

**EVALUATION OF ANTIRETROVIRAL USE IN CHILDREN MANAGED
IN PUBLIC CLINICS OF MOPANI DISTRICT, LIMPOPO PROVINCE:
TOWARDS A DOSING AND DISPENSING TRAINING PROGRAMME
FOR NURSES**

By

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THESIS

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DECLARATION

I declare that *Evaluation of Antiretroviral Use in Children Managed in Public Clinics of Mopani District, Limpopo Province: Towards a Dosing and Dispensing Training Programme for Nurses* is my own work and that all the sources that I have used or quoted have been indicated and acknowledged by means of complete references and that this work has not been submitted before for any other degree at any other institution.

Linneth Nkateko Mabila

15 December 2021

DEDICATION

I dedicate this thesis to the children, parents, and caregivers affected by the HI virus and the many colleagues in the HIV/AIDS management fraternity.

A special feeling of gratitude to my husband, Thembinkosi Mabila, and our children, Sithembinkosi, Luzuko, and Luthando. You are my reason why. Without your patience, understanding, encouragement, and moral support, I could never have achieved my dream of a doctoral degree. There are no words to express my gratitude to you.

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ABSTRACT

Antiretroviral (ARV) management in children is considered a challenging process, and patients receiving ARVs remain at risk of medication errors. Recently, there has also been a noticeable increase in Treatment Failure (TF) and the development of drug resistance amongst children on ART. However, ART failure amongst children seems to be an under-recognised issue, and adherence to treatment guidelines is reported to be a challenge among nurses caring for People Living with HIV (PLWHIV). Hence, the aim of this study was to explore the prescribing practices, and to determine the knowledge, understanding, and competence levels of NIMART-trained nurses' in the management of children on Antiretroviral Therapy (ART) in Public Health Care (PHC) facilities located in a rural district of Limpopo Province. To attain the purpose of the study, the researcher in this study adopted a mixed-method, in an explanatory sequential manner. The quantitative phase adopted a descriptive cross-sectional and retrospective census of medical records to determine whether or not the children on ART were prescribed the correct ARV regimen, dose, strength, dosing frequency and received the correct quantities to last until the next appointment date. Whereas the qualitative phase embraced a total purposive sampling of the NIMART-trained professional nurses to explore their knowledge, understanding and views of ART management in children. The results highlighted that these children under study even though they were prescribed a correct ARV regimen in (n=7045; 96%) of the cases; they were only correctly dosed in (n=7797; 53%); and prescribed the correct strength (n=9539; 77%), with only (n=2748; 36.9%) having received the correct quantity of treatment to last them until the next appointment date. Most nurses even though they rated themselves very knowledgeable and competent in paediatric HIV/AIDS management. This finding was contradicting the results obtained from the medical records, as well as their responses to the given case scenario depicted some level of non-adherence to treatment guidelines as well as a lack of understanding of ARV management. From the findings of this ARV utilisation review and the implementation of the developed ART dosing and dispensing training programme. The study concludes that the nurse's prescribing practice was irrational in this cohort of children, and most prescriptions did not entirely comply with the 2014/15 HIV/AIDS

treatment recommendations. Since, this cohort of children was found to be susceptible to medication related errors such as; Drug omissions in ARV regimens; Incorrect dosing & dosing frequencies; as well as incorrectly supplied quantities. From the study findings it is recommended that ARV stewardship programs should be considered in order to develop and establish a core strategy for enhancing quality improvement in the management of HIV-infected children on ART in resource-limited settings, not only to inundate viral suppression and maintain it, but also to help achieve the UNAIDS 95-95-95 target in children under 15 years.

Keywords: Prescribing Practices, Children, Antiretroviral Therapy, Virally Unsuppressed, Primary Health Care, Underdose, Overdose

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LIST OF ABBREVIATIONS

3TC:	Lamuvudine
ABC:	Abacavir
ACCP:	American College of Clinical Pharmacy
ADDIE:	Analysis, Design, Development, Implementation, and Evaluation
ADRs:	Adverse Drug Reactions
AIDS:	Acquired Immunodeficiency Syndrome
ART:	Antiretroviral Therapy
ARVs:	Antiretrovirals
AZT:	Zidovudine
CHCs:	Community Health Centres
d4T:	Stavudine
ddl:	Didanosine
DHIS:	District Health Information Software
DOT:	Directly Observed Therapy
DUPs:	Drug Utilisation Patterns
DUR:	Drug Utilisation Research
EBP:	Evidence Based Practice
EFV:	Efavirenz
FBC:	Full Blood Count
FTC:	Emtricitabine
Hb:	Haemoglobin
HIV:	Human Immunodeficiency Virus
HRH:	Human Resource for Health
HTS:	HIV testing and counselling services
IRIS:	Immune Reconstitution Inflammatory Syndrome
LMICs:	Low and Middle-Income Countries
LPDoHRU:	Limpopo Province Department of Health Research Unit

LPV/r:	Lopinavir/ ritonavir
LTFU:	Lost To Follow Up
MDR TB:	Multi-Drug Resistant TB
MSF:	Médecins Sans Frontières'
NDoH:	National Department of Health
NIMART:	Nurse Initiated and Managed Anti-Retroviral Therapy
NVP:	Nevirapine
OIs:	Opportunistic Infections
PEPFAR:	President's Emergency Plan for AIDS Relief
PHC:	Primary Health Care
PHCs:	Primary Health Care Clinics
PLHIV:	People Living with HIV
PNs:	Professional Nurses
QOL:	Quality of Life
RSA:	Republic of South Africa
SAPC:	South African Pharmacy Council
SPSS:	Statistical Package for Social Sciences
SSA:	Sub-Saharan Africa
TB:	Tuberculosis
TdF:	Tenofovir
TF:	Treatment Failure
TREC:	Turfloop Research Ethics Committee
TS:	Task Shifting
UNAIDS:	United Nations Joint Programme on HIV/AIDS
VF:	Virological Failure
VS:	Virological Suppression
WHO:	World Health Organisatio

DEFINITION OF CONCEPTS

CONCEPT	DEFINITION/DESCRIPTION
Antiretrovirals:	Refers to “drugs that are acting, used or effective against retroviruses” (https://www.merriamwebster.com/dictionary/antiretroviral). In this study, the concept of antiretrovirals will be used as defined.
Antiretroviral Use:	For this study, antiretroviral use shall refer to the prescribing and dispensing of antiretrovirals to children receiving HIV care in public clinics.
Children:	According to the <i>National Consolidated Guidelines for the prevention of Mother-to-Child transmission of HIV (PMTCT) and the management of HIV in children, adolescents, and adults</i> (NDOH, 2015), this concept refers to children under the age of fifteen (15). Once the child turns 15yrs, it is recommended that they are treated with adult medication. Hence, in this study, this concept will refer to a child from birth to below 15 years of age.
Dispensing	This refers to the “preparation, labelling, record keeping and transfer of a drug to a patient or an intermediary who is responsible for the administration of the drug” (https://medical-dictionary.thefreedictionary.com/drug+dispensing). In this study, dispensing will refer to the preparation, labelling, record keeping and handover of antiretrovirals to the patient or the caregiver responsible for the administration of the therapy thereof.
Dosing	This is derived from the word dose, a quantity of medicine prescribed to be taken at one time (https://www.dictionary.com/browse/dosing). In this study, dosing will be used to define the number of antiretrovirals prescribed to be taken at one time by patients.

CONCEPT	DEFINITION/DESCRIPTION
Evaluation:	<p>This is defined as the process of judging something's quality, importance, or value, or a report that includes this information (https://dictionary.cambridge.org/dictionary/english/evaluate).</p> <p>Evaluation is deemed an essential part of the educational process. With a focus on local quality improvement, it is analogous to clinical audit (Morrison, 2003). In this study, the evaluation will be denoted as defined.</p>
Nurse:	<p>In this study, the concept nurse shall be used to refer to a professional nurse working at a primary health care facility, trained to initiate and manage patients on antiretroviral therapy.</p>
Public Clinic:	<p>A facility at a community level funded by the government and the department of health, from which a range of primary health care services are provided. It usually operates eight or more hours a day based on the community needs (Kwa-Zulu Natal Department of Health, 2001). In this study, a public clinic will refer to government-funded Primary Health Care (PHC) and Community Health Centers (CHCs) without permanently employed pharmacists.</p>
Regimen Hopping:	<p>The Regimen Hopping context is derived from the understanding of the English word "hop" which is to pass quickly from one place to the next, wherein these children were moved from the regimen at initiation to the next to as often as more than five times.</p>

CONCEPT	DEFINITION/DESCRIPTION
Training:	<p>In its very basic form, training refers to planned and systematic activities designed to promote the acquisition of knowledge, skills, and attitudes (KSAs) (Salas, Tannenbaum, Kraiger & Smith-Jentsch, 2012). To be effective, it should occur when trainees are intentionally provided with pedagogically sound opportunities to learn targeted knowledge, skills and attitudes provided through instructions, demonstrations, practice and timely diagnostic feedback about their performance (Salas and Cannon-Bowers, 2001). In this study, training refers to the process of providing and empowering NIMART nurses in public clinics with the knowledge and skills to enable them to use antiretrovirals in children rationally.</p>
Viral Load:	<p>A viral load is in HIV care defined as a measure of the number of virus particles per cubic centimetre of blood, and therefore used in this study.</p>

CHAPTER 1

OVERVIEW OF THE STUDY

1.1 Introduction and Background to the Study

The United Nations Joint Programme on HIV/AIDS (UNAIDS, 2016) reported that the number of people living with HIV/AIDS was estimated at 36.7 million worldwide. Of this number, 2.1 million are children under the age of 15. It is common knowledge that South Africa (SA) has the most extensive Antiretroviral Therapy (ART) programme globally. UNAIDS reported that “3.7 million individuals were receiving treatment in the country. This equates to 65% of People Living with HIV (PLHIV) in SA” (UNAIDS, 2016).

Globally, the number of PLHIV escalated as more people gained access to life-saving ART (Bateman, 2007). In SA, as with many other countries classified as resource-limited, the scale-up of the national ART programme started in 2004. Since then, SA has made outstanding progress in initiating and rolling ART to patients in need (Zachariah, Tech, Buhedwa, Labana, & Chinji, 2007). Hence, Zachariah *et al.* (2007) note that the country has “the largest number of people enrolled on Antiretrovirals (ARVs) in the world”. The expansion of ART programmes in resource-limited countries has resulted in the decentralisation of primary health care (PHC) clinics. It is an act that is believed to have resulted in the increased retention and care of patients receiving ART, which has also decreased the load of managing patients with minor ailments at referral hospitals; as well as substantially improving patient outcomes (Nyasulu, Muchiri, Mazwi, & Ratshefola, 2013).

The implementation of nurse-prescribing of ARVs through Nurse Initiated and Managed Anti-Retroviral Therapy (NIMART) has been a great success in SA. For example, in several studies, such as those conducted by Sanne, Orrell, Fox, Conradie, Ive, *et al.* (2010) and Nyasulu *et al.* (2013), NIMART has proven to be no different from doctor-managed ART programmes.

However, large workloads at the PHC level are causing a ‘vicious tangle’ of problems in the clinics as nurses are reported to suffer from high levels of stress, high rates of turnover, sickness and staff shortages. It results in poor quality of care as a consequence of reduced

attention to adherence issues and the identification of Treatment Failure (TF) (Mutevedzi, Lessells, Heller, Bärnighausen, Cooke, *et al.* 2010). This is a huge challenge for children on ART since the successful treatment of children is almost entirely reliant on adherence. This is essential because it enables children to live long and fulfilling lives.

Hence, Marazzi, Bartolo, Gialloreti, Germano, Guidotti, *et al.* (2006) emphasise the importance of appropriate use of ARVs as the essence in the quest to avoid or minimise the onset of Virological Failure (VF) and resistance to ARVs as well as an appreciation of mortality rates.

In a study conducted in Port Elizabeth Metropolitan, Katende-Kyenda, Lubbe, Serfontein, and Truter (2011) argue that there is a need for constant evaluation of systems when using treatment that has the propensity to cause harm if misused. This is mainly in the case of infectious diseases such as HIV/AIDS. More specifically, the Katende-Kyenda *et al.* (2011) study also underlines the importance of educating healthcare professionals on the appropriate use of ARVs.

Moreover, Nyasulu, Muchiri, Mazwi, and Ratshefola (2013) indicate in their study that ever since NIMART was introduced in South Africa in 2010, there has been a great need for the training of professional nurses in the primary health care settings on issues of HIV management.

The preceding views connect well with the WHO's (2008) recommendation that countries implementing task shifting like SA should guarantee that the performance of all nurses is evaluated along with clearly defined roles, standards, and competency levels. Morris, Chapula, Chi, Mwango, Chi, *et al.* (2009) therefore, clarify how an ongoing all-inclusive quality assurance programme for task-shifting was implemented through:

- “(i) Evaluation of clinical care through targeted chart reviews and monthly site reports from electronic medical records;
- (ii) Feedback and training in areas of poor site performance, and
- (iii) An exchange programme between clinics to improve overall clinical quality”.

The reported study sought to embed itself within the previous paragraph's call. It sought to evaluate antiretroviral use in children managed in public clinics. Based on the findings, it sought to develop a training programme to strengthen the utilisation of antiretrovirals.

While some might doubt the significance of research in poorly-resourced settings, there are immeasurable benefits for empirical studies in these locations, especially concerning the implementation of HIV treatment strategies. According to Sanne and Van der Horst (2004), the benefits often include the commissioning and provision of infrastructure and training of staff and treatment algorithms appropriate for rural settings. Hence, this study aims to take stock of how medicines for ART are utilised in public clinics of the Mopani District.

1.2 Problem Statement

The growth in the rollout of ART in South Africa led to the issuing of a 2010 presidential mandate that gave a directive that ART should be made available in all public clinics of SA. This mandate gave birth to the NIMART training programme and implementation (Motsoaledi, 2012). While this imperative led to considerable success in HIV diagnosis and treatment, a growing problem known as treatment failure (TF) has emerged. According to Bernheimer, Patten, Makeleni, Mantangana, Dumile, *et al.* (2015), this problem threatens to undermine this progressive stance's success and cause the development of drug resistance among patients treated in public clinics.

Unfortunately, the factors contributing to this outlined problem, namely ART failure and drug resistance amongst children receiving treatment in public clinics are not effectively documented or well understood as they have received little attention (Bayu, Tariku, Bulti, Habitu, Derso, *et al.* 2017; Bernheimer, *et al.* 2015). Where available, research data paints a bleak picture. For example, the 5th South African national HIV prevalence, incidence, behaviour and communication survey reveals that the prevalence of viral load suppression (VLS) among children in SA was as low as 48.2% (HSRC, 2018).

In the Mopani district, the VLS rate in children aged 0-10 years was at a mere 58.2% (Railton, 2017). If this reality continues, the realisation of the 2020 USAID 90-90-90 targets for HIV/AIDS care that SA signed for will remain a far-fetched ideal. This is especially so

because, in SA, most children's cases are in the care of NIMART nurses in public clinics, making it essential to ensure that NIMART nurses' ART knowledge and skills are kept in check and updated to promote the rational use of antiretrovirals in children.

Despite the increase in the number of people accessing antiretroviral therapy (ART), there is limited data regarding treatment failure and its related factors among HIV-positive individuals enrolled in HIV care in resource-poor settings. Hence, Bezabih, Beyene and Bezabhe (2019) indicate that treatment failure has become a significant challenge in patients taking antiretroviral therapy (ART). Factors for first-line ART failure among patients include, discontinuation of ART, baseline CD4 lymphocyte count ≤ 50 cells/mm³ and persistent diarrhea. as independent factors for first-line ART failure. There is a need for healthcare workers and HIV program implementers to focus on patients who have these characteristics in order to prevent ART treatment failure. This study will present a novel approach to addressing this problem.

1.3 Theoretical Framework

Two theories were used in this study to guide and serve as a basis for developing and implementing a dosing and dispensing training programme as well as enhance antiretroviral use in children living with HIV by NIMART-trained Professional Nurses (PNs) located in primary healthcare clinics. These theories are discussed at length in Chapter 3 of this study.

1.4 Purpose of the Study

The purpose of this study was to evaluate the use of ART in children managed by NIMART-trained PNs at public clinics located in resource-limited settings in the Mopani District of Limpopo Province. The study evaluated the use of ART against the 2015 South African HIV treatment guidelines to develop and implement a dosing and dispensing training programme for the NIMART trained nurses who manage children on ART at public clinics.

1.4.1 Objectives

The objectives of this four-phase study were as follows:

- To conduct a four year (01 January 2015 to 31 December 2018) desktop baseline assessment to determine the clinical outcomes of children initiated on ART in public clinics of Mopani District in the year 2015.
- To explore and describe the prescribing practices of NIMART trained professional Nurses when managing children with unsuppressed VLs on ART in public clinics of Mopani District, Limpopo Province,
- To assess the NIMART-trained PNs' compliance with the 2015 South African HIV/AIDS guidelines for the treatment of children on ART,
- To identify the factors associated with regimen switching in children on ART managed at public clinics across the Mopani District, Limpopo Province,
- To determine the knowledge, understanding, and competence of NIMART-trained PNs in managing children on ART in public clinics of Mopani District, Limpopo Province,
- To establish the perceptions of NIMART-trained PNs regarding the effective management of children on ART in public clinics,
- To establish the training needs of NIMART-trained PNs regarding the effective management of children on ART in public clinics,
- To develop a training programme for the appropriate use of antiretrovirals and management of ART by NIMART-trained PNs in Mopani public clinics,
- To implement the training programme for the appropriate use of antiretrovirals and ART management by NIMART-trained PNs in the Mopani public clinics.

1.4.2 Research Questions

This primary research question steered this study: How appropriate is the use of ART in children managed by NIMART-trained PNs in public clinics located in resource-limited settings in the Mopani District, Limpopo Province?

These secondary questions guided the researcher:

- What is the baseline status of the treatment of children initiated onto ART in public clinics across the Mopani District in 2015?

- What are NIMART trained professional nurses' prescribing practices when managing children with unsuppressed VLs on ART in public clinics of Mopani District, Limpopo Province?
- To what extent do prescribers (NIMART-trained PNs) of ART in children comply with the South African HIV/AIDS treatment guidelines?
- What factors are associated with regimen switching in children on ART managed at public healthcare clinics across the Mopani District?
- What is the knowledge, understanding, and competence for dosing and dispensing among NIMART-trained PNs involved in managing children on ART in the resource-limited public clinics in the Mopani District?
- What are the perceptions of NIMART-trained PNs about effective management of children on ART in public clinics of Mopani District?
- What are the training needs of NIMART-trained PNs regarding the effective management of children on ART in public clinics?
- What is a suitable programme for training NIMART-trained PNs in the appropriate use of antiretrovirals and management of ART in Mopani public clinics?
- How should the training of NIMART-trained PNs in the appropriate use of antiretrovirals and management of ART in Mopani public clinics be implemented?

1.5 Research Methodology Overview

To attain the purpose of the study, the researcher in this study adopted a mixed-method, explanatory sequential research design. The study was conducted in all clinics (that is, eight (08) community health centres (CHCs) and eighty-six (86) PHC clinics) of Mopani District that had children under the age of 15 years enrolled on ART in 2015. The quantitative strand population comprised all medical records of children under the age of 15 years enrolled on ART in 2015. In contrast, the qualitative strand comprised all NIMART-trained PNs working in PHC clinics where children under 15 years were enrolled for HIV care and management in 2015. Both strands of the study were piloted in four (04) purposefully selected public clinics under the Greater Tzaneen Sub-district (Morapalala, Relela, Tours and Zangoma clinic). These clinics were not yet accredited for ARV roll-out in 2015. These sampling methods were used across the different phases of the study as follows;

- Quantitative Strand - employed a total population purposive sampling technique in Phase 1A, followed by a non-probability (purposive) sampling procedure in Phase 1B.
- The qualitative Strand (Phase 2) - followed a total population sampling technique.

Data for the quantitative strand of the study were collected through checklists and the evaluation of children's medical records at the clinics. Whereas data for the qualitative strand were collected through self-administered questerviews followed by semi-structured interviews, using an interview guide, a voice recorder and field notes as tools. A detailed methodology is discussed in Chapter 4 of the study.

1.6 Significance of the Study

The researcher envisages the outcomes of this study to bring a new angle to the management of HIV in children through the promotion of rational antiretroviral use at primary healthcare clinics and antiretroviral stewardship. This angle has not yet been explored in HIV/AIDS management and care. Hence, the researcher in this study anticipates that outcomes of the study will contribute knowledge towards the establishment of improvement strategies and the strengthening of systems in the management of HIV/AIDS in children living in rural areas as follows;

1.6.2 Nursing Profession

The study will also be of significance to determine further training and education of NIMART-trained PNs in ART dosing and dispensing in children.

1.6.3 Research

From a research perspective, the study's findings are expected to be of use in formulating the basis for further research. More research into the development of pharmacist-initiated training and mentorship programmes for nurses involved in the management of ART in children treated in public primary healthcare settings may also ensue.

1.6.1 Pharmacy Profession

The study will guide how pharmacists working closely with public clinics will tailor-make support for and mentorship of NIMART-trained PNs.

1.6.4 Department of Health

Outcomes of this study are envisaged to bring a new angle to the management of HIV in children through the promotion of rational antiretroviral use at primary healthcare clinics and antiretroviral stewardship. This angle has not yet been explored in HIV/AIDS management and care.

- Providing information to pharmacy managers about their role in the management of HIV/AIDS for children in primary healthcare clinics,
- Informing HIV/AIDS guidelines for health workers.

The strategies brought by the research will hopefully be adopted by the department of health, implementing partners and other relevant stakeholders in the management of HIV/AIDS.

Hopefully, the strategies will be of positive effect in the treatment and care and help prevent the development of an "antiretroviral era", as this can be a detrimental effect on the lives of children living with HIV/AIDS.

1.7 Conclusion

This chapter concisely gives an outline of the study by providing an introduction and background information of HIV/AIDS around the globe and the status of antiretroviral therapy in children treated in public primary healthcare settings by nurses.

The chapter additionally outlines the research problem and give a background theory of the study. It conjointly summarises the aim, research questions, and objectives of the study. Furthermore, this chapter summarised the research methodology with emphasis on the research design, population, sampling, data collection, and analysis.

1.8 Outline of the Chapters

The chapters of this study are outlined as follows;

Chapter 1: Overview of the Study.

Chapter 2: Literature Review.

Chapter 3: Theoretical Framework.

Chapter 4: Research Methodology.

Chapter 5: Presentation and Discussion of Results and Findings

Chapter 6: Development of a Dosing and Dispensing Training Programme for the nurses.

Chapter 7: Implementation of the Dosing and Dispensing Training Programme.

Chapter 8: Conclusions, Limitations and Recommendations of the Study.

CHAPTER 2 LITERATURE REVIEW

2.1 Introduction

This chapter of the study provides a comprehensive review of literature related to the use of antiretroviral therapy in children under the age of 15 years who are managed by NIMART trained nurses in public primary healthcare clinics.

A literature review is defined by Jaidka, Khoo and Na (2013) as “a summary of a selected collection of related research information that is organised and integrated into a logical justification for the author’s research”. These authors further elude that “literature reviews are written mainly by researchers who survey previous studies to spot research gaps and position their work in the context of previous findings”. In understanding the different techniques of reviewing the literature, the researcher used a Narrative Literature Review (NLR) method.

2.2 Methodology

The researcher in this study opted for a Narrative Literature Review (NLR) to understand that this type of approach caters for a comprehensive, critical and objective literature review of the current knowledge on the topic under study.

A Narrative Literature review is defined by Ferrari (2015) as a ‘secondary research’ study, meaning that it is based on ‘primary research’ studies. It also “summarises the body of literature, draws conclusions about a topic under study and identifies gaps or inconsistencies in the body of knowledge” (Dudovskiy, 2018).

In health disciplines, literature reviews guide gathering and synthesising the vast amount of information in the ever-increasing literature and research. Hence the chosen design of literature search will help the researcher identify patterns and trends in the literature so that gaps or inconsistencies in a body of knowledge can be identified. Therefore, this will lead to a sufficiently focused research question that justifies the project under study. Literature reviews are an essential part of the research process. They help establish “a theoretical framework and focus or context for the research conducted” (Coughlan & Cronin, 2017).

Craig and Smyth (2007) state: “Because narrative literature reviews embrace a comprehensive search strategy, appraisal and synthesis of research evidence. They can therefore be used as shortcuts within the evidence-based processes”. However, it is essential to note that narrative literature reviews do not present new information but intends to assess what is already publishes and produce the most compelling evidence that is presently out there. Guided by the understanding of the shortcomings of the NRL, to learn and improve the standard of this literature review, and to cut back on the bias, the investigator in this study borrowed the systematic literature review methodologies aimed toward reducing bias within the choice of articles for review and using an efficient research list analysis strategy as suggested by Ferrari (2015).

Therefore, this study was a diligent systematic inquiry to validate and refine existing knowledge of ART usage in virally unsuppressing children receiving care in public PHC clinics and developing new knowledge, especially on issues of ART dosing dispensing. The researcher in this project understands that a diligent systematic study indicates planning, organisation, and persistence. The ultimate goal is to develop an empirical body of knowledge for the nursing profession. Therefore, if one were to define nursing research, it will require that one determines the relevant knowledge needed by nurses. Since nursing is a practice profession, the researcher in this study acknowledges that this type of research is necessary to develop and refine knowledge that nurses can implement to improve their clinical practice and promote quality outcomes in children under 15 years of age who nurses manage in public PHC clinics (Melnyk, Gallagher-Ford, Zellefrow, Tucker, Thomas, *et al.*, 2018). Nursing research is also needed to generate knowledge about nursing education, nursing administration, health services, the characteristics of nurses, and the role of nursing. Findings from research can indirectly influence nursing practice and supplement a wealth of nursing experience. In summary, nursing research is a scientific process that validates and refines existing knowledge and generates new knowledge that directly and indirectly influences nursing practice. Nursing research is the key to building an Evidence Based Practice (EBP) for the nursing profession (Harper, Gallagher-Ford, Warren, Troseth, Sinnott, *et al.*, 2017).

2.2.1 Selection Criteria

Adopting a similar approach to that of systematic literature reviews (SLRs), this narrative review enclosed several kinds of studies with different levels of evidence. The literature review ideally included original journal articles over other narrative reviews on a similar topic. It also incorporated publications and book chapters available online during the period March 2019 until December 2019. Additionally, it also involved reports from randomised clinical trials, observational case-control, cohort studies, and editorials by key opinion leaders within the field under study. All these were executed with appropriate data searching platforms available at the University of Limpopo library database.

2.2.2 Database Searches

Literature was reviewed from the following databases and search engines:

- Electronic databases: BioMed Central (BMC), BMJ Open, EBSCOhost Discovery, Elsevier, PLoS ONE, PubMed, UNAIDS, UNICEF, Science Direct, Republic of South Africa National Department of Health, and SABINET.
- Search Engines: Google Scholar and UL E-Libraries.
- Hand Searches: Reference lists from retrieved literature.

2.2.3 Key Search Terms

The following Boolean operators were used to direct the literature search, “AND”, “OR”, as well as “NOT”. These are the key search words used;

- HIV **not** AIDS Prevalence in South Africa
- HIV treatment in children **not** Adults
- NIMART in South Africa
- NIMART AND HIV Management
- Task Shifting AND HIV Management
- Task Shifting in Primary Health Care Facilities
- Rational medicine use
- Rational Prescribing

- The prescribing process
- Role of Task Shifting in HIV Management
- Compliance with treatment guidelines
- Compliance with treatment protocols
- The process of medicine prescribing
- The impact of irrational medicine use

2.2.4 Critical Assessment

The evaluation of the fitness of the reviewed articles for this literature review was guided by the steps in Derish and Annesley (2011), wherein the studies with the best contributions were synthesised, and the possible consistencies and inconsistencies among the articles were critically evaluated looking at the following:

- Suitability of the article to the study.
- Quality and relevance of the results obtained.
- Key results and findings.
- Interpretation of the results.
- Impact of the conclusions to the field under study.
- Limitations and recommendations of the study.

2.2.5 Themes

The following are the themes of the literature review;

- HIV in South Africa
- Principles of ART in Children and Quality of Life
- Adherence to Antiretroviral Therapy in Children
- HIV Treatment Failure
- Effects of HIV Treatment Failure in Children
- Task Shifting
- The role of Task Shifting in HIV Management and Care
- The role of NIMART training in HIV management and care
- Health Care Professionals Compliance to treatment guidelines

- The process of Medicine Prescribing
- Rational Medicine Prescribing
- The impact of Irrational Medicine Use
- Strategies to Tackling Irrational Medicine Prescribing
- The Medicine Dispensing Process

2.2.6 Findings

The literature search resulted in 162 usable and relevant information, where 142 articles and 20 electronic databases such as UNAIDS, UNICEF, WHO etc., were reviewed.

2.3 HIV in South Africa

South Africa (SA) is among the countries that are worst plagued by the HIV epidemic globally (Horwood, Vermaak, Rollins, Haskins, Nkosi, *et al.* 2009), with an estimated 7.52 million people living with HIV in 2018 and more than 4.5 million people on the lifesaving antiretroviral therapy (ART) programme by the end of June 2018, which is 20% of the people on treatment worldwide (UNAIDS, 2018). This means that only 45% of the PLHIV have significant viral suppression (Prendergast & Penazzato, 2018). Therefore, a question of interest is what proportion of PLHIV with significant viral suppression is in children?

Therefore, concerning HIV, SA has partnered with the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) and adopted the United Nations Joint Programme on HIV/AIDS (UNAIDS) 90-90-90 targets which proposed that by 2020:

- i) 90% of all people living with HIV will know their status;
- ii) 90% of all people with an HIV diagnosis will receive sustained antiretroviral therapy, and
- iii) 90% of all people receiving antiretroviral therapy will achieve viral suppression.

The South African National Strategic Plan, 2017-2022

It is, therefore, no doubt at this point that South Africa has made considerable progress in its response to the Acquired Immuno-Deficiency Syndrome (AIDS) pandemic in the past decade (UNAIDS, 2018). However, the mortality rate among HIV infected children remains high, with over 50% of untreated children dying in Africa in the first two years of their life (Newell,

Coovadia, Cortina-Borja, Rollins, Gaillard, *et al.*, 2004). Hence the identification of HIV infected children and the early initiation of Antiretroviral Therapy (ART) are said to be significantly crucial to considerably improve mortality in this population group (Violari, Cotton, Gibb, Babiker, Steyn, *et al.* 2008). However, other scholars note that despite the availability of free ART, only a minority of children in need of therapy are receiving it (UNAIDS, 2017). To attest to this, recent data indicated the percentage of adults on antiretroviral treatment to be 61%, with only 58% of children estimated to be on treatment in 2017(AVERT, 2019).

Williams, Gupta, Wollmers, and Granich (2017) note that SA is the only country in the Southern African Development Community (SADC) region with a notable prevalence of HIV/AIDS infections. In addition, UNAIDS gave a worrying report in 2016, which indicates that “one in every five people in the world with HIV infection lives in SA”. Whereas, Williams *et al.* (2017) stress this point even further by stating that if AIDS is to be ended globally, it should be ended in SA. Given the intensity of the problem in the heavily burdened health system in SA, Williams *et al.* (2017) maintain that ending AIDS in SA will present an opportunity to show what can be done to deal with the pandemic and present a challenge the world to do the same.

Despite the bleak picture painted in the previous paragraph, it is promising that, not long ago, the UNAIDS (2014) gap report highlighted the fact that there has been a well-adjusted global surge in paediatric HIV treatment from 10% in 2009 to 51% in 2015. However, “for those children living with the HI Virus, AIDS-related ailments are still largely the cause of child and infant mortality” (Liu, Oza, Hogan, Perin, Rudan, *et al.*, 2015). More action is necessary to promote the prevention and treatment of HIV in vulnerable groups and address the problem in areas where HIV/AIDS is still the leading cause of mortality of children (UNAIDS, 2015).

An available report from a study conducted by Sutcliffe, van Dijk, Bolton, Persaud, and Moss in 2008 indicated that The Sub-Saharan Africa (SSA) programmes achieved similar results to the North American and European programs. However, improving the care of children infected with HIV with SSA required progress in many areas. These results underscore the need for improved access to antiretroviral treatment programs, improved HIV care in rural areas, and the integration of antiretroviral treatment programs into various medical services.

SSA's anti-retroviral therapy programmes are not available to trained clinicians and other healthcare professionals needed to provide anti-retroviral therapy. There is also the problem of an underdeveloped drug procurement and distribution system, and are faced with many obstacles, including a ban assay to monitor drug response and side effects. These barriers can make it even more difficult to care for children living with HIV (Harries, Nyangulu, Hargreaves, Kaluwa, & Salaniponi, 2001; Stevens, Kaye & Corrah, 2004).

Mutambo and Hlongwane (2019) bring forth in their study that to accelerate the HIV response towards fulfilling the UNAIDS 90-90-90 targets for children < 15 years of age, healthcare providers need to lead the expansion of HIV services in primary health care settings. However, such increases require the investigation of existing barriers that prevent healthcare professionals from effectively providing these services to their children. In addition, it should be noted that the development of effective public health response programs for different situations can have different consequences if the identified barriers are not fully understood (Hlongwana & Mutambo, 2019).

2.4 Principles of ART and Quality of Life in Children

The use of ART is the basis of clinical interventions that can be used to prevent the transmission and progression of HIV infection in people living with HIV / AIDS. ARV has been shown to significantly reduce the rate of HIV replication in HIV-infected individuals. ART does not destroy the virus and cannot cure infections or illnesses, but it significantly reduces the viral load and significantly slows the progression of the disease, increasing the life expectancy and quality of life of people with HIV and AIDS. can do (Oguntibeju, 2012).

Quality of life (QOL) is an essential antiretroviral treatment (ART) outcome (Bunupuradah, Kosalaraksa, Vibol, Hansudewechakul, Sophonphan, *et al.*, 2013). Despite the characteristics of HIV, the means by which it is prevented, the pathophysiology of the progression from HIV infection to symptomatic AIDS, and effective antiretroviral therapy, HIV infection, progress over the last two decades in the development of AIDS, children It has become a big problem in developing countries that have not been solved yet. The range of HIV / AIDS problems measured by the number of affected children is very large (Embree, 2005).

Scholars agree that HIV in children is somewhat different from HIV in adults (The Well Project, 2018). For example, it is reported that there is a much higher CD4 cell count in children than in adults who live with HIV. It is also argued that children may have higher VLs than adults. Another distinction is that, in adults, HIV tends to weaken a mature immune system, whereas, in children, it tends to attack an immune system under development (The Well Project, 2018). This results in a more rapid disease progression in children when compared to adults. Children who are started early on ART tend to pick up their CD4 levels more quickly. Therefore, the management of HIV-infected children needs a more precise and thorough approach.

These observations have led to updating South African HIV treatment guidelines in 2015. As a result, the treatment of all children diagnosed with HIV must be started as early as possible, irrespective of their CD4 count or WHO clinical staging. In justifying this stance, the South African HIV treatment guidelines (NDoH, 2015) indicate that the objective of ART for children is to improve survival and reduce HIV-related disease and death.

The Reason the study focused on the 2015 cohort was guided by the fact that with effect from the 1st January 2015, the ministry of health in the Republic of South Africa (RSA) under the leadership of Minister Aaron Motsoaledi amended the criterion to start children on ART. Children on Stavudine (d4T) and Didanosine (ddI) containing regimens were with effect from 1st January 2015 supposed to be switched from using regimens containing these ARV agents to Abacavir (ABC) containing regimens, Table 2.1 below outlines a summary of the ART guidelines before 2015 and after 2015 as well as te regimen switching recommendations.

Table 2.1: ART guidelines before 2015 and after 2015 - Guidelines for regimen switching

PRIOR 2015	FROM 2015
FIRST-LINE REGIMENS:	FIRST-LINE REGIMENS:
Age 6 months to 3 years or < 10 kg	Children < 3 years or older and children weighing < 10kg
• d4T +3TC + LPV/r	• ABC + 3TC + LPV/r
Age > 3 years and > 10 kg	Children 3-10 years and > 10kg
• d4T+ 3TC + EFV	• ABC + 3TC + EFV
If < 40 kg	Children 10 – 15 years or < 40kg

PRIOR 2015	FROM 2015																								
<p>Efavirenz, oral, as a single daily dose as follows;</p> <table border="1"> <thead> <tr> <th style="background-color: #ADD8E6;">Body Weight</th> <th style="background-color: #ADD8E6;">Dose</th> </tr> </thead> <tbody> <tr> <td>10–15 kg</td> <td>200 mg</td> </tr> <tr> <td>15–20 kg</td> <td>250 mg</td> </tr> <tr> <td>20–25 kg</td> <td>300 mg</td> </tr> <tr> <td>25–32.5 kg</td> <td>350 mg</td> </tr> <tr> <td>32.5–40 kg</td> <td>400 mg</td> </tr> <tr> <td>> 40 kg</td> <td>600 mg</td> </tr> </tbody> </table>	Body Weight	Dose	10–15 kg	200 mg	15–20 kg	250 mg	20–25 kg	300 mg	25–32.5 kg	350 mg	32.5–40 kg	400 mg	> 40 kg	600 mg	<ul style="list-style-type: none"> • ABC + 3TC + EFV <p style="background-color: #ADD8E6;">Children on Stavudine (d4T) regimen</p> <ul style="list-style-type: none"> • Change all d4T to ABC <p style="background-color: #ADD8E6;">Children on Didanosine (ddl) regimen</p> <ul style="list-style-type: none"> • Change all ddl to ABC 										
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<p>SECOND-LINE REGIMENS</p> <p style="background-color: #ADD8E6;">Option 2.1:</p> <p>If previously on Stavudine, Lamivudine and Lopinavir/ritonavir</p> <ul style="list-style-type: none"> • AZT + ddl + NVP <p>OR</p> <p>If age > 3 years or > 10 kg</p> <ul style="list-style-type: none"> • AZT + ddl + EFV <p style="background-color: #ADD8E6;">Option 2.2:</p> <p>If previously on a d4T+3TC+EFV regimen:</p> <ul style="list-style-type: none"> • AZT + ddl + LPV/r <p>Dosing Guide per specific drug</p> <ul style="list-style-type: none"> • Efavirenz(EFV), oral, as a single daily dose <table border="1"> <thead> <tr> <th style="background-color: #ADD8E6;">Body Weight</th> <th style="background-color: #ADD8E6;">Dose</th> </tr> </thead> <tbody> <tr> <td>10–15 kg</td> <td>200 mg</td> </tr> <tr> <td>15–20 kg</td> <td>250 mg</td> </tr> <tr> <td>20–25 kg</td> <td>300 mg</td> </tr> <tr> <td>25–32.5 kg</td> <td>350 mg</td> </tr> <tr> <td>32.5–40 kg</td> <td>400 mg</td> </tr> </tbody> </table>	Body Weight	Dose	10–15 kg	200 mg	15–20 kg	250 mg	20–25 kg	300 mg	25–32.5 kg	350 mg	32.5–40 kg	400 mg	<p>SECOND-LINE REGIMENS</p> <p>Failed first-line protease inhibitor (PI) based regimen.</p> <table border="1"> <thead> <tr> <th style="background-color: #ADD8E6;">Failing Regimen</th> <th style="background-color: #ADD8E6;">Recommendation</th> </tr> </thead> <tbody> <tr> <td>ABC + 3TC + LPV/r</td> <td rowspan="3">Consult with an expert for advice</td> </tr> <tr> <td>d4T + 3TC + LPV/r</td> </tr> <tr> <td>Unboosted PI-based regimen</td> </tr> </tbody> </table> <p>Failed first-line NNRTI-based regimen (discuss with an expert before changing)</p> <table border="1"> <thead> <tr> <th style="background-color: #ADD8E6;">Failing Regimen</th> <th style="background-color: #ADD8E6;">Recommendation</th> </tr> </thead> <tbody> <tr> <td>ABC + 3TC + EFV (or NVP)</td> <td>AZT + 3TC + LPV/r</td> </tr> <tr> <td>d4T + 3TC + EFV (or NVP)</td> <td>AZT + ABC + LPV/r</td> </tr> </tbody> </table> <p>THIRD-LINE ART REGIMEN</p>	Failing Regimen	Recommendation	ABC + 3TC + LPV/r	Consult with an expert for advice	d4T + 3TC + LPV/r	Unboosted PI-based regimen	Failing Regimen	Recommendation	ABC + 3TC + EFV (or NVP)	AZT + 3TC + LPV/r	d4T + 3TC + EFV (or NVP)	AZT + ABC + LPV/r
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PRIOR 2015		FROM 2015
> 40 kg	600 mg	Children who fail second-line treatment should be referred to an expert to consider the therapy with third-line agents.
<ul style="list-style-type: none"> • Didanosine (ddl), oral, 12 hourly < 8 months 100 mg/m² /dose > 8 months 120 mg/m² /dose If age < 3 years or < 10 kg • Nevirapine (NVP), oral, 120 mg/m² /dose as a single daily dose for 2 weeks, then 12 hourly if no rash or severe side effects. 		

The 2015 new consolidated guidelines provided standardised, simplified, and less toxic drug combinations harmonised for the management of the Prevention of Mother to Child Transmission (PMTCT), children, adolescents, and adults with HIV/AIDS, TB, and other common opportunistic infections. It will guide clinicians, managers, and trainers on using available regimens within the continuum of HIV comprehensive care for prevention, treatment, and support for all age groups in the private and public sector to realise the country's vision of a long healthy life for all citizens. This approach will also ensure that people living with HIV are started on the correct regimen at the right time (Dr Aaron Motsoaledi, 11/01/2015).

Stavudine is currently no longer recommended for use in children by the Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV, the World Health Organisation, and HIV treatment guidelines for many countries across Africa and globally. This is because the use of d4T has, over the years, caused higher rates of adverse effects than any other Nucleoside Reverse Transcriptase Inhibitors (NRTIs).

Children may occasionally need to change a drug from the first-line regimen to one from the second-line regimen because of intolerance or a severe adverse reaction. Switching limits the patient's second-line treatment options. A doctor with ARV experience must decide to

switch the children failing regimens. Switching one drug should only be done if there is complete viral suppression, failing which the whole regimen may need to be altered.

