (SA), sub-Saharan Africa and globally. The literature review is an attempt to answer the study research questions outlined in Chapter 1. Most of the literature content is HIV specific and relates to issues addressing HIV and Aids, and the implementation of the ART programme.

The chapter begin by describing the search strategy used to review the studies. It describes the overview of HIV in SA. The ART programme and sub-programmes in mostly affected countries are described. Lastly, the critique and conclusions of the literature are presented.

2.2 SEARCH STRATEGY

This section explains the search strategy for conducting the literature review. The literature included the review of studies in HIV and Aids care and the implementation of the ART programme. An electronic search of publications related to HIV and Aids care, health systems, HIV programmes and the implementation of the ART programme was performed

using the following databases: Medline, Pubmed and AIDS journals. Databases and AIDS journals were searched using a broad combination of the following terms: “HIV care programme”; “implementation of antiretroviral therapy programme”; “models of HIV care” and “differentiated ART delivery”. In addition, other resources such as government publications, government websites and World Health Organisation (WHO) reports were also used. Grey literature was searched online, and abstracts from AIDS conference proceedings were electronically searched. Only articles written in English were retrieved. A further search with the Google search engine was carried out to identify all health care and public health journals globally, in Africa and SA in particular. Further, a manual search for books in libraries was conducted. References from articles and books were scanned to identify other relevant studies for inclusion in the review. No authors were contacted.

2.3 AN OVERVIEW OF HIV IN SOUTH AFRICA

With an estimated population of 56 million by June 2018, it was estimated that 7,9 million people were living with HIV in SA (Stats SA, 2018). Of these, over 2.1 million are in one province, KwaZulu-Natal (KZN). According to the South African National HIV Prevalence, Incidence and Behaviour Survey for 2017 (SABSSM V, 2017), new infections have declined over the past five years, with the HIV incidence rate of 0.48% in 2017 compared to the 2012 infection rate of 0.85%. The estimated HIV prevalence among South Africans of all ages was 14% in 2017. HIV prevalence among adults aged 15 to 49 years in SA is 20.6 percent, and among Black Africans is 16.6%, followed by Coloureds with 5.3%, Whites with 1.1% and

Indian/Asian with 0.8% (SABSSM V, 2017). The survey found that SA had made some progress in addressing the HIV epidemic as reflected by some key HIV indicators. For instance, 85% of PLHIV aged 15 to 64 have tested for HIV and know their HIV positive status, 71% of this sub-group are on ART, and 86% of the group on ART are virally suppressed. Over 60% or an estimated 4.4 million people living with HIV (PLHIV) were on antiretroviral treatment (ART) in 2017. It was also found that viral suppression was 87.3% among PLWHIV who were on ART, with females generally being more likely to be virally suppressed than males among those aged 15-64 years (SABSSM V, 2017). KwaZulu-Natal (KZN) province had the highest rate of HIV and Aids infections with a prevalence of 18% in 2017. Among adults aged 15 to 49 years, HIV prevalence in KZN was 27% (SABSSM V, 2017). In 2017, about 1.3 million people living with HIV in KZN were on ART (KZN DoH, 2017).

2.4 TYPES OF ART PROGRAMMES

The literature below discusses three sets of ART programmes and these are: (1) HIV treatment programmes, (2) HIV care and support programmes and (3) Prevention programmes.

2.4.1. HIV Treatment Programmes

In the light of a combination of factors such as major scientific breakthroughs and accumulated lessons learned from scaling up the AIDS response worldwide, WHO, in the

2013 Consolidated Guidelines, recommended an increase in the CD4 count threshold for initiation of HIV treatment from 350 to 500 cells/mm³ (WHO, 2013). The objective was to expand delivery of HIV treatment to at least 15 million people by 2015, double the number of PLHIV at the time.

In 2014, the rise of new technologies such as simpler, more affordable diagnostics, simpler, better tolerated antiretrovirals and longer-lasting and more affordable antiretrovirals that eliminate the need for daily dosing led WHO and UNAIDS to launch the ambitious Fast-Track targets for 2020. These included achieving major reductions in HIV-related mortality and new HIV infections and the 90–90–90 targets (aiming at 90% of people infected with HIV being aware of their status; 90% of those diagnosed as having HIV infection being retained in care; and 90% of those in care being virologically suppressed, by 2020) (UNAIDS 90-90-90, 2014).

Based on evidence from clinical trials and observational studies showing that earlier use of ART results in better long-term clinical outcomes for PLWHIV than delayed treatment, WHO recommended in its 2015 consolidated Guidelines what could be considered as the ultimate shift, that "ART should be initiated in everyone living with HIV at any CD4 cell count" (WHO, 2015). This universal access to treatment and rapid scale-up in coverage of ART implied the removal of all limitations on who was qualified for ART and when to start treatment and an increase in the number of people eligible for ART. The implementation of the guideline was

based among other principles, on a public health approach to scaling up the use of ARV drugs along the continuum of HIV prevention, treatment and care**.** (WHO, 2015).

Delivery of treatment at the initial phases of the scale-up was based mainly on one clinic-based model largely undifferentiated for individual needs (International AIDS Society, 2016). The 2015 WHO recommendation of "treat all" put not only health systems under extreme pressure, due to lack of human and financial resources, to provide care to the growing number of patients on ART, but also on patients who encounter barriers in accessing treatment. With the expansion of eligibility for ART, clinics became saturated and the proportion of patients being classified as loss to follow-up (LTFU) also began to rise. This posed the challenge of improving retention in care and adherence to ART. It became evident that a one-size-fits-all model of HIV services would not work for all 37 million people then living with HIV (WHO, 2016; International AIDS Society, 2016). There was a need for a responsive, client-centered approach that simplified and adapted HIV services to better serve individual needs and reduce unnecessary burdens on the health system by shifting to a nurse-based, doctor-supported decentralised model of care and by developing out-of-clinic approaches to adherence support for stable patients. The Differentiated Care approach was recommended by WHO in the 2016 'Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection'.

Médecins Sans Frontières (MSF) pioneered four innovative service delivery models to offer services to different groups of patients with the aim to enhance quality, efficiency, and patient satisfaction as well as to meet health systems challenges in various countries. The goal was to place the client at the center of service delivery while maximising health system efficiency (Médecins Sans Frontières, 2013; Bemelmans, Baert, Goemaere, et al. 2014). The argument for a differentiated care approach was that as patient needs change so does the health system's response, hence once a patient is stable on ART, the priority should be to simplify drug collection mechanisms and reduce unnecessary clinical follow-up visits to support ongoing retention and adherence. Differentiated ART delivery focuses specifically on clients who are on treatment. Models of differentiated ART delivery are divided into four categories: health care worker-managed group models; client-managed group models; facility-based individual models; and out-of-facility individual models. In all of these models, patients continue to have clinical consultations as part of their package of care. The models are flexible to accommodate patients who may want or require upward referral (Médecins Sans Frontières, 2013).

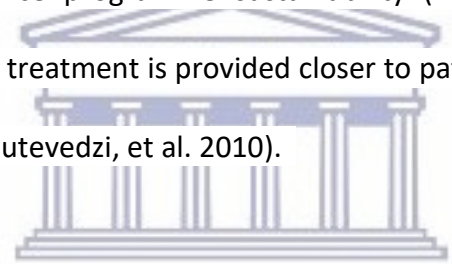
Some of the literature on the implementation of differentiated ART delivery models is discussed in 6.4 of Chapter 6 as part of the discussion for differentiated models of care.

2.4.1.1 Evidence of HIV treatment

There is evidence that the public-sector ART roll-out in rural South Africa is beginning to affect adult population mortality. Herbst, Cooke, Barnighausen, et al. (2009) found a substantial fall in population mortality, particularly from HIV-related causes, following the widespread availability of ART in a rural community with a high prevalence of HIV infection and high HIV-related mortality. However, Peltzer, Ramlagan, Khan, et al. (2011) reported a high proportion (46.3%) of mortality among their participants. The high rate of mortality happened in the first 6 months of follow-up and death was the most common reason for loss to follow-up compared with other reasons. A high proportion of patients started treatment with very advanced disease (Mutevedzi, Lessells, Heller et al. 2010; Peltzer, et al. 2011). The high early mortality rates indicated that patients were enrolling in ART programmes with far too advanced immunodeficiency (Mutevedzi et al., 2010; Peltzer, et al. 2011). Causes of late access to the ART programme were cited as delays in health care access, health system delays, or inappropriate treatment criteria (Peltzer, et al. 2011).

In a modelling study by Blaizot, Huerga, Riche, et al. (2017), the “ART for all” intervention would lead to a greater population viral load suppression (73% and 80% by 4 and 10 years, respectively) and a greater impact on reducing HIV incidence rate. The “ART at CD4<500” intervention would reduce HIV incidence by 30% overall by 4 years and 41% by 10 years. The intervention would lead to a population viral load suppression of 69% by 4 years and 75% by 10 years.

The sustainability of the large-scale ART programme in SA faces the same challenges as in any developing country: a rapidly increasing need for health workers who can deliver ART, the need to ensure long-term treatment adherence and to retain patients in the programme; the unsolved question of the optimal relationship between ART programmes and the overall health care system (Herbst, et al. 2009; Mutevedzi, et al. 2010). The use of decentralised programmes, with treatment delivered through the primary health-care system allowing rapid scale-up and task-shifting' and reducing the number of times patients attend clinics for drug collection, may enhance programme sustainability (Mutevedzi, et al. 2010). In a decentralised model, where treatment is provided closer to patients' homes, there are lower rates of loss to follow-up (Mutevedzi, et al. 2010).



2.4.2 HIV Care and Support Programmes

HIV care and support refer to key non-antiretroviral therapy clinical services, the treatment of HIV-related infections and non-clinical services that in combination with antiretroviral therapy contribute towards the reduction of rates of ill health and AIDS-related deaths among people living with HIV (UNAIDS, 2016).

The HIV care and support programmes discussed below are: (1) HIV testing and counselling (2) Retention in Care and Loss to Follow-up (LTFU) and (3) HIV Treatment Support.

2.4.2.1 HIV Testing and Counselling (HTC)

HIV Testing and Counselling (HTC) include pre-test counselling, risk-behaviour assessment, informed consent, and post-test counselling based on test results to provide individually-tailored risk reduction messages (Denison, O'Reilly, Schmid, et al. 2008). Implementation models for HTC can be facility-based, either client or provider initiated (Kennedy, Fonner, Sweat, et al. 2012), mobile, workplace or home-based (WHO, 2007).

Facility-based HTC has been the standard model in the public health sector. However, this model has been unable to attain high population coverage levels with the majority of people still unaware of their HIV status (WHO, 2011). Community-based mobile HTC is the "facility" which moves into areas with limited access to HTC (Sweat, Denison, Kennedy, et al. 2011). Workplace-based HTC also appears to offer an opportunity for increasing access (Corbett, Dauya, Matambo, et al. 2006). However, definitive coverage levels within a community remain difficult to ascertain with any of these approaches. Furthermore, none appear able to achieve the near (90%) or universal HTC coverage which modelling has suggested is needed for significant decreases in HIV incidence (Granich, Gupta, Suthar, et al. 2012; Alsallaq, Baete, Hughes, 2011). Home-based HTC has many of the advantages of mobile HTC but may further improve access and allow for more accurate assessment of community-level coverage (Chang, Serwadda, Quinn, et al. 2013). Cost-effectiveness and observational studies have also found home-based HTC to be a better strategy for reaching populations with low rates

of prior testing and higher CD4 counts (Menzies, Abang, Wanyenze, et al. 2009; Wachira, Kimaiyo, Ndege, et al. 2012).

In SA, the launch of the national HTC campaign in April 2010 resulted in a remarkable increase in the number of people accessing testing. Between 2008 and 2012, annual HIV testing increased from an estimated 19.9% to 37.5% among men, and from 28.7% to 52.6% among women. The higher testing figures seen among women have been attributed to the added effect of the PMTCT programme, which enables women to access HIV testing services during antenatal appointments (Shisana, Rehle, Simbayi, et al. 2014). South Africa developed an HCT revitalisation strategy in 2013, which focused on the private sector, farms and those in higher education. This strategy set a target of 10 million HIV tests to be carried out by 2015, of which 9.5 million were achieved, taking the total number of HIV tests since the 2010 campaign began to 35 million (SANAC, 2015).

Although many adults are in contact with clinic-based programmes for HIV testing, they do not necessarily engage in regular HIV care and do not initiate treatment as soon as they become eligible (Plazy, Dray-Spira, Orne-Gliemann, et al. 2014). George, Strauss, Chirawu, et al. (2014), found that there were perceived stigmas surrounding HCT as well as fears about the confidentiality and the result of the HIV test, which were found to be an important barrier to voluntary medical male circumcision.

Enhanced post-test HIV counselling and interventions throughout the pre-ART period should be developed to target especially men and young individuals as well as those who are not far advanced in their disease and not yet HIV-symptomatic (Plazy, et al. 2014). Attention should also be given to individuals who enter the programme without feeling sick and who thus delay returning to the clinic. These are probably the greatest challenges as the CD4 threshold for ART initiation is gradually relaxed (Plazy, et al. 2014).

2.4.2.2 Retention in Care and Loss to Follow-up (LTFU)

While many people access an HIV care and treatment programme, a substantial proportion of these are not really engaged with care in the longer term (Plazy, et al. 2014). Numerous observational studies have demonstrated the challenges in engaging PLWHIV across the entire spectrum of care (Gardner, McLees, Steiner, et al. 2010), both with initial linkage to care and subsequent retention, with estimates of only 59% being clinically staged after diagnosis and 25% of patients not retained in care one year after ART initiation (Rosen & Fox, 2011; Fay, Baral, Trapence, et al. 2011). Barriers to engagement are numerous, ranging from site-specific transport challenges (Tuller, Bangsberg, Senkungu et al. 2010), to more generalised issues such as stigma (Geng, Nash, Kambugu, et al. (2010).

Most of the programme's emphasis has been on initiating patients onto treatment; other aspects of HIV care, such as pre-ART monitoring and long-term adherence support, have received less emphasis (Mutevedzi, et al. 2010; Plazy, et al. 2014). The evidence base for

interventions to link and retain PLWHV in care remains scarce. Chang, Kagaayi, Nakigozi et al. (2010) found that in Uganda, the assistance of community-based peer treatment supporters decreased loss to follow-up rates by 44%. In Kenya, Kohler, Chung, McGrath et al. (2011) found that provision of free cotrimoxazole improved retention of ART-ineligible clients over twofold compared to historical controls. In SA patient tracers have been used to successfully return patients to care (Rosen & Ketlhapile, 2010). However, little evidence exists on how to engage largely asymptomatic HIV-infected populations with higher CD4 counts, or how to best identify and engage acutely HIV-infected patients (Chang, et al. 2013). Improving the identification and diagnosis of people with acute HIV infection using these strategies, and improving provider awareness, may offer some implementation strategies to address this challenging population (Kharsany, Hancock, Frohlich, et al. 2010; Sanders, Wahome, Mwangome, et al. 2011).

Point of care (POC) CD4 testing which refers to testing at the time of patient care, offers substantial promise for clinical staging at the time of diagnosis, thus facilitating immediate entry into appropriate care and treatment services (Mtapuri-Zinyowera, Chideme, Mangwanya et al. 2010; Bassett, Wang, Chetty, 2009; Losina, Bassett, Giddy et al., 2010). In their randomised controlled trial of POC CD4 at HIV testing in SA, Faal, Naidoo, Glencross, et al. (2011) reported a twofold improvement in linkage to care. In Mozambique, Jani, Sitoe, Alfai, et al. (2011) found an 80% reduction in the early loss to follow-up rate. The implementation evidence base for this maturing technology needs continued validation

(Harries, Zachariah, Lawn, et al. 2010; Anderson & Crowe, et al. 2011), and POC CD4 technology development and field trials should be a research priority provided CD4 cell count remains one of the standards for determining ART eligibility (Shott, Galiwango, Reynolds, et al. 2012).

While the evidence base for strategies to optimise engagement in care continues to mature, existing programme models which have demonstrated success may provide reasonable starting points for combination HIV prevention activities (Thompson, Mugavero, Amico, et al. 2012; Lawn, Kaplan, Wood, et al. 2007). These successful programmes often involve task shifting, and decentralisation with community and/or home-based services. They frequently incorporate patient tracing services and recruit PLHIV in the engagement and retention of their peers (Rosen, et al. 2011; Harries, et al. 2010; Lawn, et al. 2007; Rich, et al. 2011; Rosen, et al. 2007; Chang, et al. 2009; Rich, et al. 2012; WHO, 2007). Community-based programmes with good programmatic outcomes have included self-forming groups of patients (Decroo, et al. 2011), the use of handheld technology to support task shifting to PLWHIV (Wools-Kaloustian, et al. 2009), incorporation of electronic medical records (Alamo, et al. 2012), and emphasising pre-ART care services (Burtle, et al., 2012).

In a study by Peltzer, et al. (2011) of 735 patients prior to initiating ART who were followed up over 12 months in a predominantly rural area in KZN, a total of 24.1% of patients initiating ART were LTFU. The results draw attention to the need for early HIV diagnosis,

increased access to ART services with earlier treatment initiation, routine screening and aggressive management of opportunistic infections, particularly tuberculosis.

2.4.2.3 HIV Treatment Support

ART patients need to adhere to treatment at high levels indefinitely if treatment as prevention is to succeed (Barnighausen, Chaiyachati, Chimbindi, et al. 2011). Implementation strategies to promote and support adherence include the use of peer treatment supporters, which has shown some improvement in adherence and virologic outcomes (Chang, et al. 2010; Barnighausen et al., 2011). Integration of HIV treatment with tuberculosis or primary care services has also demonstrated potential to improve patient-oriented outcomes such as time to ART initiation (Topp, et al. 2012; Hermans, et al. 2012; Ferguson, et al. 2012).

In pilot studies, food support has been found to have some benefits in improving adherence (Cantrell, et al. 2008), but the large-scale implementation and sustainability of such interventions is daunting (Hardon, et al. 2007). Directly observed therapy studies showed that the strategy was difficult to scale up to population level (Pearson, et al. 2007; Sarna, et al. 2008; Ford, et al. 2009).

New technologies have shown promise in supporting ART adherence (Chang, et al. 2013). In Kenya, mobile phone alert to provide support decreased the risk of virologic failure by 16% (Lester, et al. 2010). In another study, text-message reminder (SMS) showed 13–16% improved adherence (Pop-Eleches, et al. 2011). However, failure of an alarm device in a third

Kenyan study demonstrated how local assessment of technological strategies must be ongoing (Chang, et al. 2011), and that reminders alone without patient support may be insufficient (Mills, et al. 2012). Additional evaluations of electronic reminders and support in other populations would significantly add to the value of these early reports (Chang, et al. 2013).

Laboratory monitoring has clinical and survival benefits (Laurent, et al. 2011; Mermin, et al. 2011; Chang, et al. 2010). Monitoring of HIV viral load may have substantial benefits through earlier regimen switching in cases of ART treatment failure and by preventing unnecessary regimen changes (Sigaloff, et al. 2011). Viral load testing strategies which target only high-risk patients based on CD4 count and adherence assessments may be less costly strategies, but need further evaluation of impact (Abouyannis, et al. 2011). The use of lay health workers and the application of technology and laboratory support, tailored to the local epidemic and treatment dynamics, is needed to assist with implementing treatment as prevention (Lester, & Karanja, 2008; Chang, et al. 2008). Continued evaluation of these support strategies and their effectiveness in supporting PLHIV on ART, especially when used in combination, will be enlightening (Chang, et al. 2013).

2.4.3 Prevention Programmes

HIV prevention programmes are interventions that aim to stop the transmission of HIV. They are either implemented to protect the individual and his/her community or are rolled out as

public health policies (UNAIDS, 2016). The HIV prevention programmes discussed below are: (1) Prevention of mother-to-child transmission – PMTCT (2) Pre-exposure prophylaxis – PrEP (3) Medical male circumcision – MMC (4) Behaviour change and condoms (5) Combination HIV prevention.

2.4.3.1 Prevention of Mother-to-Child Transmission (PMTCT)

Significant progress in scaling up PMTCT has been made over the past several years (WHO, 2011). While PMTCT implementation strategies are not well represented in the scientific literature, some approaches have shown promise. These approaches include the adoption of task shifting, integrating PMTCT services into the larger context of care for the mother and family, adopting system improvement methods, and empowering mothers to self-administer PMTCT (Uwimana, et al. 2012; Youngleson, et al. 2010; Kagaayi, et al. 2005; McNairy, et al. 2011).

PMTCT serves as a critical entry point into the health care system for both HIV-negative and positive individuals (Ferguson, et al. 2012). For HIV-negative individuals, the opportunity to access this service increases engagement in care and offers counselling opportunities and seronegative-appropriate interventions. For HIV-infected individuals, a variety of other prevention interventions may apply beyond PMTCT, such as ART and couples counselling (Chang, et al. 2013).

South Africa has made great progress in the PMTCT largely due to improvements in the choice of ARVs and the widespread accessibility of the PMTCT programme (SANAC, 2014). In 2015, more than 95% of HIV-positive pregnant women received antiretroviral medicine to reduce the risk of MTCT. As a result, MTCT of HIV in SA has fallen to 1.5% - meeting the then National Strategic Plan (NSP) target (SANAC, 2015). The South African HIV NSP 2017 – 2022 aims to reduce mother-to-child transmission (MTCT) of HIV rates to under 1,5% by 2022 (SANAC, 2017). It is widely believed that SA has reached a point where the elimination of paediatric HIV is possible (SANAC, 2017).

The studies by Horwood, et al. (2010; 2012) highlighted the high proportion of HIV testing on mothers in antenatal care as one of the reasons for the PMTCT programme's success. In the studies, most women (98.6%) attended the antenatal clinic during their recent pregnancy (Horwood, et al. 2010) and 90% and 97,3% of all mothers investigated were tested for HIV during their most recent pregnancy respectively (Horwood, et al. 2012; 2010). In Chetty, et al. (2012), HIV transmission risk was 2,7% at six weeks in HIV exposed infants whose mothers received PMTCT, and none of the remaining children who were followed up until 18 months of age were diagnosed as HIV-infected. Initiating ART in HIV-positive mothers as soon as they are detected make the greatest contribution to reducing HIV infections in children and mortality in mothers (Horwood, et al. 2012).

At antenatal care level the PMTCT programme was functioning well, achieving almost universal coverage of HIV testing among pregnant women and good coverage of other interventions. However, there was a breakdown in PMTCT coverage and continuity of care after delivery of the baby (Horwood, et al. 2010). Problems highlighted with the PMTCT programme were that services were frequently not available at the immunisation clinic, and poor recording of PMTCT interventions on the child health record meant that follow-up care depended on the mother reporting that the baby was HIV exposed (Horwood, et al. 2010; Chetty, et al. 2012). Follow-up of HIV-positive mothers and HIV-exposed infants was poor, limiting the ability to determine HIV-free survival at 18 months (Horwood, et al. 2010; Horwood, et al. 2012). Follow-up care for HIV-positive mothers was also poor; Many clinics had designated health workers for PMTCT; however, PMTCT services were frequently not provided as part of routine care and record keeping was poor. This created barriers for mothers' and babies' access to care after delivery and has led to fragmentation of services, placing the responsibility for follow-up on the mother (Horwood, et al. 2010; Chetty, et al. 2012). In many clinics, PMTCT services are rendered by a dedicated PMTCT nurse, suggesting that these services are not integrated into routine care, and mothers may be reluctant to attend specialised HIV clinics or services because they fear being identified as HIV infected by other community members attending the clinic (Horwood, et al. 2010).

Although antenatal clinic attendance is high in SA, few women attended before 20 weeks' gestation and many attended only in the third trimester (Horwood, et al. 2010; Chetty, et al.

2012; Horwood, et al. 2012). Horwood, et al. (2012) state that most of the women investigated had only been tested for HIV in the last trimester of their most recent pregnancy, possibly because of their late initial attendance at an antenatal clinic. Because they were tested for HIV late in their pregnancies, many of the HIV-infected women did not receive their CD4+ cell result during their pregnancies (Horwood, et al. 2010; 2012). According to Chetty, et al. (2012,) late antenatal presentation was a strong predictor of loss to follow up. Several reasons for late antenatal clinic attendance were highlighted in the study; expenses related to antenatal care; lack of awareness of the value of early antenatal care; or poor maternal health seeking behaviours.

HIV prevention programmes are likely to want to include PMTCT as a core prevention component, not only for the benefit of reducing HIV transmission to infants, but also to leverage PMTCT to increase access to other services for the mother and family (McNairy, et al. 2011; Ginsburg, et al. 2007).

2.4.3.2 Pre-Exposure Prophylaxis (PrEP)

Pre-exposure prophylaxis is when people who are at a substantial risk of getting HIV take HIV medicines daily to lower their chances of getting infected. A combination of two HIV medicines (tenofovir and emtricitabine) is approved for daily use as PrEP to help prevent an HIV-negative person who is exposed to HIV through sex or injection drug use from getting HIV infection. Implementation science evidence for PrEP remains limited due to minimal field experience with efficacious PrEP interventions (Underhill, et al. 2010).

The evidence base for oral and vaginal PrEP continues to evolve, with current results mixed (Van Damme, et al. 2012; Thigpe, et al. 2012; Abdool Kari, et al. 2010; Celu, et al. 2012). While modelling studies have shown that efficacious and widely implemented oral PrEP could result in a cost-effective and significant impact on HIV incidence (Pretorius, et al. 2010) given the current level of uncertainty about population-level effectiveness, oral PrEP may not be a core component of most current combination HIV prevention activities (Chan, et al. 2013). However, in select groups such as discordant couples where the HIV-infected partner is not on ART or high-risk populations such as sex workers and their clients and men who have sex with men, PrEP may play an important role (Chang, et al. 2013). Another modelling study (Blaizot, et al. 2017) showed that targeted PrEP intervention at 40% among 15–24-year-old HIV-uninfected women would reduce HIV incidence compared to the non-targeted PrEP intervention. Demonstration projects are needed to provide further evidence that this biomedical intervention can be applied at significant scale to assist in the control of generalised HIV epidemics (WHO, 2012).

2.4.3.3 Medical Male Circumcision (MMC)

In 2010, research emerged from sub-Saharan Africa suggesting that voluntary medical male circumcision (MMC) can reduce the risk of female-to-male HIV transmission by up to 60% (Shisana, et al. 2014). This led the South African government to rapidly roll out a national MMC programme, which aimed to reach 80% of HIV-negative men (4.3 million) by 2016. In

2016, the circumcision rate was stable with 50-79% of eligible men reached (UNAIDS, 2016). A modelling study by Blaizot, et al. (2017) showed that although the targeted voluntary medical male circumcision (VMMC) scenario would provide greater reduction in HIV incidence than the non-targeted VMMC scenario (15% and 8% respectively compared to "no change" scenario by 4 years), the latter would provide a greater reduction in incidence per additional number of circumcisions performed (32% per additional number of circumcisions performed).

In settings of moderate to high HIV prevalence and low male circumcision rates, MMC is a critical component of combined HIV prevention (Chang, et al. 2013). No evidence has been found supporting one type of MMC scale-up strategy versus another. However, several observational studies provide examples of potential approaches (Lissouba, et al. 2010; Mahler, et al. 2011; Mwandi, et al. 2008). South Africa has demonstrated an effective model using community-based outreach and mobilization (Lissouba, et al. 2010), and Tanzania's MMC campaign approach has exceeded original targets (Mahler, et al. 2011). In Kenya there has been significant early success through government-led, task-shifting initiatives (Mwandi, et al. 2008).

Task-shifting of MMC appears to be safe with adverse event rates similar between non-physician clinicians and doctors and specialists (Ford, et al. 2012). Non-surgical male circumcision devices such as the Shang Ring and PrePex had undergone evaluations of safety

and acceptability to determine what role they may play in accelerating MMC scale-up efforts and addressing human resource shortages (McIntyre, et al. 2011). These new devices are promising and innovative; however, their relative benefits and adverse effects compared to each other and to surgical methods require further evaluation (Chang, et al. 2013). MMC efforts may also need to be cognisant of seasonal demands and adjust their supply appropriately (de Bruyn, et al. 2007). Uptake of MMC among higher risk men remains suboptimal, and therefore innovative targeted strategies addressing this difficult to engage population are needed (Wamai, et al. 2011). Engaging a population of young men with limited or no experience in the conventional healthcare system has also proven to be difficult (Wynn, et al. 2015). VMMC programmes targeting young people should consider offering both mobile and fixed-site VMMC to accommodate the preferences of a wider range of individuals to maximise uptake (George, et al. 2014; Wynn, et al. 2015).

2.4.3.4 Behaviour Change and Condoms

HIV prevention will not succeed without significant and sustained individual and community-level HIV risk reduction behaviour change (Coates, et al. 2008). It has been difficult to separate the varied contributions of other drivers of HIV incidence from specific changes in behaviour (Gray, et al. 2006). Behaviour change counselling interventions aimed at increasing condom access and use and decreasing sexual partners and activity have demonstrated successes which can guide local implementation approaches, such as a 33% reduction in risk behaviour prevalence in a 5-country study (Group NCHSPT, 2010; McCoy, et

al. 2010). Counselling strategies addressing partner risk behaviours and promoting condom use have become standard of care for most HIV prevention efforts, and they are likely to continue as foundational components of most HIV prevention programmes (Chang, et al. 2013). In particular, discordant couples are an important population to target HIV prevention efforts using facilitated disclosure (Kairania, et al. 2010) and couples counselling strategies (Burton, et al. 2010; Eyawo, et al. 2010; WHO, 2012a).

The challenge to selection of implementation strategies is the mixed evidence for behaviour change interventions (Padian, et al. 2010; Napierala, et al. 2011; Scott-Sheldon, et al. 2011; Sweat, et al. 2012; Michielsen, et al. 2010; Medley, et al. 2009; Laga, et al. 2012). Peers may play an important role as they are economical and relatively effective behaviour change agents (Medley, et al. 2009). The effectiveness of condoms has been well established (Weller, et al. 2002), therefore ensuring adequate supply and access will aid HIV prevention efforts (Chang, et al. 2013). South Africa has responded to its HIV epidemic with a rapid expansion of its condom programme. Male condoms are widely available, and the female condom programme is one of the biggest and most established in the world (SSA, 2015). Condom distribution targets for 2016 were set at 1 billion male condoms and 25 million female condoms, with 2015 distribution levels at 723 million male condoms and 20.7 million female condoms (SANAC, 2015). However, the 2017 South African National HIV Prevalence, Incidence, Behaviour and Communication Survey, reported that condom usage has fallen in recent years. In 2008, 85% of 15- to 24-year-old males reported using a condom during their

last sexual encounter – by 2012, this had fallen to 68%. Condom use among men aged 25 to 49 also decreased, from 44% to 36%. The same survey reported that 53% of participants had never used condoms (Shisana, et al. 2014).

2.4.3.5 Combination HIV Prevention

Task Shifting:

Task shifting is the rational redistribution of tasks among health workforce teams from higher trained providers to those who require less training (WHO, 2007). It is a direct response to the health worker human resource crisis in the public health sector which is a substantial barrier to implementation of combination HIV prevention (Barnighausen, et al. 2007; Van Damme, et al. 2006). Multiple observational task shifting studies have focused on shifting ART care from physicians to nurses and have typically demonstrated that task shifting can be accomplished without significant differences in quality of care (Sherr, et al. 2010; Callaghan, et al. 2010; Long, et al. 2011; Brennan, et al. 2011; Brentlinger, et al. 2010).

Task shifting has been tested in a small number of randomised controlled trials (Mdege, et al. 2012). A study of home-based HIV care provided by field officers found it to be as effective as a clinic-based strategy with similar rates of virologic failure (Jaffar, et al. 2009). Home-based care supported by trained PLWHIV resulted in similar patient-oriented outcomes and less frequent clinic visits compared to clinic-based care alone (Selke, et al. 2010). Another

randomised controlled trial demonstrated that nurse-monitored care was non-inferior to doctor-monitored care (Sanne, et al. 2010; Fairall, et al. 2011).

Novel approaches to improve worker efficiency and the quality of services delivered are required (Chang, et al. 2013). For example, mobile electronic decision-making support for patient screening and triage to HIV prevention and care have been successfully piloted in Uganda as well as in Kenya in rural settings (Wools-Kaloustian, et al. 20019; Tumwesigye, et al. 2011). These mobile technologies for healthcare may be appropriate components of combination HIV prevention implementation strategies (Lester, et al. 2008).

Structural Interventions:

The use of structural interventions such as individual or community-based financial incentives to create demand and uptake of HIV prevention interventions is an area of growing interest (Gupta, et al. 2008). There have been clear successes in other fields with incentive-based programs (Rivera, et al. 2004). In the field of HIV, a randomised controlled trial in Malawi found that cash transfer programmes may have reduced HIV infections among young women (Baird, et al. 2012). Incentive interventions to increase participation in HTC have also been successfully piloted (Kranzer, et al. 201; Nglazi, et al. 2011). Supply-side strategies such as pay for performance and provider and facility-level incentives have shown promise for other health conditions, but evaluations of their application to HIV-related interventions remains limited (Toure, et al. 2010).

The use of financial incentives or compensation for time and travel in HIV prevention programmes can be considered provided rigorous evaluation procedures are concurrently implemented to provide ongoing demonstration of effectiveness (Chang, et al. 2013). Structural interventions that focus on food insecurity to improve adherence to ART have also shown some impact in pilot studies (Cantrell, et al. 2008), but population-level implementation of food support poses significant financial and sustainability challenges (Chang, et al. 2013).

Increasing supply of HIV prevention services will be inadequate for controlling the HIV epidemic if demand for these interventions is not also increased (Chang, et al. 2013). The MMC experience offers some insights into how to create demand (Chang, et al. 2013). A variety of community mobilisation strategies in Tanzania appeared to successfully increase demand with the programme exceeding initial MMC targets (Mahler, et al. 2011). Mass communication has also demonstrated some successes in HIV prevention to generate demand (Noar, et al. 2009). Systematic approaches utilising mixed methods and economic evaluations provide a potential framework for approaching the challenging issue of demand creation (Bertrand, et al. 2011). Strategies that involve men in prevention and care activities are needed as men have lower ART coverage and higher mortality (Mills, et al. 2012).

Key Populations:

Key populations for HIV-infection include, but are not limited to, sex workers and their clients, men who have sex with men, and injection drug users (Beyrer, et al. 2011). The importance of these populations as critical target groups for HIV prevention efforts is increasingly being recognized (Beyrer, et al. 2010; Smith, et al. 2009; Pettifor, et al. 2011; Mathers, et al. 2010; Baral, et al. 2007; Sullivan, et al. 2012).

The use of needle-syringe distribution for injection drug users is a proven HIV prevention intervention but remains largely underutilized in sub-Saharan Africa and field experience is limited (Mathers, et al. 2010). Sex workers would benefit from many interventions suitable

for generalised populations but also have certain interventions which are specific to their population such as community mobilisation and empowerment activities (Shahmanesh, et al. 2008). Men having sex with men are subject to discrimination and barriers to prevention and care access (Fay, et al. 2011), and outreach efforts and the application of established prevention interventions will be needed (Beyrer, et al. 2011). The evidence-base for implementing HIV prevention interventions among key populations in Africa remains sparse with structural, cultural, and legal barriers impeding efforts to reach these populations (Beyrer, et al. 2010). Stigma and human rights violations faced by these populations may greatly impede adoption of HIV prevention interventions, and antidiscrimination laws and ensuring health service inclusiveness are important considerations for comprehensive implementation plans (WHO, 2011). Efforts to understand the role these groups play in population-level HIV dynamics and designing and evaluating targeted implementation strategies should be important components of many combination HIV prevention programs (Chang, et al. 2013).

2.5 CRITIQUE OF THE LITERATURE

The review had sought broadly the evidence-based implementation strategies of the ART programme in order to achieve HIV prevention goals and reduce HIV incidence. A large number of strategies were identified though the evidence base for many strategies is limited. However, sufficient experience exists to guide the early design of HIV prevention programs and trials, and these initiatives can benefit from rigorous implementation science and

operational research evaluations to inform policy. Given limited evidence that exists for certain strategies and some interventions, it will be important for implementers to be flexible enough to change their approaches as they receive evaluation results.

While randomised study designs have a significant role in evaluating implementation and prevention initiatives (Granich, et al. 2011), mixed methods and modelling studies of non-randomised studies can also be of critical importance (Laga, et al. 2012). Evaluation frameworks using mixed methods and patient-oriented outcomes can assist in comprehensively assessing program impact.

The literature search was not entirely exhaustive, therefore other relevant evidence to inform this subject is likely to exist. Inclusion of articles required the researchers' judgments on whether an implementation strategy was relevant and this may have been subject to error.