The South African HIV treatment guidelines further mandate that “children should be started on ART as soon they become eligible using the standard drug regimens that have proven efficacy” and a minimal spectrum of severe side effects. Whilst these children are on ART, access to ARVs should be prioritised. Health workers need to be pharmacovigilant, monitoring drug interactions and the development of resistance and other adverse reactions. Treatment adherence is said to be the key to successful therapy. In 2015, the South African government, through the National Department of Health (NDoH) to a call that all HIV positive children, regardless of their CD4 count or clinical stage, ought to be started on ART as soon as their parents or caregivers are adequately counselled on the child’s condition and treatment management (NDoH, 2015).

Furthermore, this HIV treatment guideline outlines that children who meet the standards for fast-tracking ought to be started on antiretroviral treatment within seven days of confirming the diagnosis of HIV infection: These are; i) all children less than twelve months of age, ii) children with a CD4 count less than 200cells/ul or less than 15%, iii) children with WHO stage 4 disease, and iv) children with Multi-Drug Resistant Tuberculosis (MDR TB) or Extensively Drug-Resistant TB (XDR TB). If severe co-infections are present at diagnosis, that is, infections such as TB meningitis or Cryptococcal meningitis, the start of ART should preferably be delayed by a minimum of four to six weeks (Woods & Eley, 2020). Once the HIV infection has severely damaged a child’s immune system and the sickness has reached stage three or four, only antiretroviral treatment can control and partly reverse the disease progression (Hernandez-Vargas, & Middleton, 2013; AVERT,2020).

Hence, it is essential to note that, without antiretroviral treatment, most of the children living with HIV can die within infancy or early childhood stages. Hence, starting these HIV infected children early on treatment before the clinical stage signs appear is linked with a 75% reduction in mortality (Davies,2016; UNAIDS,2016).

It is essential also to note that ART has the potential to change HIV infection from a speedily fatal disease to a manageable, chronic illness. Hence, the success of this treatment is aimed toward guaranteeing that the infected child should feel well and once more gain weight and have few HIV-related diseases (WHO, 2021). For HIV positive children, once on treatment, their growth and mental development are also expected to enhance or be average. Moreover, the CD4 count should increase and stay on top of the baseline level, whereas the viral load should become undetectable and stay undetectable for as long as the child is on treatment. These clinical responses follow the gradual recovery of the immune system. Thus three months post ART initiation, and there should typically be an enormous distinction within the general health of these children (Woods & Eley, 2020).

If the response to antiretroviral treatment is good, the viral load is typically less than 400 copies/ml (i.e. an undetectable viral load) by six months. The viral load is in HIV care, a measure of the number of virus particles per cubic centimetre of blood. The higher the viral load, the quicker the sickness progresses, whereas an undetectable viral load indicates little or no viral production. There are clinical trials in children that have shown that about 63 – 87 % of children do attain undetectable viral load limits at some point in time during ART care (Iacob, Iacob, & Jugulete, 2017). However, some children are aforementioned never to become fully virologically suppressed and therefore likely to fail antiretroviral treatment much sooner than expected. Moreover, children who achieve undetectable viral load and maintain good adherence are expected to remain healthy for years. The average time to failure of treatment has not yet been established in a resource-poor environment (Woods & Eley, 2020).

Although ARV has been shown to significantly reduce the rate of HIV replication in people infected with HIV. It is understood that ART does not destroy viruses or cure HIV infections or illnesses. However, it can significantly reduce viral load and significantly slow the progression of the disease, thus increasing life expectancy and quality of life for children with HIV and AIDS (Oguntibeju, 2012). In as much as adherence is a critical component for therapeutic success and improved Quality of Life (QOL), there is poor adherence that is prescriber imposed that should be taken into account when dealing with children on ART.

For children, ARV dosage requirements are adjusted based on the child's growth and development. Therefore, prescribing and dispensing antiretroviral drugs at doses and doses lower than recommended can lead to treatment failure in this population group. Therefore, caregivers treating and treating HIV-infected children should check the dose of antiretroviral drugs prescribed in relation to the child's weight each time they visit the clinic, and the prescribed dose and dose. Need to make sure that remains appropriate (Woods & Eley, 2020).

2.5 Task Shifting

According to the WHO, Task shifting (TS) suggests “the rational distribution of tasks among healthcare professionals’ workforce teams. Specific tasks are moved where applicable, from extremely qualified health workers who have fewer qualifications to create a lot of economic use of the available Human Resource for Health (HRH)” (WHO, 2008).

TS is a delegation method that transfers tasks from highly specialized healthcare professionals to less specialized healthcare professionals as needed. This is a great choice and method for building the power to deliver healthcare services. For example, if there is a shortage of doctors, professional nurses and local health care workers can usually prescribe and dispense medicines or participate in emergency care. TS will be implemented in an extremely shortage of staff to better utilize available resources and provide uninterrupted medical services (Van Damme, Kober & Kegels, 2008).

TS was originally developed as a strategy for the treatment of HIV and AIDS. The general shortage of health care workers is a major disadvantage in managing the HIV / AIDS pandemic and providing universal access to critical health. The shortage of doctors was a global drawback in medical care. WHO, along with the US President's Emergency Plan for AIDS Relief (PEPFAR) and the Joint United Nations Program on HIV / AIDS (UNAIDS), has developed international guidelines on task shifts. It was adopted at the first International Task Shift Conference in Addis Ababa in January. August 10, 2008. Several countries, including South Africa, have adopted this relocation strategy. In addition to HIV / AIDS treatment, task shift strategies are also used to provide other medical services such as maternal and reproductive medical services.

Health systems around the world face primary care challenges in achieving or maintaining universal health insurance (Cometto, Boerma, Campbell, Dare & Evans, 2013). In addition, South Africa and some countries have a shortage of primary care physicians and geographical imbalances. As a result, medical students are less likely to choose primary care than before (Puertas, Arosquipa, & Gutierrez 2013).

Sub-Saharan Africa faces a crisis of human health resources due to a significant shortage of health workers. The shortage is exacerbated by high exposure to infectious diseases, migration of trained professionals, difficult working conditions, poor work ethic and lack of employee motivation. Importantly, the burden of HIV / AIDS has gradually facilitated the transfer of tasks in order to rapidly increase the capacity of personnel (Zachariah, Ford, Philips, Lynch, Massaquoi, et al., 2009). There is no doubt that nurses are the backbone of the healthcare system. Given the success of South Africa's HIV program reported by many scientists and studies, there are some comparable to doctors in the treatment of HIV. This is supported by the discovery that there is reasonable evidence and compelling logic to support the deferral principle (McPake, & Mensah, 2008).

One of the Doctors Without Borders (MSF) projects in three countries south of Sahara (Malawi, Southern Africa and Lesotho) focuses on the main opportunities and challenges of Task Shift (TS). We are proposing concrete measures to overcome the problems of. Opportunities to tackle include improving access to life-saving treatments, improving staff skills and efficiency of the medical system, empowering communities, saving costs, and reducing brain drain and international brain drain. Challenges include maintaining quality and safety, overcoming professional and institutional resistance, maintaining motivation and performance, and preventing healthcare workers from dying from HIV / AIDS. The study further emphasizes that TS should not undermine the primary goal of improving patient benefit and public health outcomes (Zachariah et al., 2009).

The increased incidence of chronic disease is expected to increase the need for primary care providers in the future. In addition, new care models and wage reforms are changing the workforce, especially in primary care. It has been found that tasks are shifting from

doctors to nurses or other non-medical service providers to reduce bottlenecks and improve quality and efficiency (WHO, 2007). Well-trained nurses in advanced practice have provided comparable quality of care compared to doctors (Martinez Gonzalez, Djalali, Tandjung, HuberGeismann, Markun, et al., 2014). However, there is no cross-border comparison of the extent of task shifts in primary care and related political reforms.

Sub-Saharan Africa has 90% of the world's HIV infections and a widespread staff shortage (UNAIDS, 2016). Mutambo and Hlongwana (2019) proposed concepts to add to this UNAIDS report, and many studies have highlighted PMTCT deficiencies, leaving some HIV-positive children undiagnosed and the necessary skills. It suggests that you should try to contact your healthcare provider with. We provide HIV testing and actively start these children with ART. Therefore, decision makers provide healthcare professionals, especially PHC nurses, with training, mentoring, and job tools to improve the level of HIV services and ensure that children receive medical care and maintain a positive attitude. It is imperative to take all necessary steps to achieve this. Experienced in health care, continue care and adhere to treatment. Finally, decision-makers ought to be informed concerning the barriers preventing their employees from providing the most effective attainable care for children to enable them to assign Sub-Saharan Africa's limited resources to the foremost relevant issues (O'Malley, Beima-Sofie, & Feris et al., 2015).

A study by Mutambo and Hlongwana (2019) explores healthcare professionals' views on barriers to providing quality HIV services to children at SSA to ensure that children are holistic and age-sensitive. Health providers have found that they need to adopt a child-centric approach. Proper care. Creating formal guidelines, training and coaching healthcare professionals on these child-centric approaches, developing child-friendly work support, and designing child-friendly areas are the areas of HIV services for children in resource-poor environments. May improve the standard slightly. This brings SSA closer to achieving its 90-90-90 goal (Mutambo, 2019).

2.6 The Role of Task Shifting in HIV Management and Care

When the South African National Antiretroviral Therapy Program (ART) was launched in 2004, it was completely dependent on the hospital's HIV clinic, where ART services were provided exclusively by doctors (NDoH, 2004). This means that ART and care at SA at the time was limited to a number of selected accredited health clinics due to the presence of doctors in these clinics. Most public clinics were run and operated by nurses, so ART services were only seen in hospitals. The doctor was then able to manage the ART program, perform a health examination, and initiate and prescribe treatment for the patient in need. Nurses were not allowed to treat HIV patients or prescribe or administer ART (Long, Brennan, Fox, Ndibongo, and Jaffray, 2011). This practice resulted in overcrowding of hospital facilities following an increasing demand for HIV care with limited personnel. Consequently, poor management of patients on ART necessitated the decentralisation of services to PHC clinics, rendering nurses essential to managing patients living with HIV.

Hence, managing the HIV/AIDS pandemic made SA struggle to reply to the troubling impact of HIV/AIDS in conjunction with upholding its democratic mandate to give impartial access to health services progressively. These challenges forced the government to rethink and reorganise its health resources and systems because of the reconsideration of the roles and responsibilities of nurses within the management and care of chronic and complicated diseases (Dohrn, Nzama, & Murrman, 2009). For example, in April 2010, ART was granted a presidential mission stipulating that ART is currently available in all 5500 South African public clinics. It asked SA to revise the HIV treatment guidelines in 2010 and asked nurses in primary care clinics for Nurse Initiated and Managed Antiretroviral Therapy (NIMART) (Cameron, Gerber, Mbatha, Mutyabule & Swart, 2012). Mandate also meant that nurses should be trained to prescribe and treat patients with ART. The program, named Nurse Initiated and Managed Antiretroviral Therapy (NIMART), has changed the role of HIV treatment and management.

The spread of HIV has led to innovations in the areas of nurse training, job shifts, retention, and practice. This expansion of HIV services was designed to meet the urgent needs of prevention, care and treatment, as well as embrace the vision of a decentralized primary health care clinic (PHC) (Dohrn et al., 2009). Other literature (eg Van Damme, Kober &

Kegels, 2008) emphasizes that the adoption of ART has increased to a reasonable level like PHC. B. There is a limit: a continuous increase in the number of patients who must be treated with ART for a lifetime. It is also constrained by the associated challenges of talent shortages and uneven distribution, coupled with the heavy workload inherent in the ART distribution systems currently in use.

Following task shifting, Nyasulu *et al.* (2013) report that a total of 2552 public clinics were involved in initiating and care of patients on ART by April 2011. By March 2015, this number had reached 3591 public clinics (DHIS, 2015). As the numbers grew, training needed to be widened and improved since NIMART required nurses to assess, diagnose and manage patients with HIV. Nurses, therefore, need to be equipped with skills such as history taking, physical assessment, interpretation of laboratory results and knowledge about the pharmacological and interaction of antiretroviral drugs (Morris *et al.*, 2009).

The main reason for this integration approach was that in SA, public primary health care (PHC) is an identified level of care that reaches most South Africans, and therefore, a relevant platform for the ART programme to reach all those in need of it (Stein, Lewin, Fairall, Mayers, English, *et al.*, 2008).

Crowley and Stellenberg (2015) caution us that, even though HIV services are a crucial part of Primary Health Care (PHC), public clinics need to be sufficiently equipped for them to be able to provide quality HIV services to children on ART. This seems to be a global challenge in that Portillo, Stringari-Murray, Fox, Monasterio and Rose (2016) eludes a worrying reality that the increasing demand for primary care services and the current health care personnel shortage is foretold to cause forceful reductions in the number of clinicians who are competent to provide HIV care in San Francisco. Moreover, Meyers, Maultrie, Naidoo, Cotton, Eley, *et al* (2007) had foreseen this situation and said that “there has been a dramatic increase in ART access for HIV infected children in SSA. However, the availability of adequate care and treatment programs remains limited. Hence, it is essential to note that the decentralisation of services to PHC without the provision of sufficient human resources (HR) as well as constant support could compromise the quality of care provided to patients at this level with long term repercussions for reaching the National Strategic Plan (NSP), strategic developmental and global health goals.

Meyers *et al* (2007) emphasise that essential HIV care, treatment services, and managerial support are vital components for ensuring quality services. Furthermore, they highlight that the provision of ART at PHC level should be supported with human resources and the implementation process of comprehensive models for the effective decentralisation of care.

2.7 Health Care Professionals' Compliance to Treatment Guidelines

The appropriate use and monitoring of ARVs have resulted in the enhancement of patients' quality of life. However, Elliott, Lynen, Calmy, De Luca, Shafer, *et al.*, (2008) argue that the complexity of treatment regimens, over and above a multitude of factors such as drug intolerance, poverty and the level of education of patients, has a direct influence on the lack of adherence. This also directly influences resistance and Treatment Failure (TF). Hence, the rational use of ART in lower- and middle-income countries is critically dependent on the precise detection of TF by clinicians (Elliott *et al.*, 2008). Proper use and monitoring of ARV has dramatically improved the patient's quality of life in recent years. However, the complex nature of these therapies, in addition to various factors such as drug resistance, socioeconomic status, and the level of patient education, can reduce patient compliance and increase resistance and TF potential. there is. On the other hand, prescribing mistakes in ART drugs are said to be common in inpatients (Rao, Patel, Grigoriu, Kaushik & Brizuela, 2012).

The rational use of ART in low- and middle-income countries (LMICs) relies heavily on accurate detection of TF and optimization of the timing of switching to alternative therapies. Monitoring and switching strategies aim to balance the risk of HIV drug resistance with reduced efficacy of second-line treatment, immunological and clinical progression, and inappropriate early switching. Current and future status of alternative therapies and drug availability (Elliot *et al.*, 2008).

There is no well-established link between antiretroviral usage and the development of virological, treatment and immunological failure except that virologic failure is highly dependent on the patient's adherence to the prescribed antiretroviral treatment. The inappropriate use of ARVs by prescribers is a topic that, in the researcher's knowledge, has never been explored more especially evaluating its impact on the clinical outcomes it might

pose to children on ART. When looking at antibiotics as an almost similar class of drugs to ARVs, the literature highlights that the well-established link between antimicrobial usage and the development of resistance emphasises the importance of developing strategies to improve antimicrobial prescribing. It further highlights the possible reasons for inappropriate prescribing: lack of education, misinterpretation of results, prescribing etiquette, and medication errors. All of these are said to have a contributory effect towards the increase in morbidity and mortality, the development of antimicrobial resistance, as well as healthcare costs to such an extent that studies have proven the importance of antimicrobial prescribing (File Jr, Solomkin & Cosgrove, 2011; McGowan, 2012; Hurford, Morris, Fisman, & Wu, 2012).

Similar to antimicrobials, there is no established nor existing reference for measuring the appropriateness of ART use. Spivak, Cosgrove and Srinivasan (2016) highlight that compliance to local, national and international guidelines as the standard for appropriate therapy is increasingly utilised to reduce subjectivity. Moreover, the evaluation of compliance to treatment guidelines provides a reproducible method for large-scale evaluations across multiple facilities, especially when sharing similar treatment guidelines such as the consolidated national guidelines for the management of HIV/AIDS (Osowicki, Gwee, Noronha, Britton, Isaacs, *et al.*, 2015).

The appropriateness of every antiretroviral prescribed can be assessed according to classic criteria established for antimicrobial evaluation by Kunin, Tupasi and Craig in 1973 (Summarised in **Table 1** below). Which even though it seems outdated has since been used and relied upon by many established researchers in the area of appropriate antimicrobial use, for example; researchers such as Dailey and Martin (2001), Bishara, Hershkovitz, Paul, Rotenberg and Pitlik (2007) as well as van Bijnen, den Heijer, Paget, Stobberingh, Verheij, *et al.*, (2011) have all conducted their studies following this criterion:

Table 2.2: Criteria for categorising the appropriateness of ART for children

ACTION	DESCRIPTION
<p>Appropriate indication</p> <p>Correct choice of antiretroviral drug and correct administration and dosing instructions</p>	<p>Correct choice in presence of one or more of the following):</p> <ul style="list-style-type: none"> - Tuberculosis - Severe Malnutrition - Neonates < 28 days of age - Infants weighing < 3kg - Hepatitis
<p>Inappropriate Indication</p>	<p>Inappropriate decision</p> <ul style="list-style-type: none"> • Selected regimen not suitable for the patient's age • Selected regimen not suitable for the patient's weight <p>Inappropriate choice</p> <ul style="list-style-type: none"> • Different ART needed, than what is prescribed: <ul style="list-style-type: none"> - unnecessary divergence from HIV/AIDS treatment guidelines - regimen spectrum was overly broad - regimen spectrum was not broad enough
<p>Incorrect choice of antiretroviral therapy</p>	<p>Incorrect use</p> <ul style="list-style-type: none"> • Incorrect dose • Incorrect dosing frequency • Incorrect route of administration • Incorrect duration of therapy • Incorrect quantity dispensed <p>Insufficient information</p> <ul style="list-style-type: none"> • No information on whether ART switching was necessary

ACTION	DESCRIPTION
	<ul style="list-style-type: none"> • Insufficient clinical information on whether ART switching was needed <p>Inappropriate indication</p> <ul style="list-style-type: none"> • Inappropriate decision on regimen selection • Inappropriate choice of antiretroviral(s) • Incorrect use of antiretroviral(s)

2.8 HIV Treatment Failure in Children

Failure of antiretroviral treatment (ART) in children is an underestimated problem and is not adequately addressed by pediatrics and HIV treatment programs. The failure rate of pediatric ART in facilities with limited resources ranges from 19.3% to over 32%, so a comprehensive analysis of the causes of failure and an approach to addressing impaired adherence to treatment are urgently needed (Osman, & Yizengaw, 2020; Getawa, Fentahun, Adane & Melku, 2021).

Studies by Davies, Moultrie, Eley, Rabie, Van Cutsem et al. (2011) and Bunupuradah, Puthanakit, Kosalaraksa, Kerr, Boonrak et al. (2011) These results indicate that a high proportion of virological failures were observed in children in an established HIV primary care environment. These studies also found that the average age at which ART begins in this cohort of primarily vertically infected children is 3.4 years, and the need to identify HIV-infected children early is latent. It suggests that you are missing out on the opportunity for a typical diagnosis. In addition, one-third of these children have never achieved virological suppression since they started treatment. An inadequate system can explain this persistent viremia in the clinic to find a failed child, or the lack of clinician knowledge or convenience to manage high viral load (VL). I can do it. This is well

reflected in the proportion of children (80%) who have remained unchanged despite long-term failures. One-fifth of patients aged 10 to 15 years were not fully disclosed at the start of the study. This is a known risk factor for failure (Davies et al., 2011 & Bunupuradah et al., 2011).

These scientists also say that VL testing in children with ART in resource-constrained environments should be prioritized over monitoring CD4 cell counts to reduce the time it takes for treatment to fail. Suggests. This facilitates the appropriate conversion of children to secondary ART therapy and minimizes immunological disorders. In addition, clinicians need to understand that the most important factor in good pediatric HIV management is achieving reasonable compliance. Gupta et al. (2016) Furthermore, they point out that easy ways to support adherence are very important in frequently visited clinics. It has been shown to significantly improve the quality of patient support that children and their caregivers receive. Finally, adherence support should not be initiated when a child has a high VL. Very often, proper basic counseling on adherence is not provided until the child fails treatment, so once the child reaches a developmental milestone, proper counseling should be initiated and reassessed at the beginning of ART. there is. Regular and continuous counseling is very important for pediatric patients, as the psychosocial situation of pediatric patients often changes and new barriers to adherence usually arise (Bernheimer, et al., 2015). In summary, one-third of children aged 0 to 19 in two HIV clinics with expanded primary care failed to achieve antiretroviral therapy, and 33% did not achieve virus suppression after the initiation of ART.

Hence, by addressing the core deficiencies in paediatric HIV care such as insufficient early diagnosis of HIV infected children, lack of VL monitoring and clinician comfort in responding to high VLs, and unstructured and inadequate adherence counselling. This will help HIV/AIDS programmes to achieve long-lasting VL suppression within the paediatric HIV population and curb this silent epidemic.

An effective response to the challenges of HIV treatment failure in LMICs must include reductions in the cost of second-line agents (Ford, Wilson, Chaves, Lotrowska, & Kijtiwatchakul, 2007).

Strategies for maximising the effectiveness of first-line treatment and optimising the timing of treatment changes are programs that fully enjoy the survival benefits of available treatment options and provide universal access to HIV treatment. Needed to stay cost-effective. The strategy should be comprehensive, evidence-based, and focused on the rational long-term use of ART in children and adolescents.

Although early mortality and retention in care has been identified by different scholars as early as the year 2002 to be remaining as a significant challenge in HIV programmes (Braitstein, Brinkhof, Dabis, Schechter, Boulle, *et al.*, 2006; Rosen, Fox, & Gill, 2007), the majority of reports from low and middle-income countries (LMICs) had in the past decade shown encouraging immunological, virological and survival outcomes (Weidle, Malamba, Mwebaze, Sozi, Rukundo, *et al.*, 2002; Ferradini, Jeannin, Pinoges, Izopet, Odhiambo, *et al.*, 2006; Laurent, Diakhate, Gueye, Toure, Sow, , *et al.*, 2002; Tassie, Szumilin, Calmy & Goemaere, 2003; Coetzee, Hildebrand, Boulle, Maartens, Louis, , *et al.*, 2004; Seyler, Anglaret, Dakoury-Dogbo, Messou, Toure, , *et al.*, 2003; Kumarasamy, Solomon, Chaguturu, Mahajan, Flanigan, *et al.*, 2003; Ivers, Kendrick & Doucette, 2005), with lower than expected reported rates of switching to second-line ART regimens (Pujades, Calmy, O'Brien, Humblet, & GroupMHAW, 2007; Renaud-Thery, Nguimfack, Victoria, Lee, Graff, *et al.*, 2007), and this was back then attributed to being in part due to actual rates of treatment success, but mainly because of the limited access to both virological monitoring (WHO,2006) and the unavailability of second-line drugs (Renaud-Thery, Nguimfack, Victoria, Lee, Graff, Samb,... & Perreriens, 2007). In a study by Orrell, Harling, Lawn, Kaplan, McNally *et al.* (2007) Clinicians were reluctant to switch treatments due to the cost of the regimen, the complexity of the regimen, the inconvenience, and the lack of subsequent treatment options. With the maturation and expansion of the cohort, and increased access to virological monitoring and second-line treatment, an increased failure rate of diagnosed treatment and a switch to second-line treatment were expected (Galarraga, O'Brien Gutierrez, Renaud-Thery, Nguimfack, *et al.*, 2007).). This is because the cost of second-line treatment is higher than the cost of first-line treatment (WHO, 2013), these increases are due to the HIV treatment programs (Friedberg, Kumara Sammy, Rossiner, Ceceria, Scott, *et al.*, (2007); Over, Revenga, Masaki, Peerapatanapekin, Gold *et al.*, 2007); Greco & Shima, (2007).

Therefore, in this study, the researcher concurs with Elliott, Lunen, Calmy, Delka, Schaefer and others. This hinted at the rational use of ART at LMIC in 2008. It relies heavily on the accurate identification of medical malpractices and the optimization of the timing of the clinician's switch to alternative therapies. In addition, consider various factors such as availability, risk, and benefit substitution to assess the risk of HIV drug resistance and reduced therapeutic efficacy, immunological and clinical progression, and inappropriate early switching of patients. Therapies that need to be monitored and switched strategies and the availability of current and future medications in public facilities.

Rivera, Frye and Steele (2014) allude that HIV resistance develops due to low antiretroviral drug (ARV) levels because of several factors and variations in drug absorption and metabolism and noncompliance owing to adverse effects or a poor understanding of the importance of the medication. Viral sanctuary sites could also be exposed to low levels of ARDs, and resistant quasispecies might develop.

The monitoring of VLs must guide effective treatment (Calmy, Ford, Hirschel, Reynolds, Lynen, *et al.*, 2007). Hence Calmy *et al.* (2007) recommend that the following two conditions be adhered to: Firstly, adequate plasma drug levels must be maintained as results may be inconclusive if adherence is not satisfactory or if the prescribed regimen has not been followed. In addition, the quality of drugs and bioavailability and drug-drug interactions can affect the outcome (Calmy *et al.*, 2007). Secondly, the availability of alternative drugs must be assured. Calmy *et al.* (2007) argue that this is important if no alternative drugs substitute a failing regimen.

2.9 The effects of HIV Treatment Failure in Children

In recent years, the number of people using antiretroviral therapy (ART) has gradually increased (WHO, 2015). As the number of patients looking to ART grows, it is necessary to maintain successful treatment and limit the progression of treatment failure. To enable early detection of malpractice, WHO proposed in July 2013 to use the viral load test as a gold standard for monitoring patient response to ART (WHO, 2013). Determining the virological suppression status of patients enrolled in ART is important for timely detection of treatment

failures and identification of patients who require more intensive treatment compliance. Minimize the development of drug resistance and unnecessary switching to expensive and limited ART therapy options (WHO, 2010). The Joint United Nations Program on HIV / AIDS (UNAIDS) diagnoses 90% of people infected with HIV, has access to treatment for 90% of known HIV-infected people, and suppresses the virus among those who have started treatment (UNAIDS, 2014). Many countries, including Uganda, are currently adopting these goals. Therefore, viral load is very important for tracking the quality of HIV treatment and progress in terms of national and international indicators. Despite the increasing number of HIV-infected patients accessing ART (WHO, 2015), data on non-suppression rates for different groups of people commonly cared for in Uganda are limited. Many facilities with limited resources do so. Studies highlighting virological suppressors in most developed countries and environments with limited resources used lower bounds to determine non-suppression. The threshold used is 300-500 copies / ml blood (McMahon, Elliott, Bertagnolio, Kubiak, Jordan, 2013). However, people with detectable viral loads endure targeted intense adherence support for 6 months followed by confirmatory viral load testing to differentiate poor adherence from treatment failure. Those with treatment failure as defined by 2 detectable viral load measurements on top of the threshold are switched to secondline ART (WHO, 2013).

Evidence suggests that health care workers fail to provide children with HIV services because they lack adequate knowledge and skills to approach children and their caregivers (McMahon, Elliott, Bertagnolio, Kubiak, & Jordan, 2013; Hosseinipour, van Oosterhout, Weigel, Phiri, Kamwendo, *et al* (2009) this is often exacerbated by health care workers' lack of training on existing guidelines for providing child-friendly HIV testing services and disclosure guidance (McMahon, *et al.*, 2013; Billioux, Nakigozi, Newell, Chang, Quinn, *et al.*, 2015). A study conducted in Ghana found that health care staff were unsure of the language or approach to use, mainly when providing guidance and health education throughout HIV testing and counselling services (HTS), and whether or not or to not offer these to the child or solely discuss with the primary caregiver (Hosseinipour, van Oosterhout, Weigel, Phiri, Kamwendo, *et al.* 2009).

2.10 Adherence to Antiretroviral Therapy in Children

The main goal of antiretroviral therapy is to reduce the viral load (VL) in the blood to undetectable levels. Decades of various scientists have determined that adhering to this treatment is important for patients to experience the full benefits of ART, including: Maximum and permanent suppression of viral replication. Reduced destruction of CD4 cells; prevention of virus resistance; promotes immune reconstitution and slows disease progression. ART improves the prognosis of people living with HIV and reduces HIV-related morbidity and mortality, as well as the development of other opportunistic infections (OIs) Memirie, 2009; Kabue, Buck, Wanless, Cox, McCollum, et al., 2012; Vreeman, Nyandiko, Ayaya, Walumbe, Marrero, et al., 2010). DiMatteo (2004) defines this as the extent to which a patient's drug-consuming behavior is in line with the doctor's recommendations. Although important, ART compliance is often a challenge for people treating ART, especially children. Factors affecting a child's ART compliance include (1) the caregiver, (2) the child himself, (3) the prescribed medication or treatment, (4) socioeconomic status, and (5) the provision of services. Issues include (Haberer & Mellins, 2009; Buchanan, Montepiedra, Sirois, Kammerer, Garvie et al., 2012; Martin, Elliott-DeSorbo, Wolters, Toledo-Tamula, Roby, et al., 2007; Prendergast, TudorWilliams, Jeena, Burchett, 2007).

The degree to which patients are compliant with their treatment regimen is an essential determinant of clinical success (Gardiner & Dvorkin, 2006). The researcher in this study believes that for the desired therapeutic and clinical outcomes, the patient needs to adhere to the correct regimen, with an adequate quantity of medication dispensed to last until the next scheduled appointment.

There is no generally accepted measure of ART compliance, and each method has various strengths and weaknesses, as well as cost, complexity, accuracy, aggression, and bias. Therefore, the development of real-time ART adherence monitoring tools can change the development of new preventive strategies to improve adherence. Ultimately, applying these strategies may prove to be the only and most important cost-effective way to reduce morbidity and mortality in individuals and reduce the likelihood of HIV transmission and the emergence of resistance in the community (Nachenga, Marconi, van Zyl, Gardner, Preiser, et al., 2011).

2.11 The Process of Medicine Prescribing

Often encountered and sometimes perceived as a routine activity, prescription is a complex process that includes knowledge and application of sound treatment principles, healthcare provider communication skills, and risk and uncertainty approaches and assessments (Maxwell, 2016). The prescribing process often begins with setting treatment goals (for example, pain relief, infection cure, and even appetite improvement). Patient expectations and preferences can usually influence which goals are set. After the goal is determined, the treatment is selected. Prescribers often face a choice from several options (Pollock, Bazaldua & Dobbie, 2007). Ideally, the final pharmacological choice should be made through a risk-benefit analysis based on dosing and patient factors, including alternative aspects such as accessibility and cost (Maxwell, 2009 & Maxwell, 2016).

Patient elements that will influence the medication choice process to embody physiological status (e.g., pregnancy, kidney failure), susceptibility to detrimental effects, and ongoing drug remedy can also be ability for drug-drug interactions. Drug elements that would affect desire encompass proof of protection and effectiveness and pharmacokinetic and pharmacodynamic properties. For example, a medicinal drug with a once-day by day dosing routine can also be desired over one with more than one dosing for compliance reasons (Claxton, Cramer & Pierce, 2001).

It is acknowledged that the prescribing process will sometimes be intimidating for health professionals, particularly once variations in risks and benefits of accessible therapies don't seem to be clear and wherever guidelines don't seem to be specific. Openness and commitment to the patient is essential at this stage, as the patient is always the ultimate recipient of the benefits and risks of taking the drug. Therefore, patients should be provided with a clear explanation of the pros and cons of taking and not taking the proposed medication, as well as treatment uncertainties (Elwyn, Edwards & Britten, 2003). For many patients, transitioning into someone who needs to take medicines is usually an arduous process. Therefore, medical personnel's presence of a diagnosis solely as a basis to require medication might not be enough rational motive (Britten, Stevenson, Barry, Barber & Bradley, 2000). This can be a lot of, thus in instances

wherever the advantages of the planned treatment might not be immediate or unclear (Elwyn, Edwards, & Britten, 2003). However, effective communication with patients may be an ability that any prescriber aspires to attain. This can be the medium through which medical data is communicated and addresses patients' desires, expectations, and emotions (Ha & Longnecker, 2010).

For centuries, the practice has been paternal, based on the basic assumption that doctors have access to information that the patient is unaware of and that it is used in a way that is uncertain whether that information is harmful to the patient's health (Dong, 2011). In recent decades, medical practice has transitioned from paternalism to individualism, with patient autonomy, for example, is thought of as a fundamental principle (Dong, 2011; Entwistle, Carter, Cribb & McCaffery, 2010). A variety of models have since then emerged. They facilitate patient-centric communication and incorporate patient influences and preferences on medical decision-making and prescribing choices (King & Hoppe, 2013).

"Good prescriptions" are commonly used in the literature, but their meaning remains elusive. This is because, in addition to patients, multiple parties to the healthcare system can design meaningful prescriptions from very different perspectives (Reddy, Ford & Dunbar, 2010).

All of the above views emphasize the subjectivity of what constitutes a "good prescription", but some people provide many objective definitions of this term. According to Aronson (2006), a good prescription is one that "recommends a drug that is appropriate for the patient's condition and minimizes the possibility of excessive harm." Aronson's definition is consistent with Barber (1995), who states that a good prescription is one that achieves four goals: (2) Minimize risk. (3) Minimize costs and (4) Respect patient decisions. Barber also points out that this conceptualization of proper prescribing means "the usual balance of risk and benefit to the need to reduce costs and the patient's decision-making power" (Barber, 1995). Both the Barber and Aronson concepts largely correspond to the requirements promoted by WHO for rational prescribing. The World Health Organization published five basic needs for a prescription to be considered good or rational (**Figure 1** below).

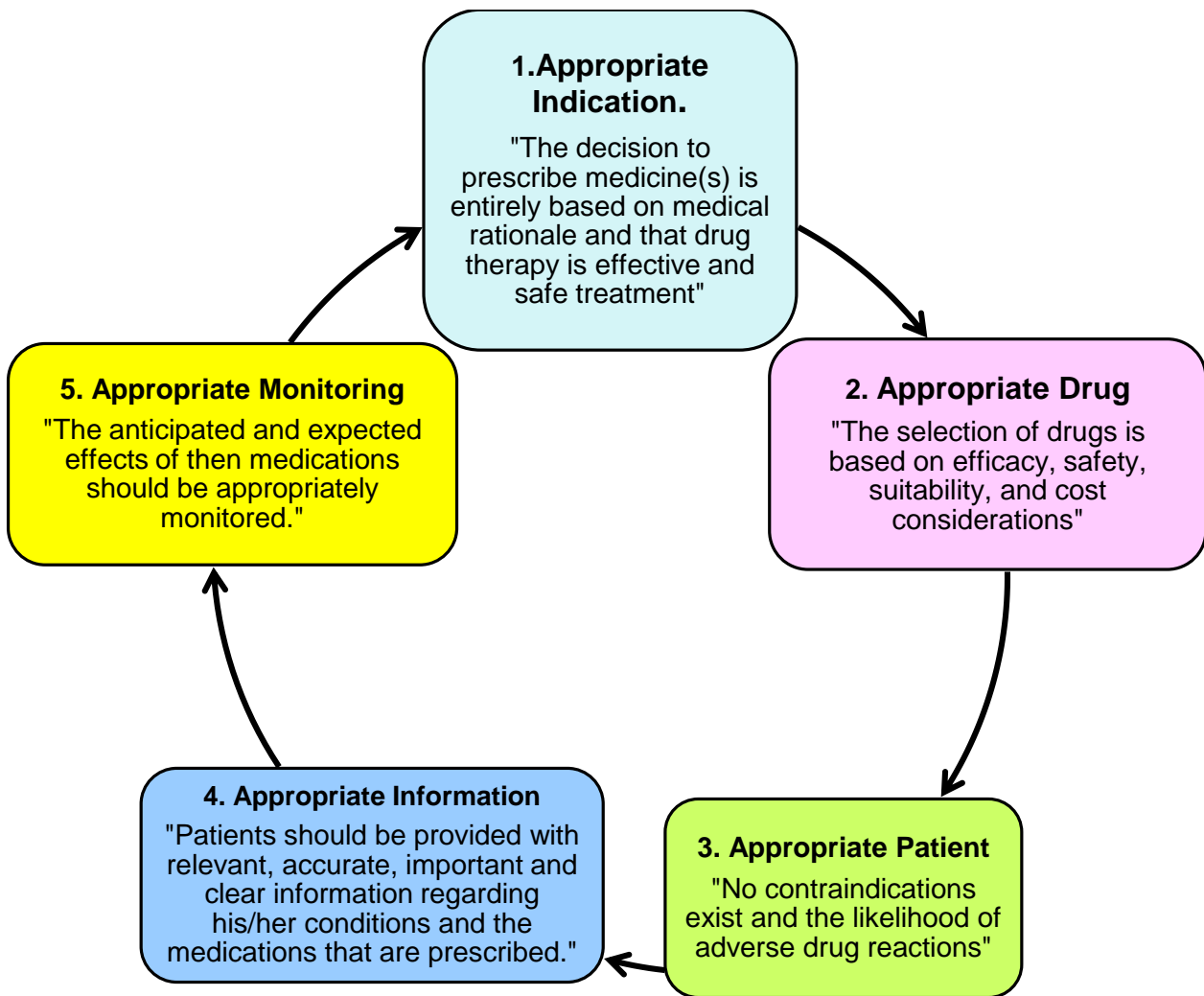


Figure 2.1: Criteria for rational prescribing promoted by the WHO

2.12 Medicine Use

The concept of rational use of medicines is old and dates back to 300 BC when the physician Herophilus said that “*medicines are nothing in themselves, but are the very hands of God if employed with reason and prudence*” (Shivhare, Kunjwani, Manikrao & Bondre, 2010). For many years, rational use of medicines has been regarded as one of the key principles of effective and quality health care (Gopalakrishnan, Udayshankar & Rama, 2014; Embrey, 2013).

In 1985, WHO convened an expert meeting on the rational use of drugs, from which the rational use of drugs was defined as a contextual picture where “Patients receive medications

appropriate to their clinical needs, in doses that meet their requirements, for an adequate period, and at the lowest cost to them and their community” (May, 2008). The World Bank also defines rational use of medical care as two basic principles. (1) Use of the drug in accordance with scientific evidence for efficacy, safety and compliance. (2) Cost-effective drug use within the constraints of a particular health system (Bissell & Traulsen, 2005; May, 2008).

The definitions of WHO and the World Bank differ in two major areas (1) Use of scientific data in prescription. This seems to be more enforced by the definition of the word bank (2) Although the World Bank definition takes into account the financial capacity of drug-using countries, WHO advocates the use of drugs at the lowest possible cost, regardless of the healthcare system in question (Bissell & Traulsen, 2005).

The WHO and World Bank definitions are primarily based on therapeutic and medical perspectives. Reasonable use of drugs can also be seen from the consumer or patient's point of view. What is considered reasonable from a medical point of view may be considered unreasonable by the patient and vice versa (Brahma, Marak & Wahlang, 2012). Therefore, both medical and consumer / patient perspectives need to be taken into account in order to gain a holistic understanding of the rational use of drugs. From a medical point of view, improper use of drugs can begin in one of four major stages (**Figure 2**) of the medicines use cycle (Embrey, 2013).

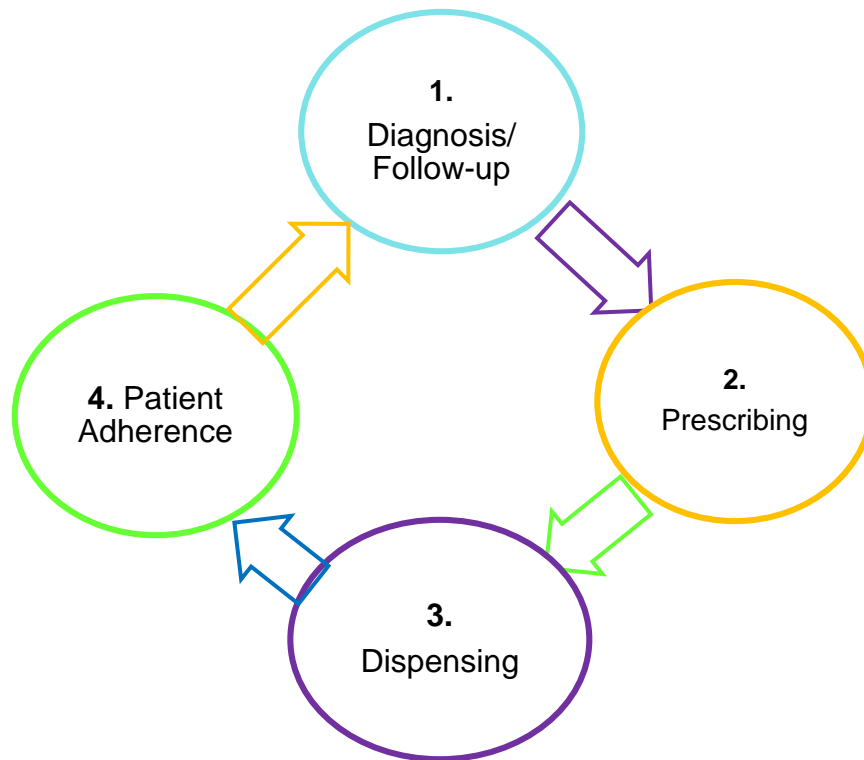


Figure 2.2: The cycle of medicine use

The diagnostic phase of a substance use cycle identifies and defines one or more problems that require intervention. This early stage can lead to a cycle of inappropriate substance use if the wrong problem (eg, medical condition) is outlined for the intervention. Treatment is usually prescribed after the diagnosis has been made. This can be pharmacological or non-pharmacological therapy. After that, the patient will be provided with the prescribed medication and will need to take the medication as prescribed (Embrey, 2013).

2.13 Rational Medicine Prescribing

Prescribing drugs is the most common and complex intervention process in healthcare. It's the first step in the medicine use process (Kar, Pradhan & Mohanta, 2010; Suthar, Patel & Vaishnav, 2014). After that, "prudent use of medicine ensures the success of the pharmacologic intervention" (Lee, Cho, Jeong & Lee, 2013). "Effective, safe medications are essential for the modern healthcare system" (Kar, Pradhan & Mohanta, 2010). The Royal Pharmaceutical Society of Great Britain recognised back in 1997 that prescribing is "a technically difficult, and morally complex, problem". Several scholars have, however,

regarded the issue of patient adherence to the prescribed medicine as honestly being a doubtful objective (Royal Pharmaceutical Society of Great Britain, 1997; Jimmy & Jose, 2011; Jin, Sklar, Oh & Li, 2008; Brown & Bussell, 2011; Atreja, Bellam & Levy, 2005). The writing of flawless, explicit prescriptions by healthcare practitioners is considered an art learned through long years of practice and indoctrination (Haque, 2018). The prescribing practices of healthcare professionals are, however, recognised by several scholars to be controlled by multiple issues, which include the healthcare professionals him/themselves, the practice backdrop, and the healthcare system (Dineen & DuBois, 2016; Mosadeghrad, 2014a; Effken, Brewer, Patil, Lamb, Verran, *et al.*, 2005; Helin-Salmivaara, Huupponen, Klaukka & Hoppu, 2003 & Mosadeghrad, 2014b).

2.14 Irrational Medicine Prescribing

Irrational use of medicines is a “critical health challenge for our planet, with significant consequences for patients, healthcare systems, and communities” (Ofori-Asenso, and Agyeman, 2016). The WHO considers irrational prescribing a disease challenging to cure through possible prevention (WHO, 2001). Educational and managerial intervention has widely been considered “a principal-targeted approach to ensure good prescribing” (Herbert, Wright, Maclure, Wakefield, Dormuth, Brett-MacLean, Legare & Premi, 2004; Hogerzeil, 1995; Supply, 2012). Hence, it is believed that educational interventions will improve practitioners' knowledge and awareness, but their “efficiency in changing deeds remains modest unless combined with regulatory and economic interventions” (Supply, 2012; Wettermark, Godman, Jacobsson & Haaijer-Ruskamp, 2009). It would be much better to start educational interventions as soon as possible, especially in medical school, in order to develop good prescribing skills (Wilcock & Strivens, 2015). When nursing students graduate, they are licensed and given the freedom to prescribe themselves and the many opportunities to prescribe without a teacher. The development of unreasonable prescribing bad habits makes treatment difficult (de Vries, Henning, Hogerzeil & Fresle, 1994).

2.15 The Impact of the Irrational Medicine Use

Irrational use of medicines is a significant challenge facing many health systems worldwide. Ofori-Asenso and Agyeman (2016) emphasise that medicines are integral in healthcare delivery. However, they are expensive products and make up a significant portion of total health care costs in most countries. Such practices can lead to poor medical care that can endanger patients and lead to the waste of scarce resources that may have been used to address other urgent health needs.

The concept of "reasonable use of drugs" can sometimes be confusing and is not easily recognized by patients, healthcare providers, policy makers, or the general public. To overcome this challenge, everyone needs to work together effectively. It summarises basic concepts such as rational substance use, proper prescribing and dispensing, and examines some factors that contribute to irrational substance use and the potential impact of such practices.

The effects of taking irrational medications are very different. Improper use of drugs increases the risk of side effects (ADRs), especially in older patients and people with comorbidities that can impair physiological function (Hamilton, Gallagher, & O'Mahony, 2009). For example, in a retrospective cohort study of elderly people in Australia, the presence of comorbidity was a strong predictor of recurrence of ADR, especially in patients with comorbidity being treated in the community (Zhang, Holman, Price, Sanfilippo, Preen & Bulsara, 2009). The cost implications of ADRs can also be enormous (Godman, Finlayson, Cheema, Zebedin-Brandl, Gutiérrez-Ibarluzea, *et al.*, 2013). ADRs are said to occur most commonly in the primary care settings, with approximately 10% of patients who are prescribed medicines are going to experience an ADR. ADRs are associated with increased morbidity, mortality, and hospitalisations (Blockman, 2015; Mouton, Mehta, Parrish, Wilson, Stewart, *et al.*, 2015).

According to a study of high-income countries, ADR is one of the top 10 causes of death. It is important that studies show that up to 50% of these ADRs are potentially preventable. In addition, common mistakes leading to ADR were specific failures of patient's illegal allergies, prescribing or dispensing errors, inadequate patient monitoring, and specific failures of healthcare professionals' important drug-drug interactions (Blockman, 2015). Similarly,

Lederberg (2000) points out that terrible human practices, such as inappropriate antibiotics, are one of the key factors underlying the emergence of antimicrobial resistance worldwide. For example, studies have shown that below therapeutic doses of antibiotics contribute to the development of antibiotic resistance by promoting genetic changes such as changes in gene expression and mutagenesis (WHO, 2014). The emergence of antibiotic resistance is not only seen as a threat to health promotion, but could bring humanity back to an era like the pre-antibiotic era where many people died of suffering from incurable bacterial infections. I have (WHO, 2014). In addition, improper use of drugs can lead to wasted health resources that are in short supply, further limiting the availability of other important drugs and increasing treatment costs. WHO (2008) estimates that proper use of drugs can make drug spending cost-effective by about 50-70%.

2.16 Strategies to Tackle Irrational Medicine Prescribing

Irrational prescribing is a “disease” that is difficult to treat even though its prevention is possible (WHO, 2001). Therefore, there are several strategies for changing patients and prescribing behavior to encourage rational prescribing. These strategies can be broadly grouped into targeted or system-oriented approaches (Embrey, 2013). Targeted approaches include educational and business interventions, and system-oriented strategies include regulatory and economic interventions (Embrey, 2013 & Hogerzeil, 1995). Educational interventions are often aimed at persuading or informative, usually including the use of printed matter, seminars, or face-to-face contacts (Kamarudin, Penm, Chaar, and Moles, 2013).

According to Wettermark et al. (2009) Educational interventions can affect the knowledge and awareness of prescribing physicians. Still, their effectiveness in behavioral change remains modest when not combined with other strategies.

On the alternative hand, managerial techniques are specially aimed toward guiding practice. Such managerial interventions that can be hired consist of monitoring, supervision and feedback, the usage of a restrictive drug treatments list, drug utilisation reviews, or the usage of based prescription forms (Hogerzeil, 1995). An example in this case is the Swedish Wiselist. This is the Essential Medicines List (EML), which adheres to only 200 medicines to increase physician familiarity with quality medicines and reduce costs, complemented by

regular medical oversight to specialists (Gustafsson, Wettermark, Godman, Andersen-Karlsson, Bergman, *et al.*, 2011)

Economic strategies, on the other hand, aim to promote positive financial incentives while eliminating the perverse incentives of prescribing physicians (Gurbani, 2011). Embrey (2013) and Hogerzeil (1995) say that economic interventions could include introducing significant changes to the healthcare provider's reimbursement system or banning prescribing drug sales.

For the intervention to be very effective, it should be targeted at the clinic or prescribing physician who has the greatest need for improvement, with a particular focus on the identified prescribing behaviour (Embrey, 2013 and Hogerzeil, 1995). In many cases, multiple interventions may be required to make the necessary changes. Again, it is worth noting that efforts to promote rational medical care / prescribing should be multifaceted, including addressing aspects of patient and community behavior (Sabuncu, David, Bernède-Bauduin, Pépin, Leroy, *et al.*, 2009; Fürst, Čížman, Mrak, Kos, Campbell, *et al.*, 2015).

The 6 steps method of pharmacotherapy education promoted by the WHO (see **Figure 3**, which follows below) need to be executed in every medical and nursing curriculum “*as part of an integrated learning program which has positive effects on medical students' knowledge of basic and applied pharmacology, pharmacotherapy skills, and satisfaction and confidence in prescribing.*”(Keijsers, Segers, De Wildt, Brouwers, Keijsers, *et al.*, 2015).

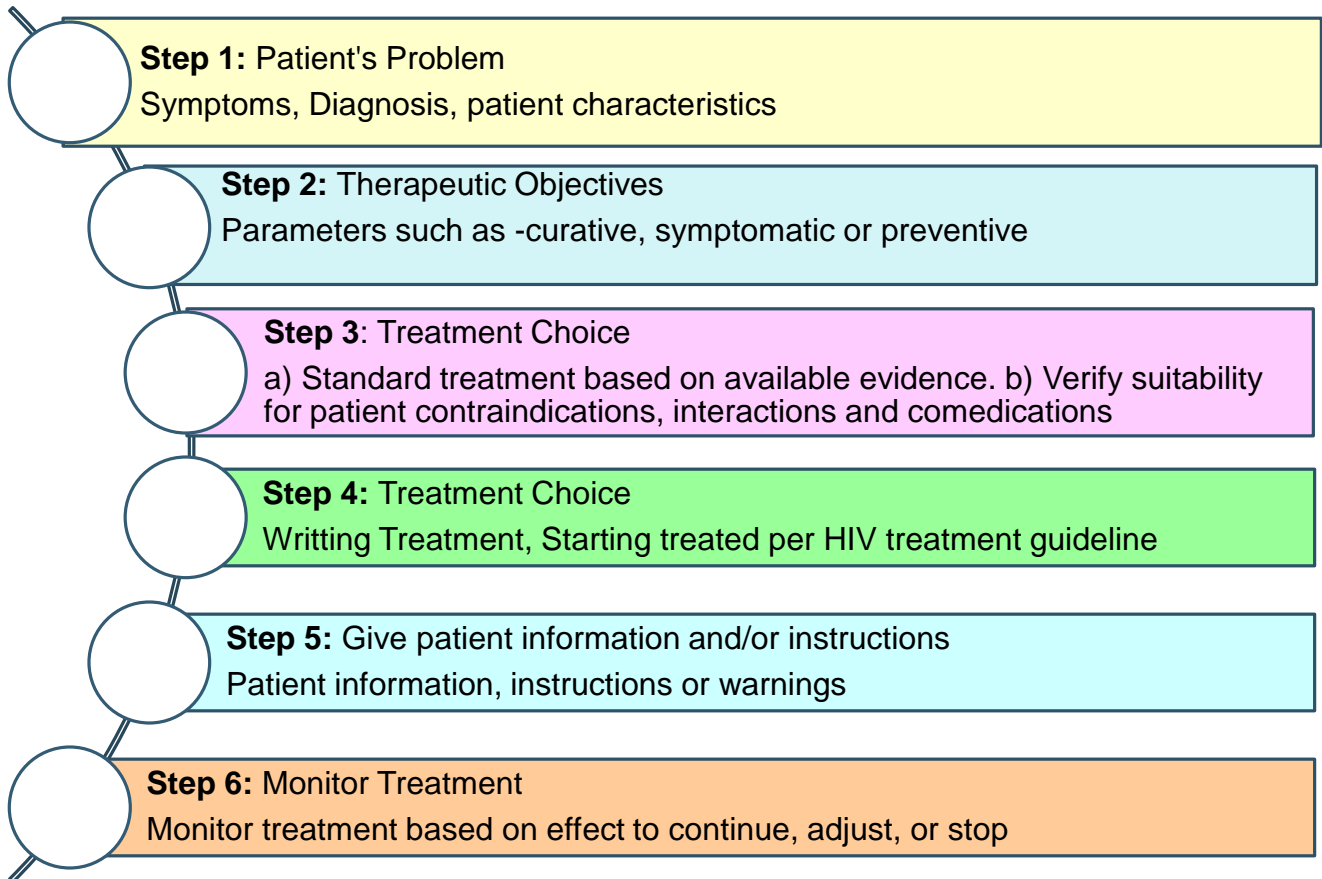


Figure 2.3: WHO-6-step pharmacotherapy method

Furthermore, for those healthcare professionals who have already graduated and are practising, it is recommended that “they should constantly update the new knowledge regarding medicine use and trends in guideline updates and clinical pharmacology to strengthen their prescribing skills” (Birkett, *et al.*, 2010). Moreover, “healthcare professionals must utilise every opportunity to counsel their patients for healthy living, a balanced diet, and physical activity. In addition, in improving the prudent use of medicine and maximizing patients' benefit, there is an urgent need for collaboration among all healthcare stakeholders, especially doctors, nurses, and pharmacists” (Smith, 1967). “Online national database regarding patient information, medical records, drug interaction, and repeat prescriptions, etc., can minimize preventable harm from the medication-related issue” (Price, Man, Bartlett, Taylor, Dinwoodie, *et al.*, 2017; Stocks, Kontopantelis, Akbarov, Rodgers, *et al.*, 2015).

2.17 The Medicine Dispensing Process

When the prescription is complete, the patient receives the drug at the dispensing stage. Patients often provide a prescription. The prescribing doctor will instruct the recipient (donor) to serve the patient as instructed. Dispensing is often done by a trained pharmacist or dispensing technician. However, in the primary health care settings of the South African department of health, professional nurses prescribe and dispense their prescriptions. An act that makes them more vulnerable to committing medication errors.

Aronson has since 2009 defined medication errors as a failure in the treatment process that leads to or has the potential to harm the patient. Furthermore, he emphasises that medication errors can transpire;

- i) Whilst deciding which medicine and dosage regimen to use. These are often referred to as prescribing faults, and they encompass irrational, inappropriate, and ineffective prescribing, under-prescribing, as well as over-prescribing,
- ii) When writing the prescription (prescription errors),
- iii) During manufacturing of the formulation (wrong strength, contaminants or adulterants, wrong or misleading packaging),
- iv) Whilst dispensing the formulation (wrong drug, wrong formulation, wrong label),
- v) During administering or taking medicine (wrong dose, wrong route, wrong frequency, wrong duration),
- vi) Whilst monitoring therapy (failing to alter therapy when required, erroneous alteration).

These errors can be categorised with the help of psychological classifications such as knowledge, rules, behavior, and memory-based errors. Dosing mistakes can sometimes be serious, but often they are not trivial. However, system failures that lead to minor errors can later lead to fatal errors, so it is essential to identify them. Velo and Minuz (2009) predicted that bug reporting should be encouraged by creating an impeccable, non-immunity environment. In addition, prescription mistakes are irrational, inappropriate and ineffective. There are also recipe spelling mistakes, including the indecipherability of the written recipe. Avoid dosing mistakes in balanced prescribing, that is, the use of drugs adapted to the

patient's condition, and dosages that optimise the ratio of benefit to harm, within the uncertainty associated with therapeutic decisions.

In clinical practice, the separation of prescribing and dispensing activities is considered a “safety mechanism to ensure an additional independent assessment of the proposed therapy before the patient begins treatment” (Chou, Yip, Lee, Huang, Sun, & Chang, 2003). In some settings, such as rural areas with limited health personnel (Lim, Emery, Lewis & Sunderland, 2011), dispensing may be carried out by the prescriber (e.g., dispensing nurses). This is considered “non-ideal and may promote irrational prescribing, especially if the prescriber stands to gain financially” (Ofori-Asenso & Agyeman, 2016).

When the prescribing and dispensing functions are separated, proper therapeutic knowledge of the dispensing device is essential to check the issued prescribing gap and provide the prescribing physician with the appropriate recommendations / interventions as needed. .. Therefore, contact between the donor and the patient is also very important. This is because it can have a significant impact on the patient's use of the drug. For example, compliance may improve only if the patient understands the importance of taking the drug, can follow the instructions appropriately, and is aware of the risk of non-compliance (Aronson, 2006).

On the other hand, the WHO advocates that “the rational dispensing principle should be followed to ensure that patients receive adequate information regarding the use of dispensed medicines to achieve the desired benefits. For instance, if dispensing practices such as counting, packaging, and labelling is poorly executed; they are likely to impact the patient's confidence in the dispensed products, and subsequently compliance to therapy” (The Pharmacy Guild of Australia, 2016).0

CHAPTER 3 THEORETICAL FRAMEWORK

3.1 Introduction

This chapter provides a comprehensive overview of the study's theoretical framework. In this study, two theories, *Clinical Pharmacy Concept* and *Drug Utilisation Research Concept*, have been utilised to guide the study and develop and implement an educational programme to enhance the dosing and dispensing of ART in children managed in primary health care settings Mopani District, Limpopo Province.

A theoretical framework is defined by Osanloo and Grant (2016) as one of the foremost vital aspects of the research process. It provides a muse where all knowledge (figurative and literally) for research is built. It is the justification of the study, the explanation of the problem, the goals, the meaning, and the structure and support for the question of the study. The theoretical framework provides the basis or anchor for literary studies and methods and analysis. The chosen theoretical frameworks served as a guide and directive for this study to prevent it from diverting from its purpose. It also aided the researcher in avoiding faults and conflicting assumptions that might alter the research findings.

3.2 Clinical Pharmacy Concept

The American College of Clinical Pharmacy (ACCP) 2018 defines clinical pharmacy as “a section of pharmacy concerned with the science and practice of rational medicine use. It is a health science discipline within which pharmacists offer patient care that optimises medication therapy and promotes health and disease prevention”. The clinical pharmacy practice additionally embraces “the philosophy of pharmaceutical care, blending a caring orientation with specialised therapeutic knowledge, experience, and judgement to ensure optimum patient outcomes”. As a discipline, clinical pharmacy also should contribute to the generation of new knowledge that advances health and the quality of life (Hassali & Al-Tamimi, 2016; Hashmi & Al-Tamimi, 2019). Whereas here at home in South Africa, Clinical Pharmacy (CP) is reported to have started within the 1990s and is a rapidly developing field for practising pharmacists (SASOCP, 2015).

According to the American College of Clinical Pharmacy (ACCP) (2018), a clinical pharmacist is a licensed professional with innovative education to work in any health care setting. Cipolle, Strand and Morley highlighted in 2012 the notion that these professionals assess the patients' health care needs, evaluate medication therapy, and implement a care plan and follow-up patients to work out their detailed clinical outcomes. Additionally, clinical pharmacists can even interpret diagnostic and laboratory tests and identify appropriate drug therapies in practice. Consequently, clinical pharmacy enables pharmacists to work together with medical doctors and other health care providers to deliver Comprehensive Management Plan (CMP) services to optimise patient care (Bronkhorst, Gous & Schellack, 2020). According to the South African Pharmacy Council (SAPC), the scope of the clinical pharmacist include the subsequent (SAPC, 2014):

- To perform acts and services concerning the profession of a pharmacist.
- Provide advanced clinical pharmacy services to a spread of specialities.
- Act as a leading pharmaceutical partner within a multi-professional healthcare team.
- Develop, implement, evaluate and supply strategic leadership for clinical pharmacy services.
- Distribute clinical pharmacy information and make informed decisions with the available evidence to justify a choice.
- Take a pharmaceutical leadership role in clinical protocol and guideline development.
- Lead clinical reviews of drug use.
- Develop policies and procedures specific to clinical pharmacy.
- Provide education and training associated with clinical pharmacy.
- Perform research, teach and publish in clinical pharmacy.
- Initiate and participate in pharmacovigilance associated with clinical practice.

The whole idea behind the concept of clinical pharmacy is to promote the rational use of medicines and ensure that there's quality medicine use (ACCP, 2018; Babar, 2019). However, the assurance of the quality of any system is not possible without adequate supervision. Moreover, a top-quality assured healthcare system should not be composed

of only the prescriber and patient; it must also include a supervisor. Thus, three role-players are critical to an efficient healthcare system: the provider, the receiver, and therefore the supervisor. For instance, this position, given the circumstances that the receiver presumably would be naïve to the technicalities and procedures of healthcare, which the provider is an imperfect being who is additionally vulnerable to errors, negligence and opportunism, who then is to make sure that care of quality and efficiency is provided. Presently this vital role of supervision within the healthcare system is left unfilled worldwide.

Consequently, healthcare resources are wasted, and coverings are mainly ineffective and uneconomical. We live in the conception stage of the clinical pharmacy profession, and highly typical of the time, there is no consensus regarding the function and structure of this noble profession. There is now much debate in academic and practice fields about what role the clinical pharmacist should fill within the healthcare structure. The support seems to be stronger on the side of those who argue that clinical pharmacists need to be accorded with some measure of authority to be ready to prescribe treatments. This may be a duplication of role, much as the role of a prescriber is already sufficiently filled by other health professions. This statement by no means expresses sufficiency in terms of the numbers of these professionals but the identity. My candid personal opinion on this issue is that we no longer need more health professions to function prescribers. We, as pharmacists, are already suitably positioned both by law and education to authoritatively vet the treatments being discharged by the prevailing prescriber-professions. With the correct orientation, we are the most effective suited to supply supervision within the healthcare system. I posit that the clinical pharmacy profession should fill this supervisory role which remains vacant up to the current times. I undertake to define a theoretical basis for this position within the succeeding sections and illustrate how it might be put into practice.

Hence Adjei (2012) proposes clinical pharmacy as a theoretical framework for studies involving the professional practice of clinical pharmacists in the clinical arena. He is supported by authors such as Donabedian (2002) and Thomas (2004). These theorists proposed a tripartite model for cooperation within the healthcare team to ensure a quality-assured healthcare system. According to this theoretical framework, “the assurance of quality for any

system is not possible without adequate supervision” (Donabedian, 2002; Adjei, 2012). “A quality assured healthcare system should not be composed of only the prescriber and the patient; it must also include a supervisor”. In this case, the “supervisor” is the clinical pharmacist (Adjei, 2012), supervising the NIMART-trained professional nurse who prescribes and dispenses medicines to manage children on ART.

In a nutshell, this theory suggests that in the triangular or “tripartite model” of healthcare, patient care constitutes a fundamental departure from the established model in the health sector where the doctor is placed in a position of command within a multidisciplinary team of other healthcare professions, including the pharmacist. As depicted in **Figure 4** below, the model is viewed as an equilateral triangular relationship between the three distinct roles. According to Adjei’s (2012) model, the roles may not be the same, but they are considered equally important and should complement one another. For example, the healthcare provider, the recipient, and the quality assurance specialist involved in the clinical pharmacy practice. This is the lens through which assessment of the use of ART in children managed by NIMART-trained PNs in public clinics will be viewed.

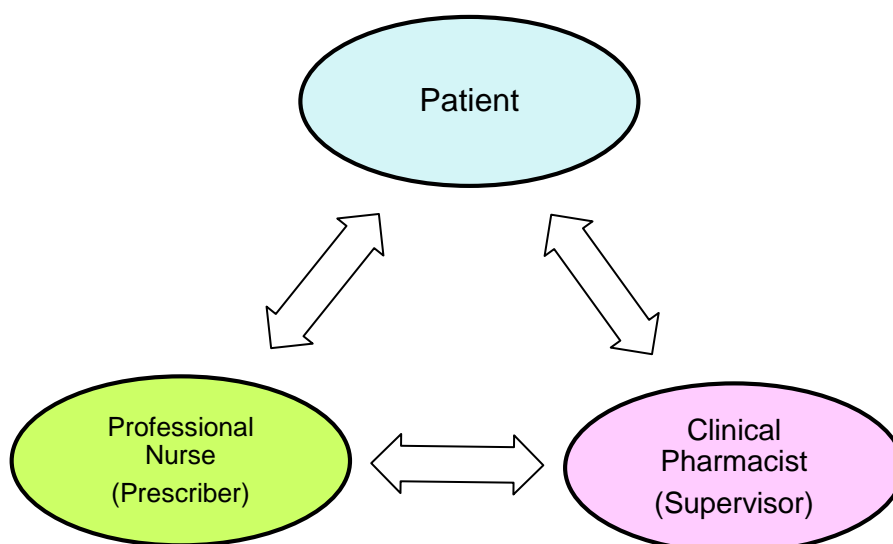


Figure 3.1: Tripartite model of the healthcare team – Adapted from Adjei, 2012

According to this theoretical framework, the quality assurance specialist, in this case, is the clinical pharmacist (Donabedian, 2002). The clinical pharmacist, in this case, can also be referred to as the *umpire* (Adjei, 2012) and necessarily exists to play a vital role in representing the interests of the patient and the healthcare system.

Adjei's (2012) theory emphasises the fact that "it is necessary for there to be an agency who may function somewhat as the patient's advocate to stand by the patient, carry the latter through the healthcare process, and to ensure that good quality and economical care is provided". The theory proposes that clinical pharmacists should fulfil such a professional function. Proponents of this theoretical framework also suggest the following benefits that can be drawn from studies of this nature: i) Pharmacoprudence, ii) Performance of clinical audits, and iii) Training and education.

Pharmacoprudence relates to the legal concept of jurisprudence and is the science and practice of the rational use of medicines (Thomas, 2004). This includes the economic, productive and efficient use of medicines associated with competent nursing practice in PHC clinics to provide adequate care and management of patients.

Performance of clinical audits is undertaken on a population-wide and individual basis to measure compliance of prescribed treatment regimens to generally accepted treatment guidelines, such as the ART therapy assessment prescribed by NIMART-trained PNs in this study. The theory, therefore, suggests that, as a consequence of clinical audits, "the clinical pharmacist institutes corrective measures to address the points of deviation of the prescribed treatment from the standard protocols" (Adjei, 2012). In this study, the performance of an antiretroviral-use audit will be of importance in determining the professional nurse's compliance with HIV guidelines when managing children on ART.

Training and education refer to training and education of service providers in the triangular model particularly and, more significantly, to training and education of the public, i.e. the patients. The relevance of this benefit is focused on in Phase 4 of the research project. The researcher seeks to develop and implement a training programme on ART dosing and dispensing for NIMART-trained PNs in public clinics.

3.2.1 Elements of Pharmacoprudence

Adjei (2012) introduced into the lexicon of healthcare the term “pharmacoprudence” to explain the work function of the clinical pharmacist. It emanates from the belief that the role we seek to determine for the clinical pharmacist is almost like that of the legal practitioner, as is jurisprudence, so is pharmacoprudence. In only a few words, I will define pharmacoprudence because of the science and practice of the rational, efficient, productive and economic utilisation of therapeutic agents. Pharmacoprudence is associated with the broader coverage of all therapeutic agents in contrast to the limited focus of medicine alone. Furthermore, the primary purpose of pharmacoprudence is the professional domain of the clinical pharmacist (Thomas, 2004). The clinical pharmacy profession could also be practised within the public and private sectors. But in whatever field of practice wherein the clinical pharmacist could also be found, there should be uncompromising practice autonomy (Adjei, 2012).

On the other hand, Hoxha, Malaj, Kraja, Bino, Oluka, *et al.* (2018) identify pharmacoprudence as the duty function of the clinical pharmacist. It embodies several interrelated activities, including the Pharmacoeconomics evaluation of therapeutic agents. The clinical pharmacist follows the worldwide scholarly biomedical literature within their specialisation's medical field(s). At predetermined intervals, the clinical pharmacist prepares review literature to be circulated among the healthcare clinics they work with maintenance of managed health records (MHRs) for individual clients. The target is to stay updated with emerging trends within diagnosis and treatment because of issues within the field(s) of specialisation.

Clinical pharmacists should maintain MHRs for their clients. These are electronic sorts of patients' medical folders organized and stored to enable faster information retrieval. It is challenging to access pertinent information from the traditional patients' medical folders, during which vital documents are scattered in chronological order. Within the MHRs, such pieces of data are stored during a classified structure. The breadth of coverage of the MHR should be wide enough for it to function as a comprehensive health record of the client. Performance of clinical audits on a population-wide and individual basis.

Execution of clinical trials. Clinical auditing is the process of measuring the degree of compliance between any prescribed treatment and usually accepted treatment protocols (Ibbott, Haworth, & Followill, 2013). Clinical audits are the most essential instruments for

quality assurance of healthcare systems (Zarei, Karimi, Mahfoozpour, & Marzban, 2019). Although international protocols are often employed, local protocols could also be developed through the leadership of the clinical pharmacist. As a result of clinical auditing, the clinical pharmacist institutes corrective measures to deal with the points of deviation of the prescribed treatment from the quality protocols. The clinical pharmacist is also a search scientist and frequently initiates or participates in clinical trials. The search for superior therapeutic agents is ever imperative. It necessitates that the clinical pharmacist should be able to experiment with therapeutic agents to work out new ways of treating diseases.

Training and education of other healthcare staff and, therefore, the general public. The clinical pharmacist may be a health educator and trainer. A daily program should be developed whereby the clinical pharmacist may disseminate the knowledge acquired through their studies to other healthcare professions, the tutorial community, and the general public. The practice office of the clinical pharmacist could function as a platform for apprenticeship and training of people in pharmacoprudence. Using this approach, a clinical pharmacist could successfully establish an endless succession of clinical pharmacy practices. History of Professions I should mean that no existing profession is of a natural origin; all of them began because men's conceptions were inaugurated and nurtured to maturity. This is often the tortuous trajectory that our noble profession ought to follow. This theoretical framework has been conceived for the clinical pharmacy profession. A subsequent important step is the organisation of all colleagues who subscribe to these propositions.

3.3 Drug Utilisation Research Concept

Even though Drug Utilisation Research (DUR) is an area of interest within clinical pharmacy, there is limited research on drug utilisation among children in general (Dahlén, 2019). The main objective of drug utilisation research is to facilitate the rational use of medicines in communities. For the prescribers, the rational use of a drug implies the prescription of a well-documented drug, at an optimal dose, with the correct dosing frequency and route of administration, at an affordable price (WHO, 2003). This type of research is essential. Without knowing how drugs are prescribed and used, it is difficult to initiate a discussion on the rational use of medicine or even suggest measures to improve prescribing habits of healthcare professionals. Hence, in this study, the framework will inform discussions on children who

were initiated on antiretroviral therapy (ART) in public clinics of Mopani district in 2015. The framework also advocates that researchers should determine the extent to which drugs are appropriately used, overused or underused based on epidemiological data on a disease. In this study, the researcher employed this framework to make meaning of observations and compare the observed patterns of antiretroviral use in the treatment of children on ART with current recommendations of the standard HIV/AIDs treatment guideline. Drug utilisation research studies are also crucial in identifying early indicators of irrational medicine use. This is also an important quality control measure for drug use, for it offers a systemic framework for continuous quality improvement in healthcare settings (WHO, 2003). Hence in this study, the researcher will follow the first three steps of addressing a drug use problem as depicted below in **Figure 3.2**.

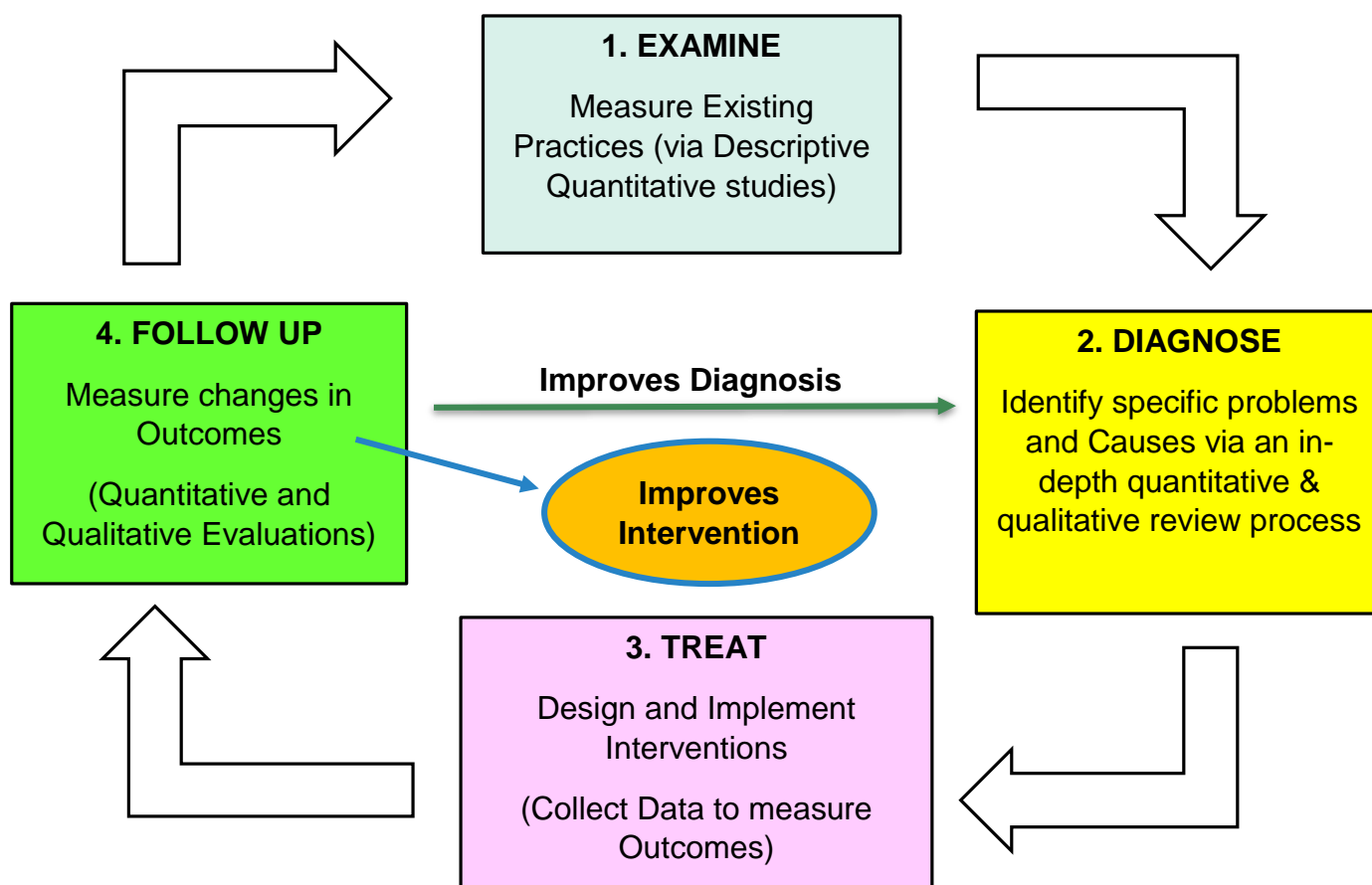


Figure 3.2: Steps for measuring drug use

3.4 What is Drug Utilisation Research

The development of drug utilisation research was sparked by initiatives taken in Northern Europe and the United Kingdom in the mid-1960s (Wade, 1984 & Dukes, 1992). The pioneering work of Arthur Engel in Sweden and Pieter Siderius in Holland (Engel & Siderius, 1968) alerted many researchers to the importance of comparing drug use between different countries and regions. The ultimate goal of drug utilisation research ought to be assessing whether drug therapy is rational or not. To reach this goal, methods for auditing drug therapy towards rationality are necessary (WHO, 2003). Hence, Drug Utilisation Research (DUR) developed quickly in three decades and soon became a good subject for consideration at international congresses in pharmacology, pharmacy and epidemiology. Successful research in drug utilisation requires multidisciplinary collaboration between healthcare professionals (Wettermark, Elseviers, Almarsdóttir, Andersen, Benko, *et al.*, 2016). Without the support of the prescribers, this type of research effort fails to reach its goal of facilitating the rational use of drugs. Hence the focus on NIMART trained nurses as the prescribers at the PHC level of care.

In 1977 the WHO defined Drug utilisation research as the marketing, distribution, prescription, and use of drugs in a society, emphasising the resulting medical, social and economic consequences. Ever since then, several other terms have come into use. Hence it is vital to understand the interrelationships of different domains such as epidemiology, pharmacoepidemiology, pharmacosurveillance and pharmacovigilance. Epidemiology has been defined as the study of the population's distribution and determinants of health-related states and events and the application to control health problems. A modern definition of Pharmacoepidemiology is the study of the use and effects/side-effects of drugs in large numbers of people to support the rational and cost-effective use of drugs in the population, thereby improving health outcomes (Montastruc, Benevent, Montastruc, Bagheri, Despas, *et al.*, 2019). Pharmacosurveillance and pharmacovigilance are terms used to refer to the monitoring of drug safety. For example, using spontaneous adverse-effect reporting systems, case-control and cohort studies.

DUR may further be divided into descriptive and analytical studies. Pharmacoepidemiology may be drug-oriented, emphasising the safety and effectiveness of individual drugs or groups

of drugs, or utilisation oriented aiming to improve the quality of drug therapy through pedagogic intervention (Anandabaskar, 2019). The former's emphasis has been to describe drug utilisation patterns and identify problems deserving more detailed studies (Elseviers, Wettermark, Almarsdóttir, Andersen, Benko, *et al.*, 2016). Analytical studies try to link data on drug utilisation to figures on morbidity, the outcome of treatment and quality of care with the ultimate goal of assessing whether drug therapy is rational or not. Sophisticated utilisation-oriented Pharmacoepidemiology may focus on the drug (e.g. dose-effect and concentration-effect relationships), the prescriber (e.g. quality indices of the prescription, or the patient, such as the selection of the drug and dose (Borges Luz & Nilsson, 2016).

Wettermark *et al.*, (2016) further describe DUR as an essential part of Pharmacoepidemiology as it describes the extent, nature and determinants of drug exposure. Over time, the distinction between these two terms has become less sharp, and they are sometimes used interchangeably. However, while drug utilisation studies often employ various sources of information that focus on drugs (e.g. aggregate data from wholesale and prescription registers), the term epidemiology implies defined populations in which drug use can be expressed in terms of incidence and prevalence (Wettermark, Vlahović-Palčevski, Lee & Bergman, 2019).

Together, drug utilisation research and Pharmacoepidemiology may provide insights into the following aspects of drug use and drug prescribing.

- **Pattern of use:** This covers the extent and profiles of drug use and the trends in drug use and costs over time.
- **Quality of use:** This is determined using audits to compare actual use to national prescription guidelines or local drug formularies (Bergman, Popa, Tomson, Wettermark, Einarson, *et al.*, 1998).

The WHO (2003) bring forth the idea of what the indices of quality of drug use may include;

- i) the choice of drug which addresses the issue of compliance with the recommended treatment guidelines/protocols,
- ii) drug cost, which addresses compliance with budgetary recommendations,

iii) Drug dosage talks to awareness of inter-individual variations in dose requirements and age-dependence, awareness of drug interactions and adverse drug reactions, and the proportion of patients who are aware of or unaware of the costs and benefits of the treatment.

- **Determinants of use:** These include user characteristics such as sociodemographic parameters and attitudes towards drugs, prescriber characteristics such as speciality, education and factors influencing therapeutic decisions, and drug characteristics that focus on the therapeutic properties and affordability of treatment.
- **Outcomes of use:** These are the health outcomes such as the benefits and adverse effects and the economic consequences (Bergman, *et al.*, 1998).

Pharmacoepidemiological studies often make valuable contributions to the knowledge about effectiveness and safety because, unlike clinical trials, they assess drug effects in large, heterogeneous populations of patients over more extended periods. Drug utilisation research also provides insight into the efficiency of drug use, i.e. whether a particular drug therapy provides value for money. The results of such research can help set priorities for the rational allocation of health care budgets (Rekha & Mubeena, 2017).

3.5 The Importance of Drug Utilisation Research

The principal aim of drug utilisation research is to facilitate the rational use of drugs in populations (Elseviers, *et al.*, 2016). For the individual patient, the rational use of a drug implies the prescription of a well-documented drug at an optimal dose, together with the correct information, at an affordable price. Farheen, Subhani, and Mohsin (2016) emphasise the relevance and importance of this type of research by mentioning that, without a knowledge of how drugs are being prescribed and used, it is ordinarily difficult to initiate a discussion on rational drug use or to suggest measures to improve prescribing habits. Information on the past performance of prescribers is the cornerstone of any auditing system. Pradhan, Shewade, Shashindran and Bapna (1988) stated decades ago that drug utilisation studies are necessary for formulating drug policies. They also offer helpful methods for teaching and training in drug therapy. It is documented that indiscriminate use of medicine leads to unwanted side effects, drug interactions and ecological disturbances and poses

difficulties in diagnosis. Problems like improper storage, distribution, compliance and selection of medicine constitute a significant threat to society (Brandy, Malone & Fleming, 2009). Pradhan, *et al.*, (1988) further emphasise that medicine utilisation depends mainly on the personalities of the prescriber and the patient.

Even then, drugs are not used to their full potential or in line with conventionally accepted criteria. Brandy, *et al.*, (2009) further designate that drug utilisation studies provide data on prescribing patterns and should help improve the prescribing habits of health care professionals. Here are some noted primary objectives of drug utilisation studies: 1) Identify excellent and bad prescribing practices (2) Encourage rational prescribing (3) Guide to help solve problems related to drug therapy (4) Assess the therapeutic, toxic and economic aspects of medicine and their combinations 5) Inform various authorities about drug-related offences 6) Critically analyse drug utilisation and help frame a drug or health policy (Pradhan, Shewade, Shashindran & Bapna, 1988). Drug utilisation research does not necessarily provide answers, but it contributes to rational drug use in meaningful ways, as described in the following subsection.

3.6 Description of Drug Use Patterns

Wettermark *et al.* (2016), as well as Parmar, Sharma and Trivedi (2018), brought forth the knowledge that drug utilisation research has the potential to increase our understanding of how drugs are being used as follows;

- It can estimate the number of patients exposed to specified drugs within a given period. Such estimates may either refer to all drug users, regardless of when they started to use the drug (prevalence), or focus on patients who started to use the drug within the selected period (incidence).
- It can describe the extent of use at a specific moment or in a particular area (e.g. in a country, region, community or hospital). Such descriptions are most meaningful when they form part of a continuous evaluation system, i.e. when the patterns are followed over time and trends in drug use can be discerned.
- Researchers can estimate (e.g. based on epidemiological data on a disease) to what extent drugs are appropriately used, overused or underused.

- It can determine the pattern or profile of drug use and the extent to which alternative drugs are being used to treat particular conditions.
- It can be used to compare the observed drug use patterns to treat a particular disease with current recommendations or guidelines.
- It can be used to apply quality indicators to patterns of drug utilisation.
- Drug utilisation data can be fed back to prescribers. This is particularly useful when the drug prescribing by a particular individual can be compared with some form of «gold standard» or best practice and with the average prescriptions in the relevant country, region or area.
- The number of case reports about a drug problem or adverse effects can be related to the number of patients exposed to the drug to assess the potential magnitude of the problem (WHO, 2003; Abrahamowicz & Tamblyn, 2014; Wettermark, *et al.*, 2016).

3.7 Indicators of Irrational Use of Drugs

Drug utilisation research may generate hypotheses that set the agenda for further investigations and thus avoid prolonged irrational use of drugs. Hence, Drug Utilisation Patterns (DUPs) and costs between different regions or at different times may be compared (Enato & Chima, 2011). Therefore, hypotheses are generated to form the basis for investigating the reasons for and health implications of the differences found. Geographical differences and changes in drug use over time may have medical, social, and economic implications for the individual patient and society.

The observed drug use patterns can be compared with the current recommendations and guidelines for treating a particular disease. Hypotheses can then be generated to determine whether discrepancies represent less than optimal practice, whether pedagogic interventions (education) are required or whether the guidelines should be reviewed in the light of actual practice (Parmar, Sharma & Trivedi, 2018). These hypotheses should apply to both the underuse and overuse of drugs. Therefore, they should be identified, explained, and, when necessary, corrected (WHO, 2003).