2.6 CONCLUSIONS

It is estimated that 7,9 million people are living with HIV in SA and of these, over 2 .1 million are in one province, KwaZulu-Natal. Over 60% or an estimated 4.4 million people living with HIV were on antiretroviral treatment in 2017 and 1.3 million of these were in KZN, making the ART programme in SA the largest in the world. There is evidence that the public-sector ART roll-out in SA has reduced population mortality, particularly from HIV-related causes. However, the sustainability of the large-scale ART programme in SA faces the same

challenges as in any developing country: a rapidly increasing need for health workers who can deliver ART, the need to ensure long-term treatment adherence and to retain patients in the programme.

The 2015 WHO recommendation of “treat all” not only put health systems under extreme pressure to provide care to the growing number of patients on ART, but also increased the difficulty of access to treatment for patients. With the expansion of eligibility for ART, there was a need for a responsive, client-centered approach that simplified and adapted HIV services to better serve individual needs and reduce unnecessary burdens on the health system. This involved the shifting of HIV services to a nurse-based, doctor-supported decentralised model of care and developing out-of-clinic approaches to adherence support for stable patients. The Differentiated Care approach was recommended by WHO in the 2016 ‘Consolidated guidelines on the use of antiretroviral drugs for treating and preventing HIV infection’.

HIV testing and counselling (HTC) coverage levels remain difficult to ascertain with facility-based, mobile or workplace approaches. None of these approaches appear to achieve the near (90%) or universal HTC coverage which modelling has suggested is needed for significant decreases in HIV incidence. The home-based HTC has many of the advantages of mobile HTC and may further improve access and allow for more accurate assessment of community-level coverage.

The PMTCT programme is functioning well, achieving almost universal coverage of HIV testing among pregnant women. However, there is a breakdown in coverage and continuity of care after delivery of the baby. In 2016, the circumcision rate was stable with 50-79% of eligible men reached in SA. Male condoms are widely available in SA and the female condom programme is one of the biggest and most established in the world. The evidence-base for implementing HIV prevention interventions among key populations in Africa remains sparse with structural, cultural, and legal barriers impeding efforts to reach these populations. Stigma and human rights violations faced by these populations hinder the adoption of HIV prevention interventions.

2.7 CHAPTER SUMMARY

In this chapter, a literature review was undertaken to explore and discuss key published findings relating to the implementation of the ART programme. The chapter briefly described a brief overview of HIV status in SA. The chapter described research studies in ART sub-programme implementation in mostly affected countries globally. Lastly, the researcher critiqued the literature and presented conclusions drawn from the review.

CHAPTER 3: RESEARCH METHODOLOGY

PHASE ONE

3.1 INTRODUCTION

This chapter provides a detailed description of the research design, setting and population, sample and sampling strategy, data collection methods and data analysis procedures for Phase 1. Aspects pertaining to reliability and validity as key principles in a research study using quantitative methods are highlighted in the relevant sections. Ethics principles fundamental to research were taken into account. The limitations of the study were identified and reported accordingly. The study used the key elements in the Donabedian model (1980), commonly used for evaluation of programmes from a system perspective. These include (1) the structure (2) process and (3) outcome as outlined in Chapter 1 of this report.

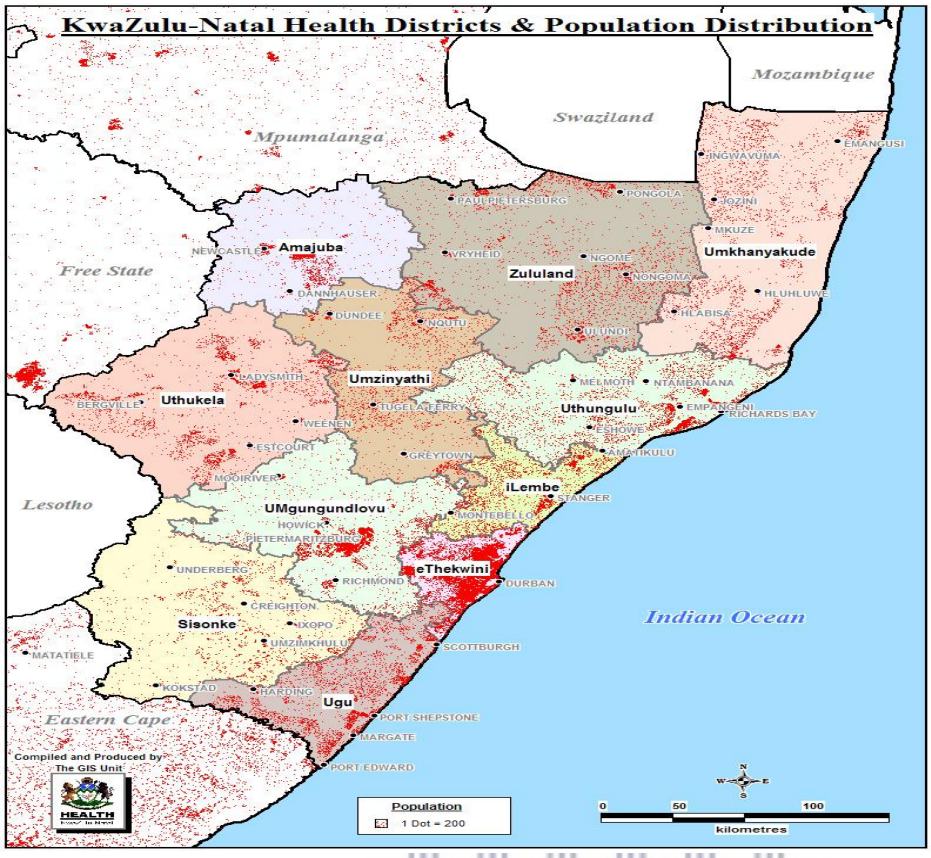
3.2 RESEARCH DESIGN

A descriptive qualitative research was used to review existing documents from government departments. Document view is defined by Bowen (2009) as a form of qualitative research in which documents are interpreted by the researcher to give meaning around an assessment topic (Bowen, 2009). The document review was chosen as the method for this research

because it was relatively inexpensive for the researcher given the cost of conducting research across fifteen facilities in different districts, while documents were easily accessible on the internet or relevant district offices. This research method was also feasible to analyse the ART program using the tree elements of the study which are structure, process and outcome.

3.3 STUDY SETTING: KWAZULU-NATAL PROVINCE

The study used data from ART programme in KwaZulu-Natal province, one of South Africa's nine provinces. This decision was made because KZN has the highest prevalence of HIV amongst the general population at 15,8% against the national prevalence of 12.6% (Stats SA, 2017). Hence data from the province will provide compelling evidence about the implementation of the ART programme in KwaZulu-Natal. It is within this context that KZN was selected for this research.



Source: UKZN, undated

Figure 3-1: Map of KwaZulu-Natal health districts

The province of KZN is the second most populous province in the country with a population of 11.1 million, which is 19.8% of the national population following Gauteng with a population of 14,2 million (25,3%) (Stats SA, 2017). The Map in Figure 1 above show KZN health districts and population distribution (in red dots). The province has eleven health districts: namely; Amajuba, eThekwini, Ilembe, Harry Gwala, Ugu, uMgungundlovu, Umkhanyakude, Umzinyathi, Uthukela, Uthungulu and Zululand (KZN DoH, 2017). Four districts, eThekwini, Umkhanyakude, Uthungulu and Ugu, were selected for the purpose of this research (see 3.4 Sampling). The health performance measurement using population-

based indicators is to a certain extent influenced by the number of people in and out of service points utilising health services in each district.

3.3.1 Ethekwini District

eThekwini District is a Metropolitan Health District with a population of 3 442 361 and comprising of eight sub-districts that are urban, rural and peri-rural in nature. The district is surrounded by iLembe district to the north, Ugu district to the south, UMgungundlovu district to the west and the Indian Ocean to the east. Despite being highly urbanised and densely populated, pockets of rural communities exist on the outskirts of the west, south and north impacting on access to services and equity. The service delivery platform consists of one academic hospital, 5 regional hospitals, 2 district hospitals, 4 specialised hospitals, 8 community health centres and 110 clinics including 57 clinics under local authority. Service delivery challenges in the district include inequitable distribution of community health centres and primary health care services provided by both local authority and province (KZN DoH, 2017).

3.3.2 Umkhanyakude District

UMkhanyakude district is the northernmost district in KwaZulu-Natal. The district has a population of 638 011. It stretches from the UMfolozi River, near Mtubatuba in the south, to the Mozambique and Swaziland borders in the north. To the east it borders the Indian Ocean and in the west, it is bordered by Zululand District; and UThungulu District to the south. The

district is deep rural and ranked amongst the most deprived districts in the country. The platform for service delivery in the District consists of five district hospitals and 56 Primary Health Care facilities. In addition, there are 17 mobile clinic teams; 2 Hlabisa, 2 Mtubatuba, 6 Jozini and 7 UMhlabuyalingana. There is unevenness in the distribution of these resources throughout the district (KZN DoH, 2017).

3.3.3 Uthungulu District

UThungulu District is located in the Northern coast of KwaZulu-Natal and has a population of 937 793. Approximately 80% of the population lives in rural areas. The district covers the area from Gingindlovu in the South to UMfolozi River in the North and inland to Nkandla. The district shares borders with UMkhanyakude District in the North, ILembe on the South and Zululand District on the North-East. The district has 6 sub-districts with has 6 district hospitals, 59 primary health care clinics, 1 community health care centre, 18 mobile clinic teams and one team for the mobile clinic vehicle (KZN DoH, 2017).

3.3.4 Ugu District

Ugu is situated on the KwaZulu-Natal South coast extending inland and has a population of 679 578. It is bordered by the Eastern Cape Province to the South, eThekwini Metropolitan to the north, the Indian Ocean to the East, Harry Gwala District to the West and UMgungundlovu to the North West of the District. The population of Ugu is predominantly rural with 86% of the population living in rural areas. The district has 6 sub-districts with 4

district hospitals, 55 primary health care clinics, 16 mobile clinic teams and 2 community health care centres (KZN DoH, 2017).

3.4 STUDY POPULATION

Study population has been defined to a broad consensus by many scholars. Akinade & Owolabi (2009) define study population as the total set of observations from which a sample is drawn; Adeniyi, et al. (2011) defines it as the total number of large habitations of people in one geographical area, for example, the population of a country while Popoola (2011) defines study population as the totality of the items or objects under the universe of study. It often connotes all the members of the target of the study as defined by the aims and objectives of the study. In this study the population consisted of documents because the study's intention was to analyse the ART programmes as a unit of analysis using the Donabedian model (1980) as a framework.

3.5 SAMPLING OF DISTRICTS AND FACILITIES

A sample refers to any portion of the population selected for the study and on whom information needed for the study is obtained (Akinade, et al. 2009; Awoniyi, et al. 2011). In this study, three step sampling was used to sample the district, ART programmes and documents for review. Different sampling strategies were applied, namely:

a) *Purposive sampling:* Four out of eleven districts were purposively selected for document review and these are; eThekwini, Umkhanyakude, Uthungulu and Ugu. The districts were selected due to the high HIV prevalence; 38.8%, 35.2%, 38.5% and 38.8% respectively (KZN DoH, 2016) and they provided a combination of urban and rural settings. In addition, the selection was based on the availability of data to provide answers to the research problems raised earlier.

Table 3-1: District information

District	Number of people on ARV per district	Urban and Rural distribution	Estimated number of patients on ARVs per site
eThekwini	77,861	Urban/Rural 86/14 (%)	3244
Umkhanyakude	34,302	Rural/Urban 98/2 (%)	6860
Uthungulu	37,437	Rural/Urban 80/20 (%)	3744
Ugu	32,005	Rural/Urban 86/14 (%)	8001

Source: KZN Department of Health (2017)

Table 3-1 above indicates the number of people on ART per district and the estimated number of patients on ARVs per site. The urban and rural settings for each district are shown in percentages.

b) *Sampling Frame:* A sampling frame (Lewis-Beck, Bryman & Liao, 2004) was used to select four ART programmes from three districts; Ethekwini, Umkhanyakude and Uthungulu; and three ART programmes from Ugu district because the fourth one was used for a pilot study (see Table 3-2). A 'sampling frame' identifies the sampling units in a population and their locations. It may consist of a listing of sampling units, or it may be based on a map of the population area within which sampling units can be observed (West, 2016). In this study, a list of accredited ART programmes was compiled for this research. The ART programmes were selected according to the services they offered which included the provision of ART and the types of activities used to address the needs of people living with HIV. The ART programmes were within district hospitals making the sample homogenous in the sense that they all provided HIV services. The number of ART programmes selected was based on the number of district hospitals available in each district. Not all districts had four district hospitals; however the average number came to four, taking into consideration the location in different sub-districts.

Table 3-2: Sampled ART programmes in districts

DISTRICT	SAMPLED ART PROGRAMMES			
ETHEKWINi	Osindisweni	Mahatma Gandhi	Prince Mshiyeni	RK Khan
UMKHANYAKUDE	Bethesda	Hlabisa	Manguzi	Mseleni
UTHUNGULU	Catherine Booth	Ekombe	Eshowe	KwaMagwaza
UGU	GJ Crookes	Murchison	St Andrews	

3.6 SAMPLING OF DOCUMENTS

A purposive sampling technique was applied to retrieve specific documents that could provide answers to the research problem from selected ART programmes. All documents relevant to the study, namely:

1. "Ideal Clinic Manual Version 17" (DoH, April 2017);
2. "National Core Standards – A framework for the assessment of health establishment" (DoH, 2011);
3. "Clinical Guidelines for the Management of HIV & AIDS in Adults and Adolescents" (DoH 2015);
4. "Multi-Sectoral Provincial Strategic Plan for HIV and AIDS, STIs and TB 2012-2016 for KwaZulu-Natal" (2016);

5. “Provincial Strategic Plan on HIV, STIs and TB – 2012-2016” (KZN DoH 2012);
6. “National Strategic Plan on HIV, STIs and TB – 2017-2022” (DoH 2016);
7. “District AIDS Councils Multi-Sectoral Response to HIV & AIDS, STIs and TB 2016/2017” (KZN Provincial Department, 2017);
8. “A guide to monitoring and evaluating HIV/AIDS care and support” (WHO, 2004);
9. “District Health Barometer - 2016/2017 (Health Systems Trust, 2016);
10. “District Health Plans” 2015/2016 (KZN DoH 2017);
11. “Annual Progress Report 2015/2016 – KZN Provincial AIDS Council” (SANAC 2017)

were sampled (see Table 3-3).

The documents were subject to desk review and were selected in relation to policy documents, operations and reports. Documentation included extracts of core standards for the assessment of health establishment, and relevant indicators. The documents were retrieved mainly from government and departments of health websites. Information which was not available from the web was requested directly from district offices.

Table 3-3: The Donabedian approach in sampling of documents

Structure of the Programme	1. Ideal Clinic Manual Version 17 (DoH, April 2017). 2. National Core Standards – A framework for the assessment of health establishment (DoH, 2011).
Processes to Implement the Programme	3. Clinical Guidelines for the Management of HIV & AIDS in Adults and Adolescents (DoH, 2015). 4. Multi-Sectoral Provincial Strategic Plan for HIV and AIDS, STIs and TB 2012-2016 for KwaZulu-Natal (2016). 5. Provincial Strategic Plan on HIV, STIs and TB – 2012-2016 (KZN DoH, 2012). 6. National Strategic Plan on HIV, STIs and TB – 2017-2022 (DoH 2016). 7. District AIDS Councils Multi-Sectoral Response to HIV & AIDS, STIs and TB 2016/2017 (KZN Provincial Department, 2017). 8. A guide to monitoring and evaluating HIV/AIDS care and support (WHO, 2004).
Outcomes of the Programme	9. District Health Barometer - 2016/2017 (Health Systems Trust, 2016). 10. District Health Plans 2015/2016 (KZN DoH, 2017). 11. Annual Progress Report 2015/2016 – KZN Provincial AIDS Council (SANAC, 2017).

3.7 INSTRUMENT FOR DATA COLLECTION

A document review checklist (see Appendix 3-1) was designed based on the literature review. The checklist was self-developed using the Donabedian model as a guide. The checklist specified exactly what items and indicators the researcher was observing in relation to the objectives of the study. This ensured that the instrument produced an equivalent result in all settings which would lead to high reliability (Bastos, et al. 2014).

The checklist contained three sections in line with the analysis components of structure, process and outcome. These sections were further divided into different sub-sections.

The first section contained sub-sections **A** to **F**. Sub-section **A** listed furniture to check the seating availability for patients; sub-section **B** listed essential equipment to check their availability and functionality; sub-section **C** contained a list of national guidelines; sub-section **D** contained a list of different categories of staff to check their availability and training; sub-section **E** contained drugs, medicines and supplies; and sub-section **F** contained turnaround times for laboratory results.

The second section listed relevant guidelines, resources, and services that indicated the availability of processes in place to evaluate and treat HIV patients. The description of guidelines, resources and services that were checked are indicated in the matrix (see Appendix 3-2).

The third section contained indicators that are relevant to the prevention, care and treatment outcomes. A core set of indicators were identified from a wider set of programmatic indicators and were included in the checklist.

The checklist was submitted to the promoter, an expert in public health programmes and health systems, and the Statistical Consultation Services of the University of the Western Cape. Recommendations were made with regard to the organisation of the items (e.g. where two variables were assessed in one statement, a correction was made to assess one variable separately so that the checklist collects unambiguous data). Items and indicators which proved difficult to measure were removed from the checklist, e.g. the indicator *"Home Based Care Integration – Home based care is provided in an integrated manner by the Community Care Giv*ers*"* was difficult to measure therefore removed from the checklist. The relevant recommendations were accepted and changes were incorporated into the checklist before the commencement of data collection.

3.8 PILOT STUDY

A pilot study is a small-scale implementation of a larger study or of part of a larger study, conducted for shorter amounts of time in order to evaluate feasibility, time, cost, and adverse events. The aim is to improve upon the study design prior to launching a full-scale research project (Given, 2008; Hulley, Cummings, Browner, et al. 2007). Leon, Davis and Kramer (2011) states that the main purpose of conducting a pilot study is to examine the

feasibility of the approach the researcher intends to use in the main study. This helps the researcher in the development or refinement of new interventions, assessments, and other study procedures.

The Ideal Clinic Manual (ICM) checklist was pilot tested with one ART programme in Port Shepstone, Ugu District. The primary purpose for the pilot test was to identify checklist translation mistakes, to ascertain whether the questioner clearly understood all the questions, to determine how long the questioner took to complete sections of the checklist and the entire checklist, and to clarify the procedure for data collection. The secondary purpose of the pilot test was to perform preliminary statistical analysis to investigate the results of different sections of the ICM checklist.

3.8.1 Procedural Considerations

One ART programme was selected as a pilot facility. The pilot facility did not form part of the larger study but had similar characteristics in that it had an ART programme providing services to patients living with HIV. Data were collected by the researcher using the ICM checklist described in Section 3.6. Documents listed in Table 3 were assembled and a desk review was conducted. The checklist took approximately 3 days to complete.

3.8.2 Amendments to the Questionnaire

The following modifications were made:

- The instructions on the completion of the checklist in different sub-sections were revised as some were ambiguous.
- In **Section One** of the checklist, the scoring for the waiting areas and consultation rooms were revised. For instance, the scoring for *"Adequate seating for all patients"* was changed from *"Available and intact"* to *"Yes OR No"*. Certain items which were combined in one sentence were listed separately for the feasibility of data collection and scoring purposes. For instance, 'A sharps disposal system" and "sterilisation system" were separated into two statements.
- In **Section Two** of the checklist, the meanings of words such as resources, services and systems were clarified to eliminate possible ambiguities.
- In **Section Three** of the checklist, some of the indicators were modified further for the measurement to be accurate. For instance, one indicator read "The estimated number of reported deaths due to HIV and AIDS has been reduced". This was changed to "Estimated number of reported deaths due to HIV and AIDS in 2015/2016".

The pilot study revealed that there could be a possibility of missing data from the sampled documents, especially in **Section One** of the checklist and therefore data might need to be requested directly from district offices. The relevant changes throughout the checklist were made in preparation for the data collection of the main study.

3.9 DATA COLLECTION PROCESS

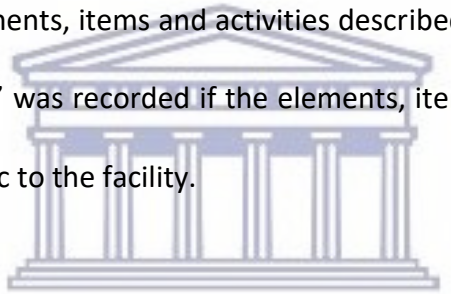
3.9.1 Data Collection Procedures

Research Guide (2018) defines data as any information collected, stored, and processed to produce and validate original research results. Data might be used to prove or disprove a theory, bolster claims made in research, or to further knowledge around a specific topic or problem. Document review data for this study were therefore collected from the documents mentioned in Section 3.5. The documents were downloaded and printed from government and department of health websites. The focus was on data for the financial year 2015/2016. Relevant information was then searched for in the documents and recorded directly on the checklist.

The first part of sub-section A in '**Section A'** (Structure of the Programme) of the checklist assessed the availability of furniture in the waiting areas. Each item of the furniture was scored as **'Yes'** if it was available, **'No'** if it was not available and **'Not applicable'**. The scores were captured as **'2'**, **'1**' and **'0'** respectively.

The items in the second part of sub-section A in **Section A** (Structure of the Programme) checked for availability of furniture in consultation rooms. The availability of items was measured as: **available** and **not available**. 'Available' was recorded if the item measured was marked '**√**'. 'Not Available' was recorded if the item measured was marked '**x**'.

For **Section Two** – 'Processes to Implement the Programme' on the checklist, the indicators were measured by looking for relevant information, guidelines, resources and services that indicated whether there were processes in place to evaluate and treat patients. Each indicator consisted of more than one element, item and/or activity to be measured. Separate notes (see Appendix 3-2) were available for the researcher for reference, describing what was meant by resources, systems and services. The availability of these processes was then measured as: '**available', 'not available' and** '**not applicable**'. 'Available' was recorded if the elements, items and activities described in an indicator were in place. 'Not available' was recorded if some of the elements, items and activities described in an item or indicator were not in place. 'Not applicable' was recorded if the elements, items and activities described in an indicator were not specific to the facility.



For **Section One and Two**, unavailable data from the documents were requested directly from district offices by the researcher. Facilities are expected to complete the 'Ideal Clinic Checklist' periodically, either quarterly or annually and send their completed documents to the district office for statistical purposes and compilation. The researcher contacted the district offices directly by telephone and requested the checklists for the year 2015/2016. The researcher introduced herself and briefly indicated the purpose of the request. The Information Management personnel at the district assisted the researcher and data were sent by email.

For **Section Three** – 'Outcome of the Programme' on the checklist, data were collected in a numeric form. Numbers and percentages were collected according to stipulated indicators. The researcher was the only person who collected the data. The time frame for the data collection process was six weeks, from August 6 to September 15, 2017.

3.9.2 Quality Control and Data Management

Quality control measures were taken into consideration from the beginning of the research. The checklist was checked for typing errors and only the last version was used to collect the data. All necessary materials such as pen, paper and calculator were made available for the purpose of writing down the information. Data were collected by hand on paper and checked for completeness and errors at the end of each session to ensure quality, and corrections were made while still in possession of records. Completed checklists were checked for completeness, errors and missing data. Data which were not available were repeatedly checked in different documents as no single document contained all the required information. In a few instances district offices were contacted directly to request information not found in the documents and the required information was sent to the researcher by email (see Appendix 3-3). The checklist would then be recompleted. Completed checklists were then filed and kept safely in preparation for data entry.

3.10 DATA ANALYSIS PROCESS

3.10.1 Data Entry

Data from checklists were entered manually using Microsoft Office Excel software. Because data were entered by the researcher only, the process was repeated (the researcher checked the checklist against the entered dataset) to verify the process. This enabled the researcher to check for missing values and inconsistencies in the data.

Scoring – in column for score mark as follows (**waiting rooms**):

Yes = 2; No = 1; Not Applicable (NA) = 0

Scoring– in column for score mark as follows (**consultation rooms**):

Available = **2;** Not available = **1**

For Section One – Structure of the Programme. In each sub-section the measurements were recorded as scores in their respective numbers; '2', '1' or '0'. For example, if the item was '**available**' or '**present**' the number '2' was recorded and if '**not available**' or '**not present**' the number '1' was recorded and if '**not applicable**' the number '0' was recorded.

For Section Two – Processes to Implement the Programme. The measurements '**available**', '**not available'** and '**not applicable'** were recorded as scores in their respective numbers; '2', '1' and '0'.

For Section Three – Outcome of the Programme on the checklist. Data were recorded in a numeric form. The indicator measured the outcome for 2015/2016 and the number or figure

was entered. For instance, for the indicator *"Number of male condoms distributed",* the exact number such as *"3930"* was entered. The numbers were captured as such and calculations were later performed on SPSS where necessary.

Data were then converted from Microsoft Office Excel to SPSS 24 computer software. Data were further checked against the checklist to ensure that the data on the computer reflected the data captured from documents.

3.10.2 Data Cleaning

Missing or irregular data entries were checked on the computer. Any duplicate records were removed from the database. To maintain consistency in terms of irrelevant and inappropriate data, data were recorded as missing. Modifications to the dataset were documented to avoid duplicate error checking. Statistical summaries were performed and simple calculations were carried out to check that data were not contaminated.

3.10.3 Data Analysis Strategy

Data collected from documents reviews were analysed using the SPSS 25 Statistics computer software. The analysis was carried out by the researcher in consultation with the SPSS Statistics training analyst. The researcher and the training analyst independently generated tables to verify the results, and statistical tests were generated for the further interpretation of results. Data were analysed using descriptive statistics; frequencies or percentages for categorical variables. Charts, tables and figures were created for data display to

communicate the findings. Analysed data were further categorised according to the three elements of the study: the structure, process and the outcome of the programme.

3.11 RELIABILITY AND VALIDITY

Reliability and Validity are two important concepts in research as they are used for enhancing the accuracy of the assessment and evaluation of a research work (Tavakol, et al. 2011). They have different meanings according to different types of research i.e. quantitative and qualitative research (Creswell, 2004). Reliability is defined by Shuttleworth, et al. (2009) as the degree to which the research instrument produces the same results each time it is used for the same topic under the same circumstances. Bastos, et al. (2014) defined validity as "the degree to which the evidence supports the interpretations of the data as correct and the manner in which interpretations used are appropriate". Validity expresses the degree to which a measurement measures what it purports to measure (Bolarinwa, 2015). Gibbs (2007) cited in Creswell (2014) further states that validity is obtained when a researcher uses certain procedures to check for the accuracy of the research findings.

The reliability analysis was performed on the checklist scales of the main study. The reliability was determined through the application of the Cronbach Alpha co-efficient and most of the scores included in the checklist were acceptable, above 0.7 (see Table 3-4). The Cronbach Alpha is a measure used to assess the reliability, or internal consistency, of a set of scale or test items (Takavol, et al. 2011). A reliability coefficient of .70 or higher is

considered “acceptable” in most social science research situations. The scales that had a low co-efficient were the *National Guidelines* and the *Laboratory Results* scales under the Structure and the Outcomes scales. The scales were not further analysed because this was the main study and no items were removed.

Table 3-4: Reliability results of checklist scales

Section of the checklist		**No. of items**	**Cronbach’s Alpha in main study** (co-efficient)
Section 1: Structure	A: Furniture	9	0.735
	B: Equipment	33	0.985
	C: National guidelines	19	0.521
	D: Staff	10	0.870
	E: Drugs, medicines and supplies	12	1.000
	F: Laboratory results	17	0.696
Section 2: Process		12	0.802
Section 3: Outcome		14	0.544

3.12 LIMITATIONS TO THE STUDY

Collecting quantitative data from different documents was a difficult process. Some of the data varied depending on the source. The researcher had to constantly verify the information as it was incomplete in some of the documents. Data on the structure of the ART programme was difficult to extract as the recording was not precise.

3.13 ETHICS PRINCIPLES

The right to privacy for participating facilities with ART programmes was observed throughout the study. The checklist completion was anonymous. All information collected for this study was treated with confidentiality and no names of these facilities appear on any data. The detailed ethical considerations were described in Chapter 1 Section 1.7.

3.14 CHAPTER SUMMARY

This chapter provided detailed methodology of Phase 1 of the research study. A descriptive qualitative research was used to review documents to analyse the ART programme in KZN province. Four districts i.e. eThekwini, Umkhanyakude, Uthungulu and Ugu were selected for this study and four facilities with ART programmes were sampled in eThekwini, Umkhanyakude and Uthungulu districts and three in Ugu district. A document review checklist was self-developed using the Donabedian model as a guide. The checklist contained three sections in line with the analysis components of structure, process and outcome. A purposive sampling technique was applied to retrieve specific documents that provided answers to the research problem from selected facilities with ART programmes. A pilot study was conducted in one of the facilities with an ART programme in Ugu district and the reliability of the checklist was determined through the application of the Cronbach Alpha co-efficient. Data were analysed using SPSS 24 computer software. The results for Phase 1 are presented in Chapter 4.

CHAPTER 4: ANALYSIS AND PRESENTATION OF RESULTS

PHASE ONE

4.1 INTRODUCTION

This chapter analyses and presents the results of data from Phase 1 of the study. Chapter 3 described in detail the methodology for Phase 1. This chapter presents descriptive quantitative results using the Donabedian (1980) framework of three key elements; the structure, process and outcome as a guide. The results are presented using tables and graphs to communicate specific findings intended to address Phase 1 objectives which were to: (1) To assess the structure in the form of physical infrastructure; human and material resource composition and availability of programme related policies (2) To assess the processes involved in evaluation and treatment of patients who utilise services in the facilities; and (3) To assess the outcome of the programme in relation to prevention, care and treatment outcomes.

4.2 REALISATION OF DATA

Antiretroviral treatment (ART) programmes in four of the selected districts in KwaZulu-Natal, i.e, Ethekwini, Umkhanyakude, Uthungulu and Ugu were analysed. Within the districts, fifteen (15) ART programmes from Prince Mshiyeni, Osindisweni, Mahatma Gandhi and RK Khan (Ethekwini); Bethesda, Hlabisa, Manguzi and Mseleni (Umkhanyakude); Catherine Booth, Ekombe, Eshowe and Kwamagwaza (Uthunguku); and GJ Crookes, Murchison and St Andrews (Ugu) were analysed.

4.3 PRESENTATION OF RESULTS

4.3.1 STRUCTURE OF THE ART PROGRAMME

The structure of the ART programme is made out of various inputs which collectively provide the resources needed to function effectively. This refers to the physical infrastructure; human and material resource and programme related policies. In ART facilities, the physical infrastructure, and human and material resources refer to the availability of equipment, number of health personnel available and trained to deliver health care, drug supply, policies and patient management and monitoring records.

Fifteen (15) ART programmes in an equal number of facilities were analysed. All four districts were a combination of rural and urban setting; eThekwini district was 86% urban and Umkhanyakude, Uthungulu and Ugu districts were between 80% and 98% rural. All the

analysed facilities consisted of two waiting areas for patients which meant that in total thirty (30) waiting areas were analysed. Twenty-nine (29) consultation rooms were analysed in all four (4) districts. One (1) facility at Ethekwini district had only one (1) consultation room and all other fourteen (14) facilities had two (2) rooms each. In all there were fifteen (15) vital signs rooms, which meant that each facility in all four (4) districts had one (1) vital signs room.

4.3.1.1 Availability of Furniture in the Waiting Areas

Table 4-1 below presents the results for the waiting areas per district. The majority of waiting areas (*n*16:53%) did not have available seating for patients. Only 9 (*n*9:30%) out of thirty (30) waiting areas across the four (4) districts had available seating for patients, mainly in Uthungulu and Ugu districts. Five (*n*5:16%) waiting areas had no indication of patients' seating. All 30 (*n*30:100%) waiting areas in all facilities had chairs or benches. Notice boards were available in one (1) waiting area of each facilities, which meant that each of the fifteen (15) facilities had at least one (1) notice board.

4.3.1.2 Availability of Furniture in Consultation Rooms

In Table 4-1, twenty-nine (29) consultation rooms were analysed in all four districts. One facility at Ethekwini district had only one (1) consultation room and all other 14 facilities had two (2) rooms each. Twenty-five (*n*25:86%) out of twenty-nine (29) rooms had consultation desks and four (4) rooms in Umkhanyakude and Uthungulu had none. All twenty-nine (*n*29:

100%) rooms in all districts had chairs for clinicians and patients. Sixteen (*n*6:20.6%) out of twenty-nine (29) rooms had a tilting examination couch and four (4) rooms in Umkhanyakude district and three (3) rooms in Ugu districts had none. Bedside footstools were available in nineteen (19) rooms across all districts and only twenty-one (21) rooms had anglepoise-style examination lamp. There was one (1) lockable medicine cupboard and a dressing trolley in one (1) room of each facility in all districts.

Table 4-1: Availability of furniture in the waiting areas and consultation rooms by districts

Variable	Ethekwini (N=4)		Umkhanyakude (N=4)		Uthungulu (N=4)		Ugu (N=3)		Total (N=15)
Waiting Area	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**	**30**
Available seating for all patients									
Yes	1	0	0	0	3	0	3	2	**9**
No	3	2	4	2	1	3	0	1	**16**
Not applicable	0	2	0	2	0	1	0	0	**5**
Chairs/benches									
Yes	4	4	4	4	4	4	3	3	**30**
No	0	0	0	0	0	0	0	0	**0**
Not applicable	0	0	0	0	0	0	0	0	**0**
Notice boards available									
Yes	4	0	4	0	4	0	3	0	**15**
No	0	4	0	4	0	4	0	3	**15**
Not applicable	0	0	0	0	0	0	0	0	**0**
Consultation Rooms	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**	**29**
Desk									
Available	4	3	4	2	4	2	3	3	**25**
Not available	0	0	0	2	0	2	0	0	**4**
Chair (clinician)									
Available	4	3	4	4	4	4	3	3	**29**
Not available	0	0	0	0	0	0	0	0	**0**
At least 1 chair (patient)									
Available	4	3	4	4	4	4	3	3	**29**
Not available	0	0	0	0	0	0	0	0	**0**
Tilting examination couch									
Available	3	2	4	0	3	1	3	0	**16**
Not available	1	1	0	4	1	3	0	3	**13**
Bedside footstool									
Available	4	0	4	0	4	2	3	2	**19**
Not available	0	3	0	4	0	2	0	1	**10**
Anglepoise-style examination lamp									
Available	3	2	4	2	3	2	3	2	**21**
Not available	1	1	0	2	1	2	0	1	**8**
Lockable medicine cupboard									
Available	4	0	4	0	4	0	3	0	**15**
Not available	0	3	0	4	0	4	0	3	**14**
Dressing trolley									
Available	4	0	4	0	4	0	3	0	**15**
Not available	0	3	0	4	0	4	0	3	**14**

N = Number of facilities under each district

Figure 4-1 below shows the percentage of available furniture in the waiting areas and consultation rooms by districts. Consultation rooms show higher figures of available furniture in all districts compared to waiting areas. Umkhanyakude district had 100% furniture in consultation rooms while Ugu district had 95% and 97% furniture in waiting areas and consultation rooms respectively. Umkhanyakude had the lowest available furniture in waiting areas at 67% followed by Ethekwini at 75%.

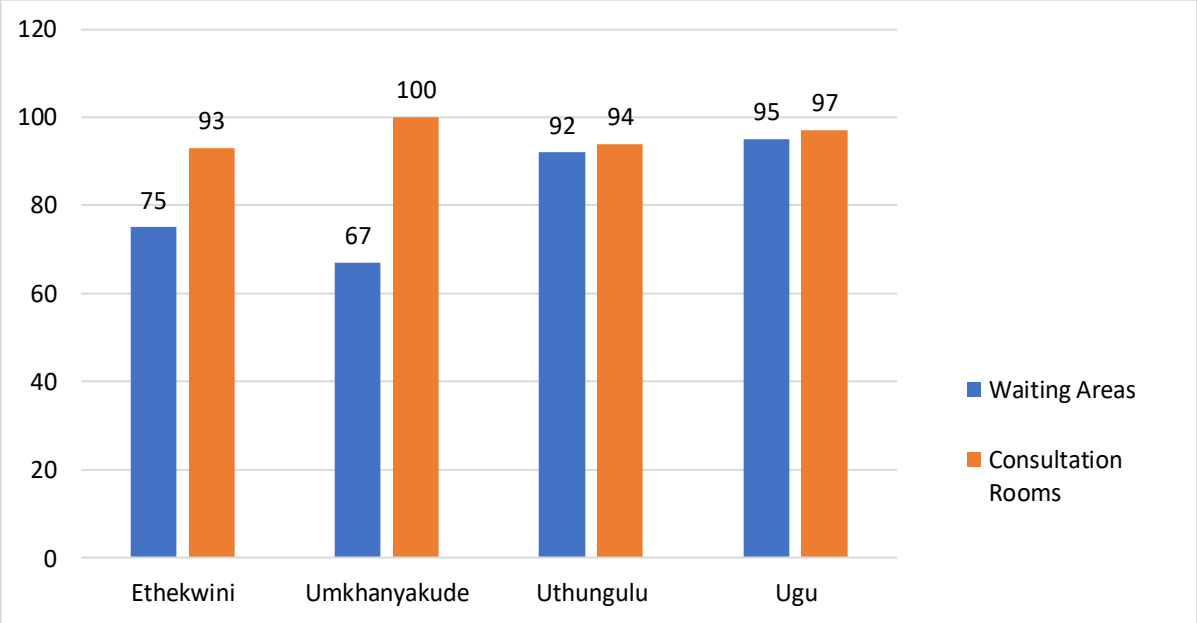


Figure 4-1: Percentage of available furniture in the waiting areas and consultation rooms by districts

4.3.1.3 Availability of Equipment in Consultation Rooms

Data in Table 4-2 show the availability of equipment in consultation rooms by district. A total of twenty-nine (29) consultation rooms were analysed. One (1) facility at Ethekwini district had only one (1) consultation room and all other fourteen (14) facilities had two (2) rooms each. The equipment: stethoscope, diagnostic set, patella hammer, turning fork, tape measure, scale to measure weight, glucometer, urine test strips and specula were not available in all rooms of all facilities across four (4) districts. Clinical thermometers were available only in one (1) consultation room of each fifteen (15) facilities in all districts.