3.8 Interventions to Improve Drug Use Follow Up

Elseviers *et al.* (2016) further emphasise that DUR is embarked on ways that may enable researchers to assess whether or not intended interventions to improve drug use have had the desired impact. They further caution that the effects of measures taken to enrich undesirable drug use patterns (such as the provision of regional or local formularies, information campaigns and regulatory policies) should be timeously monitored and evaluated. Furthermore, researchers in this field should bear in mind that prescribers may have switched regimens to other equally undesirable drugs. Therefore, the impact of regulatory changes or changes in national guidelines and regimens should be assessed using a broad survey (Stern, 2016).

3.9 Quality Control of Drug Use

Johnson and Sollecito (2018) indicated drug use should be controlled according to a quality control cycle that offers a systematic framework for continuous quality improvement. The components of such a cycle are illustrated in **Figure 3.3** as follows;

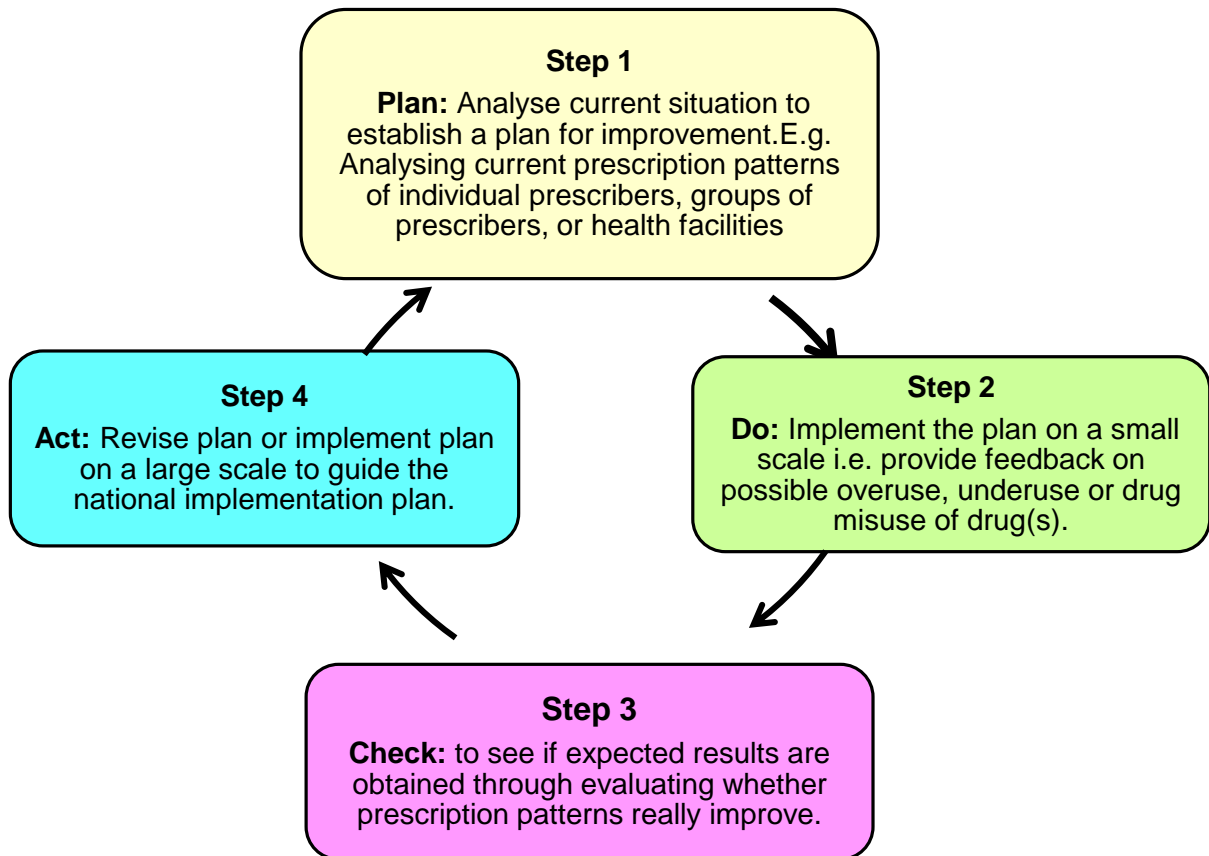


Figure 3.3: Quality control drug use cycle

The quality control cycle can be applied at many levels of care, ranging from local or regional discussion groups consisting of physicians, nurses, clinical pharmacologists or pharmacists to national and international initiatives (Christoff, 2018). An important technique that can be used in union with this cycle is benchmarking. By comparing drug utilisation data from different localities, it is often possible to detect substantial differences that require further evaluation, leading to the identification and promotion of best practices. Such comparisons will be accurate and truthful provided that the data are collected and aggregated in a standardized and uniform way (Bachhav & Kshirsagar, 2015).

In understanding the different types of DUR studies and drug use chain, the researcher in this study opted to focus on the processes of drug use to evaluate what ARV drugs are used for in virally unsuppressing children, as well as how these ARVs are used and whether their use in the population under study comply with the relevant criteria, guidelines or restrictions.

This cross-sectional study aimed at providing a snapshot of ARV use from January 2015 to December 2018.

The WHO (2003) encourages that these studies are essential in comparing with similar data collected over the same period in a different country, health facility, or a ward, and could be drug problem, indication, prescriber, or patient-based. Moreover, this type of study can be carried out before and after an educational or other intervention. Data can be made available at national, regional and local health facility levels. They may be derived from either quantitative or qualitative paradigms.

Quantitative data was used to describe the present situation at the public PHC level and the ARV use at various stages of the patient's treatment profile. This type of data was also used to assess the appropriateness of drug utilisation and to generally link prescribing data to reasons (indications) for prescribing. However, it is essential to note that the sources of drug utilisation data vary from country to country depending on the level of sophistication of record-keeping, data collection, analysis and reporting, and the operational considerations of the health care system. Furthermore, the understanding that a functional analysis requires an understanding of the sources and organisation of the data.

3.10 Practice Setting Data

Practice Setting Data (PSD) is comprised of i) Prescribing data; ii) dispensing data; iii) drug use indicators; and iv) Facility data. Bilal, Osman, and Mulugeta (2016) allude that data acquired from the health clinics under study may be used to evaluate specific aspects of health provision and drug use. The data can also generate indicators that provide information on Nurses' prescribing habits at public clinics and general aspects of HIV patient care. These indicators can be used to determine where drug use problems exist, provide a mechanism for monitoring and supervision and motivate health care providers to adhere to established health care standards.

3.10.1 Prescribing data

The WHO (2003) highlights that prescribing data is usually extracted from outpatient and inpatient prescription forms. This data may easily be retrieved where records are

computerised. Computerised data also facilitate trend analysis. In the absence of electronic databases, prescribing data are usually extracted from patient records or patient intercept studies or retrieved at dispensing points. Information obtained from prescriptions includes patient demography, drug name, dosage form, strength/dose, frequency of administration and duration of treatment. Where diagnoses are noted on prescriptions, and particularly for inpatient prescriptions, it is possible to link drug use to indications. Trends in drug utilisation for specific drugs and diseases can also be established. For example, inpatient data may link to empirical treatment of infections instead of treatment based on microbiological assessment. This may be achieved by extracting relevant data from the patient records but requires that the records be of good quality (Shalini, Ravichandran, Mohanty, Dhanaraj & Saraswathi, 2010). Prescriptions are an excellent source of information for determining some of the indicators of drug use recommended by WHO (2003), including the: i) an average number of drugs per prescription (encounter); ii) a percentage of drugs prescribed by generic name; iii) percentage of encounters resulting in the prescription of an antibiotic; iv) a percentage of encounters resulting in the prescription of an injection; v) the percentage of drugs prescribed from essential drugs list or formulary, and vi) the average drug cost per encounter.

3.10.2 Dispensing data

The WHO (2016) defines dispensing as arranging and providing medicines to a named person along with clear instructions, advice and counselling where necessary to utilise the provided medicines. It involves the correct interpretation of the order for prescribed medicines and accurate preparation and labelling of medicines to be used by the patient. Therefore, the dispensing process includes all activities that occur between the prescriptions or request for medicine is presented up to the time the medicines or other prescribed items are issued to the patient.

Consequently, the drug dispensing process ends with a client leaving the clinic with an adequate quantity of medication and instructions on how to use it. Not forgetting that the quantity of drugs dispensed depends on their availability. Thus information available from dispensers may therefore include:

- Drug(s) prescribed;

- Dose(s) prescribed;
- The average number of items dispensed per prescription;
- Percentage of items prescribed that were supplied (an indicator of availability);
- Percentage of drugs adequately labelled;
- Quantity of medications dispensed; and
- Cost of each item or prescription.

This is usually obtained from medical records kept at each health facility electronically or manually (WHO, 2016). Whereas in this case, the patient's medical record served this purpose.

CHAPTER 4 RESEARCH METHODOLOGY

4.1 Introduction

The study adopted a mixed-methods research approach, integrating quantitative and qualitative data collection and analysis in an explanatory sequential design described by Creswell (2013). “Mixed methods studies allow researchers to take advantage of the strengths of numbers and words to answer different components or stages of a research question” (Creswell, 2015). Hence, the researcher in this study believed that mixing the strengths of quantitative and qualitative methods would allow the generalisation of the study's findings.

Authors such as Glogowska (2011); Zhang & Creswell (2013) assert that “*Mixing* refers to the process whereby the qualitative and quantitative elements are interlinked to produce a fuller account of the research problem”. MMR design offers “an alternative methodology for researchers to address complex issues in a way that is more comprehensive than could be achieved by purely qualitative or quantitative research” (Caruth, 2013; Teddlie & Tashakkori, 2011).

4.2 Philosophical Foundations of MMR

Philosophically, the foundation for mixed methods research is neither an objective post positivistic view of quantitative researchers nor a subjective constructivist view of qualitative researchers. Instead, researchers who use MMR designs have exchanged the dichotomy of positivism and constructivism for the centre-ground of pragmatism (Yardley & Bishop, 2015).

4.2.1 Pragmatism

Theorists known to be foundational in pragmatism are the American philosophers Charles Sanders Peirce and William James, who advocated for this philosophy in the late 19th century (Menand 2001). MMR researchers worldwide (For example, Creswell, Klassen, Clark & Smith, 2011); Johnson & Onwuegbuzie 2004; Morgan 2014; Teddlie & Tashakkori 2009; Yardley & Bishop 2008) view pragmatism as “the most helpful and leading philosophical

paradigm for mixed methods research". According to Johnson & Onwuegbuzie (2004), the philosophy of pragmatism can help solve the problem of dualism, deal with the diverse discussions of qualitative and quantitative philosophy of the social sciences, and produce viable solutions that are acceptable to all aspects of the discussion. Therefore, it is most suitable for MMR.

Hence, it is necessary to keep in mind the purposeful understanding that pragmatism is a philosophy that focuses on solving problems by whatever methods fit the matter or question at hand (Leavy, 2017). Hence, with mixed methods designs, the researcher can allow the strengths of one method to catch up on the possible limitations of the opposite (Creswell, 2015). More positively, mixed methods research allows the strengths of every method to interact in an exceedingly complementary way with the opposite method (Leavy, 2017). This is better known as integration. This integration can occur at any stage(s) of the research process but is vital to the rigour of the mixed methods research (Glogowska, 2011).

4.2.2 Integration in MMR design

Proponents of MMR offer a general strategy for integration into mixed law research by merging quantitative and qualitative data. Integration is defined as the deliberate process by which a researcher puts together quantitative and qualitative data in a study (Creswell, 2015). Through data integration, researchers gain access to knowledge and insights not available in independently conducted quantitative or qualitative research. (Fetters & Molina-Azorín, 2017; O’Cathain, Murphy, & Nicholl, 2007). According to Fetters and Molina-Azorín (2017), researchers in MMR can achieve integration at any or all of the following four different levels. The first is the philosophical level; the second is the research design level; the third is the methods and data collection levels; the fourth is the interpretation and reporting levels of a research project. Each of the listed levels is briefly detailed in the subsequent sections below:

4.2.2.1 Integration through the philosophical

The integration advocated in MMR can be achieved logically at different epistemological positions. According to Clark and Ivankova (2016), quantitative and qualitative studies can be mixed and employed logically in MMR. Therefore, other authors such as Johnson (2017)

argued that MMR studies should use multiple and even contradictory paradigms. In particular, Johnson argues for dialectical pluralism as a "metaparadigm," integrating quantitative and qualitative paradigms equally and with respect, and the differences between them while researchers develop an integrated whole. Johnson therefore reveals that this could allow researchers to prosper with intellectual tension. Another notable stance is that individual paradigms can provide a good foundation for MMR. Mertens (2003) advocates a transformative liberation paradigm that features conscious collaboration with minorities and fringe groups. Others, such as Maxwell and Mittapalli (2010), discuss critical realism as the philosophical foundation of MMR.

4.2.2.2 Integration at the design level

Integration at the design level can be done through basic design, including descriptive sequential, exploratory sequential, and convergent design (Creswell, 2015). Descriptive sequential design begins with the collection and analysis of quantitative data and then proceeds to the qualitative follow-up phase. Exploratory sequential design begins with the collection and analysis of qualitative data and is built on the basis of subsequent quantitative phases (Fetters, et al., 2013). Convergent design collects quantitative and qualitative data, analyses it over similar periods, and compares the data (Fetters, et al., 2013). In addition to these core designs, there are other advanced or so-called "complex" designs (Nastasi, Hitchcock, Gutierrez & Oshrin, 2021), multi-level applications, interventions, case studies, and participatory designs. Device / app development is based on three core designs, but with a comprehensive purpose. Interventive MMR design in research, or transformative design to promote social justice (Creswell, 2015; Fetters, et al., 2013).

4.2.2.3 Integration at the methods level

Integration at this level methods level has been classified in several ways. First, Fetters et al. (2013) mention connecting or linking data through sampling. Second, the aspect of building or what is known as findings from one strand inform the development of data collection tools or procedures for the other strand. Third, they also indicate that this involves hypothesis-generating and testing, such as using one type of data to generate a hypothesis and another type of data to test that hypothesis. Fourth is matching or reflecting the intent to have themes/constructs match on a domain by domain basis. The fifth level is referred to as

diffracting, meaning using data cuts to understand a phenomenon. Sixth is called embedding, which entails adding qualitative data into a multistage study at multiple points. The last is known as merging, where the two databases are brought together for analysis and comparison. According to Uprichard and Dawney (2019), five of these approaches occur during data collection, while diffraction may refer to multiple levels, and merging remains the most obtuse as it refers to the analytical process.

4.2.2.4 Integration at the interpretation and reporting levels

Integration at the interpretation and reporting level can be either through narrative, data transformation, joint displays, and visualisation, for example, using Geographic Information System (GIS) mapping (Fielding and Cisneros-Puebla), or according to Fetters, *et al.*, (2013), a combination there of. This also involves the description of the quantitative and qualitative findings to enhance the integration of data through a narrative (Beck, *et al.*, 2009).

4.2.3 Considerations of MMR design

MMR design is much more than collecting qualitative and quantitative data within a single study. To ensure the rigour of the design, the methodological approach to MMR requires several issues to be considered in its application. Eight critical considerations in planning and undertaking MMR are presented here, namely; 1) examine the rationale for using mixed methods; 2) explore the philosophical approach; 3) understand the various mixed-method designs; 4) assess the skills required; 5) review project management considerations; 6) plan and justify the integration of qualitative and quantitative aspects; 7) ensure that rigour is demonstrated; 8) disseminate mixed methods research proudly.

4.3 The rationale for using MMR design in this study

Just because one can collect both numerical and narrative data concerning a single research problem, this does not mean that one should undertake an MMR study. The decision to implement an MMR design should be based on the value that using qualitative and quantitative data collection methods has above using a single method in answering the research question (Creswell, Klassen, Clark & Smith, 2011, Scammon *et al.*, 2013).

The rationale for using MMR design is usually reflected through the research questions (Lavelle *et al.*, 2013). As a result, in this study, the justification for adopting and undertaking MMR design is demonstrated in the qualitative and quantitative dimensions of the project. The relevance for MMR in this research project was because of several reasons: First, the study was intended to quantitatively conduct a four year (01 January 2015 to 31 December 2018) assessment to determine the clinical outcomes of children initiated on ART in the public clinics of Mopani District in the year 2015. Second, it intended to explore and describe (qualitative) the prescribing practices of NIMART trained Nurses. Third, it sought to quantitatively and qualitatively assess the NIMART-trained PNs' compliance with the 2015 South African HIV/AIDS guidelines for treating children on ART. Forth, it sought a qualitative approach to identify the factors associated with regimen switching and to determine the knowledge, understanding, and competence of NIMART-trained PNs in managing children on ART. Through this approach, the study also sought to establish the perceptions of NIMART-trained PNs regarding the effective management of children on ART in public clinics, establish the nurses training needs, then develop a training programme for the appropriate management and use of antiretrovirals. Lastly, the study sought to implement the training programme for the appropriate management and use of ART.

The researcher in this study is fully aware that there could be other alternatives to MMR design. One methodology that has become popular in the last ten years is the EQUATOR research methodology. This could have been a welcome alternative to adopting a MMR in the study. Using the EQUATOR Research methodology would have also set a conducive environment for an alternative to the ADDIE Model of Instructional Design which was adopted to guide the development of an intervention training for the NIMART Nurses. However, weighing the pros and cons, the researcher opted for the MMR and by consequence the adoption of the ADDIE Model. Although the EQUATOR methodology has been in use, particularly in the UK for more than 10 years, its guidelines for the reporting of health research are still not widely supported experts in the field, and thus their potential impact is lessened (Mills, Loke, Wu, Montori, Perri, et al. 2004; Smidt, Rutjes, Van Der Windt, Ostelo, Reitsma., et al. 2005). On the other hand, the MMR offsets weaknesses inherent to this methodology by using aspects of quality drawn from qualitative and quantitative.

4.3 Research Design

As already reflected in the preceding paragraph, an explanatory sequential design was adopted for this study. It comprised the collection and analysis of retrospective quantitative data, which was sequentially followed by the collection and analysis of qualitative data. This procedure is outlined in Table 4.1 that follows below:

Table 4.1: Visual model for mixed methods explanatory sequential design

PHASES	PROCEDURE	PRODUCT
Quantitative Data Collection	<ul style="list-style-type: none"> • Cross Sectional Desktop and medical records evaluation 	<ul style="list-style-type: none"> • Numeric Data
Quantitative Data Analysis	<ul style="list-style-type: none"> • Data screening (univariate, multivariate) • Factor analysis • Frequencies • SPSS Quant software version 25 	<ul style="list-style-type: none"> • Descriptive statistics, missing data, linearity, normality, multivariate outliers • Factor loadings
Connecting Quantitative & Qualitative Phases	<ul style="list-style-type: none"> • Identify gaps for further evaluation • Develop questerview questions 	<ul style="list-style-type: none"> • Questerview
Qualitative Data Collection	<ul style="list-style-type: none"> • Purposefully selecting the NIMART nurses and collecting data until saturation • Develop interview questions • Individual in-depth face-face interviews 	<ul style="list-style-type: none"> • Text Data (Interview transcripts)
Qualitative Data Analysis	<ul style="list-style-type: none"> • Coding & thematic analysis • Within case and across case theme development • Thematic analysis • ATLAS.ti version 8 	<ul style="list-style-type: none"> • Visual model of multiple case analysis • Codes and themes • Similar and different themes and categories • Cross-thematic matrix

PHASES	PROCEDURE	PRODUCT
Integration of the Quantitative & Qualitative Results	<ul style="list-style-type: none"> • Interpretation and explanation of the quantitative and qualitative results 	<ul style="list-style-type: none"> • Discussion • Implication • Future Research

In compliance with Terrell (2011) and Creswell (2013), this study employed an MMR design where both the strands, namely, Qualitative and Quantitative, were given equal priority. By adopting this type of design, it was ensured that the focus of the study was meant to explain, through a qualitative aspect, the prescribing practices of NIMART trained nurses. Specifically, this was achieved through the qualitative exploration of the knowledge, understanding, and competence of NIMART-trained PNs in managing children on ART. To obtain a better understanding of the results of the quantitative phase, the study then employed the use of follow-up interviews.

Following Creswell, Klassen, Clark & Smith (2011), the rationale for adopting this approach in this study was that the quantitative data and results provided a general picture of the research problem. Through qualitative data collection, additional analysis was deemed necessary to refine, extend, and justify the final picture of the findings. Hence, it was planned that the results obtained in the quantitative phase (Phase 1A and B) would be used to guide the purposeful sampling required for the qualitative phase (Phase 2A and B). In this case, the sampling was achieved by adopting a total population purposive sampling technique. The results obtained in Phase 2 provided the basis for explaining the results obtained in Phase 1. The mixing of methods in the study was helpful because it gave ‘a voice’ to the nurse-prescribers as they played a role in the treatment and management cascade. In Phase 3 of the study, the results and findings from the first two phases were integrated to identify gaps in the prescribers (NIMART Nurses) knowledge and understanding of ART dosing and dispensing in children. The integration in this study took place at all four levels of the study described in Section 4.2.2. This level of integration was crucial in giving detailed meaning to the findings of this study.

The last phase (Phase 4) of the study adopted a model of instructional design, known as the ADDIE (Analysis, Design, Development, Implementation, Evaluation) instructional design model, to develop the training programme with tools that will address the knowledge gaps that were identified in stage 3 of the study. This instructional design model was first created in 1975 by the Centre for Educational Technology at Florida State University for the United States Army Combat Arms Training Board. Recently, in 2017 the model was revisited for curriculum design in educational and training programmes by theorists and instructional designer Dr Serhat Kurt. Kurt (2017) model has been used across various fields of study. For example, in business to improve and increase sales, in sport to improve performance, in psychology to change behaviour, and in health to design interventions and improve services. The model was adopted to guide the design of an intervention programme to improve the services of NIMART Nurses in the provision and management of ART in children. A detailed description of the ADDIE instructional design model (Kurt, 2017) adopted for this study is provided in the next section:

4.4 Overview of the ADDIE Model and its applicability to the study

In Phase 4 of this study, it is depicted that this study adopted the ADDIE instructional design model to design and implement the training programme on ART dosing and dispensing for NIMART-trained PNs in the Mopani district public clinics. Figure 7 below represents a schematic view of Kurt (2017) ADDIE instructional design model, which was adopted as part of the MMR explanatory sequential design (Creswell, 2013) that this study employed.

Kurt, 2017) illustrates the training development process elected for this study. This process was adopted and implemented as follows:

First, the study's goals were identified and stated through the objectives (Cf: Section 1.4.1). Second, the training needs were gathered through thorough document analysis of patient files through a total population purposive sampling technique. Third, the researcher identified the knowledge gaps and after that, based on the knowledge gas went on to identify the training goals. This was followed by the proposal and collation of training content. After this, the researcher engaged in evaluating options for training delivery. This put into consideration

aspects such as the mode and cost of delivery. At the end of this process, a proposal for training was presented to the Limpopo Department of Health, which provided the field for data collection for the study and the non-governmental organisation responsible for systems strengthening in the district understudy.

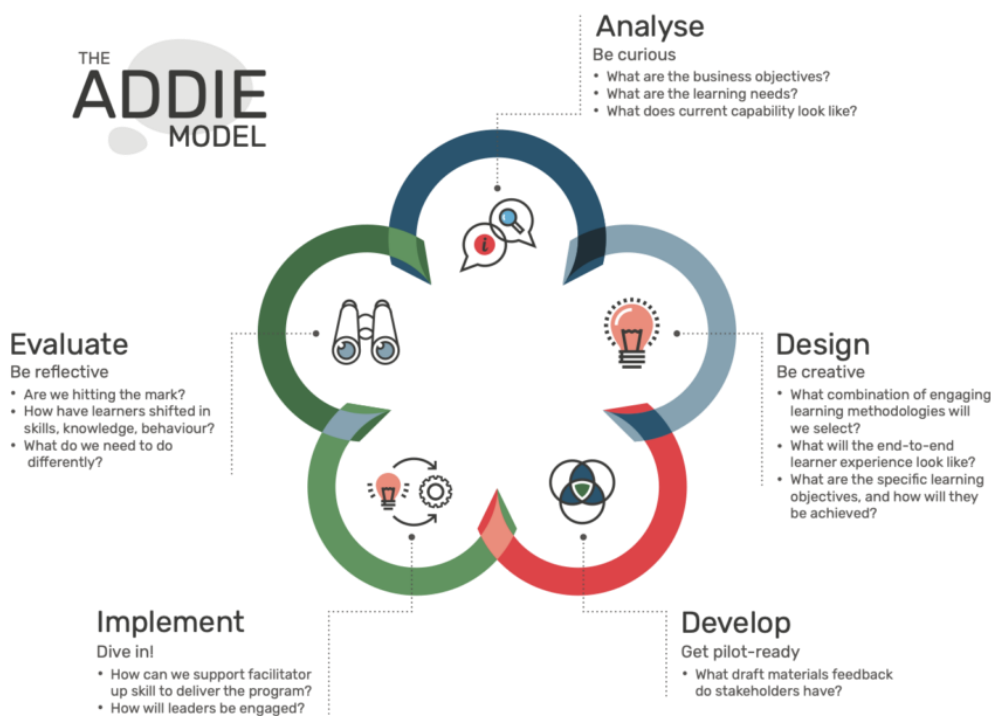


Figure 4.1: ADDIE model

The ADDIE Model is a systematic approach to creating an effective training solution based on an organisation’s training needs. The model is the generic process that instructional designers and training developers traditionally use. It is argued that the application of the five phases of this study model in health intervention programmes such as the one intended in this study represents a dynamic, flexible guideline for building practical training and performance support tools (Woo, 2018). The choice of this model for this study was also motivated by the fact that it is a preferred model in programmes that attempt to save time and money by catching problems while they are still easy to fix (Connelly & Miller, 2019).

In this application of the ADDIE model to investigate the training needs and the design of a training programme for the NIMART nurses, each step in the ADDIE model had an outcome that fed into the subsequent step. This process took place in this study as follows:

4.4.1 Analysis Phase

In the analysis phase of this study, the (instructional problem) gaps in the nurses' existing knowledge, skills and understanding of ART management were identified and clarified. Then the nurses' training needs (instructional goals and objectives) were established. Below are some of the questions that were addressed during the analysis phase in this study:

- Who are the audience and their characteristics? The demographic details and educational background of the NIMART nurses under study were established by answering this question.
- Identify the new behavioural outcome? This question helped the researcher better understand the ART management and the prescribing patterns of the NIMART nurses under study.
- What types of learning constraints exist? It was essential to understand the contextual constraints responsible for the gaps in the nurses' knowledge by addressing this question.
- What are the delivery options? Responding to this question assisted the researcher to weigh options for implementing the training programme designed for the NIMART nurses. This question was also crucial for the sustainability of the programme designed for the training of the NIMART nurses.
- What are the online pedagogical considerations? This question was significant in this stage. It ensured that the rural nature and needs of the area where this study was conducted were considered before an online programme would be put in place.
- What is the timeline for project completion? This question was necessary for this study to ensure that successful completion in the implementation of the training programme is achieved.

The next phase undertaken in the process was to engage in the design phase.

4.4.2 Design Phase

The design phase of the training development dealt with learning objectives, assessment instruments, exercises, content, subject matter analysis, lesson planning and media selection. Following Kurt (2017), it was ensured that the design phase was systematic and specific in execution. Hence, the selection of training materials and content was logical, orderly and mainly informed by sourcing of materials needed to fulfil the goals of the Department of Health and UNAIDS 90:90:90 treatment for all. Hence, to ascertain that each element of the instructional design plan was executed with attention to detail, the following steps were used in this phase of the project:

- The project's instructional, visual and technical design strategy was well documented
- Instructional strategies were applied following the intended/ desired behavioural outcomes. That is to say, the nurses' practices in the management of ART had to improve.
- The online training programme interface design was initiated in collaboration with an e-learning specialist and a health strengthening non-governmental organisation to ensure ease of delivery.

4.4.3 Development Phase

The design phase was followed by the developmental phase, where the content was created in the first phase. The researcher worked with the e-learning specialist to create and assemble the content platform in this phase. In addition, a group of NIMART Nurses from the pilot study site (Cf: Section 4.5.5) was enlisted to serve as testers to go through the content and navigation of the training programme. This assisted in having the training programme reviewed and revised according to feedback given. In the following subsection, the details of the implementation phase are provided.

4.4.4 Implementation Phase

A procedure for delivering the training programme was developed during the implementation phase. The participants in the training were identified and prepared for the programme. This preparation included orientating them on the training delivery tools and the registration process for the training. This is the phase where the researcher (as project manager) also

ensured that the materials (such as the guide) and tools for connectivity (such as mobile phones) were in place and that the learning application was functional.

The fifth and final phase in this approach is the evaluation phase. The following subsection details how this phase was handled in this study.

4.4.5 Evaluation Phase

Woo (2018) indicates that the evaluation phase consists of two parts, namely, the formative and summative. During the implementation of the training programme in this study, the researcher ensured that formative evaluation was present in each stage of the ADDIE process. This was achieved through oral questions, participants' opportunities for illustrations, and short exercises. The summative evaluation consisted of tests designed for domain-specific criterion-related referenced items. These helped provide opportunities for feedback from the NIMART nurses.

4.5 Weaknesses of the ADDIE Model

While the ADDIE Model has predominantly been used to develop content for learning for many years in the health and other sciences, Pear and Konstantinidis (2021) indicate that the model still has some significant weaknesses. Perhaps the model's biggest weakness is that it assumes that you can know all the requirements before developing the content. According to Pear and Konstantinidis (2021), this chosen model tends to be inefficient because it is not iterative. They also point to the fact that the linear approach often adopted in most model applications tends to work well for static content but may be restrictive when dealing with user-generated content or learning outcomes that do not have a predetermined end state.

To overcome the weaknesses of the ADDIE model, the researcher in this study adopted the following mitigating strategies:

- The study adopted an iterative process throughout the development of the training materials. The interaction was with participants, experts in HIV care and health systems strengthening, and the supervisory team in the project.

- As depicted in Figure 7 above, a cyclical approach to developing training content was adopted in this project.

Following Heyberi-Tenekeci (2019), using this qualitative model for instructional design in this study helped a great deal for the researcher to walk participants through each phase of the material development and training programme and assist in consolidating knowledge gaps, as well as progress and obstacles.

4.6 Study Site

The study was conducted in public Primary Health Care Clinics in the Mopani District, where children on antiretroviral therapy were cared for in 2015. Mopani is one of the five districts of the Limpopo Province. The district is divided into five Sub-districts: Ba-Phalaborwa, Greater Giyani, Greater Letaba, Greater Tzaneen, and Maruleng. The Mopani District comprises 354 villages and 16 urban areas (Mopani District Municipality Integrated Development Plan, 2016 – 2017). A map illustrating the district where the study is located is provided on the next page (see Figure 8 below):



Figure 4.2: Map of Mopani District Municipality - Source: ©municipalities.co.za

4.7 Study Population

De Vos, Strydom, Fouche and Delpont (2011) describe a study population as a whole set of participants containing all the characteristics explored by the researcher. The study population for this study included all clinics (that is, eight (08) community health centres (CHCs) and eighty-six (86) PHC clinics) that managed children under the age of 15 years on ART in all the five Sub-districts of Mopani in 2015, as presented in Table 4.2 below.

Table 4.2: Study sites – Category of participating clinics per sub-district with children < 15 yrs enrolled on ART in 2015

Sub-district	Number of Clinics	Number of CHCs	Total No. of Facilities per Sub-district Combined	Estimated No. of Children initiated on ART in 2015
Ba-Phalaborwa	08	01	9	46
Greater Giyani	23	02	25	113
Greater Letaba	20	01	21	122
Greater Tzaneen	24	04	28	176
Maruleng	11	0	11	59
District Totals	86	08	94	516

Source: Mopani District *Tier.Net/DHIS*.

The researcher in this study opted for conducting a census data collection technique (also known as the total population purposive sampling technique) of all the public clinics in the district under study. This was done to understand that excluding any of them would have introduced an element of bias into the study. It was also adopted to ensure that a complete picture of the problem under study would be painted for analysis. These public clinics were found in the different geographical locations within the five Sub-districts of Mopani, representing the different levels of PHC across the district under study

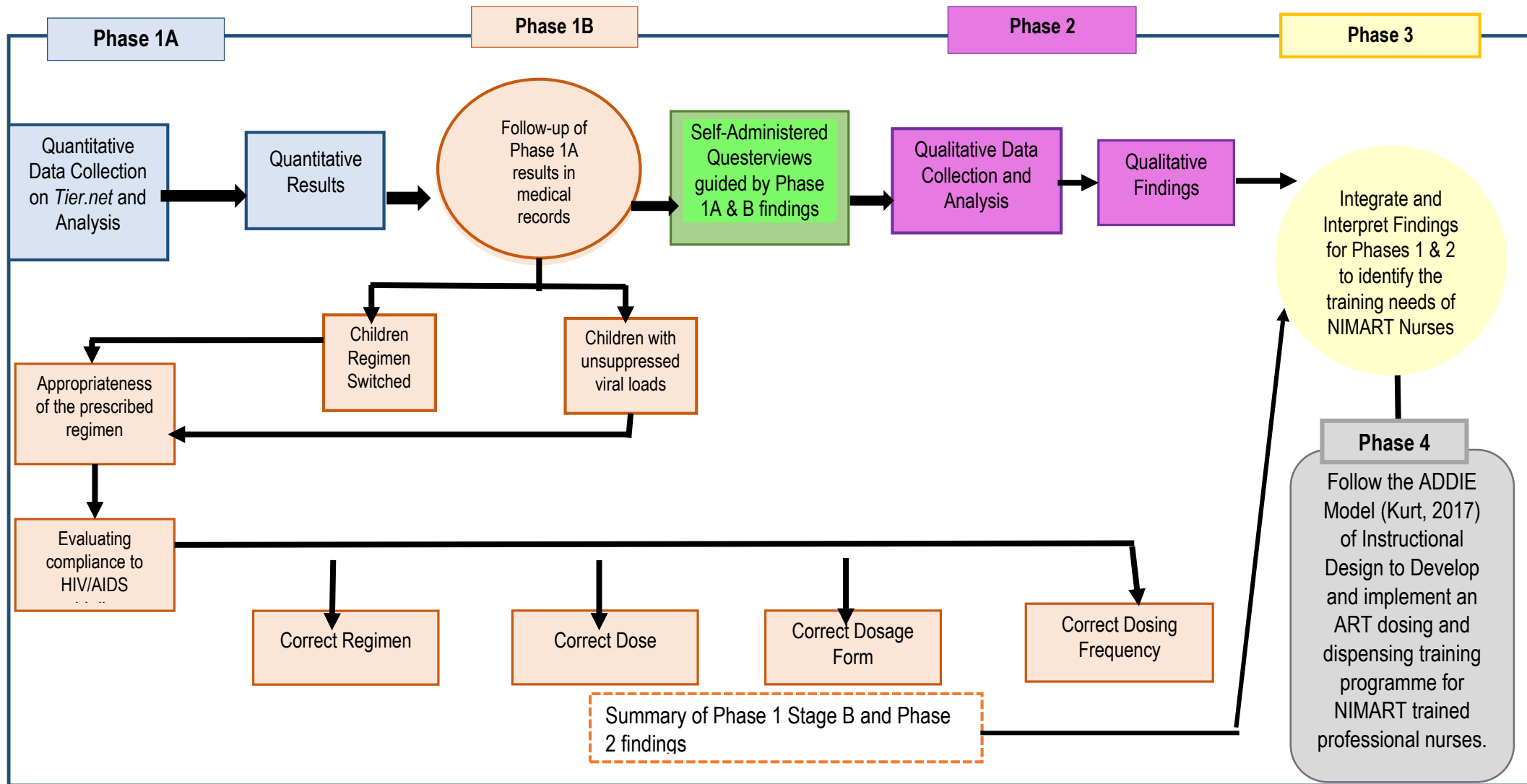


Figure 4.3: Study process flow

4.8 The Quantitative Strand of the Study

Since the study followed Creswell's (2013) explanatory sequential design of MMR design, the first part of the study was quantitative. All the study's quantitative findings focused and directed the qualitative phase of the study.

4.8.1 Sampling

Sampling is referred to by Polit and Beck (2008) and was understood by the researcher in this study as a process of selecting participants that best represent the whole population so that meaningful inferences about the population could be made. The study employed a total population purposive sampling technique where the entire population that met the criteria were included in the research conducted (Etikan, Musa & Alkassim, 2016). Hence, the sample comprised a census of all 516 electronic medical records of children under age 15 who were indicated by the district *TIER.Net* system to have been initiated on ART at the public clinics of Mopani District in 2015. This sample formed the cohort included in Phase 1A of the study. In this phase, a desktop census of all electronic medical records of children initiated onto ART in 2015 at Mopani District's public clinics was conducted. The researcher used this phase to purposively determine samples of clinics, NIMART nurses and children on ART who were switched from one regimen at initiation to another and those with unsuppressed viral loads. After that, in line with the chosen methodology for this study. **Phase 1B** resumed, and it followed a non-probability (purposive) sampling procedure of all children who were;

- i) Identified in **Phase1A** as having been switched from the regimen at the initiation of therapy in 2015 to another regimen between the date of ART initiation and the 31st of December 2018.
- ii) Identified to be having unsuppressed VLs by the 31st of December 2018.

This phase focused on all children's medical records to determine the prescribing practices, the compliance of NIMART nurses to the guidelines when managing the children, and the factors that might have contributed to poor clinical outcomes depicted by low viral load suppression rates below the 90% target.

4.8.2 Inclusion and Exclusion Criteria

Researchers use inclusion and exclusion criteria to determine the characteristics of the subjects or elements in a study (Connelly, 2020). Establishing these criteria for the participants in this study was an essential step in designing high-quality research. Hence, the following inclusion and exclusion criteria were considered:

4.8.2.1 Inclusion criteria

All 516 medical records of children under 15 years of age initiated onto ART in any public clinics in the Mopani District between the 1st of January and 31st December 2015 were included. The reason for selecting 2015 was that South African HIV/AIDS guidelines were updated during that year. Of significance for children is the fact that the South African HIV treatment guidelines (NDoH, 2015) define patients as children until they turn 15 years.

4.8.2.2 Exclusion criteria

The following exclusion criteria applied in this study:

- All medical records of children aged 15 years and above because, according to the South African HIV/AIDS treatment guidelines, these patients fall outside the definition of children,
- All medical records of children under the age of 15 years initiated on ART before the 1st of January 2015 and after 31st December 2015 because before the 1st of January 2015, different regimens were used for HIV treatment, and the eligibility criteria for receiving treatment were different to those stipulated in the 2015 guidelines.
- All medical records of children under the age of 15 years were initiated onto ART during the study period at a hospital or elsewhere (including, for example, by doctors in private practice) and transferred to a clinic facility in the Mopani District for further HIV management.
- All medical records of children under 15 years of age who were on prophylactic antiretroviral therapy because these children comprise a different cohort with different monitoring and evaluation parameters.
- All medical records of children under the age of 15 years from clinics where a pharmacist was employed during the period under study because the presence of a pharmacist in a facility rules out the role of a NIMART-trained nurse as a dispenser of medicines.

4.8.3 Data Collection

Data collection for this study commenced after ethical clearance and permission were sought from the Turfloop Research Ethics Committee (TREC) and the Limpopo Provincial Department of Health (LPDoH).

For the quantitative phase of this study, checklists were used to collect the relevant data needed to conduct the baseline study and the evaluation of medical records.

The main focus of this part of the study was to determine the appropriateness of ART-use, the compliance of NIMART-trained nurse prescribers to the South African HIV treatment guidelines when managing children on ART; the determination of the VL suppression rate within the cohort under study; and, a determination of the prevalence of regimen-switching and children who were switched regimens to establish the factors that were associated with their regimen-switching. In this part of the study, the researcher also sought to establish the factors responsible for the unsuppressed VLs of specific children in the cohort under study.

The researcher visited the public clinics to collect the relevant data, as outlined in the checklists and questerviews, systematically throughout all the phases without any deviations from the determined protocol.

4.8.4 Data Analysis

Data collected was captured and cleaned on a Microsoft Excel™ spreadsheet, and after that, it was imported into SPSS. Patients' demographic and clinical characteristics were descriptively summarised by the mean, median, mode, and standard deviation. For continuous variables, such as age, minimum and maximum values were determined. Categorical variables, such as gender were determined through frequency counts and percentage calculations. Where it became of clinical interest, the researcher also performed comparisons between subgroups of patients. Results were then summarised in texts, tables, and graphs.

Similar to the study conducted by Grossberg, Zhang, and Gross (2004); Fairley, Permana, and Read (2005), adherence to therapy was being assessed by the timeliness of clinic attendance. Actual dates for clinic visits were compared with scheduled appointments for every patient. To this end, the researcher cumulatively determined the number of days each patient was late for

ART treatment over the four-year period. This is reflected in the results of the study. This variable was standardised by determining its quotient from the number of months each patient received therapy. Guided by the HIV/AIDS treatment guidelines, prescriptions were then analysed looking at the appropriateness of the prescribed ARV regimen, the dose, dosage form, and dosing frequency, and the quantity of monthly treatment supplied.

4.8.5 Pilot Study

Greater Tzaneen Sub-district had five (05) clinics (Letaba Gateway, Morapalala, Relela, Tours and Zangoma clinic) that were not yet accredited for ARV roll-out in 2015. The researcher used four (04) of these clinics to pilot the data collection checklists and questerviews. Letaba Gateway clinic was excluded for piloting as the researcher discovered that this facility had only been accredited for ART initiation in 2018, making the four-year review impossible.

Throughout the pilot study also, the researcher ensured the maintenance of rigour. This refers to the researcher's ability to maintain a standard of quality and excellence in research. Hence, the researcher in this study adhered to research processes that included truthfulness and correctness, as advocated by Grove *et al.* (2015).

Since this study followed a mixed-methods design, it allowed for triangulation due to the use of various methods of data collection. Gaps identified on the checklists, questerview and interview guides during the pilot phase of the study were corrected before commencing with the data collection process in the main study.