Table 4-2: Availability of equipment in the consultation rooms by districts

Variable	Ethekwini (N=4)		Umkhanyakude (N=4)		Uthungulu (N=4)		Ugu (N=3)		Total (N=15)
Consultation Rooms	**1**	**2**	**1**	**2**	**1**	**2**	**1**	**2**	**29**
Stethoscope									
Available	0	0	0	0	0	0	0	0	**0**
Not available	4	3	4	4	4	4	3	3	**29**
Diagnostic sets									
Available	0	0	0	0	0	0	0	0	**0**
Not available	4	3	4	4	4	4	3	3	**29**
Patella hammer									
Available	0	0	0	0	0	0	0	0	**0**
Not available	4	3	4	4	4	4	3	3	**29**
Tuning fork									
Available	0	0	0	0	0	0	0	0	**0**
Not available	4	3	4	4	4	4	3	3	**29**
Tape measure									
Available	0	0	0	0	0	0	0	0	**0**
Not available	4	3	4	4	4	4	3	3	**29**
Clinical thermometer									
Available	4	0	4	0	4	0	3	0	**15**
Not available	0	3	0	4	0	4	0	3	**14**
Blood pressure machine									
Available	4	3	4	2	4	2	3	3	**25**
Not available	0	0	0	2	0	2	0	0	**4**
Scale to measure weight									
Available	0	0	0	0	0	0	0	0	**0**
Not available	4	3	4	4	4	4	3	3	**29**
Glucometer									
Available	0	0	0	0	0	0	0	0	**0**
Not available	4	3	4	4	4	4	3	3	**29**
Urine test strips									
Available	0	0	0	0	0	0	0	0	**0**
Not available	4	3	4	4	4	4	3	3	**29**
Speculums of different sizes									
Available	0	0	0	0	0	0	0	0	**0**
Not available	4	3	4	4	4	4	3	3	**29**

N = Number of clinics under each district

Figure 4-2 shows the availability of equipment in the consultation rooms by district. The percentage indicates the equipment that was available. Ethekwini district had the highest number of equipment at 19,9% followed by Ugu district at 19,5%. Uthungulu and Umkhanyakude had the lowest at 19,3%.

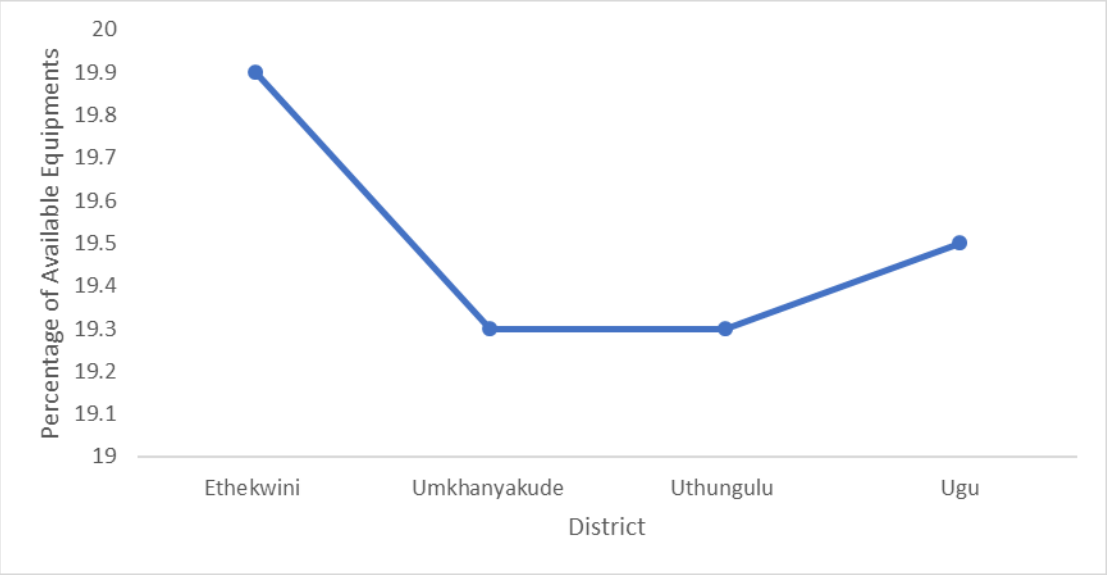


Figure 4-2: Percentage of available equipment in the consultation rooms by district

4.3.1.4 Availability of equipment in vital signs rooms

Data in Table 4-3 show the availability of equipment in the vital signs rooms by district. There were a total of 15 vital signs rooms with one for each facility in all four districts. Data show that all equipment listed in Table 4-3 were available in all facilities in eThekwini, Uthungulu and Ugu districts and the height measure was not available in 2 facilities in Umkhanyakude district.

Table 4-3: Availability of equipment in the vital signs rooms by districts

Variable	Ethekwini (N=4)	Umkhanyakude (N=4)	Thungulu (N=4)	Ugu (N=3)	Total (N=15)
Vital Signs Rooms	**1**	**1**	**1**	**1**	**15**
Non-invasive electronic Baumanometer					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Cuffs for Baumanometer					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Blood glucometer					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Rapid HIV test					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Adult clinical scale					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Stethoscope					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
HB meter					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Clinical thermometer					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Height measure					
Available	4	2	4	3	**13**
Not available	0	0	0	0	**0**
Tape measure					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Bin (general waste)					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**

N = Number of clinics under each district

Table 4-3: Availability of equipment in the vital signs rooms by districts (cont'd)

Variable (Cont'd)	Ethekwini (N=4)	Umkhanyakude (N=4)	Thungulu (N=4)	Ugu (N=3)	Total (N=15)
Vital Signs Rooms	**1**	**1**	**1**	**1**	**15**
Urine specimen jars					
Available and intact	4	4	4	3	**15**
Available but not intact	0	0	0	0	**0**
Not available	0	0	0	0	**0**
Glass slides for cervical smears					
Available and intact	4	4	4	3	**15**
Available but not intact	0	0	0	0	**0**
Not available	0	0	0	0	**0**

N = Number of clinics under each district

Figure 4-3 shows a percentage of available equipment in the vital signs rooms by district. The percentage indicates the equipment that was available. The three districts; Ethekwini, Uthungulu and Ugu had 100% percent of equipment in the facilities' vital signs rooms and Umkhanyakude had 92% of equipment.

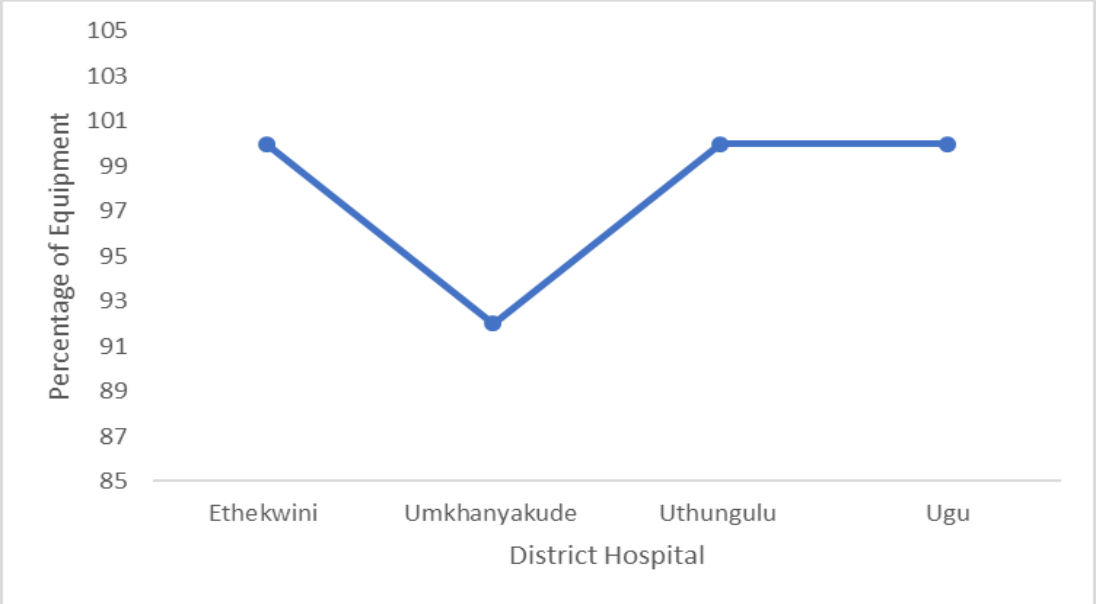


Figure 4-3: Percentage of available equipment in the vital signs rooms by district

4.3.1.5 Distribution of Health Workers Across Districts

Figure 4-4 shows the distribution of health workers across districts. Data show that in general, the number of staff was evenly distributed in all districts. The number of all categories of health workers is lower in Ugu district than in other three (3) districts. This could be explained by the fact that only three (3) facilities were sampled in Ugu district compared to other districts with four (4) facilities each. The number of lay counsellors and community treatment supporters are the highest in all districts particularly Umkhanyakude district with 38 and 53 respectively. Dieticians, social workers and ART programme managers are represented by one staff member per facility in all districts.

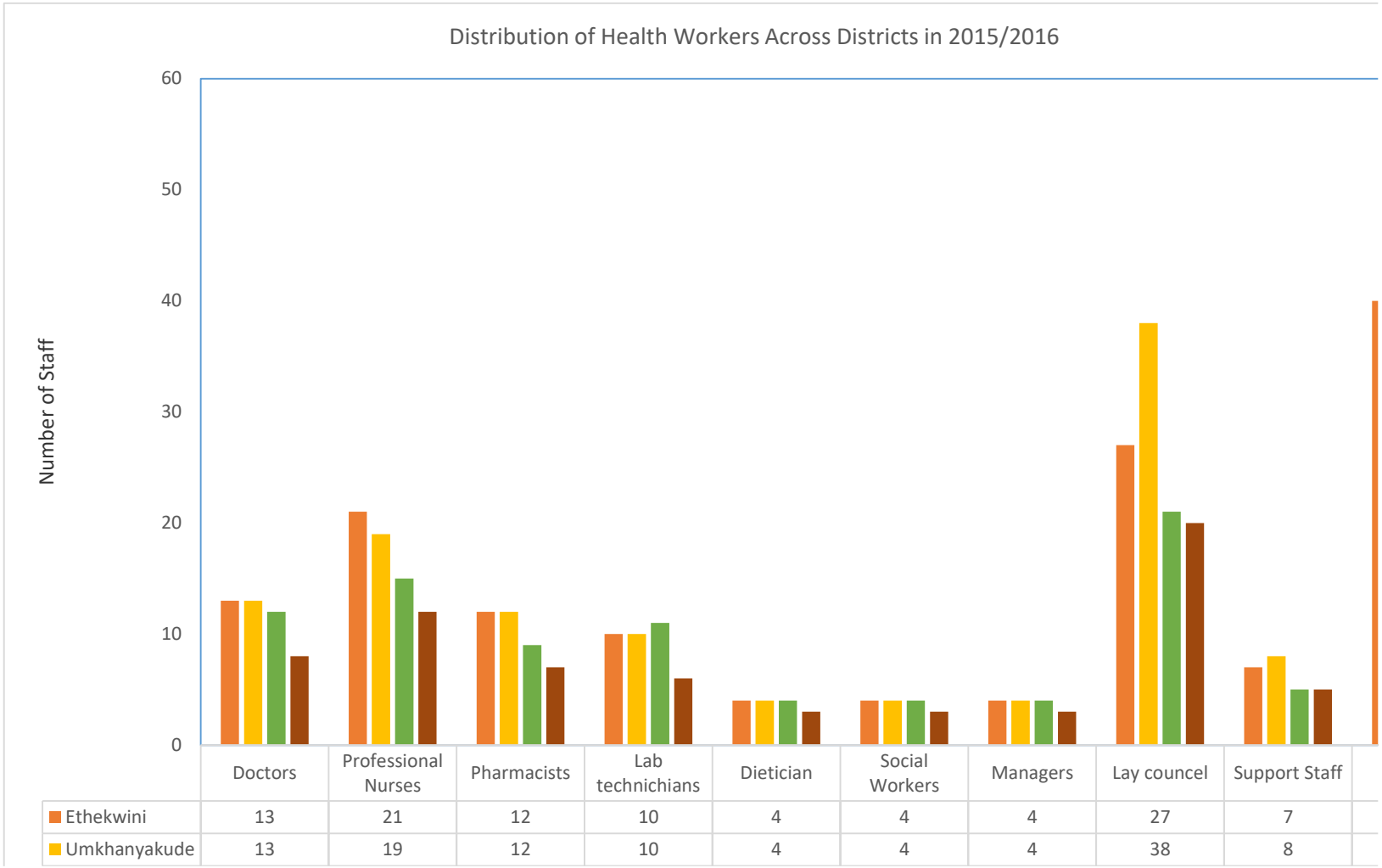


Figure 4-4: Distribution of health workers across districts in 2015/2016

Table 4-4: Average number of patients per one staff in districts in 2015/2016

DISTRICT	DOCTOR	PROFESSIONAL NURSE	PHARMACIST	DIETICIAN	LABORATORY TECHNICIAN	SOCIAL WORKER	LAY COUNSELLOR	MANAGER	SUPPORT STAFF	COMM. TREATMENT SUPPORTER
ETHEKWINI	1245	771	1349	4048	1619	4048	600	4048	2313	405
UMKHANYA-KUDE	1836	1256	1989	5968	2387	5968	628	5968	2984	450
UTHUNGULU	1348	1078	1797	4043	1470	4043	770	4043	3235	522
UGU	2017	1345	2305	5379	2690	5379	807	5379	3228	672

Effective delivery of ART per facility depends on the availability of adequate numbers of appropriately trained doctors, pharmacists, nutritionists/dieticians, professional nurses and counsellors at the service points. According to the standard practice required by the Department of Health, a minimum of one (1) medical officer, two (2) professional nurses, five (5) lay counsellors, one (1) nutritionist/dietician and half (0.5) social worker is required to treat and care for 500 patients.

Table 4-4 shows the number of patients per one staff member in districts. Data show high numbers of patients to be cared for by each staff member in all districts. In Umkhanyakude, Uthungulu and Ugu districts, doctors and professional nurses care for more than a thousand patients. At Ethekwini, a professional nurse care for more than seven hundred patients, which is the lowest number in all districts. The number of patients seen or supported by by a dietician and a social worker is very high. However, these professionals are not in contact with patients on a continuous basis. Pharmacists and laboratory technicians care for up to two thousand patients in some districts.

Table 4-5 shows the number of trained staff by district. Data show that the majority of staff are trained in all districts; all doctors and professional nurses in all districts received some form of training in HIV care. Social workers and community treatment supporters were the least trained across districts. There were a few lay counsellors who were not trained at Ethekwini and Ugu districts.

Table 4-5: Number of trained staff by district in 2015/2016

	ETHEKWINI		UMKHANYAKUDE		UTHUNGULU		UGU	
HEALTH WORKER CATEGORY	**No. of Staff**	**No. of Trained Staff**	**No. of Staff**	**No. of Trained Staff**	**No. of Staff**	**No. of Trained Staff**	**No. of Staff**	**No. of Trained Staff**
Doctors	13	13	13	13	12	12	8	8
Professional nurses	21	21	19	19	15	15	12	12
Lay counsellors	27	24	38	38	21	21	20	16
Dieticians	4	4	4	4	4	4	3	3
Social workers	4	0	4	0	4	1	3	1
Laboratory technicians	10	10	10	10	11	11	6	6
Pharmacists	12	12	12	12	9	9	7	7
ART programme managers	4	4	4	4	4	1	3	3
Support staff (including record-keepers)	7	7	8	8	5	5	5	5
Community treatment supporters (peer educators, outreach workers, volunteers, informal carers)	40	14	53	15	31	13	24	12

4.3.1.6 Availability of National Guidelines by District

Table 4-6 below shows the availability of national guidelines by district. This indicator assessed whether policies, strategies and guidelines have been developed for multiple areas of care and support. The indicator focused on measuring the extent to which such policies exist and did not attempt to assess their quality in terms of conforming to international or commonly agreed upon national standards. It also did not assess the distribution or usage at the implementation level.

The results in Table 4-6 show that strategies to address ART provision for children and young people, TB patients, and vulnerable groups such as sex workers, mobile populations, injection drug users and other high-risk or hard-to-reach groups were present in all 15 facilities in all districts. The policies and regulations giving protection against discrimination for people living with HIV were also present in all districts. Data show that legal support policies or strategies were however not present in all facilities across the four districts.

Post-exposure prophylaxis and the management of occupational exposure to HIV guidelines were present in all districts. Clinical care guidelines for adults and paediatric patients were present in all facilities of the 4 districts. The confidential patient-tracking system was not present in all facilities across the districts. Strategies to reduce Mother-to-Child Transmission of HIV and other infections during pregnancy and childbirth and the

policy guidelines for feeding of infants of HIV positive mothers were present in all facilities. The guidelines for testing and counselling for HIV, home based care and palliative care were present in all facilities. Policies for drugs and antiretroviral combination therapy specifically were present in all facilities. The guidelines for clinical HIV/AIDS management including opportunistic infections, management and treatment of STIs, monitoring and evaluation of care and support and blood safety, including blood transfusion services were present in all facilities.

Table 4-6: Availability of national guidelines by district

ITEM	ETHEKWINI (N=4)	UMKHANYAKUDE (N=4)	UTHUNGULU (N=4)	UGU (N=3)	TOTAL (N=15)
Strategy addressing ART provision: Present	4	4	4	3	**15**
Not present	0	0	0	0	**0**
Policies for protection against discrimination: Present	4	4	4	3	**15**
Not present	0	0	0	0	**0**
Legal support: Present	0	0	0	0	**0**
Not present	4	4	4	3	**15**
Post-exposure prophylaxis: Present	4	4	4	3	**15**
Not present	0	0	0	0	**0**
Management of Occupation. Exposure: Present	4	4	4	3	**15**
Not present	0	0	0	0	**0**
Paediatric HIV/AIDS: Present	4	4	4	3	**15**
Not present	0	0	0	0	**0**
Strategies to reduce MTCT: Present	4	4	4	3	**15**
Not present	0	0	0	0	**0**
Guidelines for home base care: Present	4	4	4	3	**15**
Not present	0	0	0	0	**0**
Guidelines for feeding of infants of HIV positive mothers: Present	4	4	4	3	**15**
Not present	0	0	0	0	**0**
Confidential patient-tracking system: Present	0	0	0	0	**0**
Not present	4	4	4	3	**15**
Testing and counselling: Present	4	4	4	3	**15**
Not present	0	0	0	0	**0**
Drug policy: Present	4	4	4	3	**15**
Not present	0	0	0	0	**0**
Antiretroviral combination therapy: Available	4	4	4	3	**15**
Not present	0	0	0	0	**0**
Palliative care: Present	4	4	4	3	**15**
Not present	0	0	0	0	**0**

N = Number of clinics under each district

Table 4-6: Availability of national guidelines by district (cont'd)

ITEM (CONT'D)	ETHEKWINI (N=4)	UMKHANYAKUDE (N=4)	UTHUNGULU (N=4)	UGU (N=3)	TOTAL (N=15)
Blood safety including blood transfusion services:					
Present	4	4	4	3	**15**
Not present	0	0	0	0	**0**
Management and treatment of STIs:					
Present	4	4	4	3	**15**
Not present	0	0	0	0	**0**
Monitoring and evaluation of care and support:					
Present	4	4	4	3	**15**
Not present	0	0	0	0	**0**
Clinical management:					
Present	4	4	4	3	**15**
Not present	0	0	0	0	**0**

N = Number of clinics under each district

4.3.1.7 Availability of Drugs, Medicines and Supplies by District

Table 4-7 below shows the availability of drugs, medicines and supplies. Fifteen (15) facilities in 4 districts were analysed. Data show that stock for ARVs were not available in 5 facilities in the last six months. Ten (10) out of fifteen (15) facilities had sufficient stock for treating Opportunistic Infections (OIs) in the last six months. The five (5) facilities which ran out of stock in the last six months were at Ethekwini and Umkhanyakude districts. Similarly, ten (10) facilities had sufficient stock for TB drugs in the last six months and the five (5) facilities which ran out of stock in the last six months were again at Ethekwini and Umkhanyakude districts. Gloves and protective aprons were available in all facilities. Male and female condoms were available in all facilities. Post exposure

prophylaxis of occupationally acquired HIV were available in all facilities. Medicines with mechanism in place for stock control and battery for auroscope were available in all facilities. There was water and electricity in all facilities.

Table 4-7: Availability of drugs, medicines and supplies

ITEM	ETHEKWINI (N=4)	UMKHANYAKUDE (N=4)	UTHUNGULU (N=4)	UGU (N=3)	TOTAL (N=15)
Stock for ARVs:					
Available	3	2	2	3	**10**
Not available	1	2	2	0	**5**
Stock for drugs for treating OIs:					
Available	2	1	4	3	**10**
Not available	2	3	0	0	**5**
Stock for TB drugs:					
Available	2	1	4	3	**10**
Not available	2	3	0	0	**5**
Gloves:					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Protective aprons:					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Male condoms:					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Female condoms:					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Post exposure prophylaxis:					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Medicines:					
Available	0	0	0	0	**0**
Not available	4	4	4	3	**15**
Battery and spare globes:					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Electricity:					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Water:					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**

N = Number of clinics under each district

4.3.1.8 Laboratory Results Received Within the Specified Turnaround Time by District

Table 4-8 shows the laboratory results which were received within the specified turnaround time by district. Turnaround time varied in its definition and was mainly classified by a specific test (See Appendix 3-1). Many blood test results were not received within the specified time period across districts. In all facilities, only the sputum for TB results were received on time. Fifty percent of Pap smear results at Ethekwini district were received on time, compared to 66.7% at Umkhanyakude, 100% at Uthungulu and 100% at Ugu. For the stool and urine tests results, 100% of results were received on time at Ethekwini and Umkhanyekude districts. For the microscopy, culture and sensitivity results, 66,7% were received on time at Ugu district and data were missing at Uthungulu district.

Table 4-8: Laboratory results received within the specified turnaround time by district

BLOOD TEST	ETHEKWINI	UMKHANYAKUDE	UTHUNGULU	UGU
Cholesterol	0	0	0	0
CRP (C-reactive protein)	0	0	0	0
FT4 (Free Throxine 4)	0	0	0	0
HbA1c (Glycated Haemoglobin)	0	0	0	0
Phenytoin, lipase	0	0	0	0
PSA (Prostate specific hormone)	0	0	0	0
Red Cell Folate, Triglycerides	0	0	0	0
TSH (Thyroid stimulating hormone)	0	0	0	0
Vitamin B12	0	0	0	0
CD4 Count, RPR (Rapid Plasma Reagin test for syphilis)	0	0	0	0
Hepatitis A, B or C	0	0	0	0
HIV PCR for infants, viral load	0	0	0	0
Pap smear	50%	66.7%	100%	100%
MCS (Microscopy, culture and sensitivity)	0	0	missing data	66.7%
Sputum: TB	100%	100%	100%	100%
Stool	100%	100%	0	0
Urine	100%	100%	0	0

4.3.2 PROCESSES TO IMPLEMENT THE ART PROGRAMME

The indicators in this section measured the availability of different processes in the four districts; eThekwini, Umkhanaykude, Uthungulu and Ugu. The indicators were measured by looking for relevant information, guidelines, resources and services that indicated whether there were processes in place to evaluate and treat patients.

Each indicator consisted of more than one element, item and/or activity to be measured. These are explained on the descriptions in this section below. The availability of these processes were as a result measured as: "**available", "not available"** and **"not applicable"**. 'Available' was recorded if the processes were in place; 'not available' was recorded if the processes were not in place and 'not applicable' was recorded if the information, guidelines, resources and services were not relevant for a specific facility.

Table 4-9 shows the availability of processes to treat and prevent HIV and support patients living with HIV and Aids in four districts. Fifteen (15) facilities in all four districts were analysed.

4.3.2.1 Systems for Testing and Providing Results for HIV Infection

This indicator examined the systems to provide an HIV test. Systems to provide HIV testing included: policies or guidelines for informed consent and confidentiality, adequate supplies, client register and documentation for recording whether the results were given to the client. The results in Table 9 show that all 15 facilities in all districts had these systems in place.

4.3.2.2 Resources for Providing Basic Interventions for Prevention and Treatment for People Living With HIV

This indicator assessed the resources to support basic services for opportunistic infections (other than active malaria, sexually transmitted infections and active tuberculosis) and palliative treatment for people living with HIV. he facility must have had: (a) Observed guidelines or protocols for treating common opportunistic infections for HIV and Aids and (b) Basic medicines for treating common opportunistic infections other than malaria, sexually transmitted infections and active tuberculosis. The results in Table 4-9 show that all 15 facilities in all districts had the resources available to provide basic interventions for prevention and treatment for people living with HIV and Aids.

4.3.2.3 Systems for Pre- and Post-Test Counselling

This indicator examined the systems for pre-test and post-test counselling for HIV and Aids. Systems included: a protocol and guidelines for pre- and post-test counselling, a register for pre- and post-test counselling and visual and auditory privacy. The results in Table 4-9 show that all 15 facilities in all districts had systems in place to provide pre- and post-test counselling.

4.3.2.4 Sexually Transmitted Infections (STIs) Health Services Relevant to HIV and Aids

This indicator examined whether there was provision of STIs services. The services included: protocols or guidelines, medicines and laboratory services for STI testing. If the

laboratory of the site did not perform STI testing but referred to an external laboratory through some formal agreement, the external laboratory was considered the “facility laboratory”. If the facility simply referred clients but has no formal agreement with the laboratory, the facility was classified as not having the testing services. Table 4-9 shows that all 15 facilities in all districts had STI services in place relevant to HIV and Aids.

Table 4-9: Availability of systems, resources and services by district

ITEM	ETHEKWINI (N=4)	UMKHANYAKUDE (N=4)	UTHUNGULU (N=4)	UGU (N=3)	TOTAL (N=15)
Systems: HIV Results					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Resources: prevention and treatment					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Systems: counselling					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Resources: infection prevention					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
STI: HIV					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
TB: HIV					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Systems: OI					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Systems: ART					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Services: inpatient					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Systems: advanced services					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Systems: home care					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**
Services: PEP					
Available	4	4	4	3	**15**
Not available	0	0	0	0	**0**

N = Number of clinics under each district

4.3.2.5 TB Health Services Relevant to HIV and AIDS

This indicator examined whether there was provision of TB services. The services included: protocols or guidelines, medicines and laboratory services. If the laboratory of the site did not perform TB testing but referred to an external laboratory through some formal agreement, the external laboratory was considered the "facility laboratory". If the facility simply refers clients but has no formal agreement with the laboratory, the facility is classified as not having the testing services. Table 4-9 show that all 15 facilities in all districts had TB services in place relevant to HIV and Aids.

4.3.2.6 Systems to Support the Management of Opportunistic Infections

This indicator examined whether the facility could manage advanced clinical opportunistic infections related to HIV/AIDS and other illnesses and symptoms. The systems to support the provision of advanced HIV and Aids care included; essential medicines, diagnostic laboratory tests and diagnostic equipment for providing intervention and advanced treatment. The results in Table 4-9 show that all 15 facilities in all districts had systems in place to support the management of opportunistic infections.

4.3.2.7 Systems to Support Antiretroviral Combination Therapy Services

This indicator assessed whether there were systems in place that supported the provision of antiretroviral combination therapy. The systems included: existence of guidelines and protocols, availability of essential medicines, diagnostic laboratory tests and record-keeping systems. The results in Table 4-9 show that all 15 facilities in all districts had systems in place to support the antiretroviral combination therapy services.

4.3.2.8 Services to Provide Advanced Inpatient Care

This indicator examined the availability of services to support advanced HIV/AIDS care for people living with HIV and Aids, including all relevant guidelines and protocols; and record-keeping systems to provide this care. Table 4-9 show that all 15 facilities in all districts had services in place to provide advanced inpatient care for people living with HIV and Aids.

4.3.2.9 Systems to Support Advanced Services for HIV and Aids Care

This indicator assessed the items to support inpatient care. This included the availability of essential medicines, diagnostic laboratory tests, diagnostic equipment and systems and resources to support services. Table 4-9 show that all 15 facilities in all districts had systems in place to support advanced services for HIV and Aids care.

4.3.2.10 Systems to Support Home Care Services

This indicator examined the availability of home-care services or explicit referral systems for home care services for people living with HIV and Aids, including those who are terminally ill. The results in Table 4-9 show that all 15 facilities in all districts had systems to support home care services.

4.3.2.11 Service to Support the Provision Of Post-Exposure Prophylaxis (PEP)

This indicator assessed if PEP was provided and all items to support the service were available, including written protocols and guidelines, a recordkeeping and monitoring system, availability of antiretroviral drugs for PEP and special storage. Table 4-9 show that all 15 facilities in all districts had services in place to support the provision of PEP.

4.3.3 OUTCOME OF THE ART PROGRAMME

Outcome is the third element of the framework in this study and was conceptualised as the effect of healthcare provision on patients in relation to the prevention, care and treatment outcomes. Facility-based indicators were used to provide feedback on the services of the ART programme.

4.3.3.1 HIV Testing Coverage (Including Antenatal Care)

Data in Table 4-10 show that in 2015/2016; 46.8%, 31.0%, 44.0% and 55.9% clients were tested for HIV at Ethekwini, Umkhanyakude, Uthungulu and Ugu districts respectively

4.3.3.2 The Rate of Clients Remaining on ART

Data in Table 4-10 show the rate of clients remaining on ART. For the period 2015/2016; 58,6%, 52.8%, 55,8% and 61,2% clients remained on ART at Ethekwini, Umkhanyakude, Uthungulu and Ugu districts respectively.

4.3.3.3 Estimated Number of Reported Deaths Due to HIV and AIDS

The 2015/2016 HIV estimates show that AIDS related deaths for all districts were 6.2%, 7.9%, 3.3% and 3.2% in Ethekwini, Umkhanyakude, Uthungulu and Ugu districts respectively (see Table 4-10).

Table 4-10: Situation analysis indicators for 2015/2016 by district

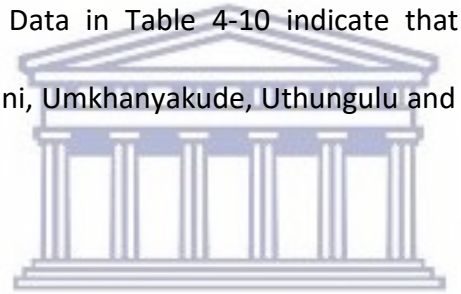
INDICATOR	ETHEKWINI	UMKHANYAKUDE	UTHUNGULU	UGU
HIV testing coverage (including ANC)	46,8%	31,0%	44.0%	55.9%
The estimated no. of reported deaths due AIDS	6.2%	7.9%	3.3%	3.2%
The rate of clients remaining on ART	58.6%	52.8%	55.8%	61.2%
HIV incidence	3.2%	3.2%	3.3%	3.2%
Babies tested HIV-positive (PCR) at six weeks	1.2%	1.4%	1,25	1.4%
Babies tested HIV-positive (CPR) at 18 months	2%	2%	2%	2%
Facility headcount 5 years and older	2 150 700	1 236 545	1 005 210	1 480 356
No. of clients 5 years and older screened for TB symptoms	60 256	77 954	10 456	140860
TB symptom 5 years and older screened rate	4.2%	6%	4%	4%
Population 15 years and older male	421 845	34 304	26 054	27 848
Number of male condoms distributed	3 328	3 130	2 674	2330
Male condom distribution rate	38%	37%	35%	44%
Population 15 years and older female	52 976	44310	42 484	33 546
Female condoms distributed	738	565	635	603
Female condom distribution rate	0.7%	0.4%	0.3%	0.3%
Medical male circumcision performed	4 653	4 793	4 440	4 396

4.3.3.4 HIV Incidence

This indicator measured the rate of new infections among persons 15 years and older per year. HIV incidence amongst this population was 3.2%, 3.2%, 3.3% and 3.2% in Ethekwini, Umkhanyakude, Uthungulu and Ugu districts respectively in the year 2015/2016 (see Table 4-10).

4.3.3.5 The Rate of HIV Transmission of Babies at Six Weeks

The indicator assessed the reduction to elimination of transmission of HIV from mother to child at six weeks. Data in Table 4-10 indicate that the rate of mother to child transmission in Ethekwini, Umkhanyakude, Uthungulu and Ugu was 1.2%, 1.4%, 1.2% and 1.2% respectively.



4.3.3.6 The Rate of HIV Transmission of Babies at 18 months

The indicator assessed the reduction to elimination of transmission of HIV from mother to child at eighteen weeks. Data in Table 4-10 indicate the same rate of mother to child transmission of HIV at eighteen weeks of testing during the period 2015/2016 in the four districts; Ethekwini, Umkhanyakude, Uthungulu and Ugu was 2%, 2%, 2% and 2% respectively.

4.3.3.7 Screening of TB Symptoms

Table 4-10 show the rate of clients older than 5 years who were screened for TB symptoms for the period 2015/2016 in the four districts; Ethekwini, Umkhanyakude, Uthungulu and Ugu were 4.2%, 6%, 4% and 4% in the respective districts; 47%, 50%, 47% and 46% of the total headcount of clients respectively.

4.3.3.8 Male Condom Distribution

Table 4-10 show male condom distribution in four districts; Ethekwini, Umkhanyakude, Uthungulu and Ugu in 2015/2016. At eThekwini, 3328 condoms were distributed to a population of 421 845, Umkhanyakude distributed 3130 condoms to a population of 34 304, Uthungulu distributed 2674 condoms to a population of 26 054 and Ugu distributed 2330 male condoms to a population of 27 848. The distribution rates to the respective districts were 38%, 37%, 35% and 44% for the same period.

4.3.3.9 Female Condom Distribution:

In Table 4-10 data for 2015/2016 show female condom distribution in four districts; Ethekwini, Umkhanyakude, Uthungulu and Ugu in 2015/2016. At eThekwini, 738 condoms were distributed to a population of 52 976, Umkhanyakude distributed 565 condoms to a population of 44 310, Uthungulu distributed 635 condoms to a population of 42 484 and Ugu distributed 603 female condoms to a population of 33 546. The

distribution rates to the respective districts were 38%, 37%, 35% and 44% for the same period.

4.3.3.10 Medical male circumcision:

Table 4-10 shows a number of circumcisions performed in four districts in 2015/2016. Ethekwini were 4653, Umkhanyakude were 4793, Uthungulu were 4440 and Ugu were 4396.

4.4 CHAPTER SUMMARY

The chapter presented descriptive quantitative results using the Donabedian (1980) framework of three key elements; the structure, process and outcome. The results were analysed based on the 3 objectives; (1) To assess the physical infrastructure; human and material resource composition and availability of programme related policies (structure); (2) To assess the processes involved in evaluation and treatment of patients who utilise services in the facilities (process) and (3) To assess the outcome of the programme in relation to the prevention, care and treatment outcomes (outcome). A total of fifteen ART facilities with ART programmes were analysed in four districts; i.e., Ethekwini, Umkhanyakude, Uthungulu and Ugu. Results in all 3 elements of the study varied across districts and facilities.

The findings from this chapter are discussed in Chapter 5.

CHAPTER 5: DISCUSSION AND CONCLUSIONS

PHASE ONE

5.1 INTRODUCTION

This chapter provides a discussion for the main findings of Phase 1 in Chapter 4 and where applicable, links the literature to the research results. The phase analysed the ART programme using the Donabedian model (Donabedian, 1980) which proposes that programmes are explored through three key elements: (1) structure (2) process and (3) outcome. The discussion is therefore categorised according to the framework of this research: the structure, process and outcome. At the end of the discussion, conclusions are made based on what has been learned from this research.