4.8.6 Validity and Reliability

The validity and reliability of a research project are essential elements used for measuring the quality of a research instrument, as detailed below. The purpose of establishing reliability and validity in research is critical to ensure that data are sound and replicable and the results are accurate.

4.8.6.1 Validity

Validity is the precision, authenticity, and genuineness of the data collecting instrument (de Vos, *et al.*, 2011). In this study, assurance of validity meant ensuring that the questerview used measured those aspects of the phenomenon under study that it was designed to measure.

Before data collection commenced, the questerview was reviewed by peers, a statistician, and the researcher's supervisors. This assisted in ensuring that the instrument was used to collect sound and accurate data.

Face Validity

This type of validity refers to the situation where a particular empirical measure may or may not conform to a standard agreement concerning a particular concept (Polit & Beck, 2008). Face validity was ensured by giving the questerview to the researcher's supervisor, peers, and a statistician to review before piloting the instrument. This exercise assisted the researcher to determine the readability and simplicity of the instrument's content.

Content Validity

Content validity is the level to which the data collection instrument has the required number of items needed to measure what the researcher intends to measure and effectively covers all aspects in the domain (Polit & Beck, 2008). Therefore, the content validity of an instrument is concerned with issues of whether or not the main themes of the phenomena being measured are integrated into the instrument. Content validity was assured through an extensive review of the literature and by giving the checklists to the researcher's supervisor and to a statistician to verify and ensure that the instruments cover all aspects under study. This validation led to a go-ahead in using the instrument since all the reviewers indicated that the instrument did cover the intended aspects well.

Construct Validity

Construct validity is defined as the level to which the measurement instrument measures the existence of the variables that the researcher intends to measure (Saunders, Lewis & Thornhill, 2009).

In this study, construct validity meant ensuring that different categories of meaning applied to the study participants in their natural settings and by grounding the applied methods in a substantial literature review that delineates the meanings of the construct and its elements.

4.6.6.2 Reliability

Reliability refers to the dependability, consistency, and stability of the data collection instrument, ensuring that the instrument will measure the same phenomenon more than once and still produce the same results (de Vos *et al.*, 2011). In other words, reliability is the consistency with which the research instruments measure the intended aspects of the study (Polit & Beck, 2008).

For this study, reliability was achieved by employing structured checklists where the researcher addressed the same questions in all clinics. These checklists were pretested to evaluate whether they were clear and concise before being used in the main study. This, therefore, indicated that the checklist was indeed clear and concise. The researcher also conducted a pilot study to evaluate the clarity of the checklists. This was determined whether or not instructions given as a guide to completing the instrument were as practical as desired.

4.9 The Qualitative Strand of the Study

The qualitative approach enabled the researcher to act as a critical instrument in collecting data in a natural setting (Marshall & Rossman, 2014). The setting was the PHC facility setting where NIMART-trained PNs manage children on ART.

4.9.1 Population

For this phase of the study, the population was all the NIMART-trained PNs from the PHC clinics where children under 15 years were enrolled for HIV care and management in 2015.

4.9.2 Sampling

The sample for the qualitative phase in the study was determined in line with the four phases described in the schematic view of the explanatory sequential design presented earlier (see Figure 2). Guided by the findings of Phase 1B, Phase 2A, the researcher employed a total population purposive sampling technique of all NIMART trained nurses working in the 94 public clinics under study. It is reported that each public clinic has at least two (02) NIMART trained nurses. This makes the number of NIMART trained nurses anticipated to participate in study 188. After that, Phase 2B employed a non-probability total population purposive sampling technique of all NIMART-trained PNs identified with gaps in their knowledge and understanding of ART dosing, dispensing, and managing children during the analysis conducted in Phases 2A.

4.9.3 Inclusion and Exclusion Criteria

The inclusion criteria identify the study population consistently, reliable, uniform and objective manner. The exclusion criteria include factors or characteristics that make the recruited population ineligible for the study. These factors may be confounders for the outcome parameter.

4.9.3.1 Inclusion Criteria

Phase 2A of the study included all NIMART- trained professional nurses working in the 94 public clinics understudy who gave consent. Whereas Phase 2B included NIMART-trained PNs with identified gaps in their knowledge and understanding of ART dosing and dispensing in children.

4.9.3.2 Exclusion Criteria

This phase of the study excluded;

- All professional nurses who were not NIMART-trained were working in the PHC clinics under study. This is because the study intended to focus on nurses trained to initiate and manage patients on ART.
- All NIMART-trained PNs identified gaps in their knowledge and understanding of ART dosing and dispensing in children.
- All NIMART-trained PNs working in the PHC clinics understudy but did not consent to participate in the study. This is in line with the ethical considerations of this study.

4.9.4 Data Collection

The data collection for the qualitative phase started with Phase 2A, where self-administered questerviews were administered to NIMART trained nurses to assess their knowledge, understanding, and competence in ART management. The questerviews were developed in line with the purpose of the study, its objectives and the research questions according to the criteria prescribed by the South African HIV/AIDs treatment guidelines.

Proceeding from the findings of the quantitative phase and Phase 2A, a semi-structured interview guide was developed (Brink, Van der Walt & Van Rensburg, 2006). The central question guiding the interview was: 'Kindly describe the knowledge, understanding, and

competence of yourself as a NIMART-trained nurse on the dosing and dispensing of ART to children receiving treatment at public Clinics?’

Bless, Higson-Smith and Kagee (2006) indicate that participants report on their own experiences in an interview study. In this study, the semi-structured interview was used to obtain primary data directly from participants who are NIMART-trained PNs. An interview guide was used to ensure the same pattern of questioning. Field notes were captured to support observations, while audio recordings were used to minimise the loss of valuable data (Greeff, 2005).

4.9.5 Pilot Study

The study was piloted using NIMART-trained PNs who are managing children on ART in five (05) clinics (Letaba Gateway, Morapalala, Relela, Tours and Zangoma clinic) that were not yet accredited for ARV roll-out in 2015 in the Greater Tzaneen Sub-district to test the qualitative data collection instrument. The results of this pilot study will be briefly outlined in Chapter 5 (Presentation of the Results and Findings).

4.9.6 Data Analysis

Thematic analysis has become a popular method for analysing semi-structured interviews (The Interaction Design Foundation, 2018). Dey (2003) says that “thematic analysis is a conventional practise in qualitative research which involves searching through data to identify any recurrent patterns”. The Interaction Design Foundation (2018) points out that “a thematic analysis strives to identify patterns of themes in the interview data”. The advantage of the qualitative data analysis lies in the fact that it is a flexible method that researchers can use for explorative and deductive studies. Hence, in this study, Braun and Clarke’s (2006) framework for thematic analysis was adopted as an approach to handle the data that would be generated from the qualitative part of the research as follows:

a) Becoming familiar with the data

The researcher in the study familiarised herself with the content’s depth and breadth. This involved reading the entire set of data before coding. In this case, emerging patterns were

shaped during the reading process. This means that the researcher listened to the tape recordings and scrutinised all field notes several times to become familiar with the data.

b) Transcription of recorded data

Verbal data transcription plays a significant part in informing the early stages of data analysis. It allows the researcher to develop a deeper understanding of the data through the thorough scrutiny of the data during transcription.

c) Generation of initial codes

The transcribed data were initially coded and collated into a long list of different codes identified by the researcher. After that, the researcher re-read the data and marked all necessary transcriptions. The researcher then used the notes to generate codes.

d) Reviewing prevailing themes

A set of themes were devised and refined by the researcher. Some themes were collapsed into each other during this phase, while others were split into different themes.

e) Defining and naming themes

This was the penultimate stage during which the researcher developed a thematic chart of the data. The researcher then described and further honed the themes subjected to analysis. This means that the researcher identified and understood every theme in depth. She thereafter determined what part of the data each theme related to.

f) Producing the final report

Producing the final report is the concluding stage of the data analysis process resulting in the production of the final report.

The six stages outlined above are summarised in **Figure 4.4** below;

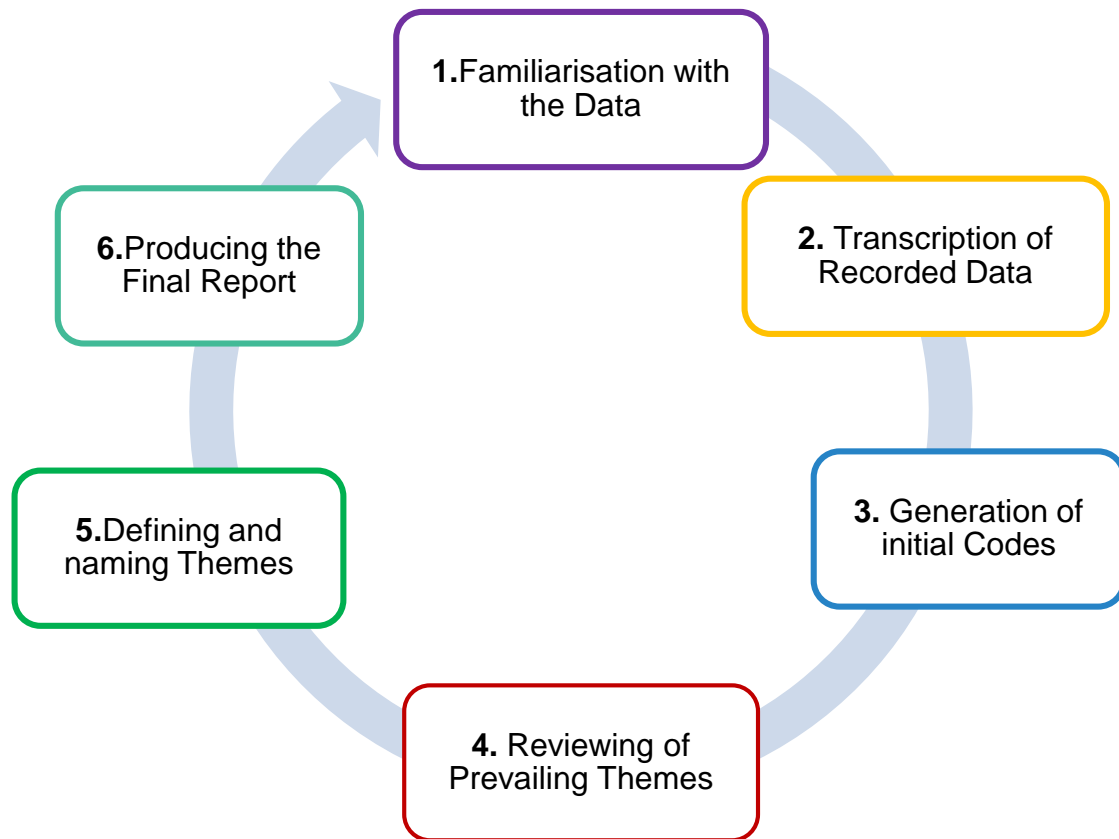


Figure 4.4: Qualitative data analysis according to Braun and Clarke (2006)

4.9.7 Measures to Ensure Trustworthiness

The researcher strived for trustworthiness during the qualitative part of the study. Several writers on research methods (Graneheim & Lundman, 2004; Maree, 2007; Lincoln, Lynham & Guba, 2011) have contributed to our knowledge about trustworthiness in qualitative research. Notably, Maree (2007) advises that researchers need to constantly keep in mind all the important procedures for ensuring the trustworthiness of data analysis. Adopting relevant and well-established procedures and consistency in applying methods and checks are essential elements of ensuring trustworthiness. Graneheim and Lundman (2004), on the other hand, advise that research findings must be weighed against established procedures deemed appropriate for the investigation. According to Lincoln, Lynham, and Guba (2011), trustworthiness is a pertinent issue in the qualitative part of mixed-methods research. Trustworthiness in this study entailed the following:

4.9.7.1 Credibility

As recommended by Shenton (2004) who emphasises the following considerations for researchers to use to promote credibility in their research:

- Adopting well-established research methods, for example, procedures followed should include how questioning is pursued during the data collection sessions. Data analysis methods should be drawn from authors with well-established and proven track records from similar or related projects.
- Full acquaintance with the culture of participating clinics involved in the study. According to Lincoln and Guba (1985), this relates to prolonged engagement between the researcher and the participants. Hence, in this study, the researcher plan to have a prolonged engagement in the field with the participants. In addition, field notes on interactions and observations will be employed.
- Triangulation involves the use of various data collection methods, such as document analysis, interviews, observations, etc. The researcher intends to use different methods “to compensate for their limitations and exploit their respective benefits”.
- Strategies to ensure the achievement of honesty among informants, which include allowing participants recruited to form part of the study to withdraw at any time or refuse to respond to any question they may consider sensitive. This will help ensure that the data collected is sincere and freely offered.
- An iterative form of questioning is used to elicit more detailed data. It is believed (Shenton, 2004) that during questioning, “contradictions may emerge, falsehoods can be detected and the researcher may opt to discard any suspect data”.
- Regular debriefing seminars by the researcher and supervisory study team will help broaden the researcher's vision.
- Peer scrutiny involves interaction with colleagues, peers, and the general academic community. This will assist the researcher in refining methods and developing a more explicit focus of the study. For example, the study will be presented in-school presentations, academic conferences, and science engagements.
- The researcher’s “reflective commentary”. By making this type of commentary, the researcher believes credibility will be achieved through Lincoln and Guba's (1985) term “progressive subjectivity”.

- Professional qualifications, background, and the researcher's experience give credibility to the researcher as the individual who will collect, manage, and analyse the data for the study. The researcher's relevant professional background and knowledge will be shared.
- Member checks, during which participants will be asked to go through the transcripts of the interviews they have participated in, ascertaining if the recorded words match what they intended to say.
- A thick description of the phenomenon under scrutiny will help convey the actual situations that the inquiry is about.
- Reviewing previous literature to integrate it with the findings of this study. In ensuring the credibility of the findings for the proposed study, the researcher will actively seek to ensure that this is done to avoid misrepresentation of data to be collected.

4.9.7.2 Transferability

Maree (2007) argues that "the description of data gathering must be inclusive so that the findings can be transferred to other contexts". In this study, the researcher scrutinised the background data to establish a clear context and provided a detailed description of the problem under study, research methodology, and findings to easily make comparisons.

4.9.7.3 Dependability

To ascertain dependability, the evidence provided must be such that if another researcher were to conduct the study again with participants of similar characteristics in another context, the findings would be comparable (Maree, 2007). To ensure the dependability of this study, the researcher went back to the setting and checked whether she would find similar results if the study were to be done again using the same methods.

4.9.7.4 Confirmability

"The concept of confirmability is the comparable concern to objectivity" (Shenton, 2004). To achieve confirmability in this study, an independent coder was employed. In addition, the researcher conducted a substantial review of the literature to identify similarities, differences, and verification of whether the literature supports the findings.

4.10 Interpretation of the Results

The researcher summarised and interpreted the results from both the qualitative and quantitative research phases (Creswell & Clark, 2011). The interpretation for the quantitative phase was made through adopting a variety of descriptive approaches, while the qualitative adopted the thematic approach. Based on the results of these study phases, the support programme or, more specifically, the training programme for NIMART-trained PNs was developed.

4.11 Bias

The researcher in this study understood that bias in research refers to any condition or influence that misrepresents the data obtained. This can occur during a research project's data collection, analysis, planning, and publication phases (Leedy & Ormrod, 2015). Brink, *et al.* (2006) describe bias as the influence that yields distortions that can, in the process, affect the value of the evidence, both in quantitative and qualitative research studies. An element of bias can occur at any level of the project. The researcher in the study then planned to prevent bias by using a comprehensive sampling method to select the participants from the target population for the quantitative research. Hence, the researcher used purposive sampling to select the participants for the study. Bias was prevented by not bringing any preconceived ideas and knowledge of the phenomenon to the study, as this could interfere with the interview process, the results or the participants.

4.12 Ethical Considerations

Ethics are a set of guidelines agreed upon by a group of people and offer rules regarding the most acceptable behaviour towards research subjects and participants (Welman, Kruger, & Mitchel, 2005). Monette, Sullivan, and De Jong (2013), on the other hand, define ethics as the researcher's responsibilities towards the study participants, sponsors and potential beneficiaries from the intended study. In this study, the following ethical considerations were taken cognisance of:

4.12.1 Ethical Clearance

The proposal was first presented to the Senior Degrees Committee of the Department of Pharmacy and thereafter to the School of Health Care Sciences Research Ethics Committee (SREC) and the Faculty of Health Sciences Higher Degrees Research Committee for scrutiny and approval. Thereafter, it was submitted to the Turfloop Research and Ethics Committee (TREC) for ethical clearance.

4.12.2 Permission to Conduct the Study

After ethical clearance from the TREC was received (TREC/81/2019: PG), permission to execute the study was sought from the Limpopo Provincial Department of Health (LPDoH) Ref: LP_20190, and the Mopani District Executive Manager (Ref: S4/2/2) and the Deputy Director of PHC, well as Operational Facility Managers.

4.12.3 Informed Consent

Informed consent has to be obtained from research participants at all times (Fouka & Mantzorou, 2011). According to Monetteó *et al.* (2013), this part of ethical considerations meant informing the prospective participants of all elements of the intended study, which could realistically affect the participants. To fulfil this ethical principle, prospective participants were adequately informed about the study through information sessions. The participants were also informed of their right to withdraw at any given time during the study if they ever deemed so. All participants were given an information sheet, accompanied by a consent form, developed according to the University of Limpopo's Guidelines for Postgraduate Students and the institution's Policy and Procedures on Postgraduate Research and Supervision.

4.12.4 Voluntary Participation

In all cases, participation in the study was voluntary. Gray (2017) suggests that researchers ensure that participants are voluntarily enlisted and involved in research studies. Following Gray's (2017) guidelines, the participants in this study were not forced to participate but were encouraged to participate freely. Concerning this, Fouka and Mantzorou (2011) mention that "Of course individuals can make informed decisions to participate in research voluntarily only if they have information on the possible risks and benefits of the research". Hence the researcher in this study only enlisted participants who were willing to be part of the study.

Moreover, the participants were required to sign a consent form to indicate their willingness to participate.

4.12.5 Confidentiality and Anonymity

Confidentiality in this study was grounded within understanding the following principles (ANA, 2001; Fowler, 2017): 1) Individuals can share personal information to the extent that they want and are entitled to possess secrets; 2) One can choose with whom to share personal information; 3) Those accepting information in confidence have an obligation to take care of confidentiality; 4) Professionals, like researchers and nurses, have a requirement to take care of the confidentiality that goes beyond ordinary loyalty. A breach of confidentiality can occur when a researcher, unintentionally or indirectly, allows an unauthorised person to achieve access to the data of a study. Confidentiality can also be breached in reporting or publishing a study if a participant's identity is accidentally revealed, violating their right to anonymity. Breach of confidentiality is of particular concern in qualitative studies with few study participants and involve reporting long quotes made by those participants. Additionally, qualitative researchers and participants often have relationships during which detailed stories of the participants' lives are shared, requiring careful management of study data to ensure confidentiality (Kaiser, 2009; Surmiak, 2018). Breaches of confidentiality that may be especially harmful to participants include religious preferences, sexual practices, income, racial prejudices, drug use, abuse, and personal attributes, like intelligence, honesty, and courage. Research reports should be examined closely for evidence that the participants' confidentiality was maintained during data collection, analysis, and reporting (Munhall, 2012; Sandelowski, 1994). Furthermore, the research findings during a published study should be reported so that a participant or group of participants cannot be identified by their responses.

Hence in this study, confidentiality meant ensuring that the information collected from the study participants was not divulged to the public in a manner related to or linked to the participant. Anonymity means avoiding using the participant's real names (Monette *et al.*, 2013). Patients' confidentiality was maintained at all times as no patient names, or any other personal information was recorded during data collection. Patient names and file numbers were also kept confidential by allocating sample numbers to each file instead of using the patient's name and file numbers. All data collected in this study were saved and stored on a computer protected by a password, firewall, and antivirus software. The data collection checklists were

kept in lockable cages where only the researcher and the study supervision team would access them. Advocating for respect for anonymity and confidentiality, Ford and Reutter (1990) suggested that researchers use pseudonyms and distort identifiable particulars of interviews dealing with information sourced from research participants. Hence, the data collected through interviews from the participants in this study is discussed using pseudonyms to ensure that this principle is adhered to.

4.12.6 Beneficence/No Harm to Participants

The right to protection from discomfort and harm in a study is based on the ethical principle of beneficence, which states that one should do well and, above all, do no harm (Zimmer, 2018). According to this principle, members of society must take an active role in preventing discomfort and harm and promoting good in the world around them (ANA, 2001 & APA, 2010). In research, discomfort and harm can be physical, emotional, social, economic, or any combination of these four (Weijer, 2000). Reynolds (1972) identified five categories of studies based on levels of discomfort and harm—no anticipated effects, temporary discomfort, unusual levels of temporary discomfort, risk of permanent damage, and certainty of permanent damage.

The ethical principle of beneficence mandates a researcher in health sciences to adhere to the Hippocratic Oath: "be of benefit, do not harm" (Fouka & Mantzorou, 2011). The researcher avoided asking questions that might emotionally harm the respondents to address this ethical consideration. The researcher also ensured that debriefing, as advocated by Fouka and Mantzorou (2011), occurred at the end of each interview, especially where she dealt with the participants who showed emotional reactions to the subject under investigation. In accordance with Burns and Grove (1993) suggestion, the participants who were deemed to have experienced some distress during the process were referred to appropriate professionals (for example, a Social Worker or Psychologist) for intervention as necessary.

CHAPTER 5 RESULTS, FINDINGS AND DISCUSSIONS

This study sought to establish the use of ARVs by NIMART-trained PNs who manage virologically unsuppressed children in the public clinics of Mopani District. Therefore, in attempting to answer the objectives and research questions, the researcher undertook an explanatory sequential mixed-methods approach. The study unfolded in two distinct phases (i.e. Phase 1(A & B) and Phase 2). Phase 1 was the Quantitative Phase (Quan Phase), and Phase 2 was a Qualitative Phase (qual Phase). The procedure followed to assess the appropriateness of ART use by the NIMART- trained nurses was guided by the 2014 edition of the South African Standard Treatment Guidelines and the 2015 National Consolidated Guidelines for the prevention of Mother-To-Child-Transmission of HIV (PMTCT) and the Management of HIV in Children, Adolescents and Adults. This chapter gives a detailed overview of the findings and results for both phases. Section 5.1 below provides the results and discussions of the quantitative part of the study, while section 5.2 gives details of the qualitative component. After that, the chapter provides a section (5.3) dealing with merging the results and findings before closing with a chapter conclusion (5.4).

5.1 Quantitative Phase Results - ART Use in Children

This phase of the study focused on evaluating the use of ART in children managed by NIMART-trained PNs at public clinics located in resource-limited settings of the Mopani District of Limpopo province. This phase aimed at giving insight into the use of ARVs in the management of virally unsuppressed children under 15 years on ART. The researcher started by exploring the objectives and research questions for Phase1A. They conducted a four (04) years (1st January 2015 to 31st December 2018) desktop census assessing all medical records for the 516 children identified as being initiated on ART in 2015 (1st January to 31st December 2015). The focus of the census was a cohort of virologically unsuppressed children initiated on ART in the public clinics of Mopani District. This process was conducted on the Mopani District's TIER.Net version 1.10.5 HIV/AIDS Data Management System (DMS) and aimed to determine the clinical outcomes for this cohort of children.

The results of this phase are presented in the form of tables, charts, and different types of graphical representations wherein the description of the results is also narrated. These results are discussed based on the information that emerged from the quantitative phase data analysis of the data acquired from 255 medical records in 94 public clinics scattered all over the five (05) Sub-districts of Mopani District. Proceeding from the findings of phase 1A, in Phase 1B, the researcher explored the medical records using a checklist developed exclusively for this study to describe the prescribing practices of NIMART-trained PNs when managing children on ART. Furthermore, this particular phase also assessed the compliance of NIMART-trained PNs to the 2015 South African HIV/AIDS guidelines for the treatment of children on ART. These findings were peer-reviewed and accepted for a podium presentation in the 11th Annual South African Society for Clinical Pharmacists (SASOCP), see **Appendix XIII**.

5.1.1 Phase 1A Findings

Figure 11 below summarises ART initiation and clinical outcomes of children under 15 years initiated on ART in 2015. These data were sourced from the Mopani District's TIER.Net system database. It was established that 516 children were initiated on ART in the 94 public Primary Health Care Clinics (PHCs) of Mopani District. From this total, it was established that 365 (which is 70.74%) children were virologically unsuppressed by 31 December 2018. This meant that each of the children was found with a detectable VL of ≥ 400 copies/ml. Only a total of 151 (29.26%) of the cohort was identified as virologically suppressed. Unfortunately, these percentages represent an indicator far away from the 90-90-90 USAID 2020 targets. This picture is ideally not easy to note since the reporting of the HIV/AIDS statistics do not closely zoom into children as a critical population but mostly give a general overview of the population of all PLHIV.

Hence, the researcher in this study believes that a closer look into children (0 – 14 years) outcomes may be a valuable strategy for quality improvement in the care and management of these children.

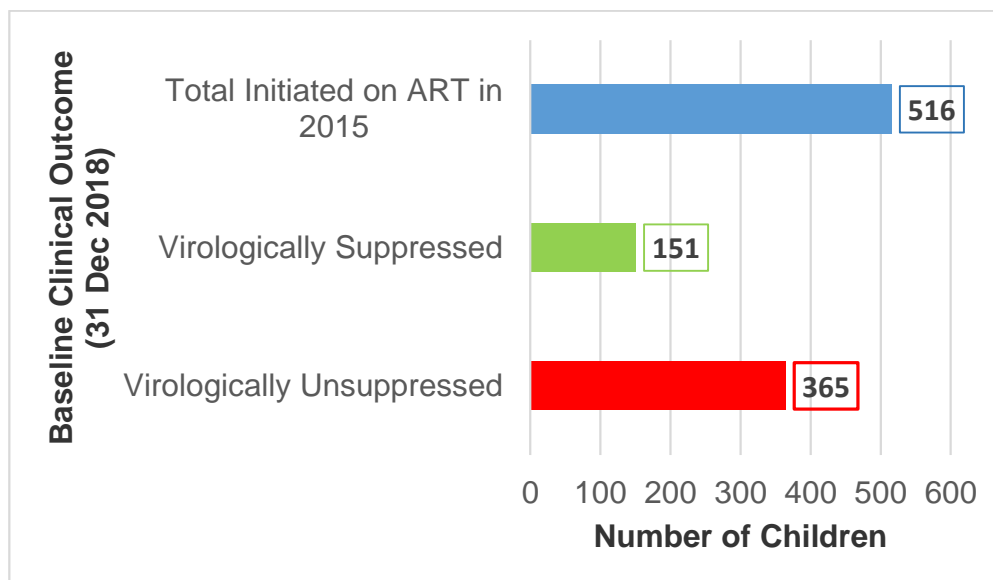


Figure 5.1: Summary of ART initiation and clinical outcomes of the cohort

The picture painted in **Figure 5.1** above is similar to the one found in a study conducted among a similar population group in Ethiopia, where the findings highlighted that there was a high rate of non-suppressed HIV viral load among children under 15 years (Shiferaw, Endalamaw, Hussien, Agegne, Amare, Estifanos, & Temesgen, 2019). This is a worrisome observation, especially considering that children infected with human immunodeficiency virus (HIV) have exceptionally higher morbidity and mortality than adults (WHO, 2011). Children do not have a vast array of HIV treatment options from which to choose. This finding is in agreement with the conclusions of a study that was conducted in Uganda which found that the proportion of HIV-positive children (under 15 years) enrolled on antiretroviral therapy (ART) has increased in recent years, with up to 60% of children started on ART not achieving virological suppression (Nabukeera, Kagaayi, Makumbi, Mugerwa, & Matovu, 2021). Even though the overall suppression rate is estimated to be around 47% (UNAIDS, 2021), what is worrisome is that the suppression rate among children is not documented.

Moreover, HIV prevention and treatment efforts aim to reduce morbidity and mortality and the risk of transmission among PLHIV. Likewise, several studies and reports have made notice that viral load suppression rates among children on ART are low, considerably poorer compared to that of adults (Azia, Mukumbang, & Van Wyk, 2016; Boerma, Boender, Bussink, Calis, Bertagnolio, *et al.* 2016; UNICEF, 2017; Shiferaw *et al.*, 2019). However, the factors associated with virological non-suppression among children (0-14 years) receiving ART are not documented (Nabukeera, *et al.*, 2021).

Hence, a dire need for strategies to ensure virological suppression to undetectable levels among children on ART. This is supported by the South African Consolidated HIV/AIDS Treatment Guideline (2015) as well as the WHO 2017 Policy Brief on consolidated Guidelines on HIV prevention, diagnosis, treatment, and care for key populations, which recommended that children with initial positive virological test results are initiated on ART immediately, and routine viral load monitoring be carried out at 6 and 12 months, then every 12 months if the patient's viral load becomes stable.

Furthermore, the comprehensive management and follow-up of children on ART and testing for resistance and viral load are recommended as this could help reduce the problem in advance (Shiferaw et al., 2019). The biggest challenge is that the absence of intervention strategies for children has been identified as the leading cause of death for up 52% and 75% of children who perish before turning two or five years, respectively (Federal Ministry of Health, 2017).

5.1.1.1 Medical Records Demographics

The researcher in this study embarked on a journey to explore all the medical records of children initiated on ART in 2015 in all the 94 public clinics of Mopani District. It was intentional for the researcher in this study to 'explore the phenomena' of ARV use among NIMART nurses within a context of quantitative research even though exploratory research is often associated with qualitative studies. Stebbins (2001) reflects that, a study such as this one with a large sample (i.e., 16 694 prescriptions – see **Figure 5.16**) conducted in an exploratory manner can be quantitative as well. Hence, the researcher sought to explore numeric patterns to determine the rationality of ARV use by the nurses under study. With the assistance of the facility managers as gatekeepers and data the capturers who manage the clinic database, 516 patient files were retrieved. From this experience, the picture depicted in Figure 12 below emerged during the data collection, cleaning, and analysis process. The exercise revealed a total of 365 usable medical records. After that, it was established that from the 365 medical records, only 255 (69.86%) contained analysable data. Secondly, 47 (12.88%) were excluded because the medical records had no data (meaning that the pages of the medical records were blank). Thirdly, three (03) (0.82%) files were excluded because they belonged to adults who were erroneously captured as children on TIER.Net. A 110 (30.14%) medical records were excluded from the study because of the following reasons: Firstly, (n=56; 15.34%) were excluded from the study because even though the children

were initiated on ART in 2015, they were initiated in hospitals and only referred to the clinics for continued management. Two files of children were initiated on ART in December 2014 but captured on TIER.Net in January 2015. They also had to be excluded. Lastly, there was a case of a duplicated file which was recorded on TIER.Net as two (02) different children cases of (0.55%). The records in these files were merged and analysed as a single case.

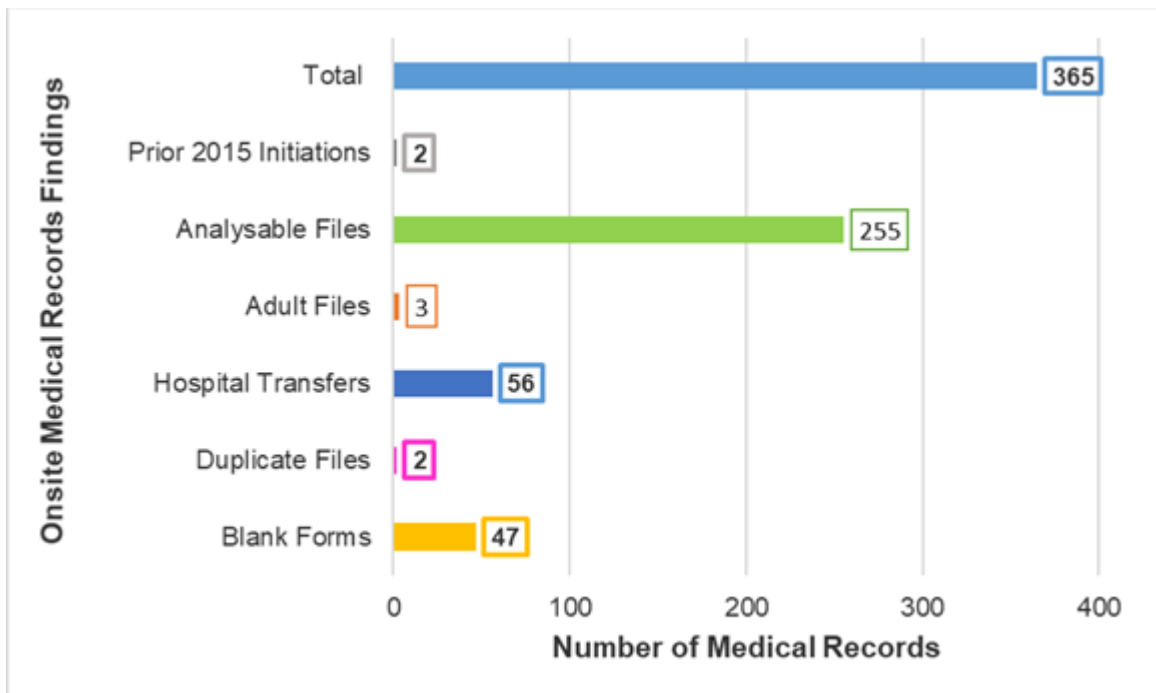


Figure 5.2: Demographic summary of onsite medical records findings

From the identified cohort of 365 children on TIER.Net, the researcher further sought to establish how many of these children switched regimens were during their first four (04) years of treatment. In this case, a total of 357 (97.80%) patient files were identified as having been switched from one regimen at initiation to another in the first 4 years of their treatment journey. Only in eight (08; 2.20%) cases did children on ART remain on the regimens prescribed on the first day of ART initiation (see **Figure 5.3** below).

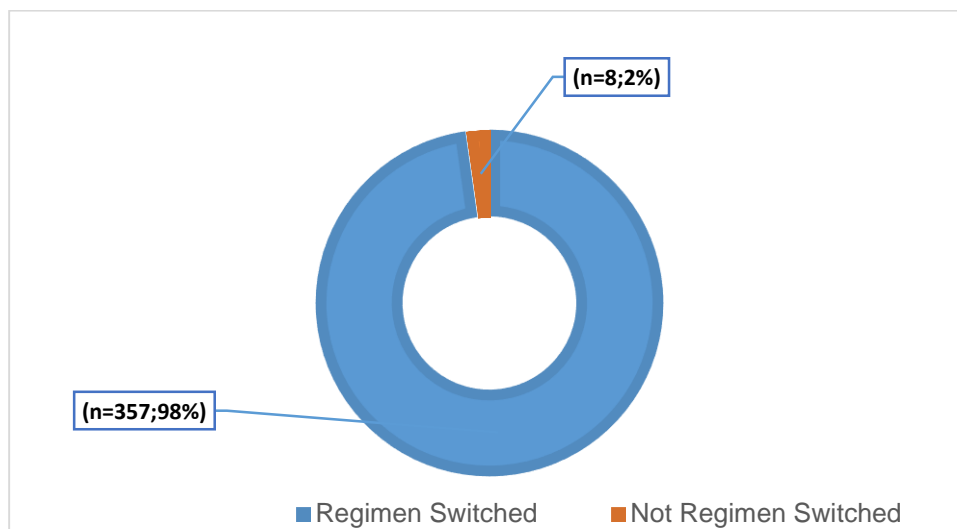


Figure 5.3: An overview of baseline ART regimen switching status

The finding above is alarming, especially when one considers the primary goal of ART, which is to suppress the viral load to improve survival and decrease HIV-related morbidity and mortality through the restoration of immune functions of the infected individual (Republic of South Africa Department of Health, 2015).

Furthermore, considering that regimen switching in patients on ART could clinically be a sign of Treatment Failure (TF) and may indicate the development of Drug Resistance (DR).

5.1.2 Phase 1B Findings

Through this phase of the study, the researcher sought to explore and describe the prescribing practices of NIMART-trained PNs when managing children with Unsuppressed Viral Loads (UVLs) on ART in the 94 public clinics of Mopani District in the Limpopo Province of South Africa. It also assessed the NIMART-trained PNs' compliance to the 2015 South African HIV/AIDS guidelines for the children on ART. It identified the factors associated with regimen switching in children on ART.

This phase resumed following the findings of Phase 1A, and the researcher physically went to every one of the 94 clinics and used a semi-structured data collection checklist that was designed explicitly for this study. It was used to extract from the 255 medical records demographic & baseline clinical data. This specifically meant that the age at ART initiation, Gender, WHO clinical staging at ART initiation, the availability of concomitant diseases at ART initiation, and the ART regimen at

initiation were checked. The data collection checklist also captured the longitudinal ART treatment history for this cohort of children understudy from the date of ART initiation in 2015 until 31 December 2018 and recorded the following; 1.) Clinic visit date and the next scheduled appointment date (on-time pill pickup); 2.) Weight monitoring practices at each visit; 3.) Regimen prescribed and issued at each visit; 4.) The prescribed dose (strength) for each drug in the regimen; 5.) The prescribed dosage form for each ARV drug in the regimen; 6.) The prescribed dosing frequency for each ARV drug in the regimen; 7.) The quantity issued for each prescribed ARV drug in the regimen; 8.) The prevalence of regimen switching & reasons for regimen switching, as well as, 9.) Viral load monitoring

5.1.2.1 Patients' Demographic Data

a) Summary of Children's Age at Initiation

In trying to address the question of the children's age at ART initiation, the researcher in this study, with guidance from Kail (2011)'s children and their development, categorised the age for this cohort of children are as stated in **Table 5.1** below.

Table 5.1: Age categories of children on ART

Category	Age
Newborns	0 – 2 months
Infants	3 – 12 months
Toddlers	3 – 23 months
Pre-Scholars	24 months – 5 years
School-Aged	6 – 14 years

Data for this cohort represented in **Table 5.2** below highlights that the majority (n=153; 60%) this cohort were of school going age group, this is followed by the toddlers (n=30; 11.76%), pre-scholars (n=32; 12.55%), newborns (n=26; 10.20%), and lastly the infants (n=14; 5.49%).

Table 5.2: Demographic data summary of the cohort

Age Categories	Gender				Grand Total	
	Female		Male		n	%
	n	%	n	%		
Newborns	14	10,22%	12	10,17%	26	10,20%
Infants	8	5,84%	6	5,08%	14	5,49%
Toddlers	13	9,49%	17	14,41%	30	11,76%
Pre-scholars	19	13,87%	13	11,02%	32	12,55%
School Age	83	60,58%	70	59,32%	153	60,00%
Grand Total	137	100,00%	118	100,00%	255	100,00%

The next sub-sections present further demographic details that are believed to be pertinent in this study. Most of the information is presented in clusters that reflect the picture per specific sub-district. The sub-districts are largely homogenous in nature, especially in terms of socioeconomic status. Although this is so, it was deemed important to adopt this approach since the sub-districts are also culturally diverse in nature, owing to the political history of how the former Gazankulu and Lebowa Bantustan governments were demarcated. According to Lowe and Archibald (2009) cultural diversity has an influence on health behaviour. This was another reason to demarcate into the demographic areas presented in the study. The approach to this presentation was necessary to assist the researcher to customise the training according to area shortcomings and needs.

b) Children's Gender Distribution per Sub-district

Figure 5.4 below highlights the gender distribution for the children in this cohort per Sub- District. The findings of the 255 children with analysable data from their medical records reveal that the gender proportion was not that different. The cohort consisted of (n=132; 51.76%) Females and (n=123; 48.24%) Males.

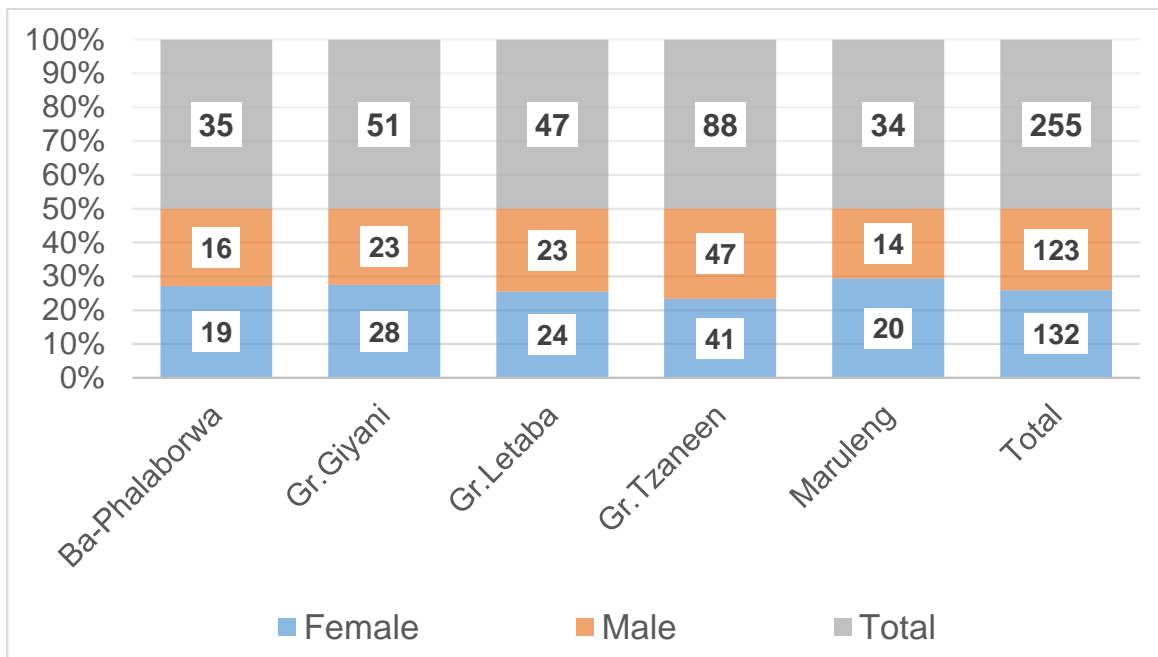


Figure 5.4: Gender Distribution Summary per Sub-district:

c) World Health Organisation clinical staging practices

The researcher also explored the WHO clinical staging status during ART initiation for this cohort of children, and **Figure 5.5** below illustrates that the majority of the children (n=101; 39.61%) were initiated on ART whilst stage 1, with, however, (n=72; 28.24%) of children who were never staged during the ART initiation period. Whereas, (n=48; 18.82%) of children were on Stage 2, and (n=28; 10.98%) were initiated whilst on Stage 3, with only (n=6; 2.35%) on clinical Stage 4. Furthermore, the study examined whether or not the children had notable concomitant diseases at ART initiation. It was found that from the 255 cohort of children, only (n=51; 20%) of the children had notable concomitant diseases. However, in 8% of the children, it was established that there were notes written about this in their medical records.

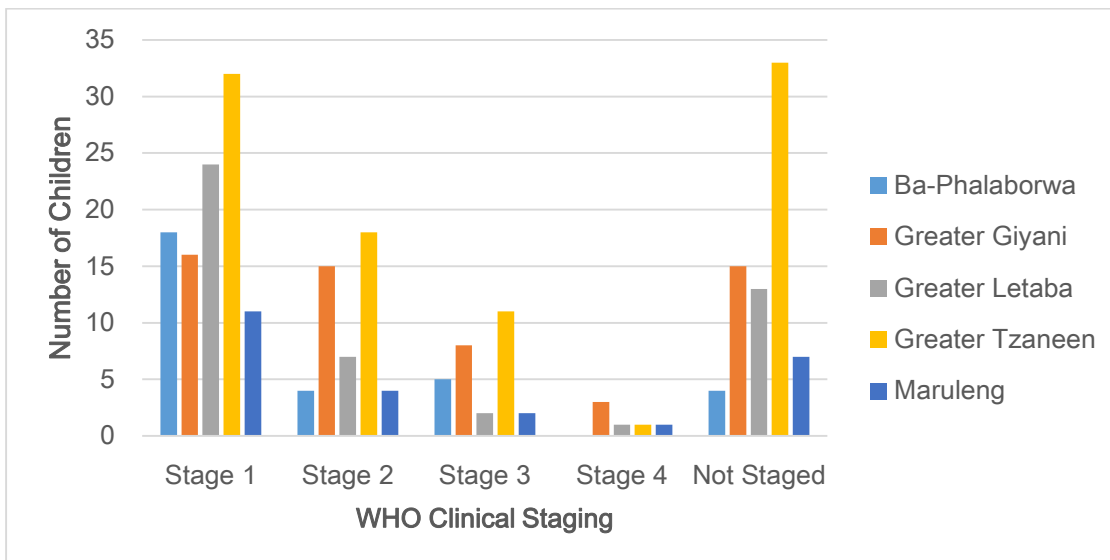


Figure 5.5: WHO clinical staging status per sub-district

A majority (n=11; 21.56%) of those with notable concomitant diseases had Lymphadenopathy, whereas (n=8; 15.69%) of children had Pulmonary Tuberculosis (PTB). 08 (15.69%) of the children had fungal infections while (n=6; 11.76%) were recorded to have had Severe Malnutrition. There were also those (n=4; 7.84%) who had GIT problems (see **Figure 5.6** below).

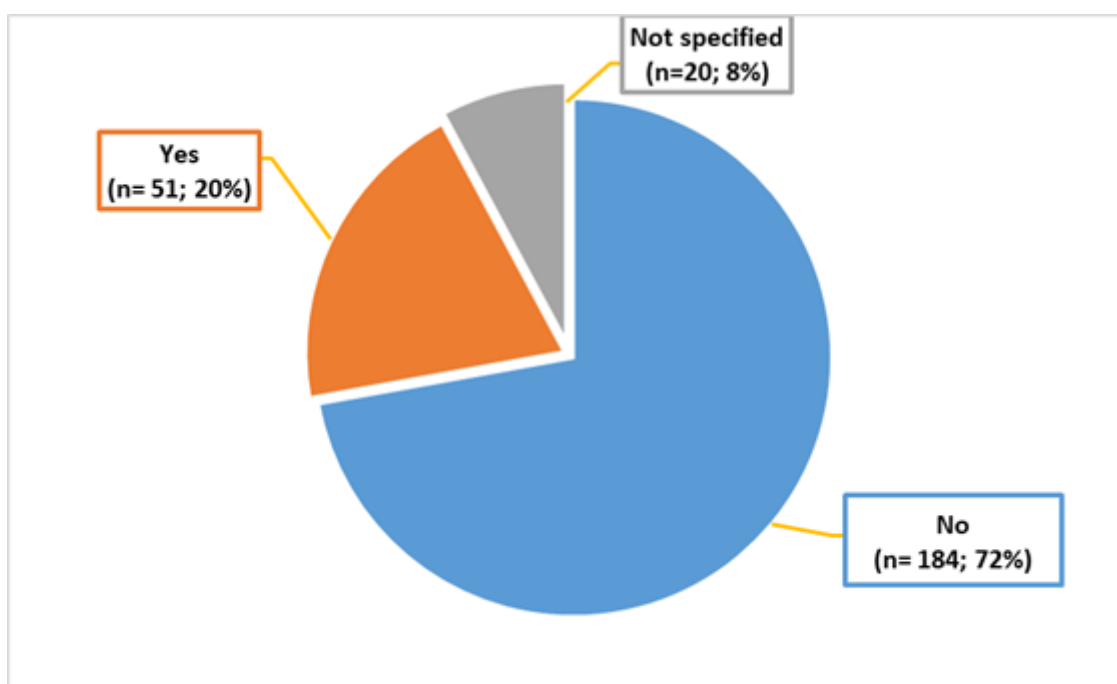


Figure 5.6: Concomitant disease(s) at ART initiation

d) Summary of Regimen Prescribing Practices at Initiation per Sub-district

Figure 5.7 below gives an overall summary per Sub-district, of the ART Regimens that the 255 children under study were initiated on in the 94 public clinics. Whereas **Table 5.3** gives an overview of the ART regimens the children were initiated on per Sub-district. The illustration depicts that most children (n=88; 34.51%) were initiated on ART in the Greater Tzaneen Sub-district. The second-largest group (n=51; 20%) was initiated in the Greater Giyani Sub-district. This was followed by those (n=47; 18.43%) initiated from Greater Letaba Sub-district. An almost similar percentage to the latter (n=35; 13.73%) was initiated at Ba-Phalaborwa. The least number of patients were initiated at (n=34; 13.33%) Maruleng Sub-district.

This data highlights that the majority of children (n=198; 77.65%) were initiated on an Abacavir (ABC) containing regimen as recommended by the 2015 South African HIV/AIDS guidelines, with a surprising (n=17; 6.67%) of the children still initiated on Stavudine (d4T) containing regimens. This practice was primarily prevalent in the following Sub-districts, Greater Giyani (n=6; 35.30%), followed by Greater Letaba (n=5; 29.41%), Greater Tzaneen (n=4; 23.53%), and lastly Maruleng (n=2; 11.76%).

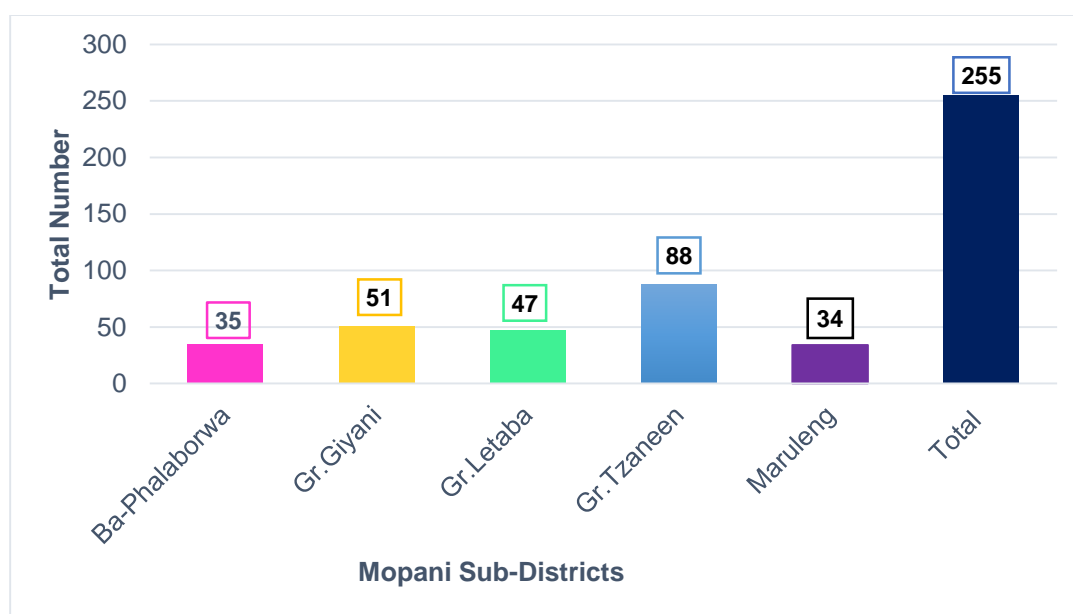


Figure 5.7: ART initiations summary per sub-district

Furthermore, (n=11; 4.31%) children were initiated on Zidovudine (AZT) containing regimens, whilst (n=8; 3.14%) of the children were initiated on Tenofovir (Tdf) containing regimens. What was surprising was the realisation that, even though the guidelines recommended that 'no child

should be initiated on a Stavudine containing regimen by the 1st of January 2015', some children had already been put on a Stavudine containing regimen before this date (See Section 2.4, Table 2.1). A total of 17 (6.62%) children in this cohort were initiated on a Stavudine containing regimen. This practice mainly was prevalent in the following three Sub-districts; Greater Giyani (n=6; 2.36%), followed by Greater Letaba (n=5; 1.96%) and Greater Tzaneen (n=4; 1.56%).

5.1.2.2 Baseline Clinical Data Findings

5.1.2.2.1 Summary of Clinic Visits

In terms of clinic visits, the researcher in this study looked at a maximum of 50 visits in the four years under study due to the understanding that in the first month following ART initiation, children are given treatment at two (02) weeks intervals. **Table 5.3** below indicates that most children (n=88; 22.75%) had 31 to 40 visits, followed by (n=69; 27.50%) of children who had between 21-30 clinic visits. This is preceded by (n=38; 14.90%) with 41-50 visits as well as (n=35; 13.70%) with 11-20 of clinic visits.

Table 5.3: Summary of the total number of visits

Frequency of Visits	No. of Medical Records (n)	Percentages (%)
1-10 visits	23	9.00
11-20 visits	35	13.70
21-30 visits	69	27.50
31-40 visits	88	34.10
41- 50 visits	38	14.90
51-55 visits	2	0.8
Total	255	100.00

5.1.2.2.2 Honouring of Scheduled Appointment Dates (On-time Pill Pickup)

Furthermore, the researcher in this study embarked on a journey to assess and describe the pattern for this cohort when coming to the honouring of scheduled appointment dates, with the

understanding that on-time pill pickup is an indicator for medication adherence and a significant determinant of ART success (Anoje, Agu, Oladele, Badru, Adedokun, Oqua, Khamofu, Adebayo, Torpey, & Chabikuli, 2017).

Findings for this indicator are depicted in **Figures 5.8 and 5.9** below. These figures illustrate that from a total of 7105 analysable visits for this objective, only (n=3134; 44.11%) visits were honoured as scheduled, and (n=2828; 39.80%) of visits were honoured after the scheduled appointment date (hereafter referred to as missed appointments). A total of 768 (10.81%) of treatment collections were done before the actual scheduled appointment date (hereafter referred to as early show-ups). However, it was noted that (n=294; 4.14%) of the visits couldn't be analysed because the next appointment date was not documented in the medical records, whereas (n=81; 1.14%) of the visits did not have a record of the next date of visits.

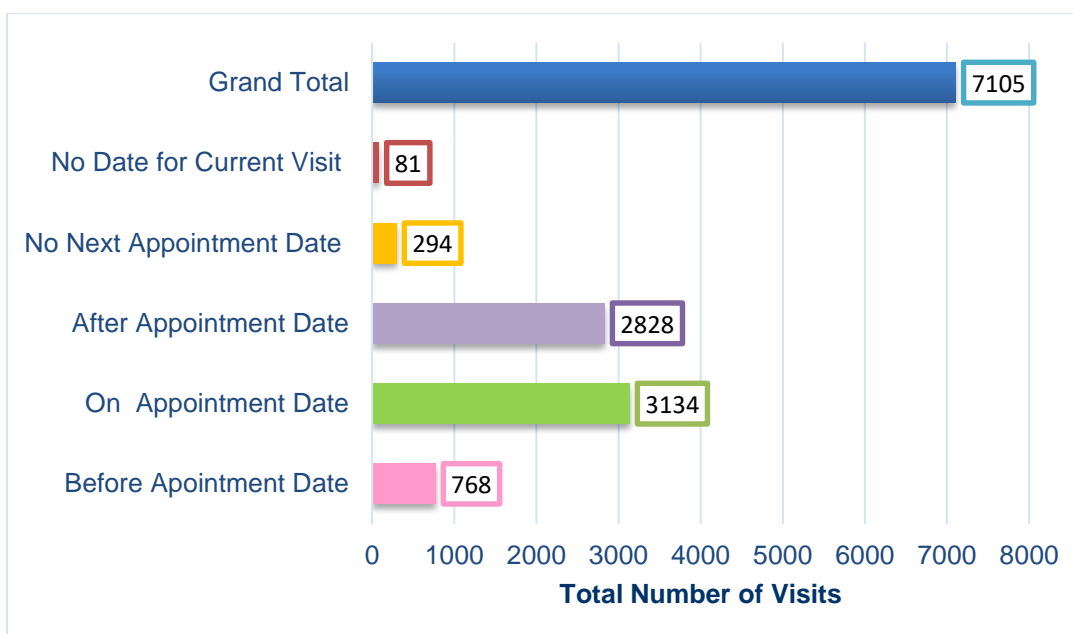


Figure 5.8: District summary of monthly treatment collection practices

Figure 5.9 below gives a visual outlook of the pill-pickup practice per Sub-district. The findings bring forth the clarity that from the 3134 on-time treatment collections (n=1126; 35.92%) took place in Greater Tzaneen, whereas (n=673; 21.47%) happened in Greater Letaba, with (n=524; 16.72%) in Ba-Phalaborwa, (n=511; 16.31%) in Greater Giyani, and (n=300; 9.57%) in Maruleng Sub-district.

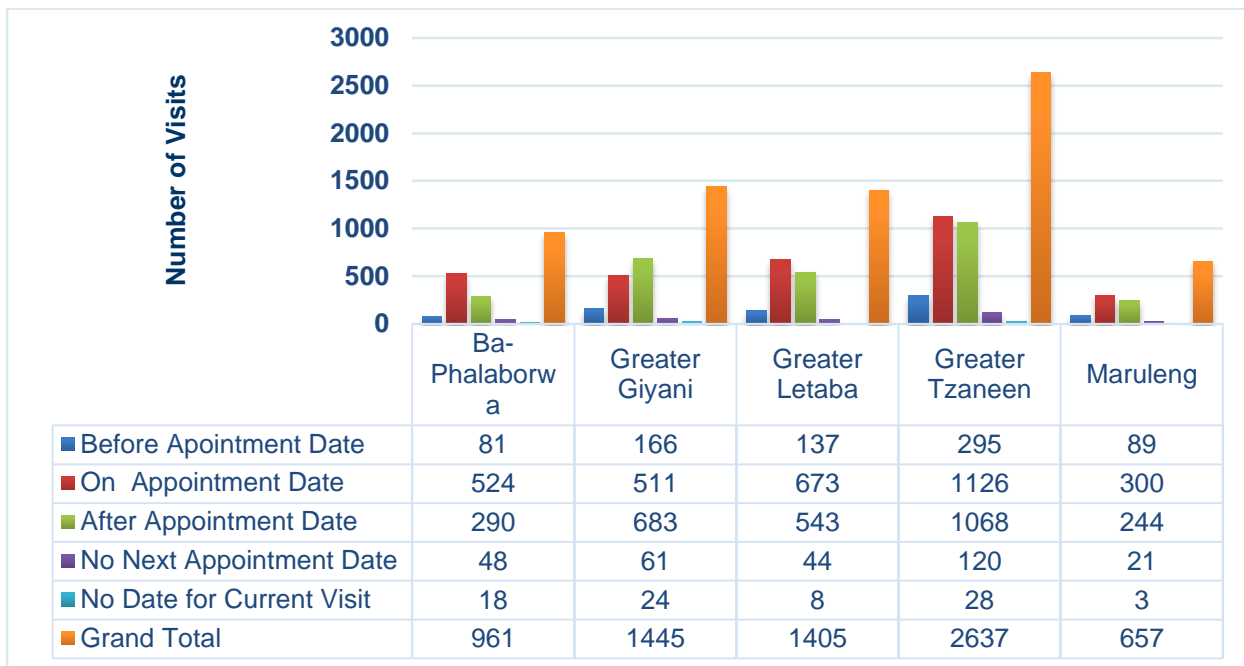


Figure 5.9: Monthly treatment collection practices per sub-district

- *Before Scheduled Appointment Date Pickups (Early Show-Ups)*

The findings above give a clear view that the majority of the children presenting early for their scheduled appointments were also recorded in Greater Tzaneen (n=295; 38.41%), followed by Greater Giyani (n=166; 21.61%), Greater Letaba (n=137; 17.84%), Maruleng (n=89; 11.59%) and lastly Ba-Phalaborwa (n=81; 10.55%).

The researcher further looked into the number of days 'before or after' the scheduled appointment date the children mostly presented to the Clinics. **Figures 5.10 and 5.11** below give a visual narration of this practice across the Sub-districts of Mopani.

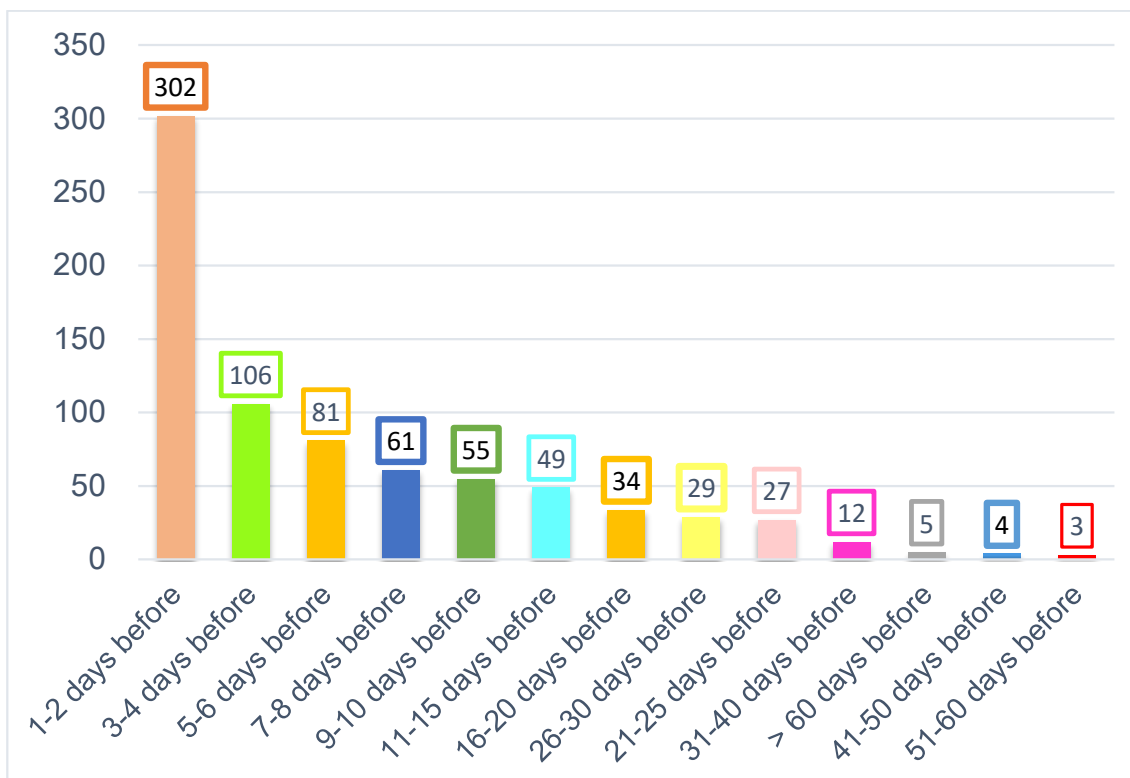


Figure 5.10: Summary of the number of days before treatment collection

These findings further show in **Figure 5.11** below that the majority (n=302;19.66%) of children in these Sub-districts presented a day or two before their actual scheduled appointment dates, and these were most prevalent in Greater Tzaneen (n=112; 37.09%), Greater Giyani (n=65;21.52%), and Greater Letaba Sub-districts (n=58;19.21%). This was followed by children who presented to the clinic three to four days (n=106; 9.32%) before their scheduled appointment date. This picture shows that children often came to the clinics for their treatment collection as early as a week or two (n=246; 16.01%) before their scheduled appointment dates and at times more than 15 days before the scheduled appointment date (n=109; 14.19%).

- *On-Time Pill Pickups*

In terms of honouring scheduled appointments dates (on-time pill-pickups) at the Clinics, the majority of the children who honoured their scheduled appointments were recorded in Greater Tzaneen (n=1126; 35.93%), followed by Greater Letaba (n=673; 21.47%), and Ba-Phalaborwa (n=524; 16.72%).

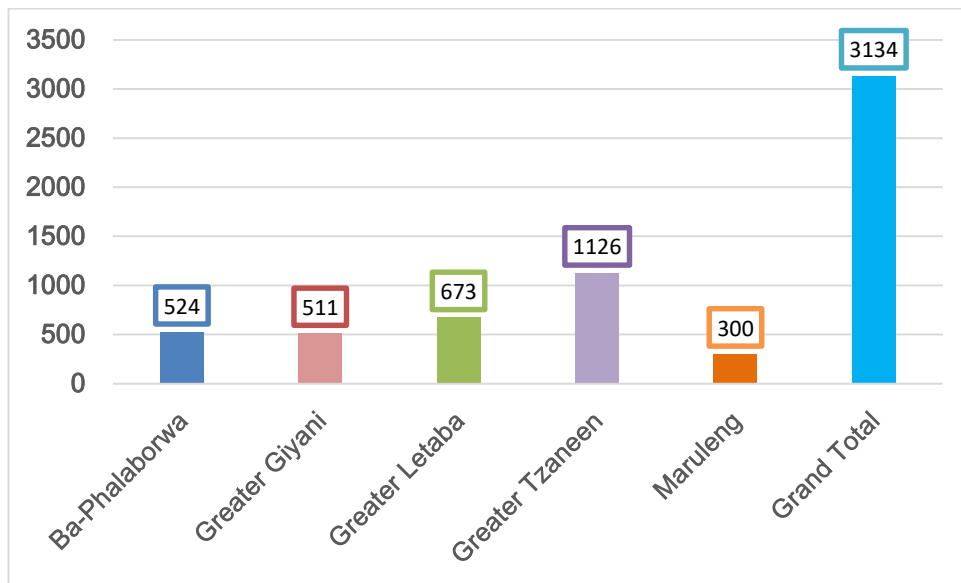


Figure 5.11: Summary of on-time treatment collections per sub-district

- *After Schedule Pickups (Missed Appointments)*

When looking at treatment collections after the scheduled appointment date, it is noted that the majority of this practice was considerably prevalent in the Greater Tzaneen (n=1068; 37.77%), followed by (n=683; 24.15%) in Greater Giyani, and (n=543; 19.20%) in Greater Letaba Sub-district. The further analysis highlights that most children (n=643; 22.74%) present to the clinic for treatment collection 1-2 days after their scheduled appointment dates (See **Figure 5.12** below).

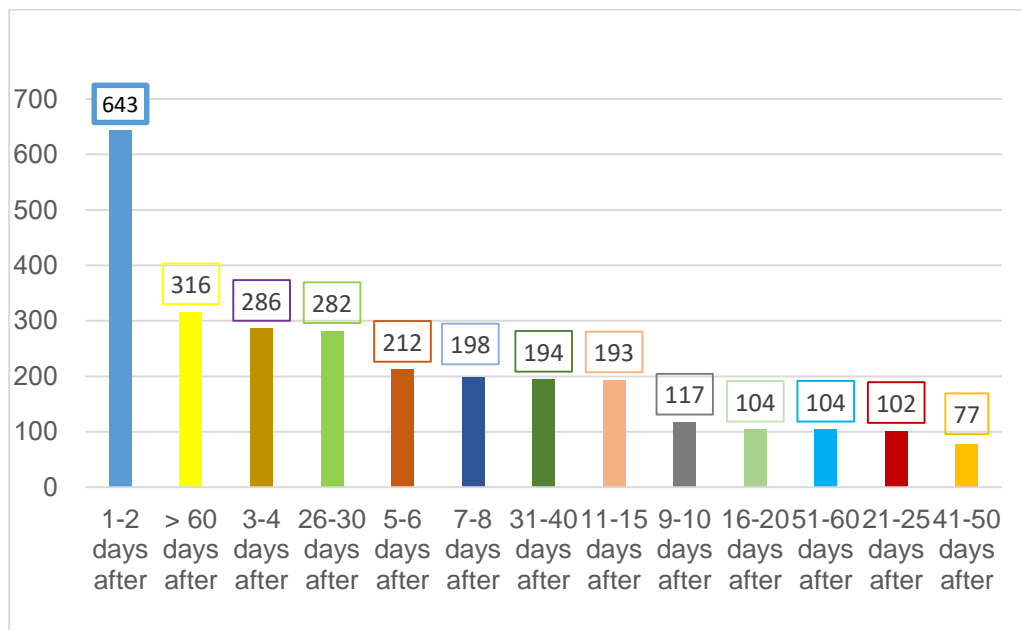


Figure 5.12: Summary of the number of days after treatment collection

- *Next appointment Date not Recorded*

There were noted cases wherein the next appointment date was not recorded, which made it difficult to determine whether the appointment was honoured or not by the patient. These cases were found to be most prevalent in the Sub-districts as follows; Greater Tzaneen (n=120; 40.82%), followed by Greater Giyani (n=61; 20.78%), Ba-Phalaborwa (n=48; 16.33%), Greater Letaba (n=44; 14.96%), and Maruleng (n=3; 7.14%).

- *Visit Date not Recorded*

There were noted cases wherein the next appointment date was not recorded, which made it difficult to determine whether the appointment was honoured or not by the patient. These cases were found to be most prevalent in the Sub-districts as follows; Greater Tzaneen (n=120; 40.82%), followed by Greater Giyani (n=61; 20.78%), Ba-Phalaborwa (n=48; 16.33%), Greater Letaba (n=44; 14.96%), and Maruleng (n=3; 7.14%).

The researcher further tried to establish the number of days before or after the scheduled appointment date did these children were primarily present in the clinics. It was noted that the majority of the children (n=489;63.67%) presented to the clinics between one (01) and six (06) days before their appointment date, and this practice was found to be most prevalent in Greater Tzaneen, Greater Giyani and Greater Letaba Sub-districts.

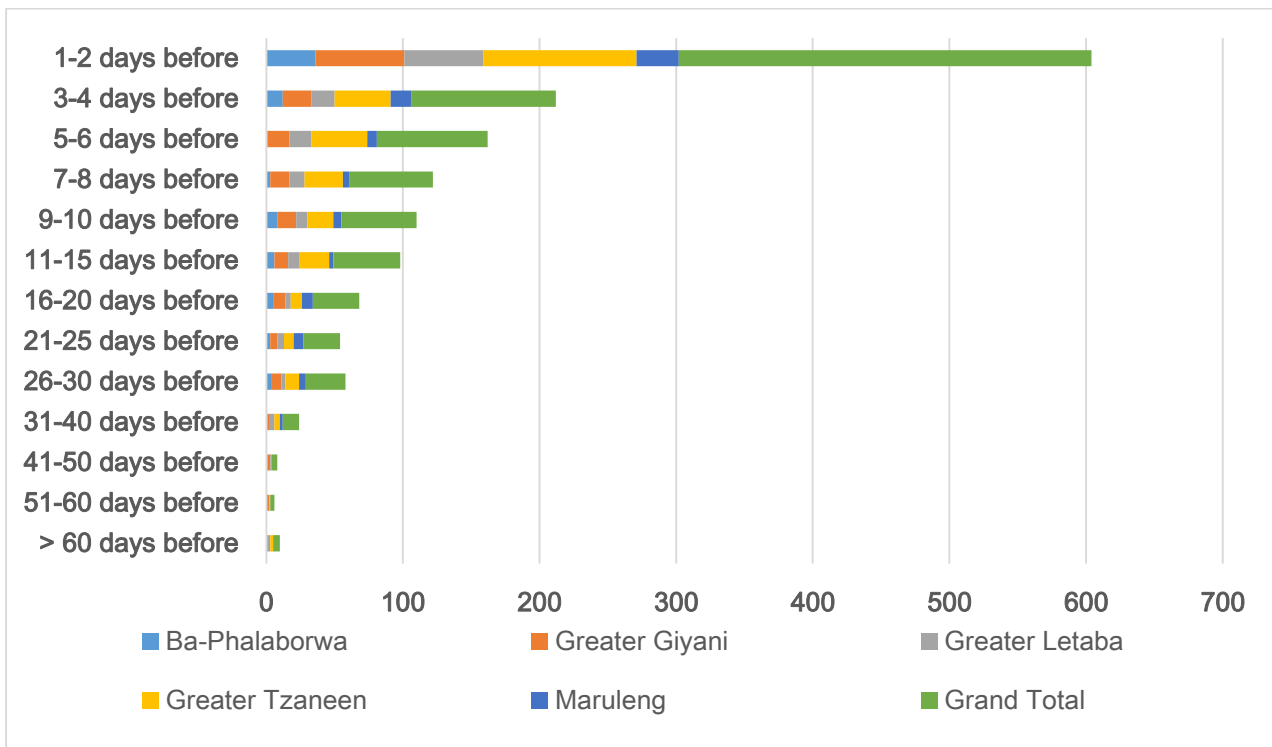


Figure 5.13: On-time pill pick-up per sub-district

It was also noted that children presented to the Clinics to collect their monthly treatment after the scheduled date. The majority of these children closely into the number of days before or after the scheduled appointment date do these children primarily present in the facility. It was noted that the majority of the children (n=489;63.67%) presented to the facility between one (01) and six (06) days before their appointment date, and this practice was found to be most prevalent in Greater Tzaneen, Greater Giyani and Greater Letaba Sub-districts.

The punctuality in medication refill pick-ups may indicate medication adherence to a certain extent since it has been revealed to be a significant determinant of the outcome of ART (Conway, 2007; Turner, 2002). Hence, the researcher noted that caregivers were crucial for the welfare of the vulnerable children for the population under study. The active role of caregivers has been reported to be burdensome because, among other things, a caregiver's participation in ART clinic visits and administration and psychological care (Tapscott, 2016). Moreover, the measurement of medication adherence in a public health program setting is a noted challenge, simply because there is no "gold standard" for measuring adherence to ART (Wagner, Justice, Chesney, Sinclair, Weissman, *et al.*, 2001).

There have been growing concerns over the threat of developing and transmitting drug resistant strains of HIV resulting from poor medication adherence (Pillay, 2001; Gill, Hamer, Simon, Thea, & Sabin, 2005; Osterberg, & Blaschke, 2005). Lower rates of adherence to ART in children are associated with decreased CD4 counts, increased viral load (VL), treatment resistance, disease progression, and death (Wood, Montaner, Yip, Tyndall, Schechter, *et al.*, 2004; Wood, Hogg, Yip, Harrigan, O'Shaughnessy, *et al.*, 2004).

5.1.2.2.3 Monthly Monitoring of Children's Body Weight

The study assessed whether the Nurses were doing bodyweight monitoring at each clinic visit from ART initiation until December 2018 since their treatment is weight band-dependent (see **Appendix IX**). From a total of 7351 clinic visits, the children's body weight was only monitored in a total of (n= 5761; 78.4%) visits, with (n=1590; 21.6%) of body weights not monitored. **Table 5.4** below gives a summary of the findings.

Table 5.4: Summary of weight monitoring per sub-district

Sub District	Caregiver or another relative (CBO collected)	Weight not Recorded during Visit	Recorded Weight for Visit	Total Weight Records
Ba-Phalaborwa	35	31	927	993
Greater Giyani	154	44	1297	1495
Greater Letaba	261	79	1116	1456
Greater Tzaneen	692	139	1895	2726
Maruleng	125	30	526	681
Total visits	1267(17.2%)	323(4.4%)	5761(78.4%)	7351

Factors associated with no monitoring of children's body weights during clinic visits were two-fold (n=1267; 17.2%). First, bodyweights were not observed because the child's treatment was 'Collected by Other' (CBO) people, meaning that treatment in that visit treatment was either collected by a caregiver, a relative, or a guardian in the absence of the child. This is a practice that was witnessed to be taking place in certain instances for even three (03) to four (04) subsequent visits (see **Figure 5.14** below).

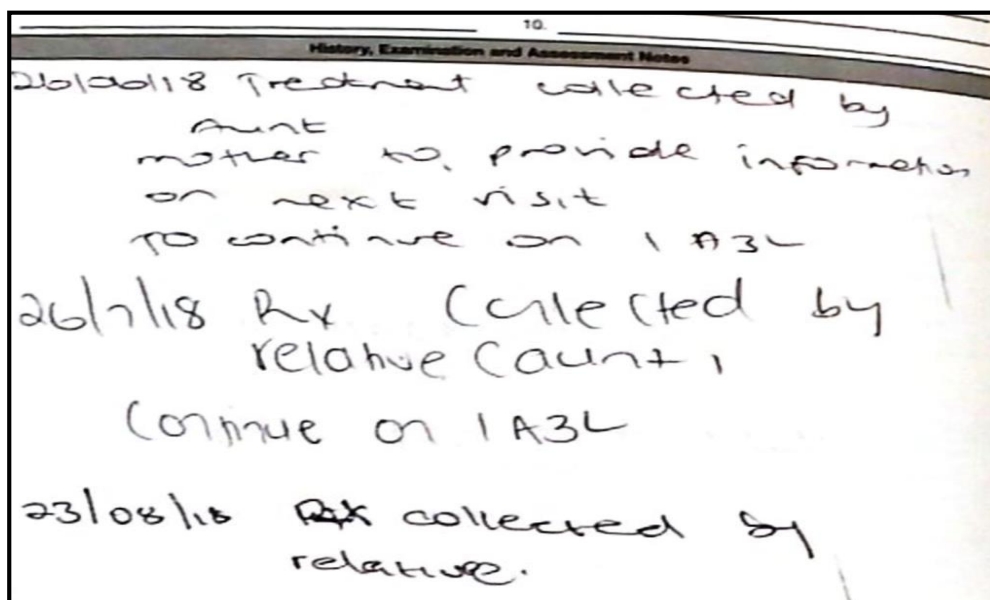


Figure 5.14: Evidence of treatment collection by a caregiver

Secondly, notwithstanding this observation, in a number ($n= 323$; 4.4%) of the clinic visits, there was just no record of the child's body weight for that particular visit. This means that there was no stated reason for the absence of body weight information. This was a challenge, especially when one considers that the dosing of ARVs in children is based on the child's weight. Therefore, the challenge of not monitoring the body weight when treating children on ART but issuing/dispensing out treatment is that the nurse(s) run the risk;

- of either under-or over-dosing the child in that particular visit, and
- miss out on an opportunity to identify any untoward effects that the patient (child) might be experiencing for that specific visit.

5.1.2.2.4 Regimen Prescribed and Issued at Each Visit

Figure 5.15 below gives a descriptive summary of the ART regimens the cohort of children received in the four years (2015 to 2018) of treatment under study. In exploring the prescribing practices, it was discovered that in all the 7351 analysable visits obtained from the 255 medical records, 7045 (95.84%) of the visits were prescribed a triple regimen of ART. Secondly, 65 (0.89%) were prescribed a dual regimen therapy. Only 15 (0.20%) of the children were prescribed a single or monotherapy drug.

It was also noted that about 223 visits (3.03%) had no medication prescribed. An alarming observation was with a 0.04% ($n=3$) of cases where a quadruple (04) ARVs were prescribed.

This was noted as something beyond the guideline recommendations. Further scrutiny of the files where this information emanated from revealed that at the bottom of the nurses' divergence was some gross misunderstanding of the formulation of Abacavir/Lamivudine fixed-dose combinations. Henceforth, the nurses prescribed Lamivudine in addition to the fixed-dose combination. This act resulted in a Lamivudine overdose for the three cases reported in this study.

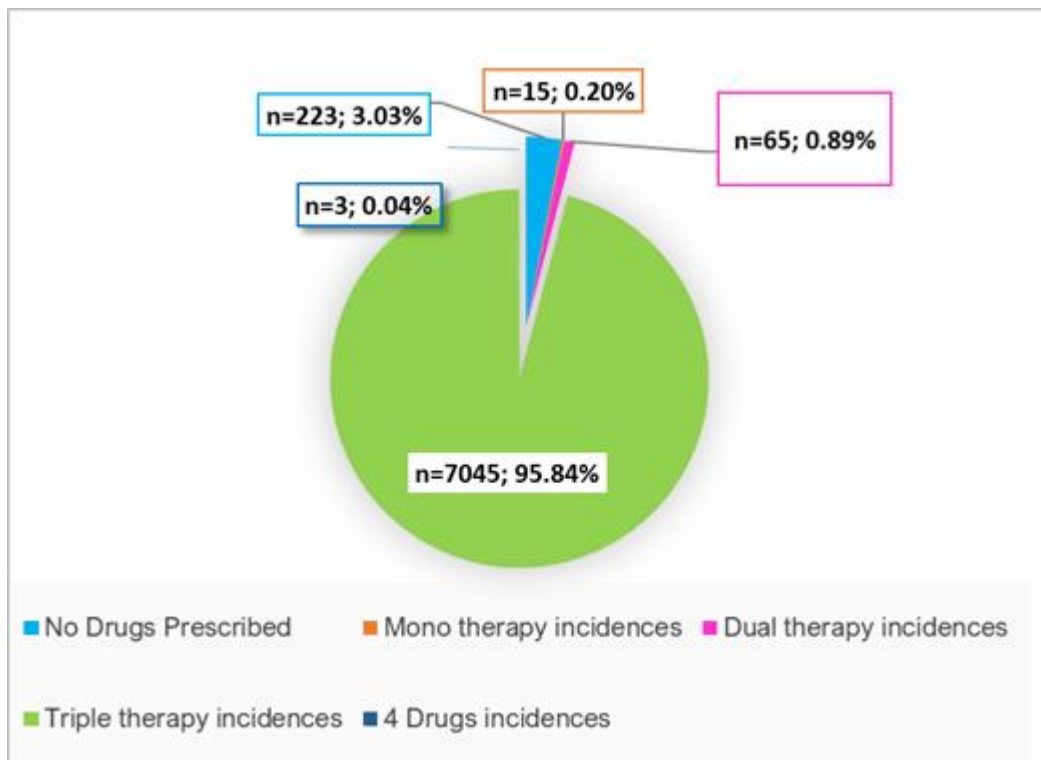


Figure 5.15: District summary of prescribed regimens

Table 5.5 below gives a detailed performance of each Sub-district when coming to the Nurses' prescribing practices, and it clarifies that in terms of prescribing a *Triple Regimen* as recommended in the guidelines, the Sub-district that did very well is Greater Tzaneen (n=2635;37.40%), followed by Greater Giyani (n=1453;20.62%), Greater Letaba (n=1384;19.65%), Ba-Phalaborwa(n=937;13.30%) and Maruleng (n=636;9.03%). This concurs with this finding that lack of adherence to health policies and guidelines implementation remains a contributory factor to poor management of HIV-exposed children (Buthelezi, Modeste, & Phetlhu, 2021).

Table 5.5: Summary of regimens prescribed per sub-district

Sub District	No ARV Drug Prescribed		Mono-Therapy Prescriptions		Dual-Therapy Prescriptions		Triple-Therapy Prescriptions		Quad-Therapy Prescriptions	
	n	%	n	%	n	%	n	%	n	%
Ba-Phalaborwa	46	20.63	1	6.67	9	13.85	937	13.30	0	0.00
Gr. Giyani	26	11.66	4	26.67	12	18.46	1453	20.62	0	0.00
Gr.Letaba	44	19.73	8	53.33	18	27.69	1384	19.65	2	66.67
Gr.Tzaneen	64	28.70	1	6.67	25	38.46	2635	37.40	1	33.33
Maruleng	43	19.28	1	6.67	1	1.54	636	9.03	0	0.00
Total	223	100.00	15	100.00	65	100.00	7045	100.00	3	100

Even though it was established that an acceptable percentage of children were initiated on a Triple regimen, there were some notable discrepancies in the nurses prescribing practices. For example, 323 (3.03%) of the visits had “*No ARV Drug Prescribed*” even though clinical data for the particular visits was written. Such a practice was most prevalent in clinics located in Greater Tzaneen (n=64; 28.70%) followed by Ba-Phalaborwa (n=46; 20.63%), then Greater Letaba & Maruleng (n=44; 19.73% & n=43; 19.28%) respectively. In this finding Maruleng was at 11.66% (n=26). It was also noted that some Dual-Therapy Prescriptions (n=65; 0.89%) wherein children were prescribed only two ARV drugs during visits. The Sub-district where this practice was mostly was also Greater Tzaneen (n=25; 27.91%), followed by this time by Greater Letaba (n=18; 27.69%), Greater Giyani (n=12; 18.46%), Ba-Phalaborwa (n=9; 13.85%), and lastly Maruleng (n=1; 1.54%).

Another issue of concern was the prescription of one ARV drug or mono-therapy. Prescriptions (n=15; 0.20%), wherein this practice was primarily prevalent were in Greater Letaba Sub-district (n=8; 53.33%) followed by Greater Giyani (n=4; 26.67%) and lastly Greater Tzaneen, Ba-Phalaborwa and Maruleng with (n=1; 1.54%) each. There was also an alarming 0.04 % (n=3) of Nurses prescribing four (Quad - Therapy Prescriptions) ARV drugs, and from these

three cases, % (n=2) took place in greater Letaba with 33.33% (n=1) that took place in Greater Tzaneen Sub-district.

5.1.2.2.5 The Prescribed Dosage Form for Each Drug in the Regimen

Furthermore, the study explored whether the dosage form(s) prescribed during the four years was appropriate. It was established that 16694 prescriptions were acquired from the 255 medical records, as depicted in **Figure 5.16** below.

A total of (n=15502; 93%) of the prescriptions were prescribed the correct dosage form suitable for their weight and age as recommended in the 2015 HIV/AIDS guidelines, with only (n=1192;7%) of the dosage forms incorrectly prescribed. These cases revolved mainly around issues of Efavirenz (EFV) 50mg stockouts wherein the children on the 300mg weight band dose were prescribed a 600mg dose of Efavirenz with caregivers instructed to administer half of the tablet (see **Figure 5.16** below) even though the 2013 paediatric dosing chart advises against doing so (see **Appendix IX**).