5.2 DISCUSSION

5.2.1 STRUCTURE OF THE PROGRAMME

Results from this section came from the analysis of the physical infrastructure, human and material resources and ART programme related policies.

5.2.1.1 Equipment and Furniture

This study found that seating for all patients was not available in most facilities in the three districts; Ethekwini, Umkhanyakude and Uthungulu. The non-availability of seating for patients could mean that patients spend most of the time standing while waiting for treatment. The discomfort experienced by patients who in most cases travel a long distance to access the health facility can lead to exhaustion. This contributes to a negative experience of the health care service and creates a barrier to care by the health system. Many of the patients live in rural communities some distance from the health care services, and this kind of experience creates another barrier to accessing the lifesaving treatment of HIV. The manner in which care is organised and delivered often has an impact on the acceptance of care by patients. Beer, et al. (2009) and Sohler, et al. (2009) found that the barriers to care include negative experiences with and distrust of the health care system. Health services barriers such as are among the findings from this study need to be eliminated to encourage patients to visit health care facilities.

The findings by this study that all facilities in the studied districts had the required equipment was an indication that the health system had basic resources to provide HIV care services. Basic health infrastructures have also benefited significantly from the scaling up of responses to HIV. For example, the Brazilian AIDS programme has established a specific network of units for the provision of care, often by strengthening existing ones with additional resources (Oliveira-Cruz, et al. 2004). In Haiti, Ethiopia,

Malawi, and many other countries, programmes provide funds for the construction of health posts, renovation of existing facilities at health centres and hospitals, and training of health personnel (Banteyerga, et al. 2006; Gbangbadthoré, et al. 2008; Mtonya, et al. 2006). In Cambodia, various disease-control programmes, including HIV/AIDS, TB, and malaria programmes, have been integrated to optimize services and outputs at the district hospital level. The construction and rehabilitation of the district hospitals' common laboratories have been supported (WHO Representative Office Cambodia, (2006).

5.2.1.2 Guidelines, Policies and Strategies

The findings from this study revealed that the guidelines, policies and strategies that were developed for the multiple areas of care and support were available in all the districts. The study focused on measuring the extent to which guidelines, policies and strategies exist and did not attempt to assess their quality in terms of conforming to national standards. It also did not assess the distribution or usage at the implementation level.

The health care system policies, guidelines and strategies are written mainly by policy-makers in SA. Because SA has opted for a decentralised District Health System to deliver primary health care, the National Department of Health has a policy mandate for the National Health System of SA while the health services rendered by the District Health System are managed by Provincial Departments of Health.

5.2.1.3 Availability of Staff

The findings by this research suggest that the number of staff were not sufficient to enable the ART programme to run efficiently and effectively, given the high numbers of HIV patients and the fact that ART delivery is a highly labour-intensive undertaking (Vella et al., 2008). According to the standard practice required by the Department of Health, a minimum of 1 medical officer, 2 professional nurses, 5 lay counsellors, 1 nutritionist/dietician and 0.5 social worker is required to treat and care for 500 patients. In Umkhanyakude, Uthungulu and Ugu districts, doctors and professional nurses cared for more than thousand patients per staff member. The numbers of patients cared for by a dietician and a social worker were very high. However, it should be borne in mind that these professionals are not in contact with patients on a continuous basis. Pharmacists and laboratory technicians cared for up to two thousand patients in some districts.

5.2.1.4 Drugs, Medicines and Supplies

This study found that there were shortages of antiretroviral drugs in all districts in the last six months following the review. Drug stockouts mean that health centres are unable to dispense the complete amount of one or more HIV medication to patients. The Stop Stockout 4th National Survey Report (2017) reported that most facilities reporting stockouts of antiretroviral medicine reported only one item out of stock, as compared with multiple stockouts reported in previous years. The survey showed that most drugs are available in SA's medicine depots but patients are unable to get their prescriptions

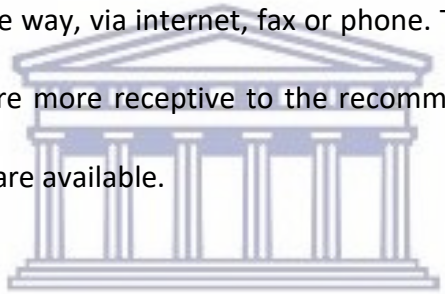
filled in local health centers because of local logistical and management problems, ranging from inaccurate forecasting to storage or transport issues. Only a minority of shortages were due to pharmaceutical companies being unable to provide enough drugs worldwide. The survey further showed that shortages of essential HIV medicines in most South African provinces were a systematic obstacle to the success of the largest antiretroviral treatment programme in the world.

The South African National HIV Prevalence, Incidence, Behaviour and Communication Survey 2017 (HSRC, 2017) estimated that 4.4-million people were receiving HIV treatment in 2017. As SA implements the universal test and treat strategy for HIV positive patients, the number of people receiving treatment will increase to accommodate the 7.35 million people estimated to be living with HIV in SA in 2017. It becomes more urgent to address complex and deep-rooted issues that are hampering the ability to run the largest ARV programme in the world. There is a need to ensure procurement and proper management of drugs at all levels to avoid drug shortages.

5.2.1.5. Turnaround Times for Laboratory Results

This study found that many blood test results were not received within the specified time period across districts. Delays in receiving test results risk patient loss from diagnostic and treatment pathways. Strategies to deal with associated delays create new problems, such as prolonged turnaround times, strains on human resources and quality of testing,

compounding additional diagnostic and treatment delays (Engel, et al. 2015). Some studies have shown high rates of loss to follow-up during the waiting period (Claassens, et al. 2013; MacPherson, et al. 2013). The unavailability of results could mean that patients were not provided with the required care timeously. Failure to rapidly diagnose and treat diseases puts patients at risk for increased morbidity and mortality (Millen, et al. 2008). The main challenge in the South African public health care system is the transportation of samples and results between clinics/ hospitals and laboratories. Public clinics and smaller hospitals send samples via couriers to centralised laboratories and retrieve results the same way, via internet, fax or phone. The study by Alemayehu (2009) showed that patients are more receptive to the recommended HIV care regimen when their laboratory results are available.



5.2.2 PROCESSES TO IMPLEMENT THE PROGRAMME

This research found that all facilities had the systems, resources and services in place to implement the ART programme. The findings show that services to people living with HIV and Aids have rapidly expanded over the years. In many countries infrastructure and laboratories have been strengthened, and in some, primary health care services have been improved (Yu, et al. 2008).

There has been a considerably increased resource allocation towards the HIV programme in SA. The unprecedented attention afforded to HIV as a health issue has enabled many

people living with HIV to survive and sustain their families. However, the introduction of ARV treatment, along with other interventions that the health sector has made, also exposed the effects of neglect of the health sector, economic crises, structural adjustments, declining public expenditures, and decentralised financing, particularly in Sub-Saharan Africa (Schneider, et al. 2006).

Access to ART and other HIV-related services in the health sector has both positive and negative effects on the supply of and demand for health services. On the one hand, it is known from industrialised countries and Brazil that patient demand for hospitalisation and diagnostic evaluation for opportunistic diseases decreased following the introduction of ART (Beck et al., 2004). In those settings, this also resulted in savings in health sector expenditures. On the other hand, where health care is less sophisticated and less costly, this is might be offset by the need to provide long-term outpatient care to more and more people requiring lifelong treatment and laboratory tests to monitor ART (El-Sadr & Abrams, 2007) and scaled-up some HIV prevention interventions, such as male circumcision and prevention of mother-to-child transmission.

In SA, the ART programme has dramatically improved the delivery of prevention and care services to people living with HIV. Human Immunodeficiency Virus (HIV) prevention and treatment programmes in some places have helped to reinvigorate efforts to promote primary health care by providing services such as childhood vaccinations, family planning,

tuberculosis case-finding and treatment, and health promotion services. In rural Haiti, the "four pillars" approach to HIV prevention and care introduced by Partners in Health radically increased overall patient visits at the Las-Cahobas primary health clinic, resulting in greatly increased tuberculosis case-finding: within 14 months of initiation, over 200 TB patients were identified and began receiving directly observed therapy (Yu, et al. 2008).

The current scaled-up responses to HIV and Aids in SA and particularly in Kwazulu-Natal must be maintained and strengthened.

5.2.3 OUTCOME OF THE PROGRAMME

5.2.3.1 HIV testing coverage (including Antenatal Care)

Reporting on HIV testing coverage indicates the progress of HIV testing, which aims to ensure that 90% of persons living with HIV know their HIV status (DoH, 2016). Early identification of HIV status is therefore fundamental to the implementation of all HIV prevention interventions. This study found that HIV testing coverage rates ranged between 30% and 56% in all four districts. The rates are far below the 90% target despite the mixed model HIV testing services provided by the South African government, which include provider-initiated testing, community-based testing for reaching large numbers of first-time testers, diagnosing people living with HIV at earlier stages of their HIV infection, and linking those who test positive to care, workplace and home-based testing (HST, 2017). Community-based mobile HIV testing services are also available and these facilities move into areas with limited access to testing services (Sweat, et al. 2011). However,

definitive coverage levels within a community remain difficult to ascertain with any of these approaches. Furthermore, none appear able to achieve the near (90%) or universal HIV testing coverage which modelling has suggested is needed for significant decreases in HIV incidence (Granich, et al. 2012; Alsallaq, et al. 2011). The KZN policy on HIV Testing Services has been developed as part of a community-based approach in line with the National Department of Health to include self-testing and family testing within the context of KZN and its epidemic picture (KZN DoH, 2017).

In Africa the proportion of people with HIV who are aware of their HIV-positive status grew from an estimated 10% in 2005 to 55% in 2015 (WHO, 2016). This achievement becomes even more significant when considering that individuals who know their status are less likely to engage in HIV-related risk behaviors (Fonner et., 2012) and following an HIV-positive diagnosis, can have early initiation of ART, as recommended by the World Health Organization (WHO), which can lead to a suppressed viral load, thereby reducing the risk of HIV transmission (UNAIDS, 2014).

While recent estimates report that 77% of all people diagnosed with HIV are on ART, 40% of all people with HIV remain undiagnosed (WHO, 2016). Although the number of annual HIV tests has increased, many people at greatest risk remain unreached by testing (WHO, 2016). Studies conducted in sub-Saharan Africa have identified several factors that may influence an individual's decision to seek or participate in HIV testing; these often include

sex, residence, and education level (Helleringer, et al. 2010; Staveteig, et al. 2013; Wanyenze, et al. 2011; Takarinda, et al. 2016). Factors such as antenatal care visits and other maternal health services provided for pregnant women, distance to an HIV testing facility, cost and convenience, knowledge and understanding of HIV and treatment, previous testing experience, number of lifetime sexual partners, and age have also been found to influence HIV testing behaviors (Helleringer, et al. 2010; Staveteig et al., 2013; South, et al. 2013; Wanyenze, et al. 2011; Takarinda, et al. 2016).

5.2.3.2 Clients Remaining on ART

The rate of clients remaining on ART indicates continued efforts to achieve the 90-90-90 targets by 2020 (UNAIDS, 2014). In this study the rate of clients remaining on ART ranged from 53% to 61% while the national average for the same period was 55%. This implies that many patients on ART are lost to follow up. Loss to follow up (LTFU) of patients from ART negatively impacts on the immunological benefits of ART, increasing Aids-related morbidity, mortality and hospitalisation. LTFU of patients from ART can result in serious consequences such as discontinuation of treatment, drug toxicity, treatment failure due to poor adherence, and drug resistance (Assefa, et al. 2011; Abbas, et al. 2006).

Numerous observational studies have demonstrated the challenges in retaining HIV patients across the entire spectrum of care (Gardner, et al. 2010), both with initial linkage to care and subsequent retention, with estimates of only 59% being clinically staged after diagnosis and 25% of patients not retained in care one year after ART initiation (Rosen, et

al. 2011; Fay, et al. 2011). According to Tier.Net June (2016), in 2015/2016, 71.2% of patients were known to be on ART treatment 12 months after the initiation. The remaining 27.5% were lost to follow up. Barriers to retention are numerous, ranging from site-specific transport challenges (Tuller, et al. 2010), to more generalised stigma (Geng, et al. 2010). There is little evidence on how best to link and retain HIV patients to care. Countries use different methods; in South Africa patient tracers have been used to successfully return patients to care (Rosen, et al. 2010).

The study by Plazy, et al. (2014) showed that while many people access an HIV care and treatment programme, a substantial proportion of these are not really engaged with care in the longer term. Retention was far from optimal after first clinic contact, both for individuals already eligible for ART at that time and for those not yet eligible for ART. The rate of ART initiation from first contact with this programme is higher than that reported elsewhere (Plazy, et al. 2014). Individuals who were not retained in care may not even have returned to the clinic to receive their CD4 results (Larson, et al. 2010; Faal, et al. 2011; Govindasamy, et al. 2011; Clouse, et al. 2012). Plazy,et al. (2014) showed that once individuals not yet eligible for ART were engaged in care and returned for monitoring (as evidenced by repeat CD4 measurements), they were more likely to initiate ART when becoming eligible than individuals who were eligible at entry. This association between ART initiation and time was consistent with previous studies conducted in South Africa (Clouse, et al. 2012) and in Malawi (Feldacker, et al. 2012). In Mutevedzi, et al. (2010), a

decentralised programme with treatment delivered through the primary health-care system allowed rapid scale-up, with 5719 adult patients initiated on ART in a 4-year period. They showed low rates of loss to follow up and attributed that to a decentralised model, with treatment provided closer to patients' homes. The adoption of the 'Treat All Approach' (WHO, 2016) along with increasing government investment in simplified patient-centred ART delivery through the scaling up of differentiated care strategies for stable adult patients may make it difficult to track clients who remain on ART.

5.2.3.3 HIV-Related Deaths

This study assessed the number of deaths from HIV related causes and the results rates ranged from 3.2% to 7.9 in all districts. The findings are consistent with other studies; in Plazy et al., (2014), the mortality rate before initiating ART was 5% in the Hlabisa programme, and thus only partially explained the attrition from first clinic contact to ART initiation. Meanwhile, Peltzer et al., (2011) found that a high rate of mortality (11.2% of participants initiated on ARVs) happened in the first 6 months of follow-up and that death was also the most common reason for loss to follow-up compared with other reasons.

Compared with an urban study from Johannesburg, South Africa, where rate of loss to follow-up and mortality were 16.3% and 5.1% respectively (Dalal, et al. 2008) and in another urban study in Johannesburg of 154 patients' loss to follow-up, a mortality rate of 27% was found as opposed to 42.6% in Peltzer, et al. (2011). The overall mortality rate

in Mutevedz,i et al. (2010), 12.6 deaths per 100 person-years was high but still comparable to the rates found in other cohorts in southern Africa (Boulle et al., 2008; Lawn, et al. 2008). Most deaths occured in the first 3 months after ART initiation, as seen in other cohorts, largely because of people presenting with late-stage disease (Mutevedzi, et al. 2010). The findings from these studies should be part of a clear public health message of the benefits of treatment and to encourage people to find out their HIV serostatus and seek care (Herbst, et al., 2009). They draw attention to the need for early HIV diagnosis, increased access to ART services with earlier treatment initiation, routine screening and aggressive management of opportunistic infections, particularly tuberculosis (Lawn, et al. 2010; Macpherson, et al. 2008). Peltzer, et al. (2011) found that the relative risk of death was associated with lower CD4 cell counts and HIV depression scores, which was also found in other studies (Cornell, et al., 2009; Geng, et al. 2009; Hartzell, et al. 2008). The finding suggested that treating depression and considering the differences in health status at ART initiation may be indicated in the HIV population (Peltzer, et al. 2011).

5.2.3.4 HIV Incidence

This study assessed the incidence of HIV amongst persons fifteen years and older and found that the rate was 3.2% - 3.3% in all districts. These figures were high compared to the national HIV incidence of 1.8 for the same period (DoH, 2016). A modelling of data from KZN showed that HIV incidence rate would be reduced by around 60% within four

years with a combination of four interventions: increasing the coverage of testing and counselling, reducing risky behaviour, increasing the coverage of VMMC, and increase ART coverage with extending eligibility to all HIV-positive individuals (Alsallaq, et al. 2013). Cori, et al. (2014) estimated that in SA a combination of increasing home-based voluntary testing and counselling, increasing VMMC coverage, and increasing ART coverage with a treat-all strategy over three years would lead to a 60% reduction.

Looking at the impact on the incidence of each intervention isolated, ART initiation regardless of CD4 count had the greatest impact (Blaizot, et al. 2017). The results by Blaizot, et al., (2017) are consistent with those from previous mathematical models applied to Sub-Saharan populations showing that substantial reduction in HIV incidence could be achieved with scale-up of ART (Granich, et al. 2009; Dodd, et al 2010; Eaton, et al. 2012; Hontelez, et al. 2013). Blaizot, et al. (2017) compared the potential impact of ART interventions and combined interventions on HIV incidence in a hyperendemic setting in KZN using age-specific targets for the ART, VMMC, and PrEP interventions, and age-targeted scenarios for the VMMC and PrEP interventions. They found that age-targeted interventions had a greater impact on incidence reduction than interventions without.

5.2.3.5 Prevention of Mother to Child Transmission of HIV

This study assessed the rate of mother to child transmission of HIV at six weeks and the results ranged from 1.2% to 1.4% in all districts. The results from this study confirm the national results which showed that the national risk of early (six weeks postpartum) mother-to-child transmission of HIV plummeted from approximately 25-30% prior to 2001 to an estimated 1.4% in 2016 (Goga, et al. 2017). The reduction of mother to child transmission of HIV at eighteen weeks was 2% in all districts. The results do not give the correct picture as universal testing is done for all children at 18 months, including those who were not HIV exposed. In Chetty, et al. (2012), an integrated mother-child postnatal clinic achieved good outcomes in the first 13 months of its inception. The outcomes included infant HIV testing of 83% and HIV transmission risk of 2.7% at six weeks in returning HIV-exposed infants whose mothers received PMTCT. However, loss to follow up by six months was substantial, limiting their ability to determine HIV-free survival at 18 months.

In the province with the highest HIV prevalence in South Africa, low rates of mother-to-child transmission were achieved. According to Horwood, et al. (2010), the PMTCT programme is functioning well in the antenatal period, achieving almost universal coverage of HIV testing among pregnant women and good coverage of other interventions. The major gap in provision of antenatal PMTCT care was the failure to obtain CD4 results, refer women for ART and start HAART where appropriate. Although

antenatal clinic attendance is high in South Africa, few women attend before 20 weeks' gestation (Bradshaw, et al. 2008) and furthermore, because they are tested for HIV late in their pregnancies, many of the HIV-infected women do not receive their CD4+ cell result during their pregnancies implying that they are not started on lifelong antiretroviral treatment (Horwood et al., 2012). Ensuring that women know their HIV status is the starting point for achieving low rates of mother-to-child transmission (Barker, et al. 2011). Initiating lifelong antiretroviral treatment in such HIV women will also make the greatest contribution to reducing HIV infections in children and mortality in mothers (Horwood, et al. 2012). According to Horwood et al. (2010), follow-up of HIV-exposed infants remained poor and PMTCT services are frequently not available at the immunisation clinics with HIV-positive mothers attending regular follow-up for their own care.

Given the progress in reducing MTCT globally, the 'Global Plan towards the Elimination of New HIV Infections among Children and Keeping their Mothers Alive' was introduced by UNAIDS in 2011, largely because of increased access to PMTCT-related services and increased number of pregnant women living with HIV being initiated on lifelong antiretroviral medicines (UNAIDS, 2011). This is a complex health intervention involving mothers and infants at all levels of the healthcare system and affected by the actions of their partners (through their HIV status) and other members of the community (through

stigmatisation and discrimination). As such, structural and health-system factors that facilitate or hinder implementation must be examined (Goga, et al. 2017).

5.2.3.6 Screening of TB Symptoms

This study assessed the number of clients screened for TB symptoms in ART programme facilities. The rate of clients who were screened for TB symptoms in all districts was 50% and below. In 2009, WHO reviewed the South African TB program and concluded that the biggest area of concern in SA was the dual epidemics of HIV and TB (WHO, 2009). TB and its strong association with HIV infection are the most important causes of the high rates of infectious morbidity and mortality in South African adults (Wassennar, et al. 2014). The study by Bassett et al. (2010) found an enormous tuberculosis burden; 20% of study subjects were already receiving tuberculosis treatment at the time of starting ART literacy training. According to the District Health Barometer 2016-2017, only an estimated 72.8% of people in SA in 2016 with diagnosed TB were started on TB treatment (HST, 2017). According to the 2017 WHO Global TB Report, an estimated 124 000 people died of TB in South Africa in 2016 and of these 101 000 were HIV positive. The 50% screening rate found by this study is low given that TB was the leading cause of death in HIV infected people (Stats SA, 2018). Many more clients should be screened as an attempt to reach the national target of 94% (Health Systems Trust, 2018). SANAC (2017) reported that the screening rates in KZN province had improved as a result of intensified focus on TB

prevention and screening as part of the 90-90-90 Strategy implementation, which is the strategy to end AIDS and forms the Framework for the Global AIDS response by 2020.

5.2.3.7 Condom Distribution

The SA HIV and TB investment case report (DoH, 2016) indicated that in order to maximise the HIV response in the country, it is necessary to firstly scale up prevention interventions that include condom distribution to prevent HIV infections and reduce future need for ART. SA responded with a rapid expansion of its condom programme. Male condoms are widely available, and the female condom programme is one of the biggest and most established in the world (Stats SA, 2015). This study assessed the male and female condom distribution rates and found that the male condom distribution rates in all four districts ranged between 35% and 38%. The distribution rates were below the national average of 47,5%, implying insufficient distribution rates in the four districts. KZN province in general reported 53,9% distribution rates during the same period (HST, 2017). Although the province has more free condoms at public health facilities, the study by HSRC (2014) reported that condom usage among men aged 25-49 has decreased from 44% to 36% in South Africa and that 53% of participants had never used condoms.

In this study the distribution rates for female condoms in the studied districts ranged between 35% and 44%. This study found that the distribution rate of female condoms was relatively the same as that of male condoms. Following the National Female Condom

Evaluation Study conducted by the MatCH Research Unit and cited in the Health Systems Trust (HST) National Health Review (2017), SA is one of the world's largest users of female condoms. Twenty-seven million female condoms were distributed in South Africa in 2015/2016, exceeding the country's National Strategic Plan (NSP) target of 25 million annually by 2016 (HST, 2017). The study by Beksinska, et al. (2017) found that only two-thirds of clients knew that female condoms were available at their healthcare facility and that most facilities lacked information, education and communication materials and demonstration models. Accordingly, their findings underscore the need to promote awareness of female condom availability in SA for HIV, sexually transmitted infection (STI) and pregnancy prevention and also to demonstrate the pivotal role of the provider in delivering female condoms to potential users. There are not many studies that document the distribution rates of female condoms in SA or KZN province.

5.2.3.8 Medical Male Circumcision

This study assessed the number of male circumcisions performed in the four districts and found that between 4396 and 4793 circumcisions were performed in each district. In 2010, research emerged from sub-Saharan Africa suggesting that voluntary medical male circumcision can reduce the risk of female-to-male HIV transmission by up to 60% (HSRC, 2014). This led the South African government to rapidly roll out a national MMC programme. In settings of high HIV prevalence like KZN and low male circumcision rates, MMC is a critical component of combined HIV prevention (Chang et al., 2013). No

evidence has been found supporting one type of MMC scale-up strategy versus another. However, several observational studies provide examples of potential approaches (Lissouba, et al. 2010; Mahler, et al. 2011; Mwandi, et al. 2008). South Africa has demonstrated an effective model using community-based outreach and mobilization (Lissouba, et al. 2010). The Asiphile male circumcision program in KZN was able to scale-up an evidence-based, HIV prevention service that was previously unavailable to the high-risk population of KZN (Wynn, et al. 2015). Based on this simple model, it was possible that Asiphile prevented about 2,000 new HIV infections and generated substantial future savings in HIV treatment and care costs (Wynn, et al. 2015). Although decreases in HIV incidence were not measured, several disease modelling studies suggest that in such HIV hyperendemic settings, one future HIV infection is prevented for every 5 males circumcised (Malowany, et al. 2012). The Asiphile program was, however, unable to meet its goal of 50 procedures per day and the total number of circumcisions performed (9,980) represented only 5% coverage in the catchment area of 200,000 men (Wynn, et al. 2015). These results were similar to other programmes in Africa (UNAIDS, 2015).

While HCT and screening for other STIs is an important precursor to VMMC, there was perceived stigma surrounding HCT as well as fears about the confidentiality and the result of the HIV test which were found to be an important barrier to VMMC (George, et al. 2014). In this regard, it is important that young men are given support to deal with their HIV positive result during the disclosure process with the counsellor. This calls for

adequate HCT counselling and a good referral system for young people seeking VMMC (Mavhu, et al. 2011). It is clear that male circumcision is a potentially valuable method for the prevention of HIV and other STIs, with relevance for sub-Saharan Africa. However, it appears to be under-utilised (Tibian, et al. 2014).

5.3 CONCLUSION STATEMENTS

Structure of the ART Programme

1. Most facilities did not have seating available for all the patients in the three districts, Ethekwini, Umkhanyakude and Uthungulu.
2. All districts had adequate furniture in consultation rooms.
3. Vital signs rooms of all facilities in all districts had the required equipment.
4. The guidelines, policies and strategies that were developed for the multiple areas of care and support were all available in all facilities of all four districts, Ethekwini, Umkhanyakude, Uthungulu and Ugu, except policies regarding legal support to people living with HIV.
5. The majority of staff in all districts were trained; all doctors and professional nurses in all districts received some form of training in HIV care. Social workers and community treatment supporters were the least trained across districts.
6. There were shortages of antiretroviral drugs in all facilities of all districts in the last six months following the review.

7. Delay in the return of laboratory results hampers service delivery.

Processes to Implement the ART Programme

1. Facilities in all districts had systems, resources and services in place to implement the ART programme.

Outcome of the Programme

1. HIV testing coverage rates were below the 90% target set by the national government.
2. The rate of clients remaining on ART ranged from 53% to 61% while the national average for the same period was 55%.
3. The number of deaths from HIV-related illnesses ranged from 3.2% to 7.9% in all districts.
4. The incidence of HIV among persons fifteen years and older was 3.2% - 3.3%, higher than the national HIV incidence of 1.8 for the same period.
5. The rate of mother to child transmission of HIV at six weeks was lower in some districts at 1.2% and in other districts was 1.4%, similar to the national estimate of 1.4% for the same period.
6. The rate of clients who were screened for TB symptoms was 50% and below in all districts.

7. The male and female condom distribution rates were below the national average of 47,5%, implying insufficient distribution rates in the four districts.
8. All districts recorded a high number of medical male circumcisions.

5.4 LIMITATIONS TO THE STUDY

The policy documents used in this study were available mainly online and it was not established whether they were available at a local clinic. It was unclear if facilities had the most up-to-date policy documents and whether or not recommendations within the reviewed documents were actually verified to be in place at a facility level.

The introductory chapter (Chapter 1) described the 90-90-90 HIV care and treatment cascade as the focus of this thesis. However, data on the viral load suppression which is the last '90' of the cascade were not available. Information on viral load suppression was reported per province only and the reason was that only 54% of PLHIV and receiving ART were tested for viral load (KZN DoH, 2016). In all documents, viral load suppression was not listed as an outcome indicator therefore not included in Chapter 4.

5.5 CHAPTER SUMMARY

Chapter 5 discussed the research findings from the analyses of the ART programme in KwaZulu-Natal presented in Chapter 4. The discussions were categorised according to the framework of this research; the structure, process and outcome using the Donabedian model. Conclusions on the findings were made based on what was learned from this

research. The conclusion statements were outlined and will assist the researcher to develop concepts for the model development in Chapter 7. Chapter 6 will describe the systematic literature review on existing ART delivery models in South Africa undertaken for Phase 2 of the study.

CHAPTER 6: SYSTEMATIC LITERATURE REVIEW

PHASE TWO

6.1 INTRODUCTION

In 2017, an estimated 37 million people were living with HIV (UNAIDS, 2017). With the expansion of eligibility for ART, the proportion of patients being lost to follow-up (LTFU) also began to rise as clinics became saturated, which posed the challenge of improving retention in care and adherence to ART. It became evident that a one-size-fits-all model of HIV services would not work for all 37 million people living with HIV (Médecins Sans Frontières, 2013). There was a need for a responsive, client-centred approach that simplifies and adapts HIV services across the spectrum to better serve individual needs. It would reduce unnecessary burdens on the health system by shifting to a nurse-based, doctor-supported decentralised model of care and by developing out-of-clinic approaches to adherence support for stable patients (WHO, 2013; WHO, 2016; International AIDS Society, 2016). This approach was known as Differentiated Care (Médecins Sans Frontières, 2013).

This chapter presents a review of studies on the implementation of different models of Antiretroviral Therapy (ART) at different levels of care. The chapter further presents the methodology, results, discussion and conclusions of the review process. The results are presented using a table to communicate specific findings intended to address the Phase 2 objective, which was to conduct a review of relevant available literature on the implementation of existing models of the ART programme.

6.2 METHODOLOGY

This section contains the methodology used to conduct the systematic literature review. The researcher describes the steps that were followed in conducting the study. The aspects outlined in the methodology included the research design and research methods.

6.2.1 Research Design

The researcher followed a systematic review design to conduct a review of relevant available literature on the implementation of existing models of the ART programme. According to Hempel, Xenakis and Danz (2016), a systematic review is an overview of existing evidence pertinent to a specific research question. It uses systematic and explicit methods to identify, select and critically appraise relevant research and to collect, report and analyse data from the studies that are included in the review.

6.2.2 Research Methods

6.2.2.1 Steps of Systematic Review

According to Khan, Kunz, Kleijnen, et al. (2011), there are five steps involved in conducting a systematic review, and these were adopted in the research process.

These steps include:

(1) Formulation of a focused review;

(2) Identification of relevant publications;

(3) Performing the critical appraisal;

(4) Summarising the evidence and

(5) Interpreting the findings.

6.2.2.1.1 STEP 1: Formulation of a Focused Review Question

The purpose of this study was to systematically review the available literature on the implementation of existing models of the ART programme in South Africa. In formulating the review question, the PICO technique was used as an organising framework to conceptualise the research question (see Table 6-1). The PICO technique focuses on the Population, Intervention, Comparison and Outcomes of an article. It is commonly used to identify components of clinical evidence for systematic reviews and is endorsed by the Cochrane Collaboration (Higgins & Green, 2013).

The review question for this review was specified as follows:

Review question: What are the existing models of the ART programme in South Africa and how are they being implemented?

Table 6-1 Components of the review question using PICO

Population of interest (P)	People living with HIV (PLWHIV)
Intervention (I)	Implementation of different models
Comparative intervention (C)	No comparison intervention
Outcome (O)	Effectiveness of the ART model - Adherence to ART - Retention to HIV care

The review was designed to meet the following objective:

- To conduct a systematic review of relevant available literature on the implementation of existing models of the ART programme.

6.2.2.1.2 STEP 2: Identification of Relevant Publications

In this step the researcher discusses the process followed to search credible and relevant data sources, and how documentation of the search was done. The step included the use of multiple resources to identify articles and the application of the selection criteria. Firstly, the databases and additional sources were specified. Secondly, the study selection

criteria were decided upon as directed by the research question and were specified prior to the study. Thirdly, the publication status and related biases such as the type and language of the reports, and the timing of the publications were considered (CRD, 2009).

Data sources and search strategies:

The focus of this systematic review was to get evidence from existing studies in order to get a broad view of the dominant perspectives on the topic under study. The review used a range of possible sources to identify relevant peer reviewed articles and conference proceedings (see Table 6-2). Between June and July 2018, the reviewed articles were recorded. The record included electronic searches and hand searching. Electronic search yielded results using the search terms:

"antiretroviral treatment programme" OR "HIV programme" OR "HIV care delivery" AND "implementation" AND "models" AND "differentiated care". No relevant documents were found during the manual search process.

The researcher included all possible studies that were relevant to the review question with specific focus on different delivery models. The search terms were applicable in the categories or title field, and abstracts. The study selection was conducted in two stages. In the first stage the articles were screened by analysing their titles and/or abstracts. Articles that did not meet the inclusion criteria were excluded. In the second stage of the search, the full-text articles were examined to view full details.

Only articles written in English were retrieved and no authors were contacted. To retrieve the most relevant information, only studies conducted or published from 2013 to 2018 were included in the review. The five years were selected based on the recent scale-up of HIV programmes in prevention, treatment, care, and support. These years also reflect the rapid expansion of ART programmes worldwide.

Table 6-2 shows the summary of the electronic search. During the search thirty-nine (39) articles were retrieved from EBSCOHost and of those, thirty-one (31) were full text articles. Eight (8) articles were retrieved from PubMed and of those, one (1) was a full text article. Nineteen (19) articles were retrieved from Google scholar and all of them were full text articles. Ten (10) retrieved articles were AIDS conference proceedings and none were full text. In total, of the seventy-six (76) articles retrieved, fifty-one (51) were full text and only eight (8) were appraised.

Table 6.2 Summary of the search per database

Electronic database			
Database	**Search**	**Full text**	**For appraisal**
EBSCOHost	39	31	4
PubMed	8	1	0
Google Scholar	19	19	4
Type	**Search**	**Full text**	**For appraisal**
AIDS conference proceedings	10	0	0
Total	**76**	**51**	**8**

Inclusion Criteria:

The inclusion criteria were based on the PICO strategy (Squires, Valentine & Grimshan, 2013) and the criteria for selection of studies were as follows (see Appendix 6-1):

1) Participants in the study were patients or clients receiving HIV services.
2) The purpose of the study was to implement an ART model in South Africa.
3) The outcome of the study was to describe the effectiveness of the ART model.

Figure 6-1 depicts the process leading to the final selection of articles studies used in this study. Based on the search strategy, a total of seventy-six (76) articles published between 2013 and 2018 were identified. After reviewing the title and date, and removing duplicates, sixteen (16) articles were excluded as clearly irrelevant. Sixty (60) articles were selected for review as potentially relevant. Of the sixty (60), eight (8) articles were included in the critical appraisal. A flow chart of this process is presented in Figure 1. These articles were independently appraised by two (2) reviewers. After critical appraisal and a consensus meeting with the second reviewer, eight (8) articles were retained for data extraction and then they were analysed. The eight (8) articles met this study's inclusion criteria. That is the end product of step 2 of the systematic review.

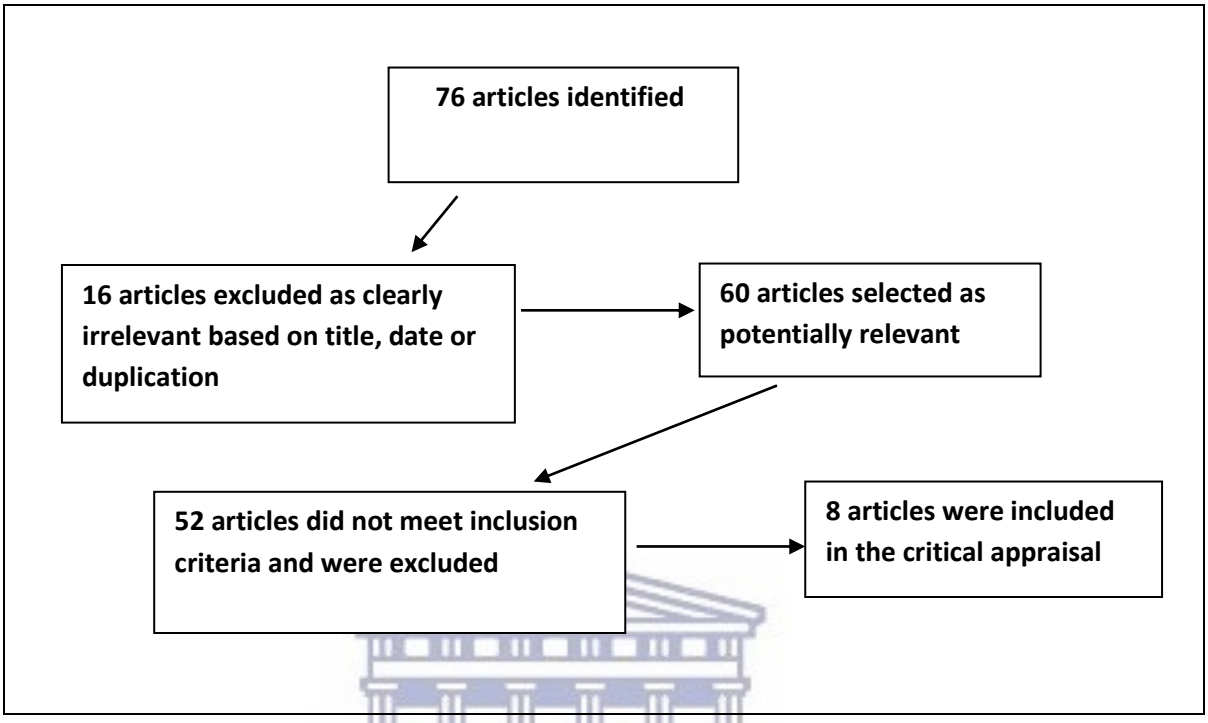


Figure 6-1: Outcome of studies identified from the search strategy

6.2.2.1.3 STEP 3: Performing the Critical Appraisal

The third step of the systematic review involved a critical appraisal of studies included for the review in order to evaluate their validity. The process entailed checking for both the internal and external validity. Internal validity refers to the minimisation of method error and bias, and external validity refers to the generalisability of the conclusion of a trial to another population (Wright & Brand, 2007). The degree to which the internal and external validities are addressed within each study enables one to judge the quality of each study, in the process of assessing the methodological quality of included studies. It

involves using tools to identify those aspects of study design, data extraction processes and analysis which involve a possible risk of bias.