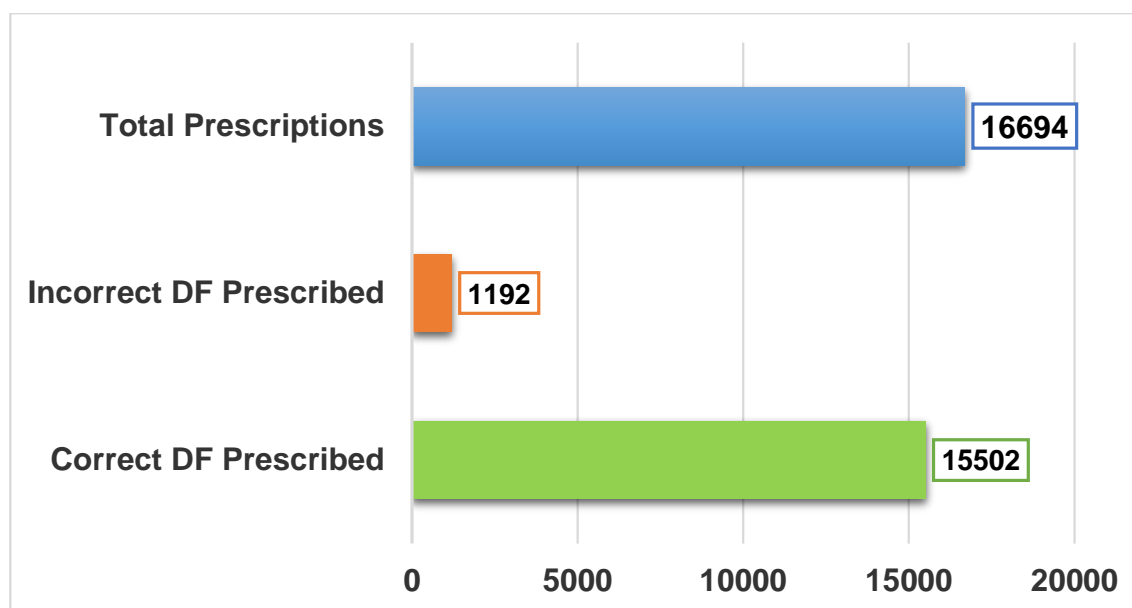


Figure 5.16: District summary of prescribed dosage forms

5.1.2.2.6 The Prescribed Dose (Strength) for Each Drug in the Regimen

In assessing whether the NIMART-trained PNs prescribed the correct dose (i.e. the amount/weight of a drug taken at any time). This was determined by considering the child's weight for that visit and looking at the drug(s) prescribed against the guidelines. Out of the

7351 visits analysed, there was a total of 12467 prescriptions (see **Figure 5.17** below). The findings revealed that the NIMART-trained PNs in Mopani prescribed the correct dose (strength) in only 9539 (76.51%) of the prescriptions. At the same time, 903 (7.24%) of these children received a sub-optimal dose (under-dose) for their prescribed ART regimen, with a total of 2025 (16.24%) prescriptions where children received an overdose of the prescribed ART regimen. Hence, the unavailability of either one of these two indicators made it challenging to determine whether the prescribed strength was correct or not.

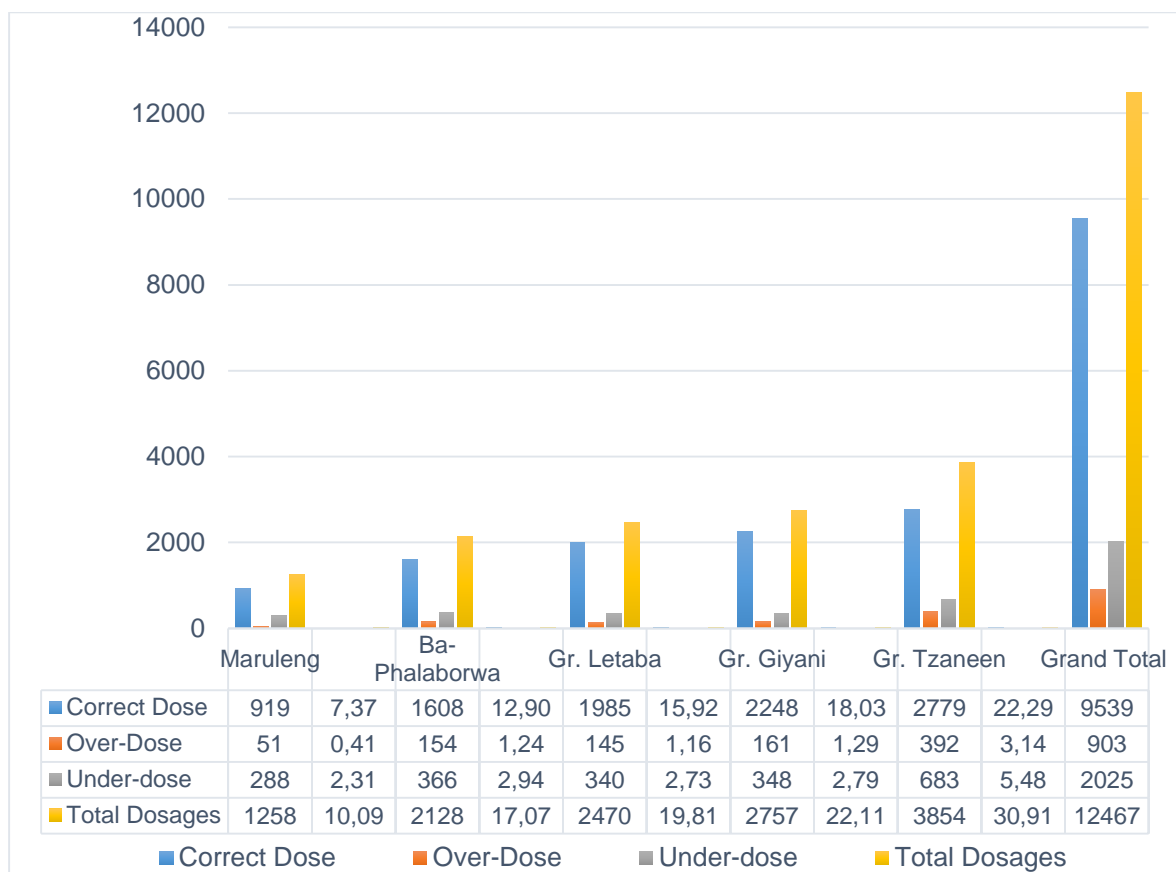


Figure 5.17: Summary of prescribed doses per sub-district

Figure 5.18 below illustrates the extent to which the individual Sub-districts contributed to the prescribed doses practice. The findings highlight that the majority of correct dosing (81%) were from Greater Giyani public clinics, whereas 10% of the overdosing cases (see **Figure 5.19** below for an example) took place in Greater Tzaneen public clinics, whilst most (23%) of the underdosing cases were from Maruleng public clinics. This is seconded by 80% of correct dosing practices from Greater Letaba clinics, and 7% of the overdosing instances were found in Ba-Phalaborwa, with 18% of underdosing cases from Greater Tzaneen clinics.

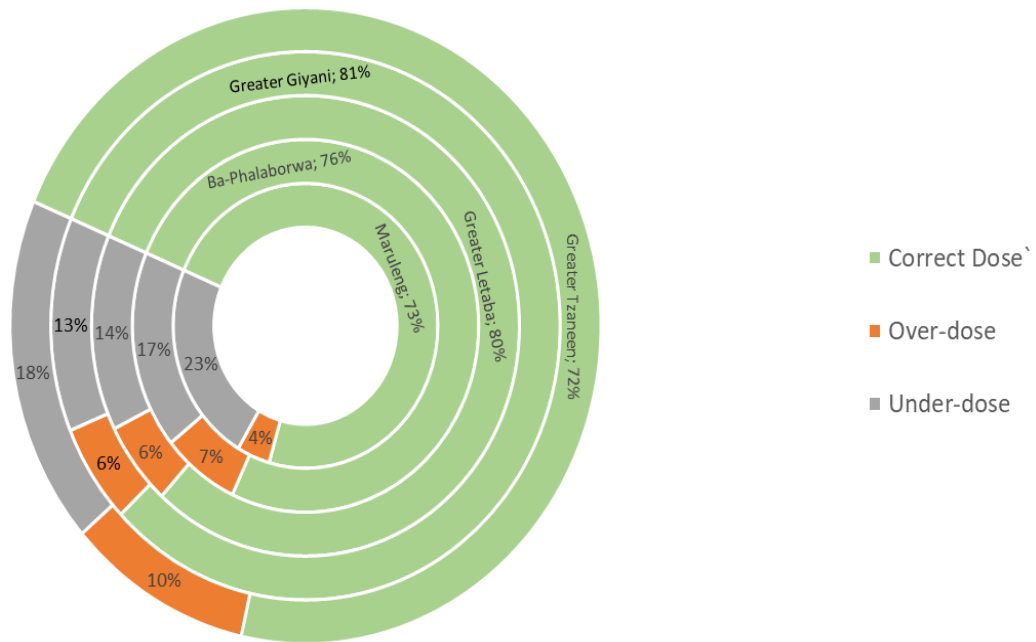


Figure 5.18: District summary of prescribed dosing practices per sub-district

Thirdly, 76% of the correct doses and 17% underdosing were from Ba-Phalaborwa public clinics, with 6% of overdosing obtained individually from Greater Giyani and Letaba public clinics. Fourthly, 73% of the correct dosing and 4% of the overdosing practice were from Maruleng clinics, whereas 14% of the underdosing cases were from Greater Letaba. Lastly, 72% of the correct dosing cases were from Greater Tzaneen, and 4% of overdosing cases were obtained from Maruleng clinics, whilst 13% of underdosing cases were from Greater Giyani public clinics.

12250

Next Bloods: dd / mm / yy

Arrival Time: dd / mm / yy

General History

Patient present at the appointment: Yes No

Pregnant: Yes No

If yes, how many weeks: _____

If yes, how many months: _____

If yes, when: dd / mm / yy

Disclosure Status: Disclosed Partially Disclosed Not disclosed

Emotional Status: Moody Withdrawn Depressed

Positive Calm Anxious Optimistic

Has the patient lost a family member / loved one to death: No Yes

If yes, refer patient for counseling and / or to the social worker as necessary

Nutritional Assessment

Ht: 122 cm Temperature: 37.5 °C

Wt: _____ cm Head circum*: _____ cm

*Circumference as per RTHC

Danger Signs

Danger signs present, specify: _____

Yellow eyes

Fever, vomiting, rash (if on Abacavir)

Symptoms / Problems

Fever Ear problem Diarrhoea

Lethargic

TB Screen

Current TB TB Exposure

If on treatment, how many months: _____

Monitor ARV Treatment

Assess Development (Birth - 5 years)

Developing well

Some delay

Losing milestones

School Progress (6-15 years)

Progressing well

Not progressing

Not applicable

Rash

Diarrhoea

Dizziness

Other, specify: _____

Occasionally misses a dose

Not taking medication

Investigations

Test should be done according to current policy

Date of current bloods taken: dd / mm / yy

CD4 count: _____ cells/mm³

Viral Load: _____

HB / WCC / PLT

Creatinine clearance

Other investigation results (including XRF): _____

ALT: _____

TG: _____

LDL Chol: _____

TB M/C/S: _____

Medication

Medication	Dosage	Frequency	Duration	Phl In	Phl C
ARV 1	ABC	BD	1/12		
ARV 2	3TC	BD	1/12		
ARV 3	EFV	BD	1/12		
ARV 4					
Multivitamin					
Cotrimoxazole					

Handwritten notes in the 'History, Examination and Assessment Notes' section:

ABC on Rx follow up
No ClO raised.

According to the 2013 ART Drug Chart; weight = 21kg
ABC = 10ml 12hly OR 300+60mg OD
3TC = 150mg 12hly
EFV = 300mg 12hly

23/1/18

Figure 5.19: Example of an Abacavir overdosing case

5.1.2.2.7 Factors associated with incorrect dosage measurements

When closely zooming into the factors associated with the identified incorrect dosing measurements. These are split between cases of overdosing and underdosing. It was established that the aspects related to this practice revolved around the following noted issues; (n=928; 77, 85%) of the cases resulted from a tendency of nurses prescribing ARV drug(s) but not indicating either the prescribed dose, dosing frequency or the quantity issued (see **Figures 5.20 - 5.22** below).

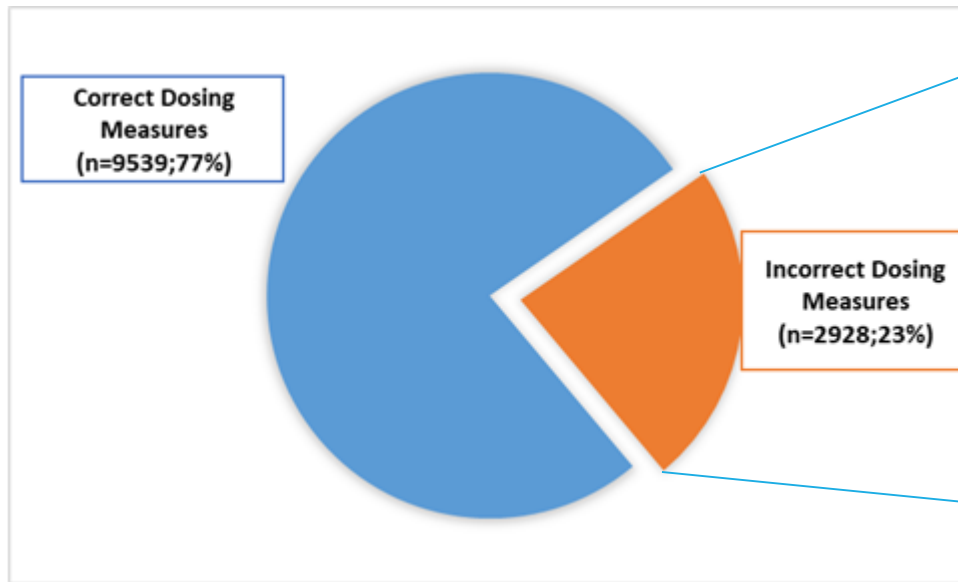


Figure 5.20: Factors associated with incorrect dosing measurements

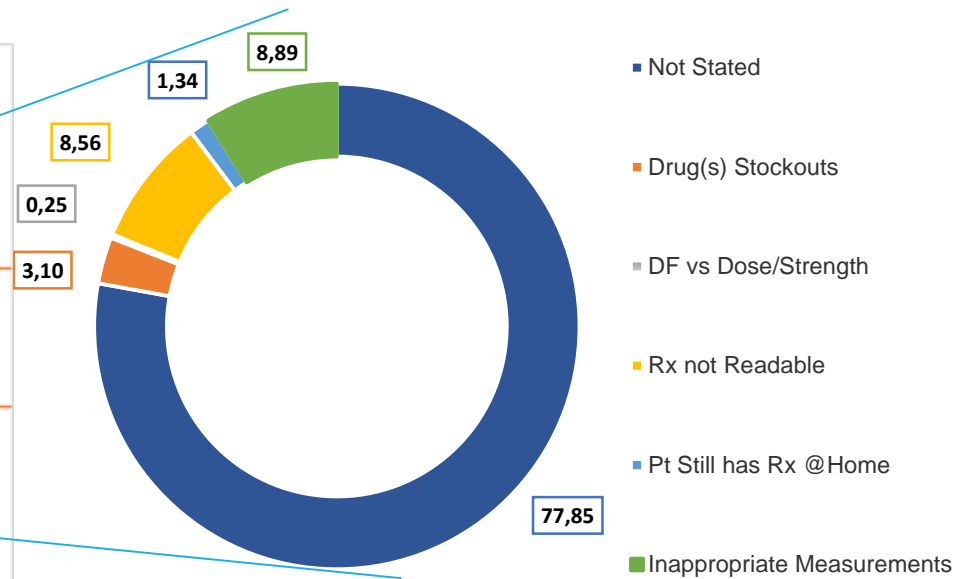


Figure 5.21: District summary of dosing practice

Treatment given			
	IN ▼	OUT ▼	Σ
ABC			
37C			
EFV			

Figure 5.22: Example of a drugs only prescription

This was followed by (n=106; 8.89%) of incorrect doses prescribed and (n=102; 8.56%) cases of illegible/unclear prescriptions due to bad handwriting. Moreover, there was an indication by the Nurses of (n=37; 3.10%) cases of ARV stockouts in the space meant for indicating the strength for the prescribed drug(s). This was followed by (n=16; 1.34%) cases where the strength was not indicated because the patient still had treatment at home (see **Figure 5.23** below).

Treatment given to Granny				Patient reports to have enough treatment. TO come with the treatment next visit to check adherence				Spent mother treatment			
	IN ▼	OUT ▼	Σ		IN ▼	OUT ▼	Σ		IN ▼	OUT ▼	Σ
								Sex			
37C 150mg 12hr - 800mg								AB 15mls			
EFV 400mg 12hr - 1000								37C 150mg			
								EFV 400mg 12hr			
Month 1				Month 2				Month 3			

Figure 5.23: Examples of prescription discrepancies

This practice evokes questions about how the nurses quantify or determine if the treatment at home is enough to last the patient until the next scheduled appointment date. What is even worse is that in the previous month (Month 1), an incomplete treatment (dual therapy) consisting of 3TC 150mg x 56 tabs and EFV 400mg nocte was issued to the grandmother in the absence of the child. In the following month (viz, Month 2), the child is reported to be still having treatment, and the grandmother is advised to bring the tablets in the subsequent visit so that treatment adherence can be determined. The following month after that (viz, Month 3), the child still did not present to the facility but “*sent*” the grandmother to come and collect treatment. This is a simple, transparent case of treatment non-adherence accompanied by an irrational prescribing of ARVs by the nurse(s). Firstly, this child was prescribed dual therapy, and secondly, it was not indicated how much of EFV was issued out in the medical record.

Therefore one can only assume that it was not issued because, according to the Nursing Management Principle, “If it is not written down, it did not happen” (Andrews, & St Aubyn, 2015; Lillis, Leedham, & Twiner, 2017). Thirdly, the treatment issued as guided by the quantity of 3TC was only enough for one month, making it impossible for this patient to have treatment still the following month. Unless the grandmother is referring to 28 leftover EFV 200mg, the last month could have been 84 tablets issued if this was issued. There were lastly (n=3; 0.25%) cases wherein a dosing frequency was written in the medical record without indicating the dose/strength prescribed.

5.1.2.2.8 The prescribed dosing frequency for each drug in the regimen

The study also sought to determine whether the children in this cohort received during the four years under study, a correct dosing frequency prescribed for them. **Figure 5.24** below gives a finding that from a total of 15 502 prescriptions (n=12467; 80%) had a dosing frequency for the prescribed ARVs stated, with however (n=3035; 19.58%) of prescriptions without an indication of the dosing frequency for the ARVs prescribed.

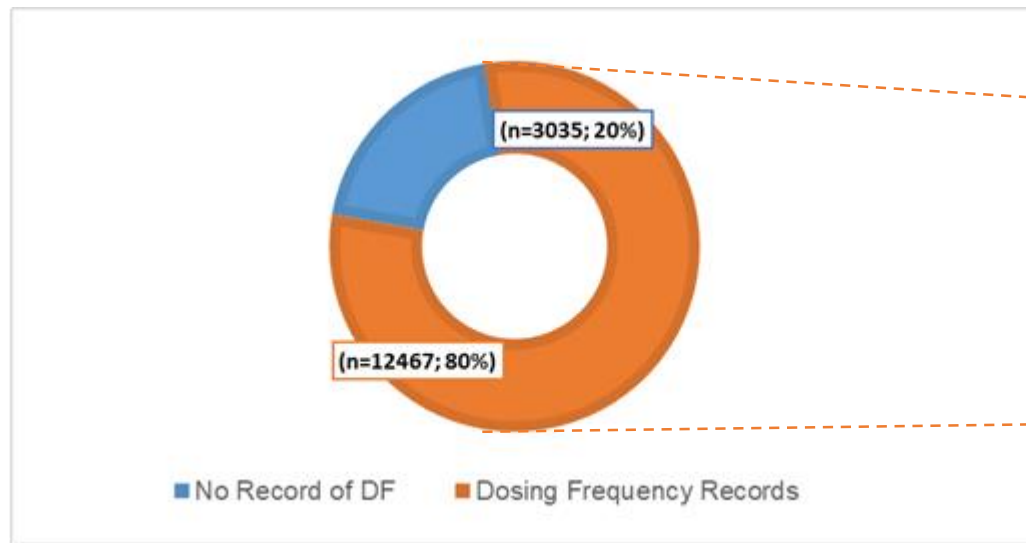


Figure 5.24: Summary of prescribed dosage frequencies

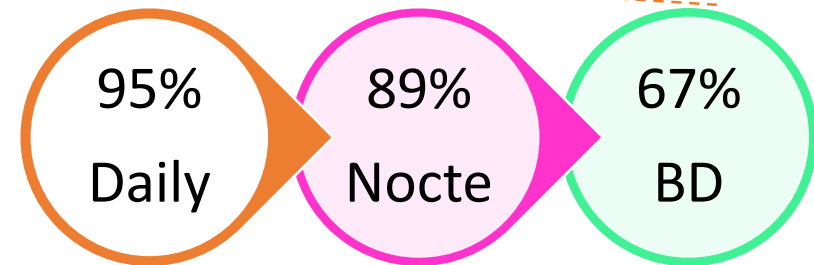


Figure 5.25: Prescribed dosage frequencies

Whereas, **Figure 5.25** illustrates how compliant the nurses were with the HIV/AIDS guidelines. The findings are that the Nurses' compliance to dosing frequencies was at 51% (n=6359), with 49% (n=6108) of the prescriptions receiving an incorrect dosing frequency. Therefore, this finding was zoomed into even further to determine the extent of this practice. It was established that from the 12467 prescriptions, 95%(n=1692) of those that required a daily dosing frequency did get it prescribed as such, with 89%(n=2591) of the cases that required a nocte dosing frequency being prescribed as such and only 67%(n=6768) of the cases that required a BD dosing frequency having been prescribed as such. With the BD dosing frequency, we noted the prevalence of doubling of the 12 Hourly formulations of Lamivudine and Abacavir tablets dose in children on an Efavirenz containing regimen and they, are prescribed all ARVs be taken nocte. This act can pose adverse clinical effects, especially when considering the pharmacokinetics and pharmacodynamics of these ARV formulations.

5.1.2.2.9 An Adequate Amount of Treatment Issued

In analysing the NIMART-trained PN's ability to determine the amount of monthly treatment to issue out, the results are as depicted in **Figure 5.26** below, wherein from a total of 15 502 prescriptions, it was established that only in (n=7449; 48%) prescriptions did the Nurses indicate the amount/quantity of ART issued, and (n=8053; 52%) of the prescriptions the Nurses did not indicate the amount dispensed or issued out to the patient.

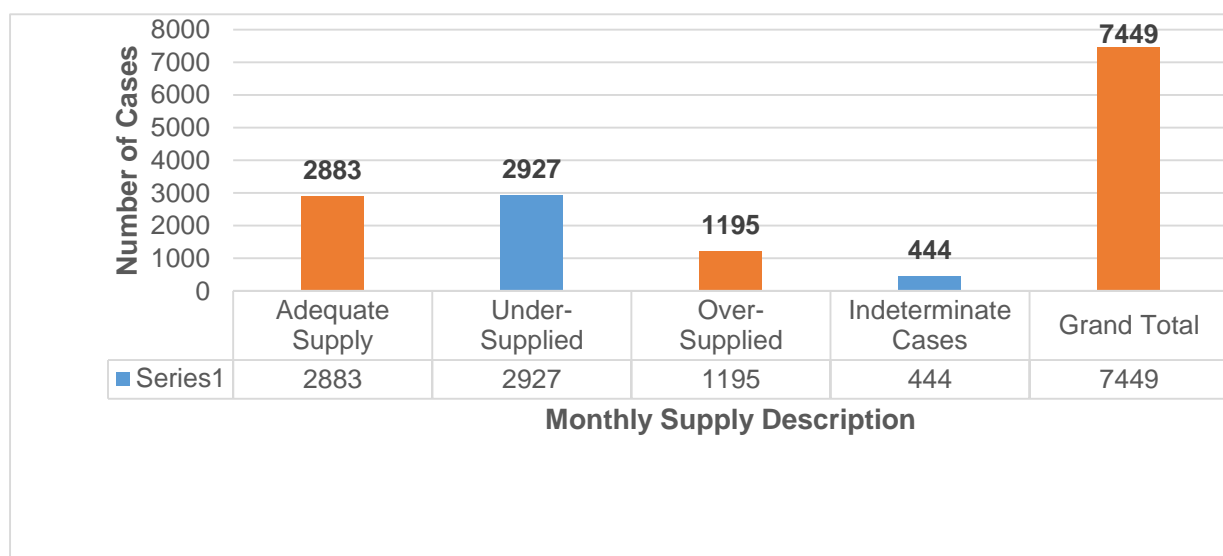


Figure 5.26: Summary of the quantity of monthly treatment supplied

From these 7449 prescriptions, it was established that only (n=2883; 38.70%) of the children in the cohort received an adequate amount of treatment to last them until the next appointment date, and in (n=2927; 39.30%) of the prescriptions, these children were undersupplied on their treatment, with (n=1195; 16%) of the prescriptions receiving an over-supply of their prescribed ARV treatment.

5.1.2.2.10 Nurses' Regimen Switching Practices

After reviewing the 357 medical records identified on TIER.Net during phase 1A of the study as having been switched from one regimen at initiation to another during the four years (2015 - 2018). The findings revealed the NIMART-trained PNs' regimen switching practices in this cohort of children as outlined in **Figure 5.27** below, wherein it was established that a total of 293 (82.07%) regimen switches took place, with (n=64; 17.93%) being cases wherein children were given a dual- (n=54; 15.13%) or a mono- (n=10; 2.80%) therapy to take home and this practice was therefore identified as a regimen switch on TIER.Net.

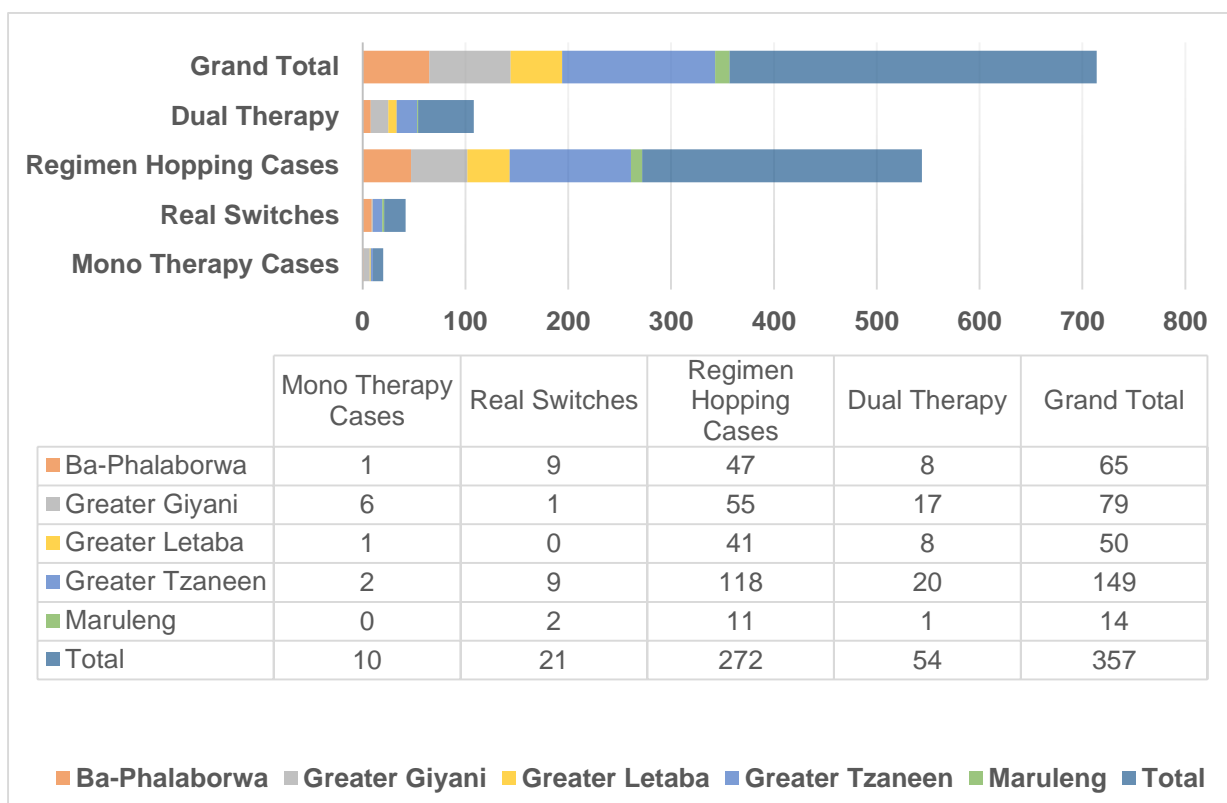


Figure 5.27: District summary of regimen switching per sub–district

Furthermore, it is also noted that, from the 293 switches, only a minute number (n=21; 7.17%) of children were switched from one regimen at initiation to another. The practice of switching regimens more than once was in this study noted as “Regimen Hopping” instead of “Regimen Switching” since most of these children were taken back and forth of a particular regimen. The Regimen Hopping context is derived from the understanding of the English word “hop”, which is to pass quickly from one place to the next, wherein these children were moved from the regimen at initiation to the next to as often as more than five times. From **Figure 5.27** above, it is identified that the “*regimen hopping*” practise most prevalent in four (04) Sub-districts, where almost half of the 272 cases (n=118;43.38%) took place in Greater Tzaneen, followed by (n=55;20.22%) in Greater Giyani, (n=47;17.28%) in Ba-Phalaborwa and (n=41;15.03%). The figure also brings forth an irrational prescribing practice, noted in cases wherein two ARV drugs (Dual -Therapy) were prescribed instead of the three guideline-recommended ARV drugs. This practice was also found to be very prevalent in four Sub-districts. Wherein Greater Tzaneen (n=20; 37.04%) and Greater Giyani (n=17; 31.48%) are also top of the list leading, followed by Greater Letaba and Ba-Phalaborwa

Sub-district with (n=8; 14.81%) of the cases each. In cases wherein the children were prescribed one ARV drug (Mono-Therapy) instead of the three recommended ARV drugs. This practice was most prevalent in Greater Giyani (n=6; 60%), with 20% (n=2) of the cases recorded in Greater Tzaneen, and Ba-Phalaborwa and Greater Letaba Sub-district, each contributed (n=1; 10%) to this irrationality.

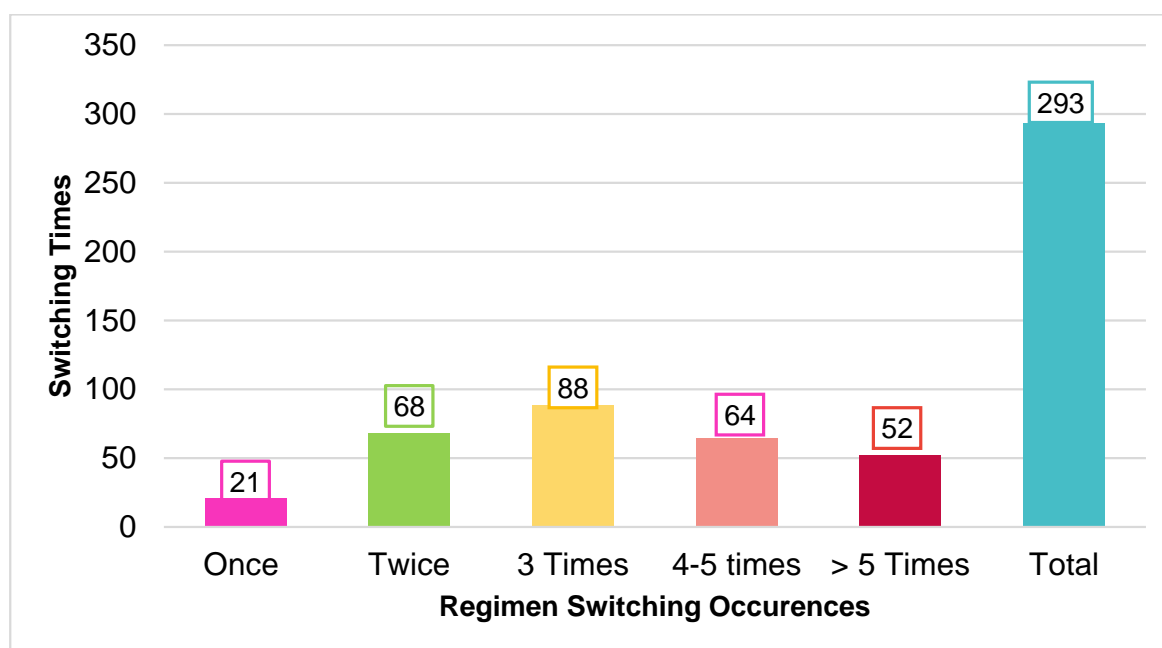


Figure 5.28: Regimen switching occurrences

Figure 5.28 above depicts that the majority of the children (n=88; 23.53%) were switched ARV regimens three (03) times, whereas (n=68; 22.43%) were switched regimens twice, and (n=64; 25%) were switched regimens about four to five times, whilst (n=52; 19.12%) children were switched regimens more than five (05) times.

5.1.2.2.11 Factors Associated with Regimen Switching

When looking at the factors associated with regimen switching for this cohort (see **Figure 5.29**), it is established that the majority (n=11; 52.38%) of what is noted as the “*real regimen switches*” actually took place without indicating the reasons these children were switched regimens. This was significantly noticed in Greater Tzaneen (n=5; 45.45%) and Ba-Phalaborwa Sub-district (n=4; 36.36%). Other identified reasons as indicated in the medical records associated with the switching of regimens were due to unsuppressed viral

loads(n=2;9.52%), apparent treatment failure (n=2;9.52%), children failing the first regimen(n=2;9.52%), and these were noted as just switched to regimen 2 (n=2;9.52%) with (n=1;4.76%) of a switch informed by non-adherence and (n=1;4.76%) due to clinical instability. All these factors were primarily found in three Sub-districts, namely, Greater Tzaneen (n=9; 42.86%) and Ba-Phalaborwa (n=9; 42.86%).

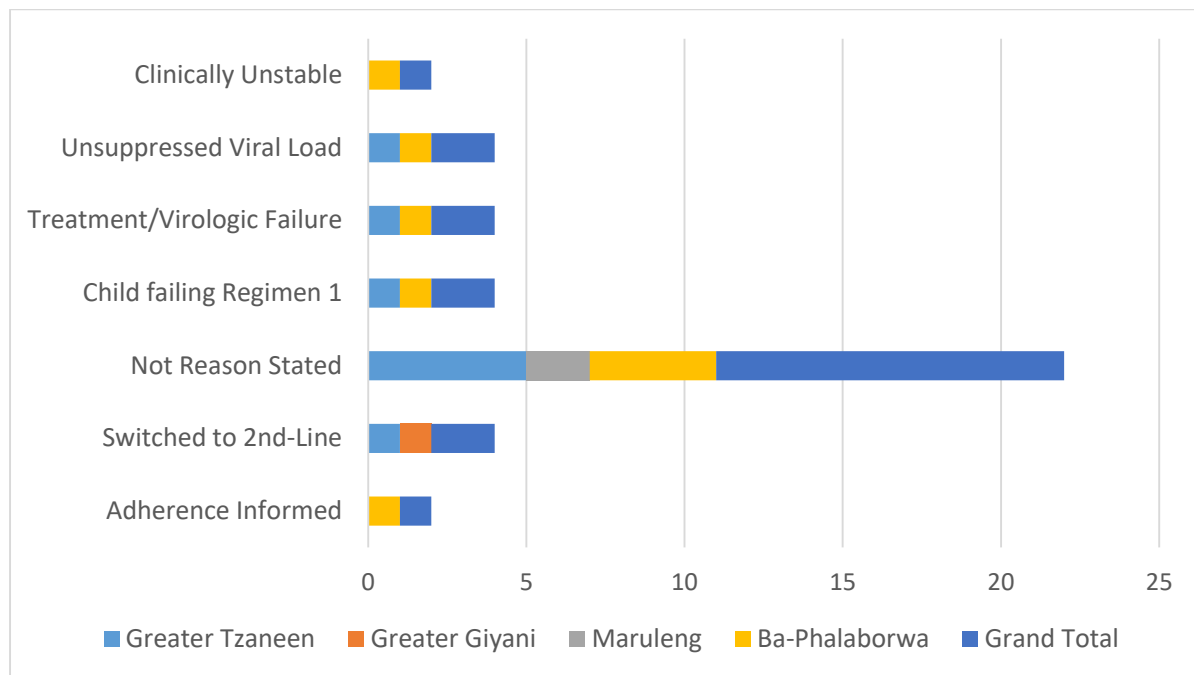


Figure 5.29: Factors associated with regimen switching per sub-district

The above results demonstrate an irrational prescribing practice even though the NIMART-trained PN's of Mopani District prescribed the children in 96% of the prescription a triple regimen and correct dosage forms as recommended by the treatment guidelines. These results highlight that the nurses lack rational prescribing since some children were prescribed mono-and dual regimens. Even though ART is weight-based, children were prescribed treatment without recording their body weight. The honouring of scheduled appointment dates was also not satisfactory in that a pattern of issuing treatment to the caregivers in the absence of children was identified.

Furthermore, there is some level of underdosing and overdosing and a lack of consideration of the ARV drug formulations, especially when coming to Abacavir 300mg, Lamivudine 150 Efavirenz 200mg and 600mg. Moreover, children have mostly undersupplied treatment. These

findings depict a level of non-compliance to the treatment guidelines that needed to be explored in the following phase of the study.

5.2. Qualitative Findings - Knowledge, Understanding of NIMART Nurses in dosing and dispensing ART

This section of the findings gives a detailed narration of the project's Qualitative Phase (Phase 2). **Table 5.6** below provides a summary of the themes, as well as sub-themes that emerged in this phase of the study.

Table 5.6: A Summary of Emergent Themes and Sub-themes

Objective of the phase	Emergent Themes	Emergent Sub-themes
	1. Participants' Socio-Demographic Details	1.1. Gender Distribution 1.2. Participants' highest level of Qualification 1.3. Participants' Further Training Status
	2. Nurses' Knowledge and Understanding of ART in Children	2.1. Nurses Understanding of NIMART 2.2. Nurses' Understanding of the ART Management Process in Children 2.3. Nurses' Understanding of ART Dosing in Children 2.4. Nurses' Understanding of ART Dispensing in children
	3. Nurses' Knowledge and Understanding of ART Management in Children Self Ratings	3.1. Monitoring of Viral Load in Children as per HIV/AIDS Guideline(s). 3.2. Monthly Monitoring of Children on ART as per HIV/AIDS Treatment Guidelines.

Objective of the phase	Emergent Themes	Emergent Sub-themes
		<p>3.3. The Recognition of Opportunistic Infections (OIs) in children on ART.</p> <p>3.4. The Management of Opportunistic Infections in Children on ART.</p>
	<p>4. Nurses' ART Competency Level Ratings</p>	<p>4.1. Regimen Switching</p> <p>4.2. ART Regimen Selection</p> <p>4.3. Monthly Weight Monitoring</p> <p>4.4. Determination of Monthly ART Supply</p> <p>4.5. Management of Missed Appointment Dates</p> <p>4.6. The Recognition of Treatment Failure</p> <p>4.7. The Management of Unsuppressed Viral Loads (VLs)</p> <p>4.8. Antiretroviral Therapy (ART) Dispensing in Children</p> <p>4.9. Antiretroviral Therapy (ART) Dosing in Children</p>
	<p>5. Nurses' Experiences and Perceptions of Managing Children on ART</p>	<p>5.1. Nurses' Perceptions of Caring and Managing Children on ART</p>
	<p>6. Nurses' Experiences of Caring and Managing Children on ART</p>	<p>6.1 The existence of social-related factors</p> <p>6.2. The existence of Health System -related Factors</p>

Objective of the phase	Emergent Themes	Emergent Sub-themes
		6.3 the existence of Caregiver-Related Factors
	7. Nurses Views and Perceptions on Missed Appointment	7.1 Observed non-adherence practice 7.2 Identified poor clinical outcomes
	8. Nurses Views on Monthly Weight Monitoring	8.1 Identified a useful prescribing Tool 8.2 A noted treatment success monitor 8.3 An observed Growth & Development Monitor
	9. Nurses' Views on ART Dispensing in children	9.1 A high level of knowledge and understanding of ART Dispensing in children
	10. Determining the Nurses Competency in Managing Children on ART	10.1 An observed non-compliance to treatment guidelines 10.2 An identified compliance to treatment guidelines

Firstly it presents the participants' socio-demographic details (see Section 5.3.2 below). Secondly, it describes the knowledge, understanding, and competence of NIMART-trained PNs who consented to participate in the study and are located in fifty-seven (57) resource-limited public clinics in the Mopani District of Limpopo Province (see 5.3.3 below). The findings describe these aspects concerning dosing and dispensing of Antiretroviral Therapy in children who are managed by these. Thirdly, this phase of the project also explored the perceptions and experiences of these NIMART-trained PNs when coming to the management of children on ART in these fifty-seven (57) public clinics under study.

Theme1: Participants' Socio-Demographic Details

Sub-theme 1.1: Gender Distribution

The gender distribution of the 108 NIMART-trained PNs who consented to participate in the study was as follows; (n=88; 81%) of the participant nurses were female, and (n=20; 19% were males.

Sub-theme 1.2: Participants' highest level of Qualification

Table 5.7 below brings forth the highest level of qualification as well as the age categories for the NIMART-trained PNs who participated in the study, and it highlights that the majority of nurses (n=78;72%) who are in the care and management of these children under 15 years in the fifty-seven (57) public PHC clinics of Mopani District holds a Diploma in Nursing Qualification with 20% (n=22) of these nurses holding a University Bachelor's Degree and only 4% (n=4) of the nurses containing an Honours Degree in Nursing with a minute 1% (n=1) Master's Degree.