According to Khan, et al. (2011) the quality of a study is defined as the degree to which the design of the study and its conduct minimises the risk of bias and error. The quality of these studies was assessed with the aim of presenting outcomes in a descriptive manner. The quality of studies was appraised using the Quality Assessment of HIV/AIDS Provider Training Tool (Health Services Group of the HIV Group on HIV Infection/AIDS, 2003) (see Appendix 6-1). The tool is recommended by the Cochrane (Systematic) Review Group on HIV/AIDS (The Cochrane Collaborative Review Group on HIV infection and AIDS, 2006). The tool has 10 appraisal questions under the sub-headings: Design, Sample, Data collection, Analysis, Findings and Reporting (see below).

1. How defensible is the research design?
    - Clear description of methods used and justification of use.
2. Was the sample selected based on the aims and expected outcomes of the study (participation selection, sample size, generalisability)?
    - Methods supported the selection of a representative sample from the study population/community (randomization, participation criteria).
    - Efforts were made to include 'hidden populations'.

- Sample size allowed for validity of findings and for statistical power of analytical tests.

3. How well was the data collection carried out?
    - Measurement bias: Use of validated and piloted data collection tool.
    - Information bias: Discussion of:
        - who conducted data collection
        - procedures/documents used for collection/recording
        - checks on origin/status/authorship of documents
4. Were rigorous data analysis tools and methods used?
    - Data analysis software or methods were described and rationalized.
    - Statistical tests used to determine outcome.
    - Evidence of statistical power to detect effect.
    - Confounding factors were controlled for.
5. How credible were the findings?
    - Findings/conclusions are supported by data/study evidence.
    - Findings confirmed by study participants or community.
6. How has knowledge/understanding been extended by the research?
    - Literature review summarising knowledge to date/key issues raised by previous research.

- Credible/clear discussion of how findings have contributed to knowledge and understanding *(e.g. of the policy, programme or theory being reviewed);* might be applied to new policy developments, practice or theory.
- Discussion of limitations of evidence and what remains unknown/unclear or what further information/research is needed.

7. How well does the evaluation address its original aims and purpose?
    - Clear statement of study aims and objectives; reasons for any changes in objectives.
    - Findings clearly linked to the purposes of the study – and to the initiative or policy being studied.
    - Summary or conclusions directed towards aims of study.
    - Discussion of limitations of study in meeting aims *(e.g. are there limitations because of restricted access to study settings or participants; incomplete analysis; time constraints?).*

8. Scope for drawing wider inference – how well is this explained?
    - Discussion of what can be generalised to wider population from which sample is drawn/case selection has been made.
    - Detailed description of the contexts in which the study was conducted to allow applicability to other settings/contextual generalities to be assessed.
    - Evidence supplied to support claims for wider inference *(either from study or from corroborating sources).*

- Discussion of limitations on drawing wider inference *(e.g. re-examination of sample and any missing constituencies: analysis of restrictions of study settings for drawing wider inference).*

9. How clear are the links between data, interpretation and conclusions – i.e. how well can the route to any conclusions be seen?
    - Discussion of negative cases and possible explanations.
    - Discussion of how conclusions were derived – and how they relate to interpretations and content of original data.
10. How clear and coherent is the reporting?
    - Demonstration of link to aims of study/research questions.
    - Information is accessible for intended target audience(s).
    - Key messages highlighted or summarized.

With the use of this tool, the methodological quality of the selected studies was assessed independently. The quality of studies was appraised and determined to be of weak, moderate or strong quality. Quality indicators related to each question were used to appraise the sections of the study and rate them. An overall assessment of the methodological quality was determined based on the results from each question. The total score was out of 10. All the checked marks in the **Yes** column were to be added to the **Total** column under **Yes**. The same would be done for the **No** column.

The following decision rule was used to determine the overall assessment for the review based on the numbers in the **Total** columns.

→ Reviews with a score of **8 or higher** in the **Yes** column were rated as **Strong**

→ Reviews with a score between **5-7** in the **Yes** column were rated as **Moderate**

→ Reviews with a score of **4 or less** in the **Yes** column were rated as **Weak**

In the case that a score did not necessarily reflect the researcher's impression of the actual quality of a review (i.e., Strong/Moderate/Weak), the criteria for inclusion in the study and the "yes" and/or "no" scores were revisited so that the corresponding quality category was a reflection of the review's overall methods and that the score was an accurate reflection for use by public health decision-makers.

An independent individual with knowledge of systematic reviews was involved as the second reviewer in this study to ensure reliability. A consensus between the researcher and an independent reviewer on the quality of the appraised document was reached for audit purposes; completed critical appraisal instruments for each paper were submitted to the supervisor for assessment of the quality of the process. The researcher reported the quality appraisal of each of the relevant studies in Table 6-3.

Table 6-3: Summary of critical appraisal

1. Dudhia, R. & Kagee, A. (2015). Experiences of participating in an antiretroviral treatment adherence club. Psychology, Health & Medicine, 20(4), 488–494.			
	APPRAISAL QUESTIONS	**YES**	**NO**
Design	1. Was the research design defensible?		√
Sample	2. Was the sample selected based on the aims and expected outcomes of the study (participation selection, sample size, generalisability)?	√	
Data Collection	3. Was the data collection carried out well?	√	
Data Analysis	4. Were rigorous data analysis tools and methods used?		√
Findings	5. Were the findings credible?	√	
	6. Did the research extract any knowledge/understanding?		√
	7. Does the evaluation address its original aims and purpose?	√	
	8. Is the scope for drawing wider inference well explained?		√
Reporting	9. Are the links between data, interpretation and conclusions clear? i.e. can the route to any conclusions be seen?	√	
	10. Is the reporting clear and coherent?	√	
TOTAL SCORES:		**6**	
OVERALL QUALITY LEVEL:		**Moderate**	

2. Grimsrud A, Sharp J, Kalombo C, Bekker L-G & Myer L. (2015). Implementation of community-based adherence clubs for stable antiretroviral therapy patients in Cape Town, South Africa. Journal of the International AIDS Society. 2015;18(1).			
	APPRAISAL QUESTIONS	**YES**	**NO**
Design	1. Was the research design defensible?	√	
Sample	2. Was the sample selected based on the aims and expected outcomes of the study (participation selection, sample size, generalisability)?	√	
Data Collection	3. Was the data collection carried out well?	√	
Data Analysis	4. Were rigorous data analysis tools and methods used?	√	
Findings	5. Were the findings credible?	√	
	6. Did the research extract any knowledge/understanding?	√	
	7. Does the evaluation address its original aims and purpose?	√	
	8. Is the scope for drawing wider inference well explained?	√	
Reporting	9. Are the links between data, interpretation and conclusions clear? i.e. can the route to any conclusions be seen?	√	
	10. Is the reporting clear and coherent?	√	
TOTAL SCORES:		**10**	
OVERALL QUALITY LEVEL:		**Strong**	

3. Wilkinson, L., Harley, B., Sharp, J., Solomon, S., Jacobs, S., Cragg, C., Kriel, E., Peton, N., Jennings, K. & Grimsrud, A. Expansion of the Adherence Club model for stable antiretroviral therapy patients in the Cape Metro, South Africa 2011–2015. Tropical Medicine & International Health. 2016 Jun 1;21(6):743-9.			
	APPRAISAL QUESTIONS	**YES**	**NO**
Design	1. Was the research design defensible?	√	
Sample	2. Was the sample selected based on the aims and expected outcomes of the study (participation selection, sample size, generalisability)?	√	
Data Collection	3. Was the data collection carried out well?		√
Data Analysis	4. Were rigorous data analysis tools and methods used?	√	
Findings	5. Were the findings credible?	√	
	6. Did the research extract any knowledge/understanding?	√	
	7. Does the evaluation address its original aims and purpose?	√	
	8. Is the scope for drawing wider inference well explained?	√	
Reporting	9. Are the links between data, interpretation and conclusions clear? i.e. can the route to any conclusions be seen?	√	
	10. Is the reporting clear and coherent?	√	
TOTAL SCORES:		**9**	
OVERALL QUALITY LEVEL:		**Strong**	

4. Tsondai, P., Wilkinson, L., Grimsrud, A., Mdlalo, P., Ullauri, A. and Boulle A. (2007). High rates of retention and viral suppression in the scale-up of anti-retroviral therapy adherence clubs in Cape Town, South Africa. Journal of International AIDS Society. 2017;20 (Suppl 4):21649.

	APPRAISAL QUESTIONS	**YES**	**NO**
Design	1. Was the research design defensible?	√	
Sample	2. Was the sample selected based on the aims and expected outcomes of the study (participation selection, sample size, generalisability)?	√	
Data Collection	3. Was the data collection carried out well?	√	
Data Analysis	4. Were rigorous data analysis tools and methods used?	√	
Findings	5. Were the findings credible?	√	
	6. Did the research extract any knowledge/understanding?	√	
	7. Does the evaluation address its original aims and purpose?	√	
	8. Is the scope for drawing wider inference well explained?	√	
Reporting	9. Are the links between data, interpretation and conclusions clear? i.e. can the route to any conclusions be seen?	√	
	10. Is the reporting clear and coherent?	√	
TOTAL SCORES:		**10**	
OVERALL QUALITY LEVEL:		**Strong**	

5. Grimsrud A, Lesosky M, Kalombo C, Bekker L-G, Myer L. (2016). Community-Based Adherence Clubs for the Management of Stable Antiretroviral Therapy Patients in Cape Town, South Africa: A Cohort Study. Journal of Acquired Immune Deficiency Syndromes. 2016;71(1).			
	APPRAISAL QUESTIONS	**YES**	**NO**
Design	1. Was the research design defensible?	√	
Sample	2. Was the sample selected based on the aims and expected outcomes of the study (participation selection, sample size, generalisability)?	√	
Data Collection	3. Was the data collection carried out well?		√
Data Analysis	4. Were rigorous data analysis tools and methods used?	√	
Findings	5. Were the findings credible?	√	
	6. Did the research extract any knowledge/understanding?	√	
	7. Does the evaluation address its original aims and purpose?	√	
	8. Is the scope for drawing wider inference well explained?	√	
Reporting	9. Are the links between data, interpretation and conclusions clear? i.e. can the route to any conclusions be seen?	√	
	10. Is the reporting clear and coherent?	√	
TOTAL SCORES:		**9**	
OVERALL QUALITY LEVEL:		**Strong**	

6. Luque-Fernandez, G.; Goemaere, E.; Hilderbrand, K.; Schomaker, M.; Mantangana, N.; Mathee, S.; Dubula, V.; Ford, N.; Hernan, M. A.; Boulle, A. Effectiveness of patient adherence groups as a model of care for stable patients on antiretroviral therapy in Khayelitsha, Cape Town, South Africa. PLoS One. 2013;8(2).			
	APPRAISAL QUESTIONS	**YES**	**NO**
Design	1. Was the research design defensible?	√	
Sample	2. Was the sample selected based on the aims and expected outcomes of the study (participation selection, sample size, generalisability)?	√	
Data Collection	3. Was the data collection carried out well?	√	
Data Analysis	4. Were rigorous data analysis tools and methods used?	√	
Findings	5. Were the findings credible?	√	
	6. Did the research extract any knowledge/understanding?	√	
	7. Does the evaluation address its original aims and purpose?	√	
	8. Is the scope for drawing wider inference well explained?	√	
Reporting	9. Are the links between data, interpretation and conclusions clear? i.e. can the route to any conclusions be seen?	√	
	10. Is the reporting clear and coherent?	√	
TOTAL SCORES:		**10**	
OVERALL QUALITY LEVEL:		**Strong**	

7. Bango F, Ashmore J, Wilkinson L, Cutsem G, Cleary S. Adherence clubs for long-term provision of anti-retroviral therapy: Cost-effectiveness and access analysis from Khayelitsha, South Africa. Tropical Medicine & International Health. 2016.			
	APPRAISAL QUESTIONS	**YES**	**NO**
Design	1. Was the research design defensible?	√	
Sample	2. Was the sample selected based on the aims and expected outcomes of the study (participation selection, sample size, generalisability)?		√
Data Collection	3. Was the data collection carried out well?	√	
Data Analysis	4. Were rigorous data analysis tools and methods used?	√	
Findings	5. Were the findings credible?	√	
	6. Did the research extract any knowledge/understanding?	√	
	7. Does the evaluation address its original aims and purpose?	√	
	8. Is the scope for drawing wider inference well explained?	√	
Reporting	9. Are the links between data, interpretation and conclusions clear? i.e. can the route to any conclusions be seen?	√	
	10. Is the reporting clear and coherent?	√	
TOTAL SCORES:		**9**	
OVERALL QUALITY LEVEL:		**Strong**	

8. Wilkinson L.S. (2013). ART adherence clubs: A long-term retention strategy for clinically stable patients receiving antiretroviral therapy. Southern African Journal of HIV Medicine. 2013;14(2):48-50.			
	APPRAISAL QUESTIONS	**YES**	**NO**
Design	1. Was the research design defensible?		√
Sample	2. Was the sample selected based on the aims and expected outcomes of the study (participation selection, sample size, generalisability)?	√	
Data Collection	3. Was the data collection carried out well?		√
Data Analysis	4. Were rigorous data analysis tools and methods used?	√	
Findings	5. Were the findings credible?	√	
	6. Did the research extract any knowledge/understanding?	√	
	7. Does the evaluation address its original aims and purpose?	√	
	8. Is the scope for drawing wider inference well explained?	√	
Reporting	9. Are the links between data, interpretation and conclusions clear? i.e. can the route to any conclusions be seen?		√
	10. Is the reporting clear and coherent?		√
TOTAL SCORES:		**6**	
OVERALL QUALITY LEVEL:		**Moderate**	

After the critical appraisal was conducted, eight (8) articles were finally selected for data extraction.

6.3 DATA EXTRACTION AND FINDINGS

This section provides a summary of the data extraction process, the synthesis, and interpretations of the study results. The purpose of extraction and synthesis of data was to obtain usable and useful information to report, describe, discuss and summarise the findings.

6.3.1 Data Extraction

The collection of data was performed using data extraction. The objective of this stage was to obtain the necessary information about study characteristics and findings from the primary studies (Guidelines for performing, 2007). The data were extracted by two reviewers. The following data were extracted from each study: author‘s last name and year of publication, location, study characteristics which included the period when the studies were conducted and the number of participants in that study, intervention, outcomes (conclusion), quality rating of the study and recommendations.

Table 6.4 below depicts the summary of the extracted data.

Table 6.4: Data extraction

Study No.	Author, Date	Location	Title of the Study	Type of Model	Study Design	Participants & Sample Size	Data Collection	Outcomes/ Results	Conclusions/ Recommendations
1.	Dudhia et al., 2015.	Cape Town, South Africa	Experience of participating in an antiretroviral treatment adherence club	Adherence Clubs	Not clearly described	Six ART adherence club members and seven health care workers, which included HIV nurses, medical doctors, pharmacists and counsellors.	Interviews which covered ART users' experiences of the clubs.	• Cohesion among club members emerged as a strong theme. • Different patient identity. • The need for more clubs	• Adherence clubs are a potentially important and useful innovation in ART care in the South African public health system • The resolution of logistical problems requires research at a health systems level, rather than at an individual personal level.
2.	Grimsrud et al., 2015	Cape Town, South Africa	Implementation of community-based adherence clubs for stable antiretroviral therapy patients in Cape Town, South Africa.	Community -based Adherence Clubs	Model Implementation	All patients down-referred to an adherence club between May 2012 and December 2013	A summary of the CAC data aggregated at the level of the CAC was completed by the CHW following each CAC visit and monthly group level reports were compiled for the DOH	• From June 2012 to December 2013, 74 CACs were established, each with 25–30 patients, providing ART to 2133 patients. • CAC patients were predominantly female (71%) and lived within 3 km of the facility (70%). • During the analysis period, 9 patients in a CAC died (<0.1%), 53 were up-referred for clinical complications (0.3%) and 573 CAC patients sent a buddy to at least one CAC visit (27%). • After 12 months in a	• Over a period of 18 months, a community-based model of care was rapidly implemented decentralizing more than 2000 patients in a high-prevalence, resource-limited setting. • Further research is needed to support down-referral sooner after ART initiation and to describe patient experiences of community-based ART delivery. • Further research is needed to assess

								CAC, 6% of patients were lost to follow-up and fewer than 2% of patients retained experienced viral rebound.	factors associated with retention in this model of care and long-term outcomes of decentralized patients.
3.	Wilkinson et al., 2016.	Cape Town, South Africa	Expansion of the Adherence Club model for stable antiretroviral therapy patients in the Cape Metro, South Africa.	Adherence Clubs	Model implementation (cohort)	1st – 15 willing ART facilities struggling with congestion, with ART cohorts of more than 1000 patients. 2nd – the clinic size criteria was dropped. 3rd – all remaining willing facilities to implement the AC model were allowed.	Data on patient visits were collected from two routine sources. The first was the monthly AC data aggregated for each club and reported monthly by sites, the second source was the routine EMR in the health district that was used to derive the total ART cohort over the study period.	• Between January 2011 and March 2015, the AC programme expanded to reach 32 425 patients in 1308 Acs at 55 facilities. • The proportion of the total ART cohort retained in an AC increased from 7.3% at the end of 2011 to 25.2% by March 2015. • The number of facilities offering Acs also increased and by the end of the study period, 92.3% of patients were receiving ART at a facility that offered Acs.	○ Additional funding needed to manage the model ○ Research on patient outcome in this model is needed. ○ Studies using qualitative methods to examine patient perspective on this model of care should be conducted. • Conduct a health systems analysis describing the enablers and barriers to scale up within government health services.
4.	Tsondai et al., 2017.	Cape Town, South Africa	High rates of retention and viral suppression in the scale-up of antiretroviral therapy adherence clubs in Cape Town, South Africa.	Adherence Clubs	Cluster random	• Patients enrolled in an AC at non-research supported sites between 2011 and 2014. • 10% of Acs (n = 100) in quintets proportional to the number of Acs at each	• Photographic images of the selected Acs registers were taken at the health care facility. Data from these images were abstracted and entered using double data entry and validation, into	• Retention was 95.2% (95% CI, 94.0-96.4) at 12 months and 89.3% (95% CI, 87.1-91.4) at 24 months after AC enrolment. • In the 13 months prior to analysis closure, 88.1% of patients had viral load assessments and of those, viral loads ≤400 copies/mL were found in 97.2% (95% CI, 96.5-97.8) of patients.	- Growth of and changing eligibility for ART services requires models that provide options of varying formal health service intensity in order to provide patient-centred quality services for all patients - The findings support patient responsive ART services, extending the ART refill interval and

						facility.	the Research Electronic Data Capture (REDCap) database. • Patient clinic folders were then reviewed and data on clinic visits, ART refills and viral loads were abstracted for all patients who had either defaulted from the Acs or been referred back to the clinic. • Data on formal service contacts and viral load results were extracted from the Provincial Health Data Centre.		reducing the need for clinical review consultations to once a year with access to routine viral load monitoring - Research is needed to understand patient expectations and challenges within differentiated care models - With the findings of good outcomes at scale, there is increased evidence for adoption. - Health system research examining the process issues related to establishing, extending and maintaining the model would be beneficial to health policy makers
5.	Grimsrud et al., 2016	Cape Town, South Africa	Community-Based Adherence Clubs for the Management of Stable Antiretroviral Therapy Patients in Cape Town, South Africa: A Cohort Study	Community-Based Adherence Clubs	Cohort Study	Club members and non-members	Data were obtained from the prospectively collected CHC clinical database, the CAC database, and the National Health Laboratory Service database.	• Of the 2113 CAC patients (71% female, 7% youth ages #24 years), 94% were retained on ART after 12 months. • Among CAC patients, LTFU [adjusted hazard ratio (aHR): 2.17, 95% confidence interval (CI): 1.26 to 3.73] and viral rebound (aHR 2.24, 95% CI: 1.00 to 5.04) were twice as likely in youth (16–24 years old)	• Stable primary care patients were successfully managed by CHWs within a community-based model of ART delivery. • Community-based models of care represent a potential alternative to traditional facility-based models of ART delivery. • Higher rates of retention and viral

								compared with older patients.	suppression were maintained in both men and women. • Long-term data are needed to understand how best community-based models of care can improve retention in care with particular attention given to supporting youth
6.	Luque-Fernandez et al., 2013.	Cape Town, South Africa	Effectiveness of patient adherence groups as a model of care for stable patients on antiretroviral therapy in Khayelitsha, Cape Town, South Africa.	Adherence Groups	Retrospective observational evaluation	Adult patients (≥18 years old) who had been on ART for at least 18 months, or who reached 18 months on ART during the study period, and who's most recent CD4 count was above 200 cells/µl.	Data were extracted from the electronic medical record system used in the HIV clinics.	• Of 2829 patients on ART for >18 months with a CD4 count above 200 cells/µl, 502 accepted club participation. • At the end of the study, 97% of club patients remained in care compared with 85% of other patients.	• Models based on patient adherence groups meeting outside of pressurized clinical consultation areas, and facilitated by non-clinical staff, are a promising approach to assist in the next wave of increased access to HIV treatment. • The management of these groups is becoming increasingly challenging as the number of groups associated with a single clinic increases, requiring new management strategies and related research.
7.	Bango et al., 2016	Cape Town, South Africa	Adherence clubs for long-term provision of anti-retroviral therapy: Cost-effectiveness and access analysis from	Adherence Clubs	Observational	Not clearly stated	• Estimation of costs: Provider health care costs for each model of care were calculated per patient year and were expressed in	• Adherence clubs were the more cost-effective model of care and retention in care at 1 year of 98.03% • Viral suppression in clubs was 99.06% for clubs versus 97.20% for	- Adherence clubs offer the potential for enhanced retention in care, enhanced viral suppression, lower provider costs, and improved accessibility when compared to

			Khayelitsha, South Africa				2011 prices, converted to US Dollars (US$ 1 = ZAR 7.56). • Estimation of effectiveness: Estimates of retention in care and viral suppression at one year on ART were derived from a retrospective observational study that evaluated the effectiveness of clubs versus SOC at the same clinic (Luque-Fernandez et al., 2013).	standard of care.	routine clinic-based ART care. - Similar models of care should be considered for wide-scale implementation
8.	Wilkinson et al., 2013	Cape Town, South Africa	ART adherence clubs: A long-term retention strategy for clinically stable patients receiving antiretroviral therapy	Adherence Clubs	Model implementation (No design)	At first, 50 patients on ART from >18 months. Later, 30 patients on ART from >12 months.	Roll-out of the club: -Formation of steering committee - Training of mentors Facility club teams were formed	- The group met either at a facility or community venue for less than an hour every 2 months. - Group meetings were facilitated by a lay club facilitator who provides a quick clinical assessment, referral where necessary, and dispenses pre-packed ART.	- The ART-adherence club model improves adherence and long-term retention in care among clinically stable ART patients, while ptimizing health resources to manage new ART patients and patients at risk of failing treatment. - It is imperative that SA considers a similar model for national rollout.

6.3.3 STEP 4: Summarising the Evidence

This section included data synthesis.

6.3.3.1 Data Synthesis

Narrative synthesis was used because the review included studies of diverse designs and therefore meta-analysis was scientifically not justified. According to the Social Science Research Unit (SSRU, 2010) the objective of narrative synthesis is to bring together the results of empirical research that are in a narrative form to provide an accessible combination of results from individual studies in structured narratives or summary tables. According to SSRU (2010), conducting a narrative synthesis involves four main elements:

- Developing a theory of how the intervention works, why and for whom.
- Developing a preliminary synthesis of findings of included studies.
- Exploring relationships within and between studies.
- Assessing the robustness of the synthesis.

Element 1: Developing a theory of how the intervention works, why and for whom

In 2014, UNAIDS (2014) set new and ambitious targets to have 90% of people living with HIV know their status, 90% of those diagnosed HIV positive accessing ART, and 90% of those virally suppressed, or '90-90-90', by 2030. These goals became even more important as we officially entered the test-and-treat era. WHO now recommends ART initiation immediately after HIV

diagnosis (WHO, 2015), reflecting evidence from the START and TEMPRANO trials (Danel et al., 2015; Lundgren, Babiker, et al. 2015). The question was no longer when to start ART, but rather how to effectively deliver ART and support life-long retention and adherence for all HIV diagnosed patients in ART care (Wilkinson, et al. 2016).

Models of care that increase ART management efficiencies for patients by reducing visit frequency and decentralising services closer to patients' homes have since evolved in resource-limited settings and have demonstrated improved retention and viral suppression outcomes (Kredo, et al. 2013; WHO, 2014; Duncombe, et al. 2015). A differentiated care approach argues that the health system responds as patient needs change, and so once a patient is stable on ART, simplifying drug collection mechanisms and reducing unnecessary clinical follow-up visits should be prioritised to support ongoing retention and adherence (Wilkinson, et al. 2016). The evidence for differentiated models of ART delivery is expanding (Luque-Fernandez, et al., 2013; Wilkinson et al. 2013; Grimsrud, et al. 2014; Jaffar, et al. 2009; Kipp, et al. 2011; Grimsrud, et al. 2016; Grimsrud, et al. 2015). However, there is limited evidence available on the feasibility of taking these models to scale.

Element 2: Developing a preliminary synthesis of findings of included studies

In this review 9 studies were reviewed. Most of the evidence for health care worker-managed group models came from implementation of the ART adherence club (AC) model in Cape Town, South Africa. The aims of the studies were mainly to evaluate the ACs, measure the outcomes specific to the ACs and describe issues related to ACs.

In their qualitative study, Dudhia, et al. (2015) sought to document the experiences of patients attending adherence clubs, and health care workers at clinics where clubs were operating. Details of the ACs model expansion by Wilkinson, et al. (2016) highlighted that from January 2011 to March 2015, 32,425 clients were in an AC (25.2% of the total ART cohort), and fifty-five facilities were offering a total of 1,308 ACs. In a cluster random sample of 10% of the Cape Town ACs (3,216 adults) from non-research supported ART sites, retention was 95.2% at 12 months and 89.3% at 24 months. In the 13 months prior to database closure, 88.1% of clients had viral loads (VL) taken with VL ≤400 copies/ml in 97.2% (Tsondai, et al. 2017).

Two comparison cohort studies reported client outcomes from ACs (Luque-Fernandez, et al. 2013; Grimsrud, et al. 2016). In the pilot study in Khayelitsha, Cape Town, retention at study end was 97% for those stable clients who enrolled in an AC versus 85% for those who did not. Loss to follow up (LTFU) was reduced by 57% and viral rebound (re-emergence of detectable plasma HIV viral load) by 67% (Luque-Fernandez, et al. 2013).

In a cohort study (Grimsrud, et al. 2016), 94% were retained at 12 months post AC enrolment, with 3% experiencing viral rebound by study end. A costing study found the Khayelitsha piloted AC model cost effective, with a cost per patient year of $300 versus $374 for standard of care (Bango, et al. 2016). In a cross-sectional study, Grimsrund, et al. (2015) described the adjusted AC model implemented in Gugulethu, where ACs were run at a community venue instead of the clinic.

Element 3: Exploring relationships within and between studies

Table 6-5: Relationship within and between studies

Study	Type of Model	Benefits	Challenges
1. Dudhia et al., 2015.	Adherence Clubs	• Reduced amount of time ART users needed to spend at the clinic. • ART users processed more rapidly. • Opportunity for cohesion among patients.	• Logistical problems associated with the timely and correct delivery of drugs. • Poor communication between the clinic and the Central Dispensing Unit • Stigma • Understaffing
2. Grimsrud et al., 2015	• Community-based adherence clubs • Task-shifting	• High levels of retention and virologic suppression. • Improved patient self-management. • Decongested primary health care facility.	• Patients in community-based models not viewed as the responsibility of the facility • Ensuring access to a clean and appropriate community-based facility. • Different categories of staff have different line managers • Policies regarding dispensing and distribution (i.e. only two months of ART allowed to be dispensed per visit). • Frequent ART shortages in many areas of the country • Limited resources within the community venue and distance to CHC for supplies.
3. Wilkinson et al., 2016.	Adherence Clubs	Not reported	Not reported
4. Tsondai et al., 2017.	Adherence Clubs	• High rates of retention and viral suppression. • Generalisability of the study	None reported

5. Grimsrud et al., 2016.	Community-Based Adherence Clubs	Decrease in the risk of LTFU regardless of CD4 cell count	None reported
6. Luque-Fernandez et al., 2013.	Adherence Groups	• Improved retention on ART • Decreased rates of virologic rebound	
7. Bango et al., 2016.	Adherence Clubs	• Fewer missed visits • Shorter waiting times • Higher acceptability of services	None reported
8. Wilkinson et al., 2013.	Adherence Clubs	• Increased retention in clinic care • Patients less likely to experience virological rebound indicating better adherence	• Bigger groups difficult to manage • The club model doesn't alleviate overall pharmacy burden

Element 4: Assessing the robustness of the synthesis

The same tool (Quality Assessment of HIV/AIDS Provider Training Tool) used to appraise the selected articles as explained in 6.2.2.1.3 STEP 3: Performing the critical appraisal, was used to evaluate the quality of this review.

Overall, the studies that were included in the review met all the criteria stipulated in the Quality Assessment of HIV/AIDS Provider Training Tool. The tool as an instrument was used to reduce the researcher's bias and guide the critical appraisal. The researcher reported the quality appraisal of each of the relevant studies. The level of evidence was also assigned for each critically appraised article and was rated. The data was extracted by two reviewers. Based on this assessment process, we concluded that the findings obtained based on these studies

and presented in this review could provide valuable and credible information on which sound conclusions could be drawn.

6.4 DISCUSSION OF FINDINGS

This section summarises the findings of the study and its implications. The aim of the discussion is to deliberate on the key findings of the study, thus placing the study in context (Russell, 2009). The purpose of this study was to review literature on the implementation of existing models of the ART programme in SA.

Médecins Sans Frontières (MSF) pioneered four innovative ART service delivery models (differentiated models) to offer services to different groups of patients (Médecins Sans Frontières, 2013): (1) Healthcare worker-managed groups (known as adherence clubs ACs), (2) Client-managed groups (Adherence Groups or CAGs), (3) Facility-based individuals models (the six-monthly appointment or SMA programme) and (4) Out-of-facility individual models (known as Community Drug Distribution Points (CDDPs).

Many of the reviewed studies came from the implementation of the ART adherence club (AC) model in Cape Town in SA, suggesting that there were no other ART models implemented in SA during the review period. Including the studies that did not meet the review criteria, this research found that there were no other studies implementing ART delivery models outside Cape Town. Overall, the studies revealed that adherence clubs offer the potential for enhanced

retention in care, enhanced viral suppression, lower provider costs and improved accessibility when compared to routine clinic-based ART care (Grimsrud, et al. 2015; Bango, et al. 2016; Tsondai, et al. 2017; Luque-Fernandez, et al. 2013; Grimsrud, et al. 2016). The extensive and quick rollout of the ACs demonstrates the need for quick, patient-friendly access to care and treatment for clinically stable ART patients (Grimsrud, et al. 2015).

Two studies (Grimsrud, et al. 2015; Grimsrud, et al. 2016) describe community-based adherence clubs. Community-based models of care allow patients to return to normal life and increase their self-management, thus increasing the effectiveness of ART delivery (Ford & Mills, 2011; Alamo, Wagner, & Sunday, 2012). The challenge of community-based delivery models comes from the physical location outside of existing health facilities, maintenance at community venues and unclear responsibilities of staff outside the facilities (Grimsrud, et al. 2015). Being located of the primary care facility also provides daily logistical challenges due to transportation of materials between the community facility and the primary care facility (Grimsrud, et al. 2015). There is a need to put measures in place to guard against deteriorating quality of care within these types of models as treatment cohorts expand and as ART cohorts mature (Tsondai, et al. 2017).

This review has important policy implications. It found that ACs were cost-effective compared with standard of care with regard to achieving two of three of the UNAIDS 90-90-90 targets, namely retaining 90% of people tested for HIV on antiretroviral therapy and maintaining viral

suppression in 90% of people on ART (UNAIDS, 2014). Within this context, the ACs represent an important public health strategy as they have the potential to expand the capacity of the current health system while at the same time making it easier for patients to stay on long term treatment effectively. However, if South Africa is to accomplish its aim of adopting the WHO's test and treat strategy (Motsoaledi, 2016), addressing human resource shortages is among the factors that needs urgent attention.

Other studies on client-managed group models which did not form part of this review were conducted in Tete community ART groups in Mozambique (Decroo, et el. 2013; Rasschaert, et al. 2014; Jobarteh, et al. 2016). The studies reported improved client outcomes with reduced financial and time costs compared to those associated with frequent clinic visits. Other limited studies on facility-based individual models were reported from three studies in Uganda (Babigumira, et al. 2011; Alamo, et al. 2013; Obua, et al. 2014). The models involve extending appointment spacing and refill periods, resulting in increased cost effectiveness for the health system, improved quality of care and client outcomes and reduction in client time spent accessing health care.

Out-of-facility individual models were also reported in various countries outside SA. Fixed community points were reported from the study on the community drug distribution point model in Uganda (Okoboi, Ding, Persuad, et al. 2015) and the community ART distribution points in the Democratic Republic of Congo (Vogt, Kalenga, Lukela, et al. 2016). There was

limited published evidence of utilising mobile outreach services to distribute ART refills away from the health facility. The outcomes from home ART delivery models were reported from two randomised control trials in Uganda and Kenya (Jaffar, Amuron, Foster et al. 2010; Selke, Kimaiyo, Sidle, et al. 2010). The two studies reported no differences in client outcomes between the groups; however, in Kenya, intervention clients made half as many clinic visits as did controls.

Widespread implementation of ART distribution models is relatively new, and studies will continue to emerge. Differentiated models of care are an inevitable necessity (Tsondai, et al. 2017). Understanding the benefits and challenges of different models of care can help SA to identify and implement models of care for patients to meet the growing needs of long-term ART patients (Tsui et al. 2017). The AC model has already been adopted (NDoH, 2016) as South African national policy and similar models are in the national guidelines of Swaziland (MoH Swaziland, 2016) and Zimbabwe (MoHCC Zimbabwe, 2015).

6.5 LIMITATIONS OF THE STUDY

1). The review was limited to SA and only the Western Cape province has implemented the adherence clubs model as an ART delivery model. This has limited the review for other ART delivery models outside SA.

2). The study focused on studies which were published or reported during the period 2013 to 2018 only. This excluded studies which were published prior to 2013.

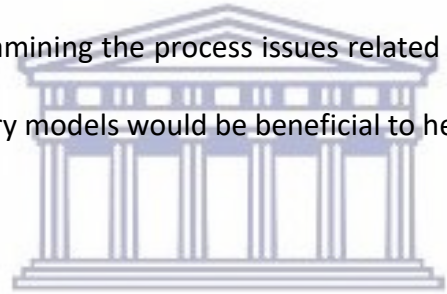
6.6 RECOMMENDATIONS

1). The adherence clubs model of care should be considered for wide-scale implementation in SA.

2). Additional data and shared experiences from innovative community-based models of care are needed in SA to support long-term ART retention. ART cohorts in resource-limited settings continue to expand and mature.

3). Further research is needed to understand patients' expectations and challenges within differentiated care models.

4). Health system research examining the process issues related to establishing, extending and maintaining the ART delivery models would be beneficial to health policy makers.



6.7 CONCLUSION STATEMENTS

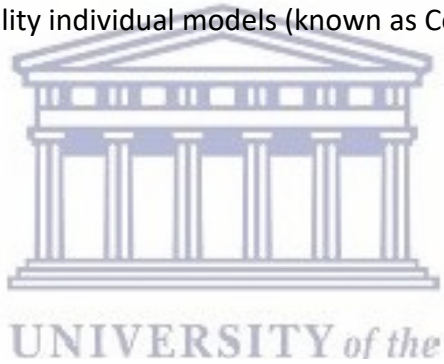
1. Two models, namely (a) adherence clubs and (b) community-based adherence clubs are implemented in different parts of SA, with (a) more commonly implemented.

i. The adherence clubs model (a) is facilitated by lay club facilitators who provides a quick assessment, dispense pre-packed ARTs, and refer to a clinician.

ii. The community-based adherence club model (b) is facilitated by community health workers and supported by a nurse.

2. The adherence clubs model seems to be more successfully implemented because there are measurable outcomes derived from it.

3. Although the adherence clubs model is used, the management of the groups will become increasingly challenging as the number of groups increases, requiring new management strategies and related research.
4. Much of the literature on adherence clubs has focused on reporting results of the specific interventions carried out; however, there were few details on the enablers and barriers that are key to replication and scale-up.
5. There is no evidence of implementation of the other 2 models of differentiated care i.e. facility-based individuals models (the six-monthly appointment or SMA programme) and out-of-facility individual models (known as Community Drug Distribution Points) in SA.



6.8 CHAPTER SUMMARY

Chapter 6 presented the systematic literature review of studies on the implementation of different ART models in SA. Many of the reviewed studies came from the implementation of the ART adherence club (AC) model in Cape Town, SA. Two studies implemented community-based adherence clubs. The limited range of ART delivery models in SA indicate the urgent need to implement community-based ART models that have been tested in other countries, or the need to develop new ones if SA is to accomplish its aim of adopting the WHO's test and treat strategy (WHO, 2016).

Chapter 7 will describe the ART model development using the Delphi technique.

CHAPTER 7: DEVELOPING AN ART MODEL USING THE DELPHI STUDY TECHNIQUE

PHASE THREE

7.1 INTRODUCTION

The focus of this phase is on the development of the ART model. In the first section of this chapter the researcher discusses the identification of the main concepts using the Delphi technique, classification, and the definition of the concept that form the building blocks of the model for the ART programme. The main concepts were identified from the conclusion statements derived from Chapter 5 (empirical data) and Chapter 6 (systematic literature review). Identified core concepts were classified using the survey list of Dickoff, et al. (1968). A summary of the conclusion statement is outlined in Table 7-1.

The second section of the chapter describes the model which was developed based on the objective of Phase 3 which was:

- To develop a model that will be used to improve ART programmes in KwaZulu-Natal using the Delphi technique.

The model developed for this study used the Donabedian approach (1980) which has three elements: the structure, process and outcome as the framework for this research in Phase 1.

The description of the model is presented to permit the reader's understanding of the substance and beliefs on which the model is based. Aspects that are addressed include assumptions of the model, description of the model and evaluation of the model. The model evaluation is discussed followed by the guidelines for operationalisation of the model. The chapter summary is provided after model evaluation is addressed.

Table 7-1 Conclusion statements of the analysis of the programme and the systematic review

EMPIRICAL DATA: ANALYSIS OF THE ART PROGRAMME *(CHAPTERS 3,4 & 5)*			**SYSTEMATIC REVIEW** *(CHAPTER 6)*
STRUCTURE OF THE ART PROGRAMME	**PROCESSES TO IMPLEMENT THE ART PROGRAMME**	**OUTCOME OF THE PROGRAMME**	
1. Most facilities did not have adequate seating for all the patients in the three districts; Ethekwini, Umkhanyakude and Uthungulu. **2.** All districts had adequate furniture in consultation rooms. **3**. Vital signs rooms of all facilities in all districts had the required equipment. **4.** The guidelines, policies and strategies that were developed for the multiple areas of care and support were all available in all facilities of all four districts (Ethekwini, Umkhanyakude, Uthungulu and Ugu) except policies for legal support to people living with HIV. **5**. The majority of staff in all districts were trained; all doctors and professional nurses in all districts received some form of training in HIV care. Social workers and community treatment supporters were the least trained across districts. **6**. There were shortages of antiretroviral drugs in all facilities of all districts in the last six months following the review. **7**. Delay in the return of laboratory results hampers service delivery.	**8.** Facilities in all districts had systems, resources and services in place to implement the ART programme.	**9**. HIV testing coverage rates were below the 90% target set by the national government. **10.** The rate of clients remaining on ART ranged from 53% to 61% while the national average for the same period was 55%. **11**. The number of deaths from HIV related illnesses ranged from 3.2% to 7.9% in all districts. **12**. The incidence of HIV amongst persons fifteen years and older was 3.2% - 3.3%, higher than the national HIV incidence of 1.8 for the same period. **13.** The rate of mother to child transmission of HIV at six weeks was lower in some districts at 1.2% and in other districts was 1.4%, similar to the national estimate of 1.4% for the same period. **14**. The rate of clients who were screened for TB symptoms was 50% and below in all districts. **16**. The male and female condom distribution rates were below the national average of 47,5%, implying insufficient distribution rates in the four districts. **17**. All districts recorded a high number of medical male circumcisions.	**18**. Two models, namely (a) adherence clubs and (b) community-based adherence clubs are being implemented in different parts of SA, with 1 (adherence clubs) implemented more than the other. (a). The adherence clubs model is facilitated by lay club facilitators who provide a quick assessment, refer to a clinician and dispense pre-packed ART. (b). The community-based adherence club model is facilitated by community health workers and supported by a nurse. **19**. The adherence clubs model seems to be more successfully implemented because there are measurable outcomes derived from it. **20**. Although the adherence clubs model is used, the management of the groups will become increasingly challenging as the number of groups increases, requiring new management strategies and related research. **21**. Much of the literature on adherence clubs focused on reporting results of the specific interventions carried out; however, there were few details on the enablers and barriers that are key to replication and scale-up. **22**. There is no evidence of implementation of the other 2 models of differentiated care i.e., facility-based individuals models (the six-monthly appointment or SMA programme) and out-of-facility individual models (known as Community Drug Distribution Points) in SA.

SECTION ONE: IDENTIFICATION, CLASSIFICATION AND DEFINITIONS OF CONCEPTS

7.2 IDENTIFICATION OF CONCEPTS USING THE DELPHI TECHNIQUE

The Delphi technique was used to identify concepts which were classified and conceptualised using the six elements of practice theory as described by Dickoff, et al. (1968:434), namely:

(1) Agent; (2) Recipients; (3) Context; (4) Procedure; (5) Goal; and (6) Dynamic.

Delphi is a method for the "*systematic solicitation and collation of judgments on a particular topic through a set of carefully designed sequential questionnaires interspersed with summarised information and feedback of opinions derived from earlier responses*" (Gould, 2011; Okoli, 2004).

The Delphi technique is a systematic and interactive method which relies on a panel of experts who anonymously reply to questionnaires and subsequently receive feedback in the form of a representation of the group response, after which the process repeats itself. The purpose for using this technique was to reduce the range of responses and arrive at something closer to expert consensus.

7.2.1 Selection of Delphi Participants

A nomination process was used in the selection of participants. This involved compiling a list of people with expert knowledge of ART programmes, and an understanding of the implementation of public health programmes and the South African health care system. Regarding any set standards of selecting Delphi subjects, there is no exact criterion currently listed in the literature (De Villiers, 2005). Among criteria which were considered was national or international reputation; they must have conducted research, written, or lectured on the topic of this study. Individuals were considered eligible to be invited to participate in the study if they were capable of contributing meaningfully and were willing to revise their initial or previous judgments for the purpose of reaching a consensus. The pool consisted of ten (10) panelists; this number was sufficient to provide a representative pooling judgement that would result in a Delphi study of homogeneous nature (Johnson, Miller & Summers, 1987). Delbecq, et al. (1975) recommend that researchers should use the minimally sufficient number of subjects and should seek to verify the results through follow-up explorations. Ten to fifteen subjects could be sufficient if the background of the Delphi subjects is homogeneous. In this study the background of participants was homogenous as they all had knowledge of ART programmes and HIV care services.

7.2.2 RECRUITMENT PROCEDURE FOR DELPHI PARTICIPANTS

Participants were invited to participate in the study mainly by email. They were sent a signed invitation letter by email (see Appendix 7-1). In the letter, the researcher thanked the individual for participating, and provided instructions and a response date. The letter explained why the study needed the assistance of an expert, outlined the Delphi study and process and explained how the results would be used. Of the nineteen (19) participants contacted, ten (10) agreed to participate in the study, six (6) did not respond to the researcher's email and three (3) declined the invitation. Consent to participate in the study was sought from the ten (10) participants. They were sent the consent form to complete (see Appendix 7-2) and the guidelines on how to go about responding to the questionnaires. Participants were given two weeks to return their responses, i.e. from the mailing date to receiving their responses. A day after emails were sent, the researcher contacted each participant telephonically to verify if the email was received, answer questions if any and encourage the completion and return of the questionnaire.

7.2.3 DETERMINING THE LEVEL OF CONSENSUS

A variety of methods has been proposed in different studies to determine the level of consensus in the Delphi technique (Hsu & Sandford, 2007). Some researchers have determined Delphi rounds as a basis for reaching agreement. Between 2 and 10 rounds have been reported in various articles (Windle, 2004). Ku Fan and Cheng believe research has shown that three rounds are adequate for the Delphi technique (Ku Fan & Cheng, 2006]. Some also argue that

the traditional Delphi contains four rounds, and that researchers have shortened it into two or three rounds to achieve the study's objectives (Nevo & Chan, 2007; Turoff & Linstone, 2002).

7.2.4 THE DELPHI PROCESS

Theoretically, the Delphi process can be continued until consensus is achieved. However, Cyphert and Gant (1971), Brooks (1979), Ludwig (1997) and Custer, Scarcella and Stewart (1999) point out that three rounds are sufficient to collect the needed information and to reach a consensus in most cases (Hsu & Sandford, 2007). In this study, the Delphi technique followed three (3) rounds.

7.2.4.1 ROUND 1 OF THE DELPHI TECHNIQUE

In the first round, the process began with position statements. The position statements which sought to identify the concepts were distributed to 10 participants.

The position statements were as follows:

1. **Agent**: Who should be the person performing the activity to deliver effective antiretroviral treatment (ART) programme services for maximum impact?
2. **Recipient**: Who should be the receiver of ART delivery services?
3. **Context**: In what context should ART services be conducted for maximum impact?
4. **Procedure**: What should be the technique or protocol of ART service delivery?
5. **Goal**: What should be the outcome or the end point of ART service delivery?
6. **Dynamic**: What is the interactive relationship and engagement between the Agent and the

Recipient on ART service delivery?

The suggestions were subjected to content analysis of written responses to each question (Altschuld, 1993; Delbecq, et al. 1975). Content analysis is a general term for a number of different strategies used to analyse text (Powers & Knapp, 2006). It is a systematic coding and categorising approach used for exploring large amounts of textual information to determine trends and patterns of words used, their frequency, their relationships, and the structures and discourses of communication (Mayring, 2000; Pope, Pope, Ziebland & Mays 2006; Gbrich, 2007).

The analysis followed the content analysis steps as described by Erlingsson & Brysiewicz (2017):

(1) Dividing up the text into meaning units and condensing meaning units

(2) Formulating codes and

(3) Developing categories.

Dividing up the text into meaning units and condensing meaning units:

This process involved dividing up the written text into smaller parts, known as meaning units (Erlingsson & Brysiewicz, 2017). The aim of this research was to identify concepts using the six elements of practice theory as described by Dickoff et al., (1968). Keeping the research aim clearly in focus, the written text was divided into meaning units then condensed further while retaining the core meaning of data (see Table 7-2). This meant that the written text was presented in a shorter version of the same text but still conveyed the essential message of the meaning unit. The meanings of similar suggestions in each item were summarised to formulate one statement.

Table 7-2: Dividing meaning units into condensed meaning units

CONCEPT	POSITION STATEMENT	RESPONDENTS	MEANING UNITS	CONDENSED MEANING UNITS
1. AGENT:	Who should be the person performing the activity to deliver effective antiretroviral treatment (ART) programme services for maximum impact?	**Participant #1:**	"Nurse"	*Nurse*
		Participant #2:	"Volunteer or treatment supporter"	*Volunteers / treatment supporter*
		Participant #3:	"Doctor"	*Doctor*
		Participant #4:	"Community health worker" (CHW)	*CHW*
		Participant #5:	"Clinic nurse"	*Clinic nurse*
		Participant #6:	"Pharmacist or nurse"	*Pharmacist / nurse*
		Participant #7:	"Nurse"	*Nurse*
		Participant #8:	"Community Volunteer"	*Community Volunteer*
		Participant #9:	"Nurse"	*Nurse*
		Participant #10:	"Nurse"	*Nurse*
2. RECIPIENT:	Who should be the receiver of ART delivery services?	**Participant #1:**	"Patients on ARVs"	*ART patients*
		Participant #2:	"Patients on HIV medication"	*ART patients*
		Participant #3:	"HIV patients"	*HIV patients*
		Participant #4:	"HIV- positive patients"	*PLWHIV*
		Participant #5:	"Patients"	*Patients*
		Participant #6:	"Clinic patients"	*Patients*

		Participant #7:	"ART patients"	*ART patients*
		Participant #8:	"HIV patients"	*PLWHIV*
		Participant #9:	"People living with HIV"	*PLWHIV*
		Participant #10:	"HIV positive patients"	*PLWHIV*
3. CONTEXT:	In what context should ART services be conducted for maximum impact?	**Participant #1:**	"ART must be provided at the clinic by the nurses"	*Provider-based ART*
			"The nurse can prescribe medication if the doctor is not available"	*Nurse prescribe ART*
			"The doctor must see the patient on a 3 monthly basis"	3-monthly consultations
		Participant #2:	"The volunteer can distribute ART to the patients or at their home to save time and cost"	*Volunteer must distribute ART to homes*
			"Its expensive for patients to visit the clinic some they default"	*Clinic visits are costly*
			"The resources must be made available in the community so that clinics must not be overcrowded"	*Community to play an important role*
		Participant #3:	"Patients can be treated at the hospital but collect their medication every 6 months"	*Facility-based ART and 6 monthly*
		Participant #4:	"With the differentiated ART delivery which has been adopted by DoH, ART can be provided at the community"	*Differentiated care delivery*
			"Some patients cannot afford to travel to the	*Clinic visits are unaffordable*

			clinic" "The clinic cannot accommodate all patients who need treatment"	 *Clinics are overcrowded*
		Participant #5:	"The clinics have provided ART to patients successfully, they must continue to do so". "But sometimes there no enough resources to take care of all patients" "More HIV service centers can be established"	*Clinic-based ART* *Lack of resources* *HIV service centers*
		Participant #6:	"The clinic must make sure that the pharmacist has medication because sometimes clinics run out of medication" "Patient visit the clinic every 3 months to collect their ARVs"	*Prevent medication stock out* *3-monthly appointments*
		Participant #7:	"Nurses are trained to provide ART at the clinic but they are over worked because there are many patients requiring ART" "Patients must collect their ARVs at the clinic" "Department of health must increase the human resources to meet the needs of all HIV patients"	*Nurses are over worked due to many patients* *Clinic-based ART* *Additional human resources needed*
		Participant #8:	"The number of patients receiving ARVs is increasing in the clinics. It is recommended that ART be delivered at the patient's home if government can afford" "All HIV patients can access the medication if taken closer to them"	*High number of patients in clinics. Home-based ART* *Medication taken to the patient*

			"There is a risk of patients defaulting on medication, but it can be tried"	*Risk of poor adherence to medication*
		Participant #9:	"Clinics are well positioned to provide HIV services, but they are normally full, patients wait for the entire day to get treatment" "Lay counsellors can also assist with the provision of ART in the clinics"	*Clinic-based ART but over crowded* *Lay counsellors part of ART delivery*
		Participant #10:	"ART can be provided at the clinic so that hospitals can treat serious conditions"	*Clinic-based ART*
4. PROCEDURE:	What should be the technique or protocol of ART service delivery?	**Participant #1:**	"Patients must visit the clinic every 3 months to collect their medication or when they are sick"	*3-monthly medication collection*
		Participant #2:	"The volunteer or someone must deliver ART to the patient's home but they will need training" "Nurses must supervise the volunteers and monitor patients clinically" "Patient must be referred to the clinic if their health condition deteriorates"	*Volunteers to deliver ART to homes* *Nurses supervise volunteers* *Patient referred to clinic*
		Participant #3:	"DoH has guidelines to provide ART, that must be followed"	*Guidelines for ART provision*
		Participant #4:	"It will be easier to use CHW because they live closer to the patients, but they must be trained to render HIV services"	*CHW be part of ART delivery*
		Participant #5:	"Nurses can work with lay counsellors to give ART to ease the workload"	*Nurses work with lay counsellors*

			"Patients follow up must be done according to guidelines"	*Follow up according to guidelines*
		Participant #6:	"Medication must be prescribed according to the guidelines" "ARVs must be always available to avoid drug resistance"	*ARV prescription* *No ARVs stock outs*
		Participant #7:	"The clinical guidelines to provide ART must be followed"	*Guidelines for ART provision*
		Participant #8:	"The volunteers must be trained so that they can deliver ART according to the guidelines" "ART must be delivered to the patient's home and all necessary care must be given" "The clinical staff at the clinic can be responsible for the clinical aspect of the patient."	*Volunteers to deliver ART* *ART delivered to patients' homes* *Clinical staff to care for patients clinically*
		Participant #9:	"HIV services must be integrated into other services to reduce the overburden of providing ART" "This will help to reduce the stigma"	*HIV services integrated into other services* *Stigma reduction*
		Participant #10:	"Other health care cadres like lay counsellors or treatment supporters must be trained and assist in the provision of ART" "Patients who are stable can be referred to the community and be enrolled in e.g. adherence clubs"	*Lay counsellors or treatment supporter to be trained to provide ART* *Stable patients be referred to adherence clubs*

5. Goal:	What should be the outcome or the end point of ART service delivery?	**Participant #1:**	"Adherence to ARVs must be monitored"	*Monitor adherence*
		Participant #2:	"Patient's general well being and adherence to medication while visited by the volunteers" "Patient's retention to the system must be checked"	*Patient's well being and adherence to medication* *Retention to care*
		Participant #3:	"Routine blood test results like viral load and CD4 count"	*Viral load and CD4 count*
		Participant #4:	"Patients overall health must be monitored because they will not be visiting the facility frequently" "Adherence to medication"	*Patient's overall health be monitored* *Adherence to medication*
		Participant #5:	"Viral load suppression and stable CD4 count"	*Viral load and CD4 count*
		Participant #6:	"Blood test must be checked regularly and adjustment to care done if necessary"	*Regular blood tests*
		Participant #7:	"Patients must be retained in the healthcare system and be alive"	*Retention in health care*
		Participant #8:	"Patient must be retained in the health care system because it will be easy for them not to be trained" "Adherence to ARVs"	*Retention in health care* *Adherence to ARVs*
		Participant #9:	"Patient's health status must be checked and they must do regular blood tests"	*Health status and regular blood tests*

		Participant #10:	**"**Blood tests to monitor viral load and CD4 count" "Patients must not die while on ART" programme"	*Viral load and CD4 count* *Assess mortality*
6. Dynamic:	What is the interactive relationship and engagement between the Agent and the Recipient on ART service delivery?	**Participant #1:**	"The agent must provide all the necessary HIV services to the recipient"	*Agent provide care to recipient*
		Participant #2:	**"**The clinic must establish a team that is dedicated to providing ART to patients at home"	*ART team*
		Participant #3:	"The agent must assess the patient, prescribe ART and monitor the patients' response to ART"	*Agent provide care to recipient*
		Participant #4:	"The adherence clubs can be used to deliver ART to patients" "Lay workers and peer patients can become part of the delivery process"	*Adherence clubs* *Lay workers part of ART delivery*
		Participant #5:	"The clinic must have a dedicated team to provide HIV services. Patients must receive all the required care nurse"	*HIV services team*
		Participant #6:	"The agent must ensure that there are ARVs available at all times for the recipient"	*Agent provides ARVs to recipient*
		Participant #7:	"The recipient must receive the HIV care as stipulated in the guidelines for ART provision"	*Recipient receive HIV care*
		Participant #8:	"Volunteers must work with patients and communities to ensure successful ART delivery where the patients live "	*Volunteers to work with patients and communities*

			"The clinic staff need to work with community to implement the ART programme so that the community understand the benefits of bringing ART to patient's home"	*Clinic staff to work with the community*
		Participant #9:	"The agent must treat, care and support the recipient while providing ART"	*Agent provide care to recipient*
		Participant #10:	"All the necessary steps must be taken by the agent to provide ART to the recipient"	*Agent provide ART to recipient*

Formulating codes:

The next step was to formulate the codes that are descriptive labels for the condensed meaning units (see Table 7-3). The condensed meaning units were described to help the researcher reflect on the data in a new way. The purpose of coding was to identify connections between meaning units.

Table 7-3: Coding of condensed meaning units

CONCEPT	MEANING UNITS CONDENSATIONS	CODES
1. AGENT:	Nurse	Clinic nurse
	Volunteers / treatment supporter	Volunteer
	Doctor	Doctor
	Community health worker (CHW)	CHW
	Clinic nurse	Clinic nurse
	Pharmacist / nurse	Pharmacist
	Nurse	Clinic nurse
	Community Volunteer	Volunteer
	Nurse	Clinic nurse
	Nurse	Clinic nurse
2. RECIPIENT:	ART patients	ART patients
	ART patients	ART patients
	HIV patients	ART patients
	PLWHIV	PLWHIV
	Patients	ART patients
	Patients	ART patients
	ART patients	ART patients
	PLWHIV	PLWHIV
	PLWHIV	PLWHIV
	PLWHIV	PLWHIV
3. CONTEXT:	Provider-based ART	Facility-based ART
	Nurse prescribe ART	Task-shifting
	3-monthly consultations	3 months refills
	Volunteer must distribute ART to homes	Home-based ART
	Clinic visits are costly	Limited clinic visits
	Community to play an important role	Community

	Facility-based ART and 6 monthly	Facility-based ART
	Differentiated care delivery	Differentiated care
	Clinic visits are unaffordable	Limited clinic visits
	Clinics are overcrowded	Poor service
	Clinic-based ART	Clinic-based ART
	Lack of resources	Poor service
	HIV service centers	ART expansion
	Prevent medication stock out	No stock out
	3-monthly appointments	3 months refills
	Nurses are over worked due to many patients	Human resources
	Clinic-based ART	Clinic-based ART
	Additional human resources needed	Human resources
	High number of patients in clinics	Overcrowding
	Home-based ART	Home-based ART
	Medication taken to the patient	Home-based ART
	Risk of poor adherence to medication	Poor adherence
	Clinic-based ART but over crowded	Clinic-based ART
	Lay counsellors part of ART delivery	Task-shifting
	Clinic-based ART	Clinic-based ART
4. PROCEDURE:	3-monthly medication collection	3 months refills
	Volunteers to deliver ART at home	Home-based ART
	Nurses supervise volunteers	Volunteer training
	Patient referred to clinic	Referral system
	Guidelines for ART provision	ART guidelines
	CHW be part of ART delivery	CHW
	Nurses work with lay counsellors	Lay counsellors
	Follow up according to guidelines	ART guidelines
	ARV prescription	ARVs
	No ARVs stock outs	ARVs
	Guidelines for ART provision	ART guidelines
	Volunteers to deliver ART	Volunteers
	ART delivered at patients' home	Home-based ART
	Clinical staff to care for patients clinically	Clinical staff
	HIV services integrated into other services	HIV services integration
	Stigma reduction	Stigma
	Lay counsellors or treatment supporter to be trained to provide ART	Lay counsellors
	Stable patients be referred to adherence clubs	Adherence clubs
5. GOAL:	Monitor adherence	Adherence
	Patient's wellbeing and adherence to medication	Health status
	Retention to care	Retention to care
	Viral load and CD4 count	Viral load and CD4 count

	Patient's overall health be monitored	Health status
	Adherence to medication	Adherence
	Viral load and CD4 count	Viral load and CD4 count
	Regular blood tests	Blood tests
	Retention in health care	Retention
	Adherence to ARVs	Adherence
	Health status and regular blood tests	Blood tests
	Viral load and CD4 count	Viral load and CD4 count
	Assess mortality	Mortality
6. DYNAMIC:	Agent provides care to recipient	Agent provides care to recipient
	ART team	ART team
	Agent provides HIV services to recipient	Agent provides HIV services to recipient
	Adherence clubs	Adherence clubs
	Lay workers part of ART delivery	Lay workers part of ART
	ART team	ART team
	Agent provides ARVs to recipient	Agent provides ARVs to recipient
	Recipient receive HIV care	Recipient receive HIV care
	Volunteers to work with patients and communities	Volunteers work with patients and communities
	Clinic staff to work with the community	Clinic staff work with community
	Agent provides care to recipient	Agent provides care to recipient
	Agent provides care to recipient	Agent provides care to recipient

Developing categories:

In this step the codes were sorted into categories. Codes were compared to determine which codes seem to belong together, thereby forming a category. A category consisted of codes that appeared to deal with the same issue as manifested in the data (see Table 7-4).

The process of dividing up the text into meaning units, formulating codes and developing categories was continuous throughout the analysis as the researcher kept on returning to the raw data to reflect on the initial analysis and reveal connections and relationships (Erlingsson & Brysiewicz, 2017).

Table 7-4: Organisation of coded meaning units into categories

CONCEPT	CODES	CATEGORIES
1. AGENT:	Clinic nurse Clinic nurse Clinic nurse Clinic nurse Clinic nurse	Clinic nurse
	Volunteer Volunteer	Volunteer
	Doctor	Doctor
	Pharmacist	Pharmacist
	CHW	CHW
2. RECIPIENT:	ART patients ART patients ART patients ART patients ART patients ART patients	ART patients
	PLWHIV PLWHIV PLWHIV PLWHIV	PLWHIV
3. CONTEXT:	Facility-based ART Facility-based ART Clinic-based ART Clinic-based ART Clinic-based ART	Facility-based ART
	Home-based ART Home-based ART Home-based ART	Home-based ART

	ART expansion Overcrowding Poor service Poor service No stock out Task-shifting	Health systems strengthening
	3 months refills 3 months refills Limited clinic visits Limited clinic visits	Limited clinic visits
	Human resources Human resources	Increase human resources
	Community Differentiated care	Differentiated care
	Poor adherence	Monitor Adherence
4. PROCEDURE:	ART guidelines ART guidelines ART guidelines	Follow ART guidelines
	Home-based ART Home-based ART	Home-based ART
	3 months refills Adherence clubs	Differentiated care
	Lay counsellors Lay counsellors CHW Volunteers Clinical staff	ART team
	ARVs ARVs	Antiretroviral drugs
	HIV services integration Volunteer training Referral system	Health systems strengthening
	Stigma	Address stigma
5. GOAL:	Adherence Adherence Adherence	Adherence to medication
	Health status Health status	Patient's health status
	Retention to care Retention	Retention to care

	Viral load and CD4 count Viral load and CD4 count Blood tests Blood tests Viral load and CD4 count	Viral load and CD4 count monitoring
	Mortality	Reduced mortality
6. DYNAMIC:	Agent provides care to recipient Agent provides HIV services to recipient Agent provides care to recipient Agent provides care to recipient Recipient receive HIV care	Agent provides HIV services to recipient
	ART team	ART team
	Volunteers to work with patients and communities Clinic staff to work with communities	Clinic staff and volunteers to work with patients and communities
	Adherence clubs	Adherence clubs
	Management team	Management team
	Lay workers part of ART	Lay workers part of ART

7.2.4.2 ROUND 2 OF THE DELPHI TECHNIQUE

In round 2 the participants were asked to review the categories summarised by the researcher based on the information provided in round 1. The participants were required to review their position on the original items based on feedback provided, and rating each item using the five-point Likert-type scale. Ratings ranged from 1 indicating “strongly disagree”; 2 indicating “disagree”; 3 indicating “either agree or disagree”; 4 indicating “agree” to 5 indicating “strongly agree”.

According to Schiebe, et al. (1975), consensus on a topic may be determined by having a certain percentage of votes fall within a prescribed range. Consensus on a statement was considered to have been reached when 80% of the ratings fell within two categories on a five-point scale (Ulschak, 1983). At this stage, areas of disagreement and agreement were identified. Participants were asked to support their opinion with a rationale. Space was provided for participants to add new statements or provide clarification if needed. The items which did not meet the criteria for consensus were excluded. Participants' responses were incorporated into round 3.

Table 7-5 shows results from Round 2 of Delphi. Consensus was reached on the following categories:

AGENT: Clinic nurse, Volunteer and Pharmacist.

RECIPIENT: ART patients and PLWHIV.

CONTEXT: Home-based ART, Increase human resources, Monitor adherence, Limited clinic visits and Differentiated care.

PROCEDURE: Follow ART guidelines, Home-based care, Differentiated care, ART team, Antiretroviral drugs, Health systems strengthening, Address stigma.

GOAL: Adherence to medication, Patient's health status, Retention to care, Viral load monitoring; CD4 count monitoring.

DYNAMIC: Agent provides HIV services to recipient, Clinic staff and volunteer to work with patient and communities, Adherence clubs, Management team, Lay workers part of ART, ART team.

Table 7-5: Results from round 2 of the Delphi

STATEMENT	CATEGORIES FROM ROUND 1	STRONGLY DISAGREE	DISAGREE	EITHER AGREE OR DISAGREE	AGREE	STRONGLY AGREE
1. AGENT: Who should be the person performing the activity to deliver effective antiretroviral treatment (ART) programme services for maximum impact?	Clinic nurse		2		6	2
	Volunteer	1			5	4
	Doctor		3	2	3	2
	Pharmacist		1	1	4	4
	Community health worker		3	4	2	1
2. RECIPIENT: Who should be the receiver of ART delivery services?	ART patients				2	8
	PLWHIV				5	5
3. CONTEXT: In what context should ART services be conducted for maximum impact?	Facility-based ART	1	3		3	3
	Home-based ART	1	1		4	4
	Health systems strengthening		2	3	3	2
	Limited clinic visits			1	4	5
	Increase human resources				6	4
	Differentiated care			4	4	2
	Monitor Adherence				3	7
4. PROCEDURE: What should be the technique or protocol of ART service delivery?	Follow ART guidelines				8	2
	Home-based ART		2		6	2
	Differentiated care	2		3	4	1
	ART team				6	2
	Antiretroviral drugs				4	6
	Health systems strengthening		2	4	2	2
	Address stigma			2	4	5
5. GOAL: What should be the outcome or the end point of ART service delivery?	Adherence to medication					10
	Patient's health status			2	4	4
	Retention to care				5	5
	Viral load monitoring					10
	CD4 count monitoring					10
6. DYNAMIC: What is the interactive relationship and engagement between the Agent and the Recipient on ART service delivery?	Agent provides HIV services to recipients		1	1	6	2
	Clinic staff and volunteers to work with patients and communities				5	5
	Adherence clubs				5	5
	Management team				6	4
	Lay workers part of ART		2	4	3	1
	ART team				1	9

7.2.4.3 ROUND 3 OF THE DELPHI TECHNIQUE

In the third and final round, the ratings, minority opinions, and items which achieved consensus in Round 2 were distributed to the participants using the five-point Likert-type scale. This round provided the final opportunity for participants to revise their judgments. Concepts were finally identified and applied to the Dickoff et al. (1968) survey list in Table 7-6. Figure 7-7 shows how the survey list was applied to classify concepts identified from the Delphi process.

7.2.5 DURATION OF THE STUDY

Delbecq et al. (1975), Ulschak (1983), and Ludwig (1994) recommend that a minimum of 45 days for the administration of a Delphi study is necessary. With regard to the time management between iterations, Delbecq et al. (1975) note that giving two weeks for Delphi subjects to respond to each round is encouraged. In this study, the Delphi process took around 42 days from the time of sending the invitation letters to receiving the final responses. In between the iterations, the participants were given 2 weeks to submit their responses.

7.2.6 DETERMINING RELIABILITY

In determining reliability, Hughes (1993) noted that conventional means of establishing reliability were not appropriate for a Delphi study. One function of the Delphi technique was to encourage participants to modify responses to the group, moving towards consensus. Dalkey, Rourke, Lewis, et al. (1972) reported that there was a definite increase in the reliability of group

responses with increasing group size. In their study, Dalkey (*ibid*) reported, on Rand studies, an increase in reliability of group responses with an increase in group size.

In this study, the final group size was ten. The reliability was established through encouraging participants to modify their responses towards reaching consensus.

7.3 PROCESS OF CLASSIFICATION OF CONCEPTS

Dickoff, et al. (1968) describe practice theory as a type of theory that is situation producing. These authors argue that practice theory is not only born from practice, but it also exists for practical uses. Based on this explicit purpose of a practice theory, the Dickoff et al. (*ibid)* survey list was used as a strategy to classify concepts. The methodological relevance and clarity of the survey list in isolating and placing concepts within their perspective, thereby producing practical guidelines for practice, was the reason for its selection for this study. This technique of classifying concepts points to the influence of the theoretical thinking process when developing a model. It was therefore envisaged that the use of the survey list to develop a model for ART delivery would clarify the competencies required to provide community-based ART.

The use of the survey list allowed the researcher to respond to the following six (6) questions that point to Dickoff's (*ibid*) six vintage elements.

Figure 7-1 depicts how the survey list was applied to classify concepts identified from the Delphi process.

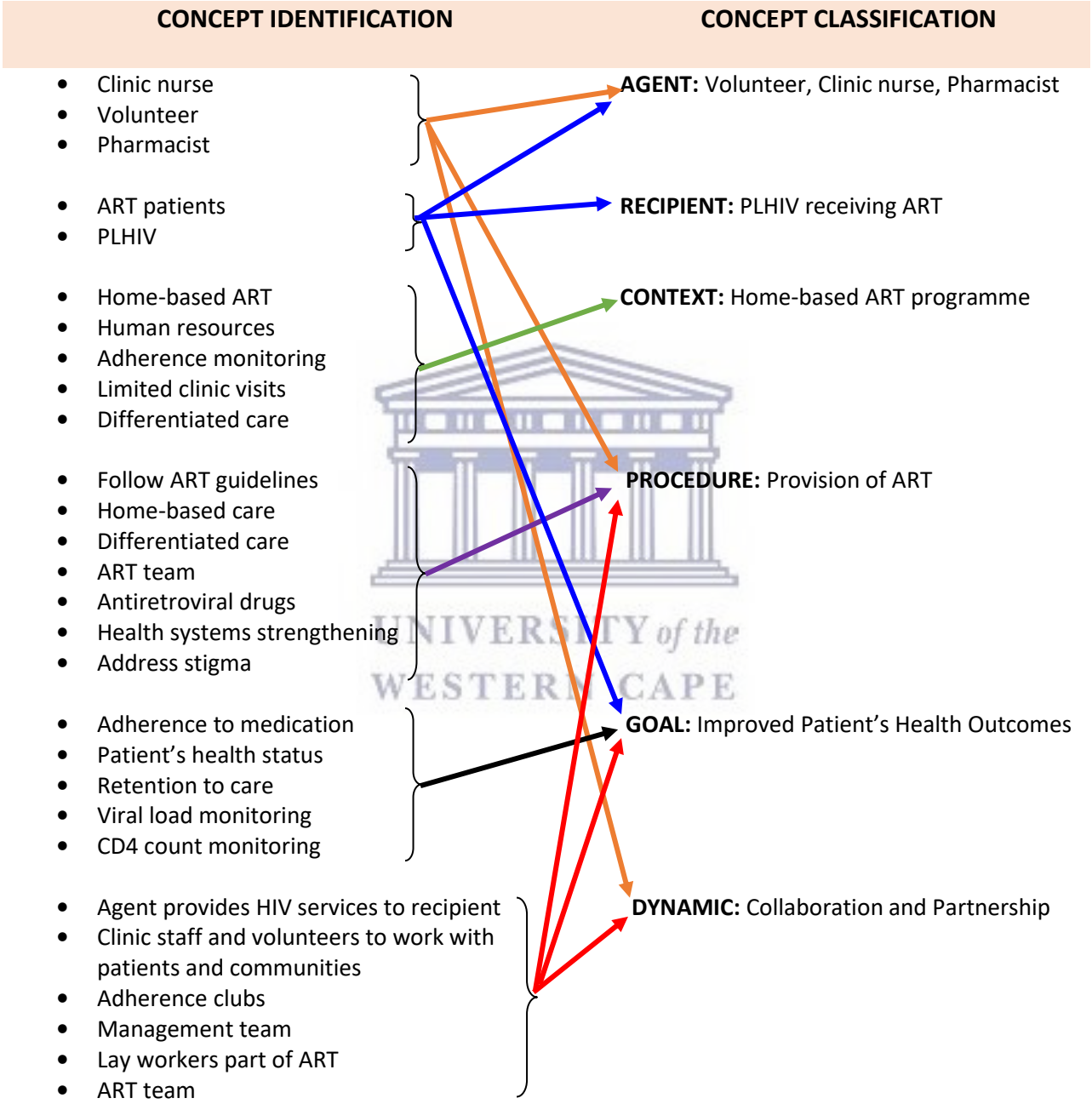


Figure 7.1: Identification and classification of concepts

The table below presents how the survey list from Dickoff, et al. *(ibid)* was applied to the core concepts of the model.

Table 7-6 Application of Dickoff, et al. (1968) survey list to core concepts

SIX SURVEY LIST QUESTIONS	SURVEY LIST COMPONENTS	APPLICATION
1. Who should be the person performing the activity to deliver effective antiretroviral treatment (ART) programme services for maximum impact?	**Agent No. 1**	Volunteer
	Agent No. 2	Clinic nurse
	Agent No. 3	Pharmacist
2. Who should be the receiver of ART delivery services?	**Recipient**	PLHIV and receiving ART
3. In what context should ART services be conducted for maximum impact?	**Context**	Home-based ART (HB-ART) programme
4. What should be the technique or protocol of ART service delivery?	**Procedure**	ART delivery
5. What should be the outcome or the end point of ART service delivery?	**Goal**	Improved health outcomes
6. What is the interactive relationship and engagement between the Agent and the Recipient?	**Dynamics**	Collaboration and partnership

7.4 DEFINITION AND DESCRIPTION OF THE CONCEPTS

The definitions of core concepts are presented below. They include a volunteer, clinic nurse, pharmacist, person living with HIV and receiving ART, Home-based ART programme, ART delivery, patients' health outcomes, and partnership and collaboration.

7.4.1 AGENT:

An agent is defined as who or what must perform the activity to attain the desired goal (Dickoff, et al. 1968). There are three agents for the model. These will be distinguished as agent one (1) for the volunteer, agent two (2) for the clinic nurse and agent three (3) for the pharmacist.

Agent No. 1 (Volunteer): Volunteers are usually considered as a sub-group of community health workers, who have previously been defined by WHO as being members of the community where they work, selected by and answerable to the local community (WHO, 1989).

In this study a volunteer who is an agent refers to a person who provides quick assessment and dispenses pre-packed ART with referral to a clinic nurse, where necessary. A volunteer refers any patient reporting symptoms of ill health, or who has recorded weight loss since their last home visit. The description of a volunteer accommodates the possibility of other factors acting as "agents" in achieving the required goal activity. The specific responsibilities of a volunteer include calling all patients before their first home visit, completing registers, compiling monthly statistics, completing the brief assessment of patients (weighing and symptom screening) on

their visit day, checking with the pharmacist to see if pre-packed ART is ready for each patient, tracing any patients who are not at home and recording blood results in the registers.

Agent No. 2 (Clinic Nurse): In this study, the clinic nurse refers to a facility-based nurse who manages the ART programme. The clinic nurse is responsible for the scheduling of dates, the smooth running of the programme, clinical governance and reporting requirements.

Agent No. 3 (Pharmacist): In this study, a pharmacist refers to a person responsible for providing antiretroviral drugs for the ART programme. The pharmacist ensures that there is a prescription for each patient and that the prescription includes the programme number and first visit date for dispensing. The implementation of the programme and its expansion within a facility is dependent on the clinic pharmacist, as the ART delivery model relies on the pre-packing of antiretroviral drugs.

7.4.2 THE RECIPIENT: Person living with HIV and receiving ART

According to Dickoff, et al. (1968), the recipient is the receiver of activity. In this study, the recipient is the person living with HIV (PLHIV) as a chronic illness and receiving ART while being closely monitored by the clinic. ART is HIV treatment which involves taking antiretroviral drugs (medicines) that maximally suppress the HIV virus and stop the progression of HIV disease in a person's body. HIV is a type of virus called a retrovirus, and the drugs used to treat it are called

antiretrovirals (ARVs). These drugs are always given in combination with other ARVs; this combination therapy is called ART.

7.4.3 CONTEXT: Home-based ART programme

Dickoff, et al. (1968) defines the framework as the context in which the activity is taking place. The context of this study includes the entire physical and non-physical organisational sstructure within which the programme is taking place. This includes organisational structure and service delivery climate relating to space, time and political agendas through which ART is provided. Therefore, description of the context includes both concrete and abstract processes for the provision of ART.

Home-based ART (HB-ART) is the new model which is developed for ART delivery in Section 2 of this Chapter. The HB-ART model will adopt the Donabedian approach (1980). This was the framework through which Phase 1 of this study was conducted. According to Donabedian, programmes are explored on three key elements; these are: structure, process and outcome.

HB-ART is defined as the provision of ART to PLHIV in their homes. Families are the central focus of care and form the basis of HB-ART. HB-ART is designed to provide ART to rural, impoverished PLHIV most of whom would otherwise have had no access to treatment due to high transport costs imposed by clinic-based treatment programmes. A comprehensive care regime for PLHIV is an essential element of any care and treatment programme. The community, and its support for and enhancement of the clinical component of care, is the most

important provider of non-clinical elements of HB-ART. The HB-ART is closely linked to the ART programme at facility level. A well-functioning HB-ART programme provides a continuum of care for PLHIV from a health care facility to the home environment.

7.4.4 PROCEDURE: ART delivery

Dickoff, et al. (1968) describe the procedure as steps to be taken towards some accomplishment including the apparatus equipment to be used. A view that considers a procedure as principle, rule, routine or protocol that legitimately governs the activity (the procedure) is acceptable from a procedural perspective. In this study, the procedure refers to the activities of providing HIV services to PLHIV and receiving ART.

7.4.5 GOAL: Improved health outcomes

The goal refers to the endpoint or accomplishment of the activity (Dickoff, et al. 1968). In this study, the goal refers to the laboratory monitoring of the viral rebound and CD4 count for ART efficacy in PLHIV and receiving ART and monitoring of the loss to follow up in the ART programme. These indicators are monitored according to the South African antiretroviral treatment guidelines 2015 (DoH, 2015).

Viral rebound is defined as having a single viral load measure of >1000 copies/ml after previous suppression while an increase in CD4 count is an effect of HIV, indicating disease progression.

For PLHIV receiving ART, viral load should be lower than detectable limits (below 50 copies/ml). If the viral load is detectable, it means that the treatment is not effective. This could either be

because of non-adherence to treatment or because the virus has developed resistance to the drugs. A normal CD4 count is between 800 and 1,500 cells/mm^3, although this varies between individuals. A CD4 count below 500 cells/mm^3 in PLHIV indicates immune suppression and vulnerability to opportunistic infections.

Loss to follow-up (LTFU) is defined as having no contact with the ART programme. For PLHIV defined as LTFU, the date of last contact is the LTFU date.

7.4.6 DYNAMICS: Collaboration and Partnership

Dynamics refers to the energy source that is required for the activity (Dickoff et al., 1968). The question of whether or not the goal is achieved is dependent on the dynamics that are at play in the context through which the agent and recipient are engaged. Energy source refers to factors such as chemical, physical, biological or psychological for both agent and recipient or anything that is of part of the context. Whilst other factors may be easier to deal with, psychological factors can pose challenges owing to abstract attributes such as an individual's willingness and/or commitment, degree of personal interest and motivation towards the execution of the goal activity.

In this study, the dynamic refers to the interactive relationship and engagement between the agents and the recipient. Any scale-up of a programme that cares for ART patients requires collaboration between different stakeholders involved in health service provision. The effectiveness of the programme depends partly on its ability to create well-functioning

partnerships between different stakeholders providing a range of care, treatment, prevention and support services.

7.5 SUMMARY OF THE SECTION

In this section the researcher identified the main concepts using the Delphi technique. The concepts were identified from the conclusion statements derived from Chapter 5 (empirical data) and Chapter 6 (systematic literature review). The identified concepts which form the building blocks of the model for the ART programme were classified and defined using the survey list of Dickoff, et al. (1968).

SECTION 2: MODEL DESCRIPTION AND EVALUATION

7.6 INTRODUCTION

In Section 1, the researcher dealt with the identification, classification and the definition of the main concepts that form the model for ART care delivery for HIV patients. The conclusion statements from the identification and classification of concepts are outlined in Table 7.3 of this section. These conclusion statements together with conclusion statement from phase 1 and 2 of this study (see Table 7.1), are used to develop a model in Section 2 of this Chapter.

Section 2 describes the Home-Based ART (HB-ART) delivery model that serves as a framework for ART delivery to care and support HIV patients in their immediate environment which is their homes. The HB-ART model adopts the Donabedian approach (1980) as a framework through which this study was conducted. According to Donabedian, programmes are explored on three key elements; these are: structure, process and outcome. Donabedian believed that structure measures have an effect on process measures, which in turn affect outcome measures. Each of the elements has a different purpose in determining whether the programme has the desired impact. Together they form the basis of what is required for an effective programme.

The HB-ART model description in this section is based on the following:

- The assumptions of the model
- The purpose of the model
- Guiding principles for a successful HB-ART model
- The context of the model
    - Structure
    - Process
    - Outcome
- The model evaluation
- The guidelines for operationalisation of the model.

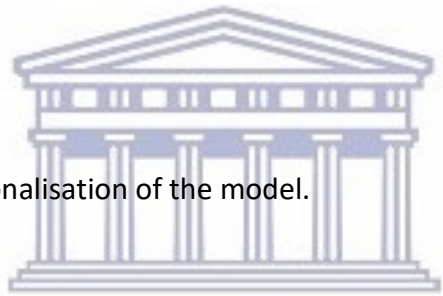


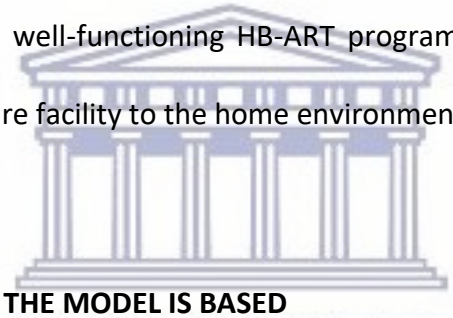
Table 7-7: Conclusion statements from the identification and classification of concepts

AGENT: *(Volunteer, Clinic nurse, Pharmacist)*	**RECIPIENT:** *(Person living with HIV and receiving ART)*	**CONTEXT:** *(Home-based ART programme)*	**PROCEDURE:** *(ART delivery)*	**GOAL:** *(Improved health outcomes)*	**DYNAMIC:** *(Collaboration and partners)*
1. Volunteers are considered as a sub-group of community health workers, who have previously been defined by WHO as being members of the community where they work, selected by and answerable to the local community. **2**. A volunteer is a person who provides quick assessment, with referral to a clinic nurse where necessary, and dispenses pre-packed ART. **3**. A clinic nurse refers to a facility-based nurse who manages the ART programme. The clinic nurse is responsible for the scheduling of dates, the smooth running of the programme, clinical governance and reporting requirements.	**5.** The recipient is the person living with HIV (PLHIV) as a chronic illness and receiving ART while being closely monitored by the clinic. **6.** ART is HIV treatment which involves taking antiretroviral drugs (medicines) that maximally suppress the HIV virus and stop the progression of HIV disease in a person's body.	**7.** Home-based ART is defined as the provision of ART to PLHIV in their homes. Families are the central focus of care and form the basis of HB-ART. **8**. HB-ART is designed to provide ART to rural, impoverished PLWHIV most of whom would otherwise have had no access to treatment due to high transport costs imposed by clinic-based treatment. **9.** The community, and its support for and enhancement of the clinical component of care, is the most important provider of non-clinical elements of HB-ART.	**11.** The procedure refers to the activities of providing HIV services to PLHIV and receiving ART.	**12.** The goal refers to the laboratory monitoring of the viral rebound and CD4 count for ART efficacy in PLHIV and receiving ART, and measurement of the loss to follow up in the ART programme **13.** The Viral rebound as an outcome measure is defined as having a single viral load measure of >1000 copies/ml after previous suppression. **14**. A CD4 cell count is tested every 3-6 months. A CD4 count below 500 cells/mm^3 in PLHIV indicates immune suppression and vulnerability to opportunistic infections.	**16.** The effectiveness of the programme depends partly on its ability to create well-functioning partnerships between different stakeholders providing a range of care, treatment, prevention and support services. **17.** Each clinic running an ART programme requires a dedicated team. **18.** The programmme need to collaborate with community leaders or PLHIV support groups. Community adherence support agents who are recruited from the local community.

4. A pharmacist refers to a person responsible for providing antiretroviral drugs for the ART programme. The pharmacist ensures that there is a prescription for each patient and that the prescription includes the ART number and first visit date for dispensing.		**10.** The HB-ART is the new model which is developed for ART delivery in Section 2 of this Chapter. The HB-ART model will adopt the Donabedian approach as a framework through which Phase 1 of this study was conducted. According to Donabedian, programmes are explored on three key elements; these are: structure, process and outcome.		**15**. Loss to follow up and outcome measure is defined as having no contact with the programme or the local clinic on return date or home visit since the date of last contact.	**19**. The programme needs the management team to be involved at the initial stages to assist with oversight and approvals of programme.

7.7 DEFINITION OF THE MODEL

Home-Based ART is defined as the provision of ART to PLHIV in their homes. Families are the central focus of care and form the basis of HB-ART. HB-ART is designed to provide ART to rural, impoverished PLHIV most of whom would otherwise have had no access to treatment due to high transport costs imposed by clinic-based treatment programmes. A comprehensive care regime for PLHIV is an essential element of any care and treatment programmes. The community, and its support for and enhancement of the clinical component of care, is the most important provider of non-clinical elements of HB-ART. The HB-ART is closely linked to the ART programme at facility level. A well-functioning HB-ART programme provides a continuum of care for PLHIV from a health care facility to the home environment.



7.8 ASSUMPTIONS ON WHICH THE MODEL IS BASED

Assumptions in programmes refer to specific factors in the planning process that are considered to be true or certain without necessarily having empirical proof. Assumptions can affect the progress or success of a programme, depending on whether or not the assumptions made prove to be correct.

The following assumptions were identified:

- PLHIV receive ART mainly through hospital or clinic-based programmes. Economic and geographic constraints severely limit access to clinics or hospitals for poor patients living in

rural areas. Since much of the population of SA is rural, these factors lead to large inequities in the provision of ART services and make universal access to ART difficult to achieve.

- To meet the challenges of a continuum of care for PLHIV, a shift must be made from hospital or clinic-based health service delivery to an organisation of health services enabling chronic disease management.
- Lessons are learned from diabetes management and TB control, which can be adapted to life-long management of HIV disease across the continuum between facilities, community services and homes.
- It is increasingly acknowledged that community-based care models hold potential to manage large volumes of patients on ART. Community-based models of ART delivery have been found to be feasible with good clinical outcomes.
- Retaining PLHIV who are receiving HIV care is a major challenge in many countries in sub-Saharan Africa where ART has been rapidly scaled up.
    - The provision of ART services in SA has improved over time; however, major gaps in access still remain. Alternative approaches are required, including those that can engage and make use of rural community resources. This study has therefore developed a home-based ART delivery model.

7.9 THE PURPOSE OF THE HB-ART MODEL

The home-based ART (HB-ART) model was defined in Section 1 of this Chapter. The purpose of the HB-ART model is to provide ART to people living with HIV who otherwise would not have access to treatment due to the distance to reach the clinic-based ART programme. Home-based ART delivery is defined as provision of HIV treatment to HIV patients in their homes. HB-ART delivery draws on the strengths of families and communities. Families are the central focus of care and form the basis of HB-ART. Various studies (WHO, 2000; Lindsey, 2002) suggest that most people would rather be cared for at home, and that effective home care improves the quality of life for chronically ill people and their family caregivers. A well-functioning HB-ART programme provides a continuum of care for persons with HIV from a health care facility to the home environment. It must be linked and integrated into the existing district health care delivery systems and plans. Inputs from families, communities and the health care systems are essential for any results-based HB-ART programme.

7.10 GUIDING PRINCIPLES FOR A SUCCESSFUL HOME-BASED ART MODEL

- HB-ART provision should be comprehensive, including medical and nursing care, counselling and psychosocial support, spiritual care, material and social support, and referral.
- HB-ART should be an essential component in a continuum of care for PLHIV but, at certain stages, cannot replace the role of other health institutions such as hospitals and clinics. Referral systems and links between services along a continuum are necessary.

- Provision of ART and prevention may be most effective if fully integrated.
- HB-ART should target PLHIV to avoid stigmatisation. Resources permitting, home care should also provide support not only to the patient but also to the entire affected family.
- HB-ART should be pursued not only as a way to divert the burden of PLHIV patients on hospitals or clinics to the community, but to provide the same kind of care in a different environment.
- HB-ART are more sustainable and feasible if they are community initiated and fully owned by the community.

7.11 THE CONTEXT OF THE HOME-BASED ART MODEL

The context of this model is the local community where HIV treatment, care and support are located outside of health facilities. The HB-ART model is designed to provide ART to rural, impoverished PLHIV, most of whom would not have access to treatment due to inaccessibility of health facilities or high transport costs imposed by clinic-based treatment. The central focus in the context of this model is home-based ART delivery for PLHIV in their homes.

The model is community-based with the primary focus on training, supervision and recognition by the community. Communities with limited health care facilities for PLHIV are prioritised. The HB-ART programme shall be linked and integrated in the existing district health care ART delivery services. People living with HIV on HB-ART are regarded as an extension of the

community health center with the facility continuing to assume full responsibility and accountability for ART delivery. The family, community and the health care system are important role players and necessary in the provision of HB-ART services.

The HB-ART model developed for this study has adopted the Donabedian approach (1980) which has three elements: the structure, process and outcome as the framework for this research in Phase 1. The three elements encompass the concepts identified and the relationship between the concepts. The relationships, in turn, determine the strength and quality of the elements of the model (Chinn & Kramer, 2008). The three elements include the central elements of the model and consist of concepts, statements and relationships between the concepts. The following concepts are addressed in this model: a volunteer, clinic nurse, pharmacist, person living with HIV and receiving ART, HB-ART programme, ART delivery, patients' health outcomes, and partnerships and collaboration.

7.11.1 THE STRUCTURE OF THE HB-ART MODEL

The structure of the HB-ART model is the essential set of resources (space, equipment, drugs, supplies and human resources) required for providing the expected HB-ART services to PLHIV. Inputs from family, community and the health care system are needed to form the structural basis of the HB-ART programme.

7.11.1.1 HB-ART Space

The HB-ART club model is adapted to reduce congestion in the CHC and to provide accessible ART to homes through the community. Phase 1 of this study found that most ART facilities did not have seating available for all the patients, indicating congestion in facilities. In the review of studies that implemented existing ART models in SA in chapter 6 of this study, community-based ART models showed the benefit of decongested primary health care facilities (Grimsrud et al., 2015). The HB-ART programme creates a transition from ART being facility-based to being provided by communities in PLHIV homes. The venue for HB-ART activities is solicited at the community and can be any space provided either at CHC or community where volunteers are able to meet.

7.11.1.2 Equipment, Drugs and Supplies

The findings by this study in Phase 1 indicated that in general facilities had the required equipment to provide HIV care services. The shortages of essential HIV medicines as

revealed by this study may hinder the expansion of the ART programme to communities. For the HB-ART programme, the clinic nurse at the health care facility will monitor the proper use of drugs. Mechanisms for the provision of drugs and supplies at community and household levels are provided for in the HB-ART programme:

- Drugs and supplies for HB-ART will be stored at the health care facility at which the HB-ART provider is based (i.e. pharmacy, health center).
- The health facility's pharmacist will be responsible for maintaining stock records and supply levels.
- The HB-ART clinic nurse at the health facility will be responsible for obtaining drugs and supplies from the pharmacy and for providing drugs and supplies to HB-ART volunteers.
- Volunteers will obtain replenishment of drugs and supplies on a weekly basis from the HB-ART clinic nurse at the health facility.

7.11.1.3 Human Resources

In order to get optimum benefits from HB-ART services each of the players will be required to perform their respective roles and responsibilities as indicated hereunder:

7.11.1.3.1 Volunteers

Members of the community participate in the ART programme as unpaid volunteers. Volunteers are selected by the community and its leadership. Criteria for selection is age 18 years or older and being literate. Volunteers must agree to participate and are provided with a

two-day training on ART benefits, risks and limitations, the critical importance of adherence to the medication and the expected adverse reactions to antiretroviral drugs as well as how to monitor patient adherence. The volunteer training is provided by the clinic ART team. The motivation of the volunteers will come from desire to support access to treatment for their fellow community members and will be reinforced through the recognition and support they receive from the health care programme and the community.

Each volunteer is allocated on average 4–5 patients in order to keep the workload manageable. On a monthly basis, the volunteers obtain a supply of pre-packed ARVs from the local health centre and deliver these to their assigned patients. In addition, they provide information on HIV and Aids prevention to the patients and distribute condoms. Volunteers make weekly visits to the people's homes, during which time they monitor adherence to treatment through pill counts, as well as assess the presence of adverse reactions. Any PLHIV reporting symptoms suggestive of illness, adverse drug effects or who have weight loss are referred to the clinic to be assessed by the nurse. In cases of doubt, the volunteer can phone the nurse at the clinic for advice. PLHIV who are absent at the time of the visit receive one follow-up visit within 1–2 days. If they are absent again, a note is left for them to visit the clinic. PLHIV visit the clinic on a 3 or 6-months basis for viral load and CD4 count testing.

7.11.1.3.2 Clinic Nurse

A clinic nurse in an HIV and community-based programme will work on a full-time basis to supervise and train the volunteers as well as to facilitate the liaison between volunteers and the communities. The clinic nurse is allocated as the ART programme nurse on the clinic roster for each day on which HB-ART takes places. Monthly rotation of the clinic nurse function within the facility will ensure collective responsibility for the management of the HB-ART programme. The nurse can usually continue to see clinic patients as he/she is infrequently required to see a HB-ART patient, other than the blood investigations and clinical consultation sessions. If a HB-ART patient needs to see a clinician on their home visit date, the patient is referred to the CHC and has priority access to the HB-ART nurse.

7.11.1.3.3 Pharmacists

- The pharmacist at the CHC is responsible for the HB-ART.
- The HB-ART pharmacist ensures that there is a prescription for each HB-ART patient and that the prescription includes the HB-ART number and first visit date for dispensing.
- On the day of the HB visit, the pharmacist provides all 3-months pre-packed ART for the HB-ART to the volunteer for distribution to HB-ART PLWHIV.
- The pharmacist always has the supplies, drugs and equipment for HB-ART PLHIV.
- The pharmacist supports the volunteers to enhance drug adherence.
- The pharmacist has the contacts of a HB-ART clinic nurse.

7.11.1.4 The Family

People living with HIV will to a large extent be cared for in their homes. Since hospital-based staff will not be available to provide care to such patients on a full-time basis, family members are expected to take over the responsibility of providing care at home. It is envisaged that family members will be the main actors in providing high quality HB-ART services.

When PLHIV are enrolled into the HB-ART programme, they are asked to identify a family member or friend as their daily treatment supporter to help with the daily intake of the drugs. PLHIV and their treatment supporters are counselled together on important aspects of treatment including lifelong duration of treatment, possible adverse reactions of the drugs and the need for high adherence to the medication. During these 30-40-minute counselling sessions, PLHIV are introduced to their volunteers. Treatment supporters are asked to remind PLHIV to take their medications and document using treatment registers, that the person took their tablets as prescribed. In addition, they are asked to generally support PLHIV in adhering to the treatment. Treatment supporters are also trained and supervised by the volunteers on their weekly home visits.

The family will need to:

- Provide the PLWHIV with adequate balanced diet.
- Prevent transmission of infections e.g. HIV, TB.
- Link with the volunteer for support and referrals.

- Make sure that the PLWHIV takes his/her medication according to prescription.
- Make sure that the PLWHIV keeps his/her clinic appointments and observes appropriate medical advice appropriate.
- Support the PLWHIV in order to avoid risk situations for infections and complications.
- Provide emotional support and spiritual care to the PLWHIV.
- Provide care and support for orphans and vulnerable children

7.11.1.5 The Community

The community plays a supportive role in all aspect of care, treatment and support for PLWHIV and their families. It is the responsibility of the District Health Management Team (DHMT) and relevant health facility leadership to introduce the concept of HB-ART to communities, after which each community should identify their HB-ART needs and develop appropriate plans to address them. However, communities should be guided in the planning by DHMT members or relevant personnel from nearby health care facilities. All along due emphasis should be made to enhance community ownership and effective support for HB-ART services.

For the implementation of HB-ART services, communities should be assisted to:

- Identify specific needs for HB-ART services.
- Identify resource for HB-ART services.
- Make appropriate decisions on health issues.

- Look for local solutions for the prevailing health problems.
- Identify the community HB-ART volunteers to be trained by the clinic nurse at the health center or pharmacy. The number of volunteers to be trained will vary from community to community, depending on the needs and available resources.
- Determine sustainable and appropriate ways to motivate the volunteers.
- Play a role in the identification of PLWHIV to be reached by the service and a system of registering new ones.
- Plan for home visits, community awareness meetings and support for referrals (e.g. transport)
- Plan for on-going community involvement in the improvement and sustainability of services.
- Work towards the reduction and elimination of stigma and discrimination at the community level.

7.11.1.6 Health Care System

7.11.1.6.1 District Health System

As part of the health sector reform, HB-ART services will be planned to be integrated in the Primary Health Care (PHC) programme.

Therefore, the District Health Management Team (DHMT) will be responsible to:

- Implement the HB-ART policy guidelines.

- Integrate HB-ART activities in the council comprehensive health plans.
- Create awareness in the community of the need for and importance of HB-ART, aiming at their involvement.
- Conduct a needs assessment and plan for HB-ART to be integrated in their health care delivery system.
- Establish an effective networking and referral system for the patients to benefit from a functional continuum of care at facility, community and household level.
- Conduct the required training for personnel to ensure provision of effective HB-ART services in the district.
- Support and ensure community involvement and participation.
- Regularly monitor and supervise the services.
- Provide the necessary equipment, supplies, drugs and transport for HB-ART
- Identify the clinic nurse and pharmacist contact persons for HB-ART and monitor/ supervise their work.
- Evaluate the service every two years aiming at its improvements.
- Allocate resources needed for HB-ART delivery in the district.
- Compile and analyse HB-ART data quarterly and annually, submit reports to the region, and give feedback to the CHC and pharmacy.

- Support activities directed at improving nutritional care and support of PLHIV as explained in 7.10.2.4 below.

7.11.1.6.2 Community Health Centre (CHC)

For the HB-ART programme to be functional, it is vital that good lines of communication are established and maintained between the different levels of patient care. The CHC will be required to make proper diagnoses, initiate the right treatment and provide appropriate counselling services. At the time of leaving the health facility, PLWHIV will be given adequate information to enable the community and volunteers to take over efficiently. PLHIV will take such information to the volunteer. This will ensure the continuum of quality health care from the health care facility to the household. The CHC must have at any one time at least one staff member trained in HB-ART services.

The responsibilities of the CHC will be to:

- Implement the HB-ART policy guidelines.
- Train the community volunteers in their catchment areas.
- Follow up patients referred from other CHC or from other hospitals residing in their catchment areas.
- Supervise the volunteers, at least on one home-visit per week.
- Raise community awareness among leaders on HB-ART programme and mobilise the same to get involved in provision of quality HB-ART in their community and stigma reduction.

- Provide horizontal supervision for the dispensary contact persons.
- Mobilise resources for HB-ART programme
- Keep records for the HB-ART programme.

7.11.2 THE PROCESS OF THE HB-ART MODEL

When setting up a HB-ART programme it is important to ensure that the following, which constitute the processes to implement the HB-ART model are in place.

7.11.2.1 Medication Adherence

People living with HIV and on life-long medication need support in ensuring that they abide by drug schedules and clinic appointments. A treatment supporter will be required to know the person's prescriptions and clinic visit schedules and constantly remind him/her to adhere to the same. The treatment supporter should also know and be known by members of the ART team at the CHC and the HB-ART volunteers.

7.11.2.2 HB-ART Eligibility and Functional Referral System

PLWHIV classified as stable on ART are recruited from the community health centre for down-referral to the HB-ART delivery programme. They are eligible to join the programme if they fulfil the following criteria: are considered stable, meaning that they have been adherent on the same ART regimen for >12 months, had two consecutive undetectable (<400 copies/mL) viral loads and did not have any other medical conditions requiring more frequent follow-up, are

resident in the local area, aged 18 years and older, willing to accept daily treatment support by family or friends and willing to be visited by a trained community volunteer once a week. PLHIV will be identified through the local clinic where they are enrolled in an ART programme. Individual PLHIV counselling at the time of referral will describe the benefits of HB-ART model, the visit schedule and how to access clinical care outside of HB-ART visits as necessary.

In terms of the referral system, HB-ART services are to be perceived as part of the continuum of care, which involves the provision of support at different levels. An effective continuum of care requires that a functional network, linkage and referral system is always in place to improve access of appropriate services for the chronic patient. Through an effective and functioning referral system, PLHIV will continue to receive appropriate services from health care facilities after registering to the HB-ART programme within their respective communities and homes and can revert back to facility care as and when needed.

The proposed referral mechanism for PLWHIV will be developed and implemented within the district health care referral system. The health referral system in districts has four levels that can be fully utilised. These include (i) the Community (ii) the Pharmacy, (iii) the Health Centre, and (iv) the District hospital. PLHIV will be referred through these levels in an ascending order and vice versa. However, the referral system will provide for a bypassing of these levels to higher levels in emergency conditions and accidents. The model should aim to assist the districts to set up a functional cost-effective referral flow within the existing health care

delivery system for PLHIV. Referral of HB-ART persons will depend on their needs and the support system existing in a particular community. All other support services that are available for PLWHIV should be known at all levels and be part of the referral system. These may include spiritual, legal, income generating activities, nutritional, and socio-economic support.

7.11.2.3 Emotional and Psychological Support

PLWHIV suffer from chronic illness and usually have a lot of fear and worries. Volunteers therefore provide emotional and psychological support and help them to ventilate and deal with their condition. The volunteer will refer the PLHIV if necessary.

7.11.2.4 Nutrition Guidance and Food Support

Nutrition Care and Support for PLHIV is one of the crucial components of the comprehensive care package of the HB-ART care programme. HIV and Aids affects nutrition by decreasing food consumption, impairing nutrient absorption, and causing changes in metabolism. Improving and maintaining good nutrition may prolong life and delay HIV disease progression. In order to improve nutrition for PLHIV, the Department of Health should play a role in facilitating discussions with partners and other stakeholders at all levels for developing mechanisms to address issues of food security and food acquisition for the most needy. The government and particularly the Department of Health in collaboration with district councils, partners and stakeholders at various levels have the responsibility of carrying out measures aimed at improving the nutritional wellbeing of PLHIV. These measures among other things include:

- Training of volunteers and other care providers on nutritional issues related to HIV and Aids. These include food, water safety and hygiene; dietary management of HIV and AIDS related complications, and food and drug interactions.
- Provision of nutrition education and counselling for PLHIV and families including nutrition for special groups such as children born to HIV positive mothers, orphans and vulnerable children.
- Monitoring of nutritional status of PLHIV and needs for their households.
- Mobilisation of communities and partners for food provision for PLHIV and their families.
- Mobilisation of resources for improving household food security for PLHIV.
- Integration of actions aimed at improving household food security into development plans.
- Making food an essential element in care and support for PLHIV on ART.
- Insuring that food security for households with PLHIV and their families is a permanent agenda for the local Ward Development Committee meeting.

7.11.2.5 Participation of People living with HIV (PLHIV)

Active involvement of people living with HIV (PLHIV) is essential in disease management at all levels. PLHIV will develop knowledge and self-care and treatment skills that will optimize their role and benefit treatment outcomes over their lifespan. The involvement of one or more significant people in their lives e.g. spouse, life partner, family member is important to assist

the volunteers and observe timely drug intake, maintain appointment schedules, and identify side effects early. Every PLHIV should be encouraged to identify a treatment supporter from within the household to whom they can disclose their HIV status. The volunteer would then counsel the PLHIV along with the treatment supporter whom would serve as support for treatment adherence and/or monitor therapy.

PLHIV must attend blood investigation and clinical consultation sessions as scheduled. A PLHIV can be removed from HB-ART and returned to mainstream care when more intensive clinical or adherence follow-up is required. A PLHIV can exit the programme when he/she not available at home on consecutive visits and fails to attend the clinic within 5 days of each visit. A PLHIV is determined by the clinic nurse to require more regular follow-up and those with elevated viral loads will also be returned to mainstream care.

The PLHIV and the providers of HB-ART must work as a team to foster the person's development of self-management skills, to transfer knowledge, and assist in counselling and social services.

7.11.2.6 Record and Reporting System

Home-based (HB) ART data are recorded in a paper register. At each home visit, the weight of each patient and results of the brief symptom screen are recorded. A summary of the HB data aggregated at the level of the HB-ART is completed by the volunteer following each home visit

and monthly reports are compiled for the CHC. Standard individual patient files at the CHC of HB-ART members are only used at the clinical visit. When a patient is down-referred to a HB-ART, a HB-ART number is placed on the CHC patient file so that clinicians could determine where the patient was receiving ART.

Monthly meetings of all volunteers and the clinic nurse will be held where problems are discussed, solutions sought and where the report forms are delivered and checked. The volunteer adherence registers, based on weekly pill counts by the volunteers in the PLHIV homes, are thoroughly reviewed and compared with the treatment information sheets from the treatment supporters who signed off each time when they observed their patients taking the drugs. The reviewed volunteer adherence registers are taken to the health center for record keeping and continuously analysed, in order to identify adherence problems as early as possible, and to target PLHIV for special counselling.

7.11.2.7 Prevention Interventions (e.g. EMTCT, Condom Distribution)

The HB-ART team supported the by the District Health System and Community Health Centre must include collaboration among communities, public health and clinical sectors to rapidly address new HIV diagnoses. Mass media campaigns, behavioural interventions, medication reminders, and other strategies will be implemented to encourage people to adopt and maintain risk reduction behaviours including condom use and adherence to HIV treatment. The HB-ART programme will use partner notification services as a component of early intervention

services, as well as other effective HIV prevention programmes, including condom dispensing and community-based HIV testing. Education, training, and capacity building for HB-ART team members are also important activities that can improve the ability of team and systems and community-based organisations to provide high quality HIV prevention, care, and treatment services efficiently and effectively. Volunteers will encourage pregnant women to seek antenatal care early in their pregnancies.

7.11.3 THE OUTCOMES OF THE HB-ART MODEL

Patient's outcomes are assessed at 3-6 monthly intervals depending on their immunological status and general condition. The outcome measures that are used to monitor PLWHIV on HB-ART are:

7.11.3.1 Viral (Load) Rebound

The management of PLWHIV has changed substantially with the availability of newer, more potent, and less toxic ARV drugs. In SA, ART is now recommended for everyone with HIV regardless of their viral load or CD4 count (Adult antiretroviral therapy guidelines, 2017).

Viral load is a marker of response to ART. A person's pre-ART viral load level and the magnitude of viral load decline after initiation of ART provide prognostic information about the probability of disease progression (Murray et al., 1999). The key goal of ART is to achieve and maintain viral suppression. Thus, the most important use of the viral load is to monitor the effectiveness of therapy after initiation of ART.

In PLWHIV on ART, viral load is measured every 6 months. However, for adherent patients with consistently suppressed viral load and stable immunologic status for more than 2 years, monitoring can be extended to 12-monthly intervals.

For this study, viral rebound is defined as having a single viral load measure of >1000 copies/ml after suppression, six months after enrolling on the HB-ART programme.

7.11.3.2 CD4 Count Monitoring

The CD4 count is used to assess a person's immunological response to ART. For most persons on therapy, an adequate response is defined as an increase in CD4 count in the range of 50 to 150 cells/mm3 during the first year of ART, generally with an accelerated response in the first 3 months of treatment. Subsequent increases average approximately 50 to 100 cells/mm3 per year until a steady state level is reached (Kaufmann, et al. 2003).

CD4 cell count is measured:

- Every 3-6 months during first 2 years of ART, or if viremia develops while the person is on ART, or if CD4 count is <300 cells/ mm3.
- Every 12 months after 2 Years on ART with consistently suppressed viral load or CD4 count of 300–500 cells/mm3 or CD4 monitoring (optional).

The CD4 count response to ART varies widely, but a poor CD4 response in a patient with viral suppression is rarely an indication for modifying an ARV regimen. For this study, an increase in CD4 cell count six months after enrolling on the HB-ART programme with viral rebound will indicate the need for clinical consultation with the clinic.

7.10.3.4 Loss to Follow Up (LTFU)

Loss to follow up (LTFU) is defined as having no contact with the HB-ART programme or the CHC in the first 4 weeks of enrolling in the HB-ART programme. For PLWHIV to be defined as LTFU, the date is the last home visit date or scheduled appointment with CHC.

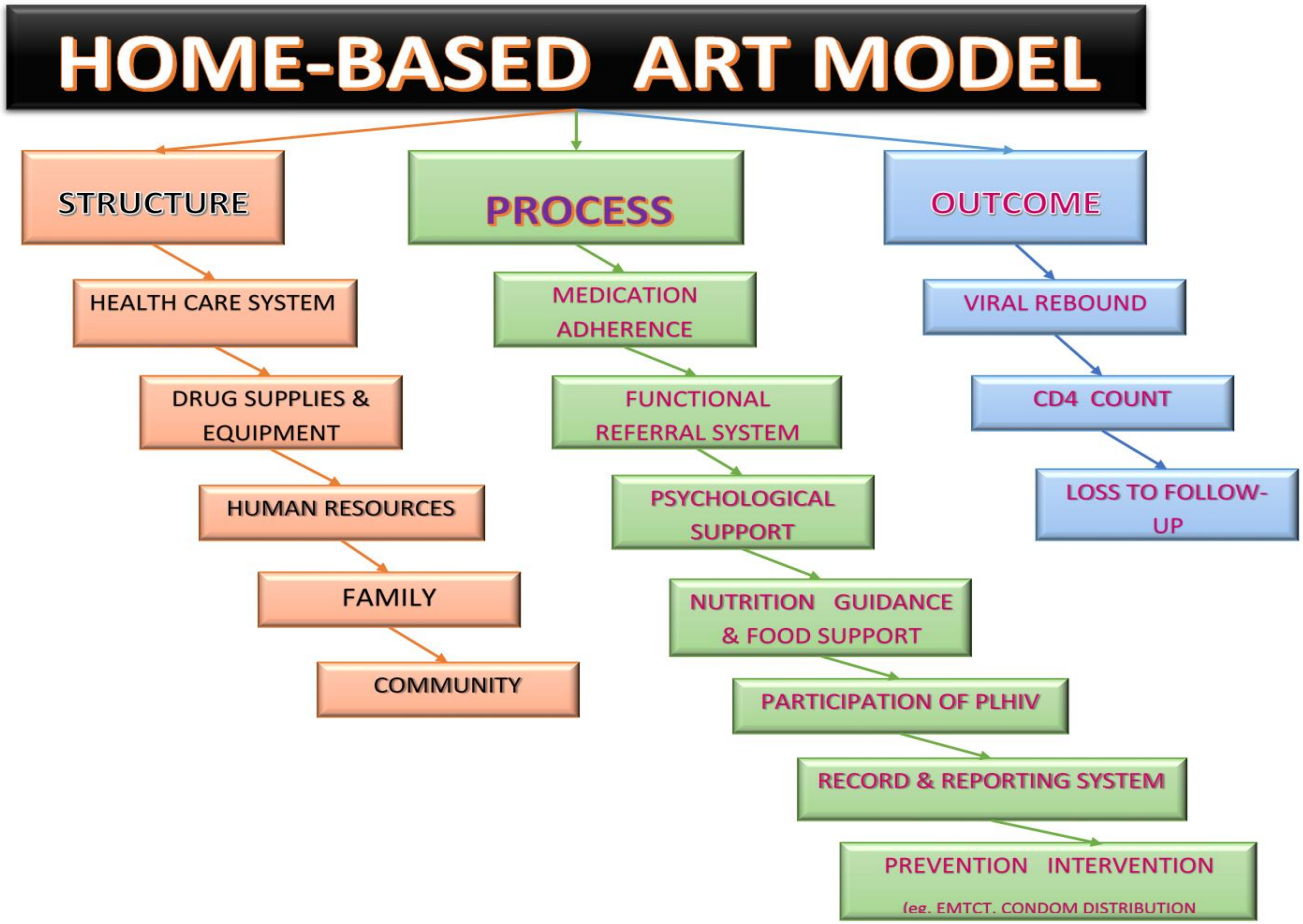


Figure 7-2: Home-Based ART Model

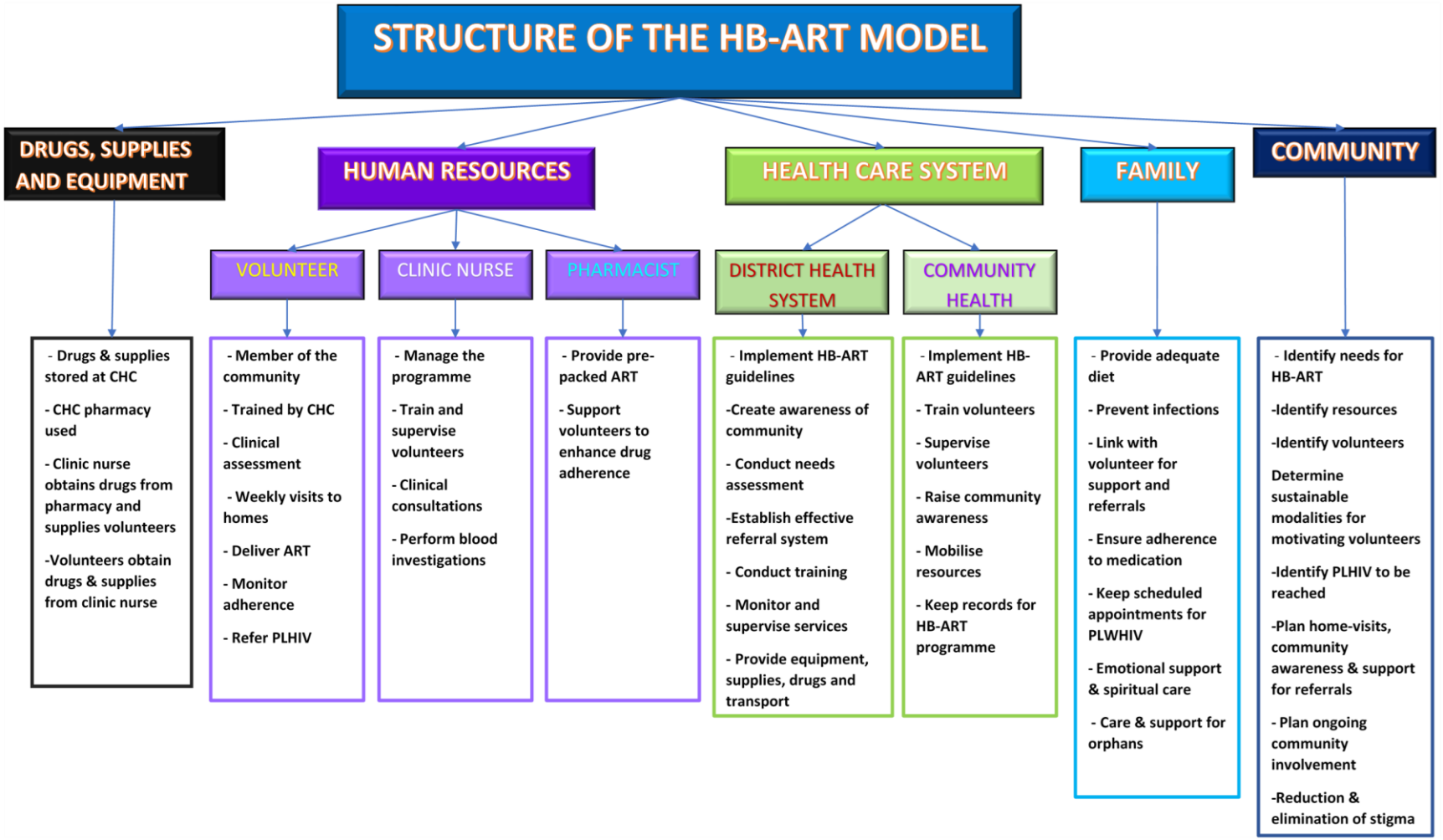


Figure 7-3: Structure of the Home-Based ART Model

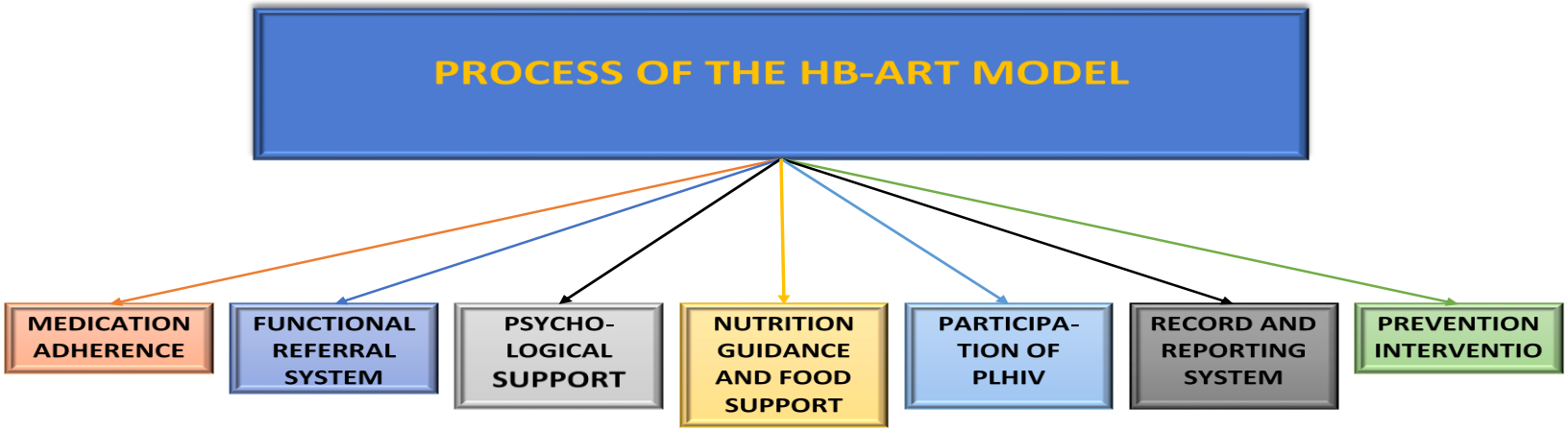


Figure 7-4 Processes of the HB-ART Model

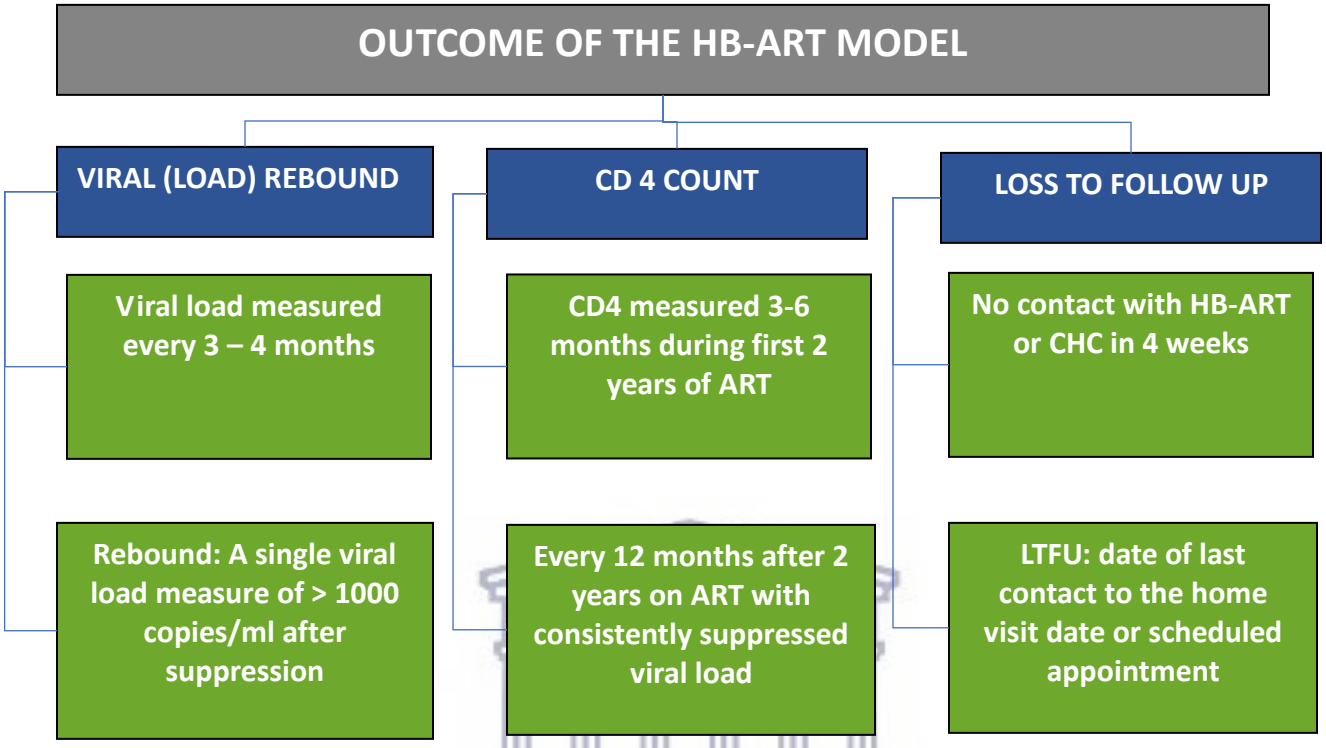


Figure 7-5 Outcome of the HB-ART Model

Figure 7-5 below illustrates the components of the HB-ART model. The basic aim of the HB-ART service is to provide a continuum of care for PLHIV from health facilities to their homes using existing resources within the current delivery system and communities. The HB-ART programme includes the following components:

Physical Care: Volunteers ensure that PLWHIV receive adequate attention in the following areas:

- Treatment of opportunistic infections.
- Identification and monitoring of ART side effects and adherence.
- Nutritional care and support.
- Hygiene – the patient and family members should be educated on the practice of basic hygiene e.g. oral, skin, hair and environmental care.
- Exercise – patients need to exercise regularly. If they are too weak, family members should assist patients to do passive exercises for body movement and to enhance blood circulation.

Social support: PLWHIV usually suffer from loneliness and neglect. It is therefore important for volunteers to interact and provide support when necessary. PLHIV should be included in decisions regarding their care. PLHIV should also be involved in recreational activities as appropriate and support or self-help groups in the community should be identified for PLHIV to interact with.

Emotional support: Patients suffering from chronic illness usually have a lot of fear and worries. Volunteers will therefore provide emotional support and help them to ventilate and deal with their concerns.

Spiritual support: Addressing spiritual needs is an important aspect in any type of care. PLHIV often lose hope and the desire to continue living. This can be relieved through reassurance and spiritual care. Spiritual needs of PLHIV must be determined and attended to appropriately.

Legal support: PLHIV will should be informed about how to get legal aid that they need especially in areas such as inheritance and human rights issues.

Economic support: When a person is diagnosed with HIV, this increases the financial burden to the family, as the family has to incur extra expenses for medical care. An HIV positive infected breadwinner may lose his or her job, while other issues such as children's education and rent require money. Therefore, it is necessary for volunteers to be aware of support networks where such issues may be addressed.

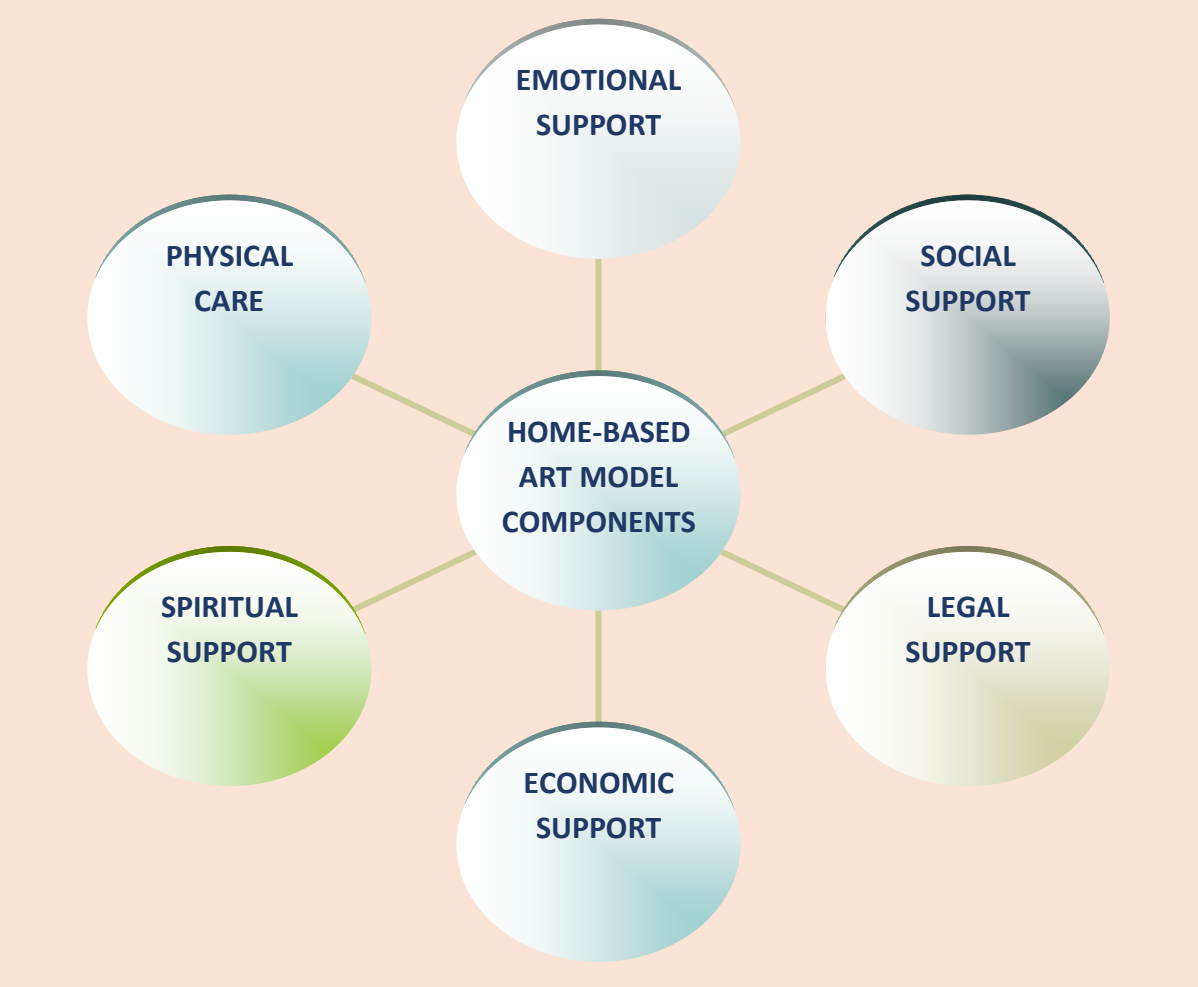


Figure 7-6: Components of Home-based ART Model

7.12 EVALUATION OF THE MODEL

The criteria described by Chinn and Kramer (2008:246) were used to evaluate the model. The questions for consideration under the specific criteria for evaluation are listed below:

7.12.1 CLARITY

Clarity has to do with the transparency of meaning of ideas used in the model.

7.12.1.1 Semantic Clarity

The definition of concepts in this model was an important aspect of semantic clarity because it helped to establish the empirical meaning of concepts in this model. The concepts in this study were clearly defined. Definitions reflected both general and specific traits. This means that concepts were not defined too specifically but generally in the sense that they provided clear and accurate guidance for the intended empiric indicators for a concept. No words with similar meanings were used to present the central concepts of the model. Tables and diagrams were used to make the model clearer.

7.12.1.2 Semantic Consistency

Semantic consistency means that the concepts of this model were used in ways that were consistent with their definition. No other meanings for definitions within this model were implied. There was a consistent use of basic assumptions within this model. The model's

purpose, definitions of concepts and relationships were consistent with the stated assumptions of the model. The purpose of this model was consistent with all other components.

7.12.1.3 Structural Clarity

Structural clarity refers to how understandable the connections and reasoning within the model are. In this model concepts were interconnected and organised into a coherent whole. The model flows; in other words, there are no structural elements that are not related.

7.12.1.4 Structural Consistency

Structural consistency is related to the use of different structural forms within the model. Consistency throughout the model concerning structure was reflected in the relationships. From the above and from the discussion the researcher concluded that this model was clear. Definitions in this model have been defined and linked in such a way that their relationships were understandable. Definitions and their structural forms were used consistently and there was a consistent evaluation of semantic as well as structural clarity.

7.12.2 SIMPLICITY

The simplicity of the model becomes evident through the minimum elements in each category. The researcher concludes from discussion that this model is not complex. Complexity implies that there are many theoretical relationships between and among numerous concepts. The

core concepts support the purpose of this model and are self-evident. The meanings of the concepts have been retained by not introducing irrelevant concepts.

7.12.3. GENERALITY

The generality of a theory refers to its breadth of scope. A general model can be applied to a broad array of situations. The scope of concepts and purposes within this model provided clues to its generality. The model was intended for the home-based ART provision for HIV patients. The model has the capacity for broader generalisation. It can be used in the application of ART provision in general.

7.12.4. ACCESSIBILITY

Accessibility refers to how attainable the projected outcomes of the model are. Concepts can be made empirically accessible through generating and testing relationships, deliberative application of the model and clarifying conceptual meaning. The model that had been developed through this research is useful and should promote home-based ART provision for HIV patients who have limited access to clinic-based HIV care. It was the researcher's belief and it became clear from the discussions that the model will definitely advance ART delivery at patients' homes.

7.12.5. PARSIMONIOUSNESS

The importance of this model is closely tied to the idea of its clinical significance or practical value. The importance of the model has to do with its applicability and practical value. This model is future directed as previously mentioned and it is also practical so that it can be evaluated. The researcher concludes from discussions that this model is needed and will be of great value in practice in order to assist HIV patients to receive ART from their homes as well as empowering them through self-management of HIV infection as a chronic condition.

Table 7-5 below shows the guidelines that are formulated for the implementation of the HB-ART model. The guidelines are formulated for implementation at different levels; i.e. the community health center, the community and the home. The community health center has the responsibility to supervise and monitor HB-ART activities in their catchment areas. The community is assisted by the community health center to perform HB-ART activities and give feedback to community leadership and volunteers. Before assuming the responsibility, the family must be counselled about the patient's illness and informed about the cause, signs and symptoms, treatment, possible complications and prevention. This should be done at the health facility where the diagnosis is made before referral for HB-ART.

Table 7-8 Guidelines for operationalisation of the model

THE FOLLOWING GUIDELINES ARE FORMULATED FOR THE IMPLEMENTATION OF THE HB-ART MODEL:	
COMMUNITY HEALTH CENTRE (CLINIC) LEVEL	Supervise and monitor HB-ART activities in their catchment areas: • Supervise visits to all HB-ART providers in their catchment areas. • Monitor adherence to services standards and policies. • Compile monitoring and evaluation reports for DoH. • Supervise HB-ART providers weekly. • Compile reports monthly. • Maintain contact with PLHIV at health center regularly (3-6 months). • Give feedback to HB-ART providers and community leaders.
COMMUNITY LEVEL	For performance-based implementation of HB-ART services, communities should be assisted to: • Identify specific needs for HB-ART services. • Identify resource for HB-ART services. • Identify the community HB-ART provider(s) to be trained by the contact persons at the health centre or dispensary. The number of HB-ART providers to be trained will vary from community to community, depending on the needs and available resources.

- Determine sustainable and appropriate modalities to motivate the community HB-ART providers.
- Plan for home visits, community awareness meetings and support for referrals.
- Plan for on-going community involvement in the improvement and sustainability of the service.
- Work towards the reduction and/or elimination of stigma and discrimination at the community level.

With the person's consent their family should be counselled about the patient's illness and informed about the cause, signs and symptoms, treatment, possible complications and prevention. This should be done at the health facility where the diagnosis is made before referral for HB-ART.

The family needs to:

- Provide the patient with an adequate balanced diet.
- Prevent complications.
- Prevent transmission of infections e.g. HIV, TB.
- Link with the community HB-ART provider for support and referrals.
- Make sure that the PLHIV takes his/her medication according to the prescription.
- Make sure that the patient keeps his/her clinic appointments and observes medical advice appropriate for his/her condition.
- Support the PLHIV in order to avoid risk situations for infections and complications.

- Provide emotional support and spiritual care to the PLHIV.

HOME LEVEL

The family needs to:

- Strengthen family ties/attachments.
- Help the family to accept the person's condition.
- Provide opportunity to learn about chronic illnesses.
- Make it easier for family members who provide care to PLWHIV to attend to other responsibilities.

THE TREATMENT SUPPORTER

- The family will be required to choose among themselves at least one person who will be trained on specific elements of care for the PLHIV.
- A close family member will be required to know the person's prescriptions and clinic visit schedules and constantly remind him/her to adhere to the same.
- The treatment supporter should also know and be known by members of the clinical care team.

7.13 CHAPTER SUMMARY

In this Section 1 of this chapter, the researcher identified the main concepts using the Delphi technique. The concepts were identified from the conclusion statements derived from Chapter 5 (empirical data) and Chapter 6 (systematic literature review). The identified concepts which form the building blocks of the model for the ART programme were classified and defined using the survey list of Dickoff, et al. (1968).

In Section 2, the researcher developed the Home-Based ART (HB-ART) model using the Donabedian model (1980) which elucidate that the success of any programmes is dependent on exploring the three elements; which are the structure, process and outcome. The HB-ART model will serve as a framework for ART delivery to care and support PLWHIV in their homes.

CHAPTER 8: EVALUATION, LIMITATIONS, RECOMMENDATIONS AND CONCLUSIONS OF THE STUDY

8.1 INTRODUCTION

The chapter provides a reflective evaluation of the research process, after which the recommendations, limitations and conclusion of the study are provided. The evaluation will focus on lessons learned from conducting the study. The areas that form part of this evaluation include: the research approach, design, methods and procedures.

8.2 THE RATIONALE FOR EVALUATING STUDY

It is the responsibility of every researcher to ensure that the research findings are credible and acceptable. This evaluation of the study is intended to provide critical reflection on the research process as undertaken both as researcher and particularly on the model development process. The evaluation is reflective with the intention to review the challenges, problems, and potential treats to the empirical process and to provide alerts on issues to be avoided in future studies.

8.3 EVALUATION OF THE STUDY

The five standards of evaluation of the empirical studies according to Burns and Grove (2009) were used. The evaluation tool is methodological and systematic arranged in a manner that allowed the researcher to objectively examine the study. The five standards of the tool include the following criteria: (i) descriptive vividness, (ii) methodological congruence, (iii) analytic and interpretive congruence, (iv) philosophical or theoretical connectedness, and lastly, (v) heuristic relevance.

Table 8.1 below is provided to show how the five standards of Burns and Grove (2009) were used in this evaluation.

Table 8.1 A synopsis of the evaluation of the study according to Burns & Grove (2009)

CRITERIA AND GUIDELINES FOR EVALUATION AND EVALUATOR COMMENTS:
STANDARD #1: DESCRIPTIVE VIVIDNESS: (a). The significance of the study was clearly described, giving a wholistic perspective on how the ART programme was implemented as presented in Chapter 1 under Section 1.5. (b). The purpose and objectives of the study was described in detail and supporting arguments provided to support the need and the aim of the study. These arguments were provided under 'Problem staement' in Chapter 1 under Section 1.3 of the study to show how they form basis on which the research question was founded. (c). The feedback from the promotor the study assisted in improving these arguments at proposal stage which was continued through-out the different phases and stages of the research process, including interpretation of the analysed data and report writing. The arguments were refined

accordingly to attain vividness to the researcher and readers with the aim of ensuring the credibility of the study process.

STANDARD #2: METHODOLOGICAL CONGRUENCE

Substandard #2.1 Adequate Documentation of the Participants

(a). The participants were described in Chapter 7 under 7.2.1. The experience of participant in the ART programme was required to give the information that was intended to respond to the study question. This has contributed to the rich description of the data and provided the evidence base for the model development.

(b). Purposive sampling was used as a scientific criterion to select the district and facilities with ART programmes for Phase 1 of this study. This meant that all the participating districts and ART facilities were selected on the similar basis which was the provision of HIV services to people living with HIV.

(c). The challenge is whether the findings from this research can be generalised to other settings. The detailed description of the setting was provided in Chapter 3 under Section 3.3 Study setting of Phase 1. The review of studies which implemented ART models in SA in Phase 2 found that in general the ART delivery models could be replicated in other settings with similar characteristics in SA. The readers, researchers and anyone who wants to use the Delphi technique to develop a model should take the risk and work out the generalisability to their context.

Substandard #2.2 Careful Attention to the Procedural Approach

(d). The assumptions of Phase 3 of the study were identified by the researcher as presented in Chapter 7 under Section 7.7 which addressed ART delivery assumptions.

(e). The relationship between the participants and the researcher was positive as this was confirmed by the turnover of participants for the Delphi process in Chapter 7.

(f). The research questions and statement questions were asked in a manner that enhanced the

inquiry by obtaining the required answers for Phase 3 the research question. The nature of the phenomenon under inquiry encouraged participants to express their knowledge and understanding regarding the delivery of ART.

(g). Data collection process and methods were described sufficiently as discussed in Chapters 3, 6 and 7 i.e. Phases 1, 2 and 3 respectively

Substandard #2.3 Adherence to Ethical Standards

This standard address ethical requirements to be met in scientific studies.

(h). The participants were informed that they could withdraw from participation at any time if they felt like doing so. The participants were protected from potential emotional and psychological harm by not calling them with their real names. Electronic files were encrypted with password to protect data and confidentiality of the participants. Hard copy data-files were locked up of in a cupboard. These records will be kept for five (5) years after the study was published then they will be destroyed or discarded.

(i). Participants signed informed consents before data was collected as an ethical measure and principle to avoid coercion to participation. Permission to conduct the study was sought by obtaining institutional consents from the Faculty and Senate Research Committees prior to data collection.

(j). Scientific honesty was discussed in depth tin Chapter One under Section 1.7.6 to show how the study and researcher's integrity were maintained. The Code of Ethics by Beauchamp and Childress (2009) was used the researcher conducted that study in an ethically sound manner. Furthermore, ethical principles guided the researcher's activities and interventions as safe guarding participants were informed verbally and in writing about the interest of the participants telling them about their rights for participate and to withdraw without providing justification.

Substandard #2.4 Auditability

(k). The referencing system was used to acknowledge the sources and to avoid plagiarism. This was also to ensure that the arguments were with acceptable standard of scientific research and nature of the phenomenon under inquiry. The empirical excerpts provided a rich in support of the findings of the study as the transcripts were handy in yielding thick descriptive data that showed how the participants perceived the phenomenon of ART delivery and HIV services to people living with HIV.

(l). The processes that guided decisions in identifying, describing, and analysing the core concepts and conclusion and relational statements provide an audit trail used in the process of developing the home-based ART delivery model for people living with HIV. Appendices which are provided at the back of this report are guarantees of traceable research process, hence they can be used to affirm existence of specific research activities.

STANDARD #3: ANALYTICAL AND INTERPRETATIVE PRECISENESS

(a) The inductive and deductive processes were used to develop the categories and study findings on which the bigger picture of the implementation of the ART programme. Thereby, giving clarity on abstraction and inferred notions on the phenomenon under study.

(b). Member checking was used to validate the results from the empirical data before the findings could be used to inform the developed model.

(c). The independent reviewer analysed the data concurrent with the primary researcher in Chapter 6. The differences were reconciled successfully as these were minimal and insignificant.

STANDARD #4: PHILOSOPHICAL OR THEORETICAL CONNECTEDNESS

(a). The connectedness between philosophical and theoretical aspects of the study was established as early as in the proposal stage where assumptions of the researcher were presented

and the Donabedian Model of programme evaluation was adopted. Furthermore, this models also relate to the developed model of home-based ART delivery.

(b). The conclusion statements and related statement are connected to the phenomenon of ART delivery as known to the participants. Which showed the importance of ART provision and the conditions under which HIV services are provided.

(c). The philosophical and theoretical standpoints adopted in this study described and affirmed in Chapter 7 Sections 7.10 the context of the mode and 7.12 evaluation of the model using the Donabedian Model (1980) and Chinn and Kramer (2011) criteria respectively

STANDARD #5: HEURISTIC RELEVANCE

Substandard #5.1 Intuitive Recognition

The use of the qualitative approach for the Delphi study promoted implementation of the emic view principle when collecting the data. This view was accepted based on its relevant perspective to collect and obtain rich from participants own voice. The emic view in data collection did not only ensured that the findings of the study were a true reflection of the participants and thus acceptable., but more importantly the participant identify with the phenomenon being reported; because the participants' experiences were used to develop and describe the model for teaching-learning of spiritual care in nursing which specify the goal activity with the context of SA in relation to nursing education, practice, and research.

Substandard #5.2 Relationship to the Existing Body of Knowledge

This section provide evaluation on the following: (i) examination of existing body of knowledge and differences of conducted studies, (ii) the contribution made by this study to existing body of knowledge.

(i) EXAMINATION OF EXISTING BODY OF KNOWLEDGE:

The dearth of contextual-based scientific studies in analysing the implementation of the ART programme in KwaZulu-Natal, SA, provided an opportunity to conduct the current study.

The unique knowledge of the study presented new insights as stated below. The problem statement presented the comprehensive gap, omissions and inconsistences that exist in the implementation of ART programme and existing models of ART delivery.

(ii) CONTRIBUTION OF THE STUDY TO EXISTING BODY OF KNOWLEDGE:

The ultimate aim of a doctorate is to contribute to the body of science of the discipline. Throughout the study, the researcher was intensely aware of this. It was accomplished by creating new knowledge through in depth analysis, emerging new knowledge, new thoughts and new insights obtained from the empirical data, systematic review of existing ART models and the Delphi technique. The empiric data was used to analyse the ART programme using the Donabedian framework (Donabedian, 1980).

Substandard #5.3 Applicability to ART delivery and Research

(a). The findings of the current study have immediate relevance to the understanding of the implementation of the ART programme in KwaZulu-Natal and existing ART models in SA.

The discussion that is provided on the limitations and recommendation thereof, of the study connects the findings of the current study with the ART provision and research (current and future).

(b). The findings of the current study are valid as long as they are acceptable to the participants who contributed to its generation, however, on the other hand it is equally acceptable that this developed model may not hold the truth to the future generations who may consider the developed model as futile.

(c). Suggestions towards this evaluation standard is provided later in this chapter under the recommendation section.

8.4 LIMITATIONS OF THE STUDY

The limitations that relate to technical aspects were insignificant and managed successfully as the study progressed. The technical limitations that were experienced related to time factor and sample size. Each of these factors are discussed below.

8.4.1 Limitations Related to Time Factor:

Time factor affected phase 3 of the study process. The Delphi participants were expected to return their responses in 2 weeks for each of the 3 rounds. The 3 rounds proved to be time consuming for some participants and there were delays which halted the study process to a certain extent.

8.4.2 Limitations Related to the Sample Size

The study did not include sample size determination as this was not appropriate for the research questions for this study. The limitation of the review of existing ART models to South Africa only reduced the ability of this study to review other studies outside SA and increase the knowledge base. For the Delphi study, the response was positive however few participants did not respond to the researcher's request which could have increased the reliability of the study had more participants agreed to take part in the study. However, with the number of ten participants, the reliability was achieved as stated in the literature.

8.5 RECOMMENDATIONS OF THE STUDY

The recommendations draw from the results of the study.

Phase 1:

Recommendations to policy-makers:

1. The physical outline of ART facilities needs to be designed to allow adequate seating for PLHIV and receiving HIV services.
2. The ART facilities need to address structural, administrative, and procurement problems which hinder the availability of essential drugs to treat PLHIV.

Recommendations for further research:

3. Further research is needed to analyse the implementation and use of guidelines, policies and strategies that were developed for the multiple areas of care and support for HIV services.
4. Further research is needed into the use of laboratory services by the ART programme.
5. Further investigation into the accuracy of routine monitoring data is needed to ensure that interventions to address the HIV epidemic are well planned, targeted and appropriately funded based on the availability of accurate and reliable information.

Phase 2:

1. Adherence clubs' model of care should be considered for wide-scale implementation in SA.
2. Additional data and shared experiences from innovative community-based models of care are needed in SA to support long-term ART retention as ART cohorts in resource-limited settings continue to expand and mature.
3. Health system research examining the process issues related to establishing, extending and maintaining the ART delivery models would be beneficial to health policy makers.

Phase 3:

For the Home-based ART model to be accepted as valid, it needs to be tested in practical terms to generate evidence that will support it. Policy makers and programme implementers will only have confidence in this model only if it is supported by evidence.

8.6 CONCLUSIONS OF THE STUDY

This study was motivated by the observation that despite the fact that SA has successfully implemented the largest ART programme in the world in an attempt to meet the needs of PLHIV, the gap still exists in rendering HIV services that truly address the holistic need of PLHIV. Shifting the provision of ART from clinic and hospital-based to the homes of PLHIV can be one way to promote and optimise health, particularly in response to HIV. In view

of the study findings a need for the home-based ART delivery model in SA and KZN in particular is acknowledged. Policy makers and ART programme implementers should acknowledge that providing HIV services in the immediate environment of PLHIV has benefits as proven by other implemented community-based ART models. The findings of this research therefore make a unique contribution to the existing body of ART programme implementation and the provision of HIV services to PLHIV.

8.7 SUMMARY OF THE CHAPTER

This chapter addressed the evaluation, limitation and recommendation of the study. As laid out in the Table 8.1 the standard of research study evaluation tool by Burns and Grove (2009) was used.

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