When exploring the undergraduate qualifications for these participant nurses. It was established that the majority (n=78; 72%) of the participant NIMART-trained PNs held a Diploma in Nursing, with (n=22; 20%) of the Nurses holding a Bachelor's Degree in Nursing, whereas (n=2; 2%) having an Advanced Diploma in Nursing Certificate, and (n=1; 1%) containing a College Certificate in Nursing. From these nurses, it was also established that only 5% (n=5) of them had a postgraduate qualification, wherein (n=4; 4%) hold a Master's Degree in Nursing and (n=1; 1%) holds an Honours Degree in Nursing.

Table 5.7: Age categories of participant nurses per gender

Age Categories	Number of Participant Nurses per Gender				Grand Total	
	Male (n)	Percentage (%)	Female (n)	Percentage (%)	Number (n)	Percentage (%)
21-29 Years	2	1,85	11	10,19	13	12,04
30 - 39 Years	6	5,56	13	12,04	19	17,59
40 - 49 Years	7	6,48	30	27,78	37	34,26

Age Categories	Number of Participant Nurses per Gender				Grand Total	
	Male (n)	Percentage (%)	Female (n)	Percentage (%)	Number (n)	Percentage (%)
50 - 59 Years	5	4,63	30	27,78	35	32,41
≥60 Years	0	0.00	4	3,70	4	3,70
Total	20	18,52	88	81,48	108	100

Sub-theme 1.3: Participants' Further Training Status

The participants were further asked about the status of additional training they have attended or completed during their years caring for and managing children on Antiretroviral Therapy (ART). The findings were somehow contradicting the district stated norm that nurses who manage children on ART at PHC settings are NIMART-trained, in that from the 108 participants, only 89% (n=96) had completed a NIMART training whereas 11% (n=12) of the nurses did not hold a NIMART training, but a Primary Care 101 (PC101) training (n=12; 11%) which is considered an equivalent of NIMART training.

From the above information it is noted that all (89% + 11% = 100%) the nurses included in the study had NIMART related training, with PC 101 being the currently available equivalent to the NIMART training courses. This welcome picture is expected because, the employer is the one who nominates and pays for the training of the nurses. Although sometimes, due to budgetary constraints, not all the nurses are sent to train at the cost of the employer. Some are assisted through the availability of technical support from implementing partners, such as ANOVA Health Institute, Foundation for Professional Development (FPD) and Right to Care. These organisation provide the much needed training and also assist with mentoring trained nurses.

However, Primary Care 101 is considered by the National Department of Health (NDoH) a symptom-based integrated clinical management guideline for managing common symptoms and chronic conditions in adults (Mahomed, Naidoo, Taylor, & Asmall, 2015; NDoH, 2013/14). Surprisingly, only 47% (n=26; 24%; n=25, 23%) of these participants had undergone training

(ART Dosing & Dispensing in Children and Paediatric HIV/AIDS Management) that focused entirely on the population under study.

In seeking to understand the onsite working experience of the nurses in the care and management of children on ART, the study brought forth the following observations (Summarised in **Figure 5.30**): First, that the majority of the nurses (n=36;33.33%) had four (04) to six (06) years working experience. These were followed by those (n=29; 26, 85%) who had seven to nine years of working experience and others (n=21; 19.44%) having ten (10) to twelve (12) years of working experience. Eighteen (18) (16.66%) of the nurses were found to be still at the beginning of their careers, with about zero to three years of work experience.

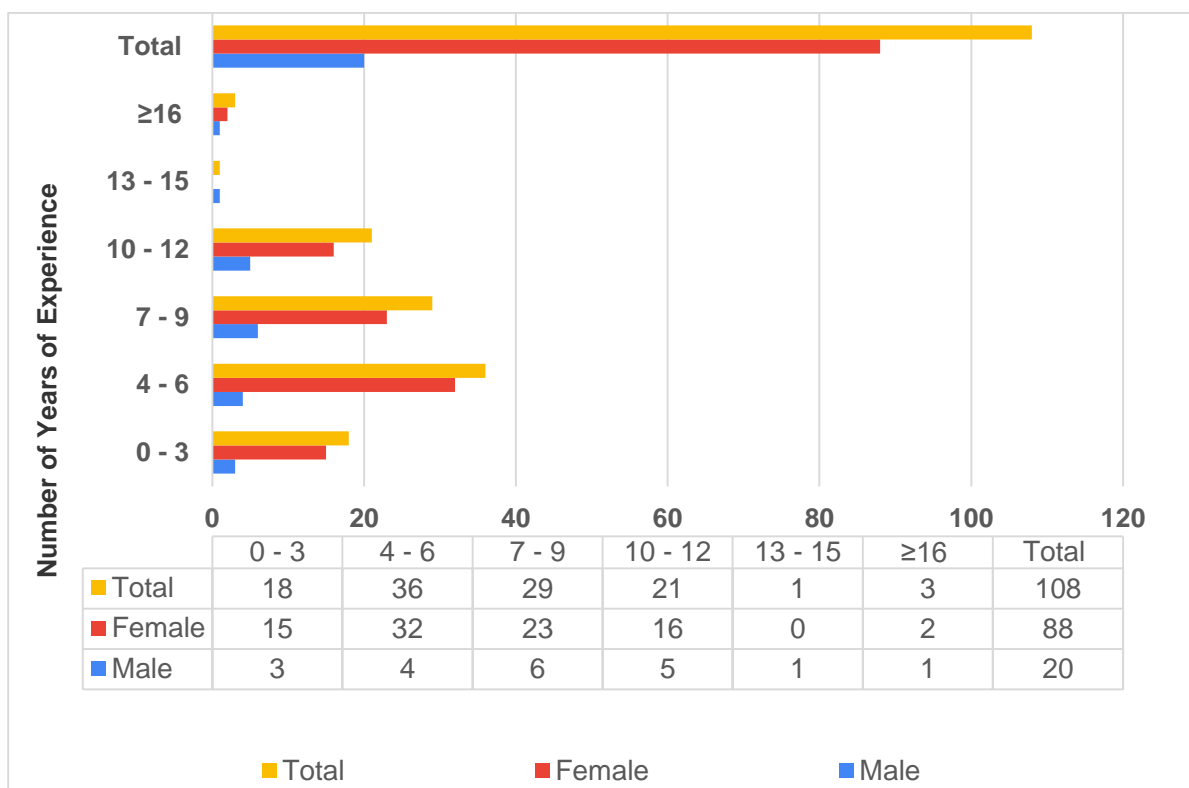


Figure 5.30: Participants’ onsite work experience

The following theme deals with the findings of the inquiries made concerning the NIMART-trained PNs’ knowledge, understanding and competence levels in the management of children on ART. Four sub-themes emerged from this theme, and the first one mainly focuses on the general knowledge of the nurses on NIMART. The second sub-theme focuses on the nurses’ knowledge, understanding and competence level of the ART management process in children. The third and the fourth sub-theme focuses on the

nurses' knowledge, understanding and competence levels of ART dosing and dispensing in children.

Theme 2: Nurses' Knowledge and Understanding of ART in Children

The Nurse-Initiated and Managed ART (NIMART) is promoted widely as a mechanism for expanding antiretroviral treatment (ART) access. However, the evidence for NIMART in Africa and South Africa is still limited (Georgeu, Colvin, Lewin, Fairall, Bachmann, *et al.*, 2012.). Hence this study further explored from the participant NIMART-trained PNs their knowledge and understanding of the following aspects; 1) NIMART as a whole as well as 2) ART managing process in children, and 3) ART dosing and dispensing in children using the 2015 HIV/AIDS treatment guidelines as well as the 2013 Paediatric Dosing Chart as a reference guide.

Sub-theme 2.1: Nurses Understanding of NIMART

Table 5.8 below gives a summary of the participant Nurses responses in terms of their *NIMART understanding*, the majority of the nurses (n=72; 66, 7%) reported a good understanding of NIMART, and (n=31; 28.7%) of the participant Nurses indicated that their understanding of this programme as very good. Whereas a total of (n=4; 3, 7%) rated their understanding as neither good nor bad (i.e. neutral or acceptable), with 0.9% (n=1) nurse indicating a poor' understanding of NIMART. This can be seen as not much, especially when one looks at the numbers. Still, if one considers the number of children who could be under the care and management of this participant, then one sees the need for attention to salvage this case.

Table 5.8: Participant nurses' understanding of antiretroviral therapy in children

Domains	1 Very Poor		2 Poor		3 Acceptable		4 Good		5 Very Good		Total
	(n)	%	(n)	%	(n)	%	(n)	%	(n)	%	
Understanding of NIMART	1	0.9	0	0.0	4	3.7	72	66.7	31	28.7	108

Domains	1 Very Poor		2 Poor		3 Acceptable		4 Good		5 Very Good		Total
	(n)	%	(n)	%	(n)	%	(n)	%	(n)	%	
Understanding of ART Management in Children	4	3.7	0	0.0	12	11.1	64	59.3	28	25.9	108
Understanding of ART Dosing using the Paediatric Dosing Chart	3	2.8	1	0.9	2	1.9	50	46.3	52	48.1	108
Understanding of ART Dispensing in children using the Paediatric Dosing Chart	3	2.8	0	0.0	5	4.6	48	44.4	52	48.1	108

Sub-theme 2.2: Nurses' Understanding of the ART Management Process in Children

When exploring the nurses' general knowledge and understanding of ART Management in children, the majority (n=92; 85.2%) of them indicated a “Good” understanding of this aspect, whereas 11.2% (n=12) of the Nurses said their understanding is neither good nor bad (Acceptable), and (n=4; 3.7%) indicated that their knowledge as being “very poor”.

Sub-theme 2.3: Nurses' Understanding of ART Dosing in Children

When exploring the nurses understanding of ART dosing in children using the 2013 Paediatric Dosing Chart, the majority (n=102; 94.4%) of NIMART-trained PNs who participated in the study indicated a “Good” understanding of this aspect, and 1.9% (n=2) of these Nurses said their understanding was neither good nor bad (Acceptable), whereas (n=4; 3.7%) indicated that their knowledge of ART dosing in children on ART was “very poor”.

Sub-theme 2.4: Nurses' Understanding of ART Dispensing in children

When exploring the nurses understanding of ART dispensing in children, from the 108 NIMART-trained PNs who participated in the study, the majority (n=100; 92.5%) of them indicated a “Good” understanding of this aspect, and 4.6% (n=5) of the Nurses said their

understanding is neither good nor bad (Acceptable), whereas (n=3; 2.8%) indicated that their knowledge in the dispensing of ART in children to be “very poor”.

The following subsection explores the NIMART-trained PNs self-rating of their knowledge and understanding of ART management in children. This subsection deals with the findings of the nurses’ ability to monitor VLs in children per treatment guidelines, the monthly monitoring of children on ART, the recognition and management of opportunistic infections in children on ART. After that, the subsection that follows presents the NIMART-trained PNs’ competency level self-rating on ART management in children. The subsection also looks into exploring their competency level in terms of regimen switching, ART regimen selection, monthly weight monitoring, determination of monthly ART supply, the management of missed appointments, the recognition of treatment failure, the management of unsuppressed viral loads in children, and ART dosing and dispensing in children.

Theme 3: Self Ratings of Nurses’ Knowledge and Understanding of ART Management in Children

Figure 5.31 below gives a visual narration of how the nurse’s self-rated their knowledge and understanding of the monthly monitoring process of children on ART in a public clinic setting, which includes, amongst other things, the monitoring of viral loads, the recognition as well as management of Opportunistic Infections (OIs).

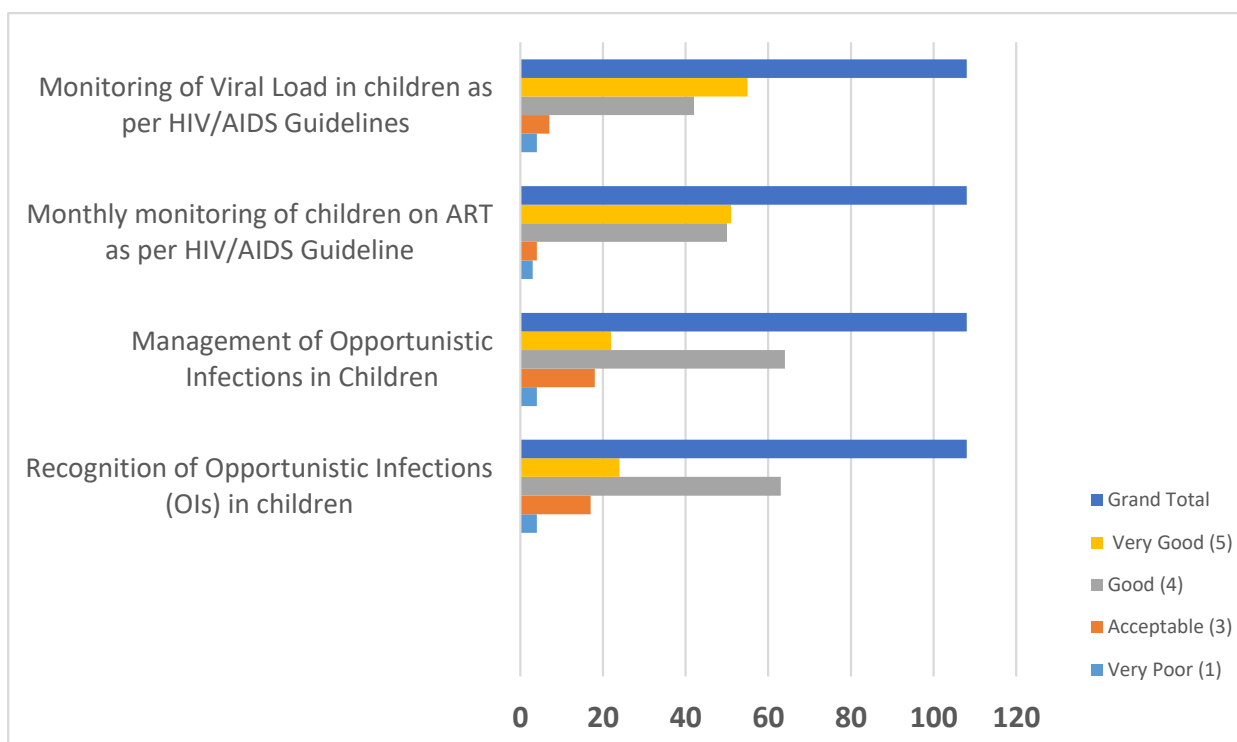


Figure 5.31: NIMART-trained PN's knowledge and understanding of ART management

Sub-theme 3.1: Monitoring of Viral Load in Children as per HIV/AIDS Guideline(s)

The majority of the nurses (n= 97; 89.8%) indicated having a “Good” understanding of VL monitoring VL in children, with (n=7; 6.5%) reporting having an “Acceptable” understanding, whereas (n=4; 3.7%) Nurses indicated that they have a “Very Poor” understanding of VL monitoring in children.

Sub-theme 3.2: Monthly Monitoring of Children on ART as per HIV/AIDS Treatment Guidelines

When coming to this indicator, several nurses (n= 101; 93.5%) indicated having a “Good” understanding of the monthly monitoring process of children on ART, with (n= 4; 3.7%) reporting an “Acceptable” understanding, whereas (n=4; 3.7%) of the nurses indicated that they have a “Very Poor” understanding of this process in children.

Sub-theme 3.3: The Recognition of Opportunistic Infections (OIs) in Children on ART

In terms of the NIMART nurses’ ability to recognise OIs in children, most of them (n= 84; 80.5%) reported having a “Good” understanding of identifying OIs in children. Whereas 17

(15.7%) of the nurses indicated that they had an “*acceptable*” understanding, whilst (n=4; 3.7%) of the nurses mentioned that they had a “*very poor*” understanding of recognising opportunistic infections in children.

Sub-theme 3.4: The Management of Opportunistic Infections in Children on ART

When looking at the nurses’ ability to manage OIs in children, (n= 86; 79.7%) of nurses indicated having a “*Good*” understanding of the management of OIs in children on ART, with (n=18; 16.7%) indicating their understanding as being “neither good” or “bad” (*Acceptable*), whereas (n=4; 3.7%) of nurses indicated that they have a “*Very Poor*” understanding of managing opportunistic infections in children.

Theme 4: Nurses’ ART Competency Level Ratings

The study also explored from the nurses who participated in the study an understanding of how they view their competency level in the following areas of ART Management; 1) HIV/AIDS Management specifically in children; 2) ART Dosing using the 2013 Paediatric Dosing Chart (see **Appendix IX**); 3) ART Dispensing in Children; 4) the management of children with unsuppressed Viral Loads (VLs); 5) the recognition of treatment failure in children, 6) the management of children on ART who miss scheduled appointment dates; 7) determining the monthly amount of treatment to be issued out to a child on ART; 8) Adherence Counselling (AC) in children on ART; 9) monthly weight monitoring in children on ART; 10) regimen selection for children to be initiated on ART; and 11) regimen switching for children failing an ART regimen. The findings are as depicted in **Figure 5.32** below.

Sub-theme 4.1: Regimen Switching

When looking at the nurses’ competence level in terms of regimen switching in children, (n= 90; 83.3%) of nurses indicated having a “*Good*” competence level, with (n=12; 11.1%) indicating their competence level as “neither good” nor “bad” (*Acceptable*), whereas (n=6; 5.6%) of the nurses indicated that they have a “*Poor*” competence level.

Sub-theme 4.2: ART Regimen Selection

When looking at the nurses' competence level in terms of regimen selection in children, (n= 92; 85.18%) of nurses indicated having a "Good" competence level, with (n=13; 12.0%) indicated their competence level as "neither good" nor "bad" (*Acceptable*), whereas (n=3; 2.8%) of the nurses indicated that they have a "Poor" competence level.

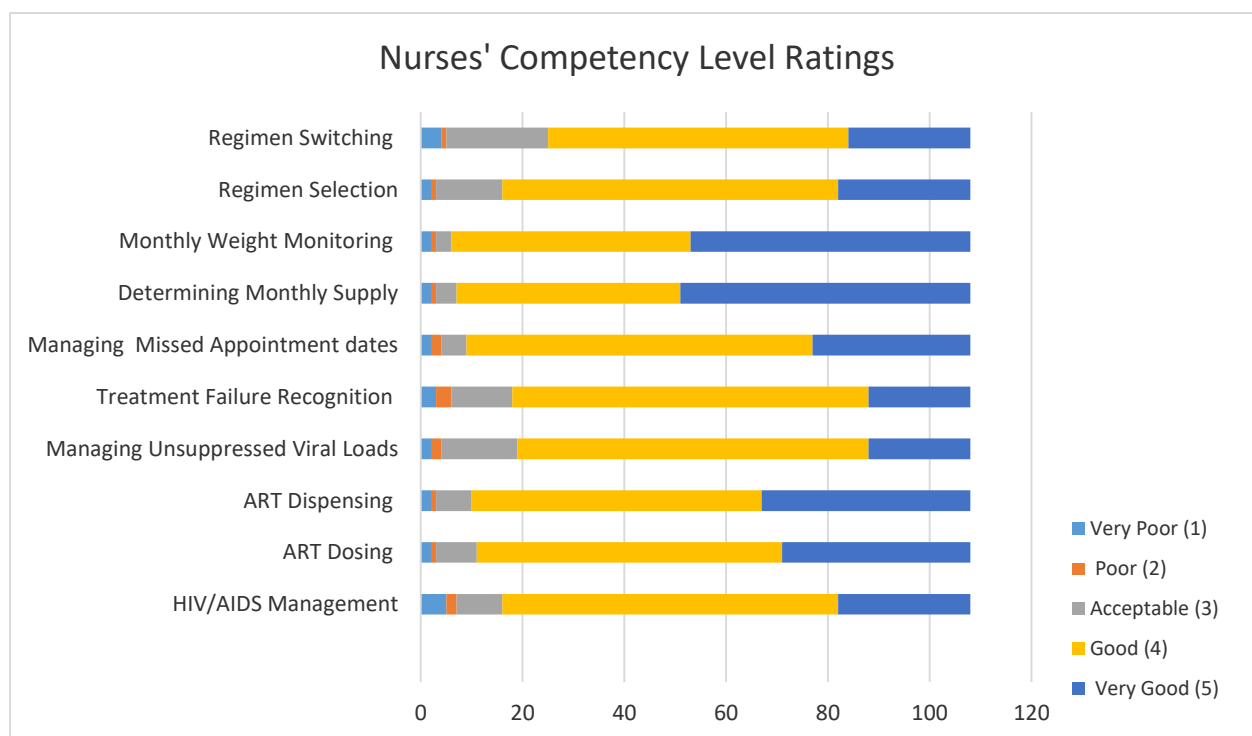


Figure 5.32: NIMART-trained PNs' ART management competency level ratings

Sub-theme 4.3: Monthly Weight Monitoring

When looking at the nurses' competence level in terms of monthly weight monitoring in children, (n= 101; 93.5%) of nurses indicated having a "Good" competence level, with (n=04; 3.7%) indicated their competence level as "neither good" nor "bad" (*Acceptable*), whereas (n=3; 2.8%) of the nurses indicated that they have a "Poor" competence level.

Sub-theme 4.4: Determination of Monthly ART Supply

In terms of the nurses' competence level in terms of the determination of the monthly ART supply in children, (n= 101; 93.05%) of nurses indicated having a "Good" competence level,

with (n=4; 3.7%) indicated their competence level as “neither good” nor “bad” (*Acceptable*), whereas (n=3; 2.8%) of the nurses indicated that they have a “*Poor*” competence level.

Sub-theme 4.5: The Management of Missed Appointment Dates

When looking at the nurses’ competence level in terms of the management of missed appointment dates in children on ART, (n= 99; 91.07%) of nurses indicated having a “*Good*” competence level, with (n=5; 4.6%) indicated their competence level as “neither good” nor “bad” (*Acceptable*), whereas (n=4; 3.7%) of the nurses indicated that they have a “*Poor*” competence level.

Sub-theme 4.6: The Recognition of Treatment Failure

When looking at the Nurses’ competence level in terms of the recognition of Treatment Failure (TF) in children on ART, (n= 90; 83.03%) of Nurses indicated having a “*Good*” competence level, with (n=12; 11.1%) indicated their competence level as “neither good” nor “bad” (*Acceptable*), whereas (n=4; 3.7%) of the Nurses indicated that they have a “*Poor*” competence level.

Sub-theme 4.7: The Management of Unsuppressed Viral Loads (VLs)

When looking at the nurses’ competence level in terms of the *management of Unsuppressed Viral Loads (VLs) in Children* on ART, (n= 89; 82.4%) of nurses indicated having a “*Good*” competence level, with (n=15; 13.9%) indicated their competence level as “neither good” nor “bad” (*Acceptable*), whereas (n=4; 3.7%) of the nurses indicated that they have a “*Poor*” competence level.

Sub-theme 4.8: Antiretroviral Therapy (ART) Dispensing in Children

When looking at the nurses’ competence level in terms *ART Dispensing in children* on ART, (n= 98; 90.8%) of nurses indicated having a “*Good*” competence level, with (n=7; 6.5%) indicated their competence level as “neither good” nor “bad” (*Acceptable*), whereas (n=3; 2.8%) of the nurses indicated that they have a “*Poor*” competence level.

Sub-theme 4.9: Antiretroviral Therapy (ART) Dosing in Children

When looking at the Nurses' competence level in terms of *ART Dosing in Children* on ART, (n= 97; 89.9%) of Nurses indicated having a "Good" competence level, with (n=8; 7.4%) indicated their competence level as "neither good" nor "bad" (*Acceptable*), whereas (n=3; 2.8%) of the Nurses indicated that they have a "Poor" competence level.

Theme 5: Nurses' Experiences and Perceptions of Managing Children on ART

This section presents findings on the investigation of the perceptions and experiences of NIMART-trained PNs in the management of children on ART. The first part of the section that follows below deals with the findings on the perceptions of the NIMART-trained PNs in the caring and management of children on ART. This is followed by presenting the findings on the nurses' experiences of caring for and managing children on ART.

Sub-theme 5.1: Nurses' Perceptions of Caring and Managing Children on ART

The participant Nurses were requested to share their perceptions about children's overall caring and managing process on ART. And their response to this question, "Caring for children living with HIV/AIDS on ART is more stressful than caring for other patients," is as depicted in **Table 5.9** below, wherein (n=62; 57.41%) of the NIMART-trained PNs agreed that the management of children on ART is more stressful than the management of other patients, with only (n=41; 37.96%) Nurses' saying that the management of children on ART is not stressful, and (n=5; 4.63%) of Nurses not sure whether it is stressful or not.

Table 5.9: Participant nurses' perceptions of the management of children under 15 years on ART

Sub-district	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree	Total
Ba-Phalaborwa	1	8	0	9	2	20
Greater Giyani	1	32	1	2	1	37

Sub-district	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree	Total
Greater Letaba	7	1	0	4	3	15
Greater Tzaneen	1	7	4	5	4	21
Maruleng	0	4	0	10	1	15
Total	10	52	5	30	11	108

Theme 6: Nurses' Experiences of Caring and Managing Children on ART

When the NIMART- trained nurses were asked if they had children on ART who miss scheduled appointments in their clinics, their responses clarify that (n=97; 90%) of the nurses agreed to have children in their public clinics who miss scheduled appointment dates, with only a 10% (n=11) of the nurses mentioning that they do have this type of cases in their clinics. Furthermore, the above stated 90% of nurses who mentioned having children who miss scheduled appointment dates in their clinics were further requested to clarify "what in their opinion/understanding could be the factors associated with children missing scheduled appointment(s)". The responses to this question were elicited through an instrument called the questerview. The responses obtained through the questerview from 108 NIMART-trained PNs were thematically analysed using a NVivo version 12 software. The emergent themes and subthemes from this theme were categorised into the following three main themes: (6.1) the existence of social-related factors, (6.2) the existence of Health System -related Factors, and (6.3) the existence of Caregiver-Related Factors. The majority of the respondents indicated that from their experience of managing children on ART, these factors contribute to children missing scheduled appointment dates: **Table 5.10** below presents a summary of the emergent themes, subthemes, and codes observed.

Table 5.10: Themes, sub-themes and codes obtained from the data analysis

Theme	Sub-Themes	Codes
6.1 The existence of social-related factors	Perceived lack of caregiver support	<ul style="list-style-type: none"> • Most of the children who are taking ART are orphans • their guardian are careless • guardians not involving themselves in their children's care.
	Observed fear of stigma amongst caregivers	<ul style="list-style-type: none"> • Negligence of parents/unsupportive parents • Lack of re-enforcement or encouragement to children to come on their scheduled dates because of stigma.
	Observed lack of HIV status disclosure by caregivers	<ul style="list-style-type: none"> • Most of the children don't know why they are taking ART. • Lack of information about their condition.
6.2 The existence of Health System - related Factors	Observed lack of treatment literacy amongst caregivers.	<ul style="list-style-type: none"> • Inability to read scheduled visit dates. • negligence of caregivers
	Experiencing challenges relating to children attending of School	<ul style="list-style-type: none"> • Children coming late from school. • Children attend school during the week.
	Observed lack of health literacy/information between the caregivers and the children on ART.	<ul style="list-style-type: none"> • Less information and ignorance.

Theme	Sub-Themes	Codes
6.3 The existence of Caregiver- Related Factors	Perceived caregivers' over commitment	<ul style="list-style-type: none"> • Over committed caregivers/guardian
	Observed caregivers' forgetfulness	<ul style="list-style-type: none"> • Caregivers forget their return dates • Parents forget appointment dates

Each of the above factors is clarified and supported through the presentation of verbatim statements obtained from the participants in the following subsections below:

Theme 1: The existence of social-related factors

Three subthemes emerged under this theme. These were: Lack of caregiver support, stigma and lack of disclosure. Examples of participants' responses are given in the following paragraphs below:

Perceived lack of caregiver support: According to **P27**, a contributing factor to missed scheduled appointment dates by children on ART is simply that some children are faced with "*negligence of caregivers*", whereas some participants mentioned that since "*Most of the children who are taking ART are orphans, their guardians are just careless*" [**P87**].

Observed fear of stigma amongst caregivers: The participant nurses also mentioned the lack of HIV status disclosure as one of the identified factors associated with children missing their scheduled appointment dates at the clinics, and this is further seen by the participants to be caused by the guardian's fear of children being stigmatised at school and in the community. An example is that by **P81**, who indicated that: "*Negligence of parents/unsupportive parents who do not re-enforce or encourage their children to come on their scheduled dates because of stigma*".

Observed lack of HIV status disclosure by caregivers: **P1** revealed that caregivers or parents do not disclose the HIV status to their children. The participant's statement

exemplified this: “*Most children do not know why they are taking ART*”. Furthermore, **P103** indicated that “*the children have a shortage of information about their condition*”.

Regarding the identified existence of social-related factors, observations of the participants in this study are similar to findings of a Systematic Review (SR) that was conducted in 2019 in Sub-Saharan Africa (SSA), which indicated that HIV status disclosure to children is pretty low in sub-Saharan Africa. This was therefore identified to be as a result of numerous factors such as parents’/caregivers’ fear of the child disclosing their HIV status to others; parent’/caregivers’ lack of knowledge on how the disclosure should be carried out; and the contention that the child is young and therefore cannot tolerate the psychological impact of their diagnosis (Doat, Negarandeh, & Hasanpour, 2019). Moreover, other reasons for the low rates of the disclosure are therefore found to include, amongst other things, the caregiver’s fear of disclosure affecting the child’s psychological well-being, fear that the child might not keep the diagnosis confidential at school or in the community whilst playing, fear of the caregiver(s) being blamed for infecting the child, stigma, as well as the assertion that the child may be immature to understand the meaning of the disease (Wiener *et al.*, 2007; Gyamfi, Okyere, Appiah-Brempong, Adjei, & Mensah, 2015).

Similarly, in Ghana, poor health outcomes have been recorded for caregivers of children living with HIV, including varying degrees of psychological distress and burden (Wiener, Mellins, Marhefka, & Battles, 2007). Although disclosing HIV status to children on ART is essential for disease management, this is not well considered in resource-limited settings (Vreeman, Scanlon, Mwangi, Turissini, Ayaya, *et al.*, 2014). This study also confirms this finding.

Even though non-disclosure of HIV status results in unsatisfactory health-related outcomes in children living with HIV, such as poor adherence and psychological wellbeing (Nichols, Steinmetz, & Paintsil, 2017; Gyamfi *et al.*, 2015.), which can have detrimental effects that can significantly affect the health of infected children, disclosure on its own also has an association with caregiver outcomes such as the burden of care and psychological health (Gyamfi, Okyere, Enoch, & Appiah-Brempong, 2017; Karthik, Kumar, Keswani, Bhattacharyya, Chandar, *et al.*, 2014). Likewise, in Ghana, poor health outcomes have

been recorded for caregivers of children living with HIV (Wiener *et al.*, 2007), including varying degrees of psychological distress and burden similar to findings from other sub-Saharan African countries (Gyamfi *et al.*, 2017; Ammon, Mason, & Corkery, 2018).

Theme 2: Health System Factors

Health System-related factors that the NIMART-trained PNs identified as inhibiting the children's on-time pill pickup included issues such as the caregiver's *Poor Treatment Literacy*, "*School Attendance*", and "*Lack of HIV status disclosure*", which is seen to be brought forth by caregivers and children being 'uninformed about their medical conditions'. Hence, from the close analysis of the participant's responses, the following observations were made:

Poor Treatment Literacy of the caregiver and the child on ART has also been a contributing factor to children not honouring scheduled appointment dates. Some caregivers do not take the child's condition seriously because of the "*Lack of information given to the patient/caregiver*" [P101].

Many participants identified school Attendance as a barrier to children missing their scheduled appointment dates because most of these children have to attend school on the days they are supposed to be visiting the clinic for their monthly follow-up. This is supported by the view of **participant 99**, who states that children miss scheduled appointment dates because the "school schedule is against clinic dates". This participant clarifies that the reason school attendance becomes a barrier to these children is because "Most of them (children) are at school and their school programme clashes with their appointments at the clinic" [P95].

Uninformed Child. This is also one of the reasons identified by some participants as a contributor to most children missing their scheduled appointments. **Participant 1** mentioned that "*Most of the children don't know why they are taking ART, which affects their treatment adherence practices.* This agrees with the view from [P92] that most children "*Lack information about their condition*", which makes them rebellious, and hence they do not adhere to the clinic schedule.

Health literacy is generally critical to the appropriate treatment of HIV/AIDS infection (Palumbo, 2015). Hence, poor health literacy has been usually described as a solid barrier to accessing healthcare services. Moreover, it is assumed to affect medication adherence and compliance with medical prescriptions (Kalichman, Cherry, Kalichman, Amaral, White, *et al.*, 2013). For this reason, limited health literacy has been associated with inadequate management of long-term conditions like HIV/AIDS. Therefore several authors argue that health literacy has been an overlooked factor, especially when dealing with HIV/AIDS.

Palumbo (2015) highlights fascinating facts addressing the effects of poor health literate patients. The study clarifies what lack of health literacy does to patients and caregivers of people living with a medical condition. Even though the effects of health literacy on the health conditions of people living with HIV infection are still poorly understood, it is depicted as a social barrier to access healthcare, which in turn paves the way for greater illness severity and thus impairing health conditions.

Low health literate patients living with HIV infection are expected to show insufficient knowledge of their health status, which produces low compliance with clinical prescriptions, inadequate treatment awareness, and poor medication adherence. Inadequate health literacy concurs in deepening the stigma attached to concealable health conditions, such as HIV. Consequently, limited health literacy engenders a biased and uncomfortable relationship between the patients and care providers.

Findings from a study conducted in SSA reports that the predictors of poor adherence in children on ART included changing residence, school attendance, and lack of HIV disclosure to children aged nine to 15 years (Haberer, Cook, Walker, Ngambi, Ferrier, Mulenga, Kityo, Thomason, Kabamba, Chintu, & Gibb, 2011). Another study conducted in Cape Town revealed school commitment, strained teacher-learner relationships, negative household dynamics, and ill-treatment by non-biological caregivers as significant barriers to adherence (Davids, 2017).

Most responses from the participants highlighted an issue of conflict between the school schedule and the clinic visit dates. This is concerning as this study reports similar findings to the study conducted in Cape Town by Davids (2017), which noted conflicted commitments to school attendance and making clinic appointments as a barrier to adherence. In addition, findings of this study revealed that the need to communicate attending regular clinic visits to teachers posed a significant barrier to attending regular clinic follow-ups as they feared unintended disclosure, which may lead to stigma and discrimination. The study's findings agree with the literature, which suggests that mainstream schooling may not necessarily always have a positive impact on adherence (Haberer, 2011, Davids, 2017 and Van Wyk, & Davids, 2019). In this study, it became apparent that schooling also made clinic visits difficult. Hence, similar to a conclusion drawn by Van Wyk and Davids (2019), it can be observed that some participant nurses felt that missing clinic appointments were due to the suspicion that frequent absences of school-going children resulted from the fear that clinic visits may lead to unintended disclosure of their HIV status.

Furthermore, in a related study, Cunha, Galvão, Pinheiro, and Vieira (2017) indicate that problems associated with being uninformed also affect treatment success and engendering significant risk of misinterpretation of the expected outcomes of HIV treatments, dosing errors, and overall poor medication adherence. Hence, Cunha *et al* (2017) maintain that poorly informed patients perceive poor self-efficacy dealing with their health conditions, are further not willing to be involved in the provision of care and are not aware of the determinants of well-being.

Theme 3: Caregiver Related Factors

Within this third theme, it was observed from the participants' responses that the other to children's lack of adherence include the **Caregiver's over-commitment** and **Forgetfulness**.

Concerning the first subtheme, the majority of the participant nurses' responded simply by mentioning that the reason most children miss scheduled appointment dates is that "*their caregivers get too committed and forget their return dates*" **P12**. This point is further

strengthened by the response from **Participant 26**, who mentioned that her observation of this practice is that *“it normally happens because caregivers often get committed with the many responsibilities they face throughout their daily lives”*.

More than 20 of the participants indicated that this often results from the fact that “parents and caregivers forget their children’s return dates to collect their medication”. For example, this was evident from the responses of the following participants:

That, nurses, believed that *“caregivers forget their return dates, (P32)* and that following **P39**: *“Parents forget”*. This assertion was further emphasised by **P50**: who indicated that *“Parents forget their dates”*.

In trying to get to the root cause of the caregivers’ noted practices, namely, being overly committed, being negligent, and most children missing scheduled appointment dates due to school attendance. The NIMART-trained PNs were further asked if they do involve parents/caregivers of these children when they schedule appointment dates. The responses to this question are summarise in **Table 5.11** below. From the Table, t can be observed that the majority (n=96; 89%) of the nurses disagreed, which means that caregivers do not have a say in deciding whether the next appointment date is suitable for them or not.

Table 5.11: Nurses responses to the involvement of caregivers in scheduling an appointment

Participants' Age Category	Participants' Responses					Total
	Strongly Agree	Agree	Undecided	Disagree	Strongly Disagree	
21-29 Years	0	0	2	4	7	13
30-39 Years	0	1	1	5	12	19
40-49 Years	1	1	0	11	24	37
50-59 Years	0	0	6	7	22	35
60 Years & above	0	0	0	1	3	4
Total	1	2	9	28	68	108

When it comes to the caregiver related factors, the themes that emerged were over-commitment and forgetfulness by caregivers, and as a result, children on ART miss appointments/ return dates. It is important to note that the whole issue of caregivers forgetting children's return dates has in some studies been linked to the caregiver's lack of social support. It was apparent in previous studies that some form of adult supervision, even with adolescents, was necessary for optimal levels of adherence (Musumari, Feldman, Techasrivichien, Wouters, Ono-Kihara, *et al.*, 2013). Given how frustrated many of these children become regarding their regimens, without strong psychosocial support or reminders of the continued importance of medication from caregivers, the consequence is that children would often skip doses.

According to Ochieng, Kitawi, Nzomo, Mwatelah, Kimulwo, *et al.*, (2015), caregivers acknowledged that when they were not around, their child was more likely to miss a visit to the clinic to collect their medications. A complicating factor in this scenario was that most caregivers had no other adults to assist them with managing children's visits to the health centre. Even in cases where extended family is available, caregivers are highly reluctant to ask for assistance with a simple issue as being reminded about the child's next visit. Ochieng *et al* (2015) contend that this is often due to stigma that causes caregivers to be fearful of disclosing the child's HIV status to other family members or friends. Instead, they become unwilling or unable to recruit others for additional assistance.

Similar to the findings in this study, the results of a project conducted by Fetzer, Mupenda, Lusiana, Kitetele, Golin and Behets (2011) revealed that the act of forgetting was also mentioned by both children and adult caregivers and tied heavily into lack of adult assistance with reminders to revisit the health care centre or clinic. It was described as "easy" or "common" to forget to go to the clinic to collect medications by the children. Children were often preoccupied with their social lives and recreational activities and would rather postpone visiting the health centre. Though taking medication was, on their admission, a priority for most children, unless the adult was vigilant or strategies for remembering return dates were in place, forgetting appeared to occur on a frequent and haphazard basis.

Furthermore, Weiser, Wolfe, Bangsberg, Thior, Gilbert, *et al.*, (2003) report that in Botswana, 31% of the patients on ART found it hard to honour appointment dates due to, among others forgetfulness, and commitments such as travel and looking for means to get food. Similar findings have also been reported in the Democratic Republic of Congo, Zambia, Uganda, Kenya and Tanzania (Hardon, Akurut, Comoro, Ekezie, Irunde, *et al.*, 2007; Wanyama, Castelnuovo, Wandera, Mwebaze, Kambugu, *et al.*, 2007; Tsai, Bangsberg, & Weiser, 2013).

The participants in this study further reported that children on ART run out of their ARVs and have no one to remind them about going to the clinic for a refill. Some eventually defaulted, especially if they had missed taking treatment for an extended period.

Participants also intimated this forgetfulness to take the child to the clinic to refill a high alcohol intake among caregivers. Although the latter was not repeatedly mentioned in the current study, it is of significant concern since the area in which the study was conducted is profoundly rural and is also, according to Makhubele (2017), characterised by unemployment and high use of hazardous substances in homemade alcohol. The finding on forgetting due to the use of substances is similar to previous studies that attributed patient defaulting to forgetfulness due to alcohol and drug use (Kranzer, Lewis, Ford, Zeinecker, Orrell, *et al.*, 2010; as well as Scholl, Zill, Härter, & Dirmaier, 2014).

Next, the study sought to establish the NIMART-trained PNs' understanding of the implications for the children missing appointments. Hence, a question was posed to them to indicate their views and perceptions regarding the implications of missed appointment dates. The following section presents the findings in this regard.

Theme 7: Nurses Perceptions and Views on Missed Appointment

Themes, Sub-themes and Codes that emerged from the analysis show that the nurses' perceptions and views about the implications of children occasionally missing scheduled appointment dates are as depicted in **Table 5.12** below.

Table 5.12: Summary of themes, sub-themes and codes that emerged on the implications of missed scheduled appointment dates

Theme	Sub-Theme	Codes
Nurses' Perceptions & Views of the Implications of Missed Appointment Dates	7.1 Observed non-adherence practice	<ul style="list-style-type: none"> • Medication will run out • Medication will finish • Indicates poor compliance to treatment • Non Compliance with ART
	7.2 Identified poor clinical outcomes	<ul style="list-style-type: none"> • Unsuppressed VLs • Development of OIs • Development of Drug Resistance(DR)

As the table above indicates, two themes emerged from this exercise. The first was an **observed non-adherence practices**, and the second was an **identified poor clinical outcomes**.

Concerning the first theme, **observed non-adherence practices**, this is what most respondents had to say:

P2 indicated that the “*Missing of appointments indicates poor adherence to treatment*”, and the reason is that if patients miss scheduled appointments “, *Their medication will be finished*” [**P1**]. Furthermore, while responding to the same question, **P35** indicated that when the treatment runs out, this “... may result in missing doses, which will allow the virus *to replicate*”. Meanwhile, **P57** pointed out that this “...*indicates poor compliance to treatment which may lead to unsuppressed viral load due to missed treatment doses*”. A statement by **P75** affirmed that the

missing of scheduled appointments “*It’s a sign that these children are not complying on ART.*”

Regarding the issue of **identified poor clinical outcomes**, the NIMART-trained PNs indicated in their responses that:

- 1) **A high viral load is a sign of viral unsuppression.** This was supported by statements such as **P43**, who indicated that “*Those missing appointments end up having high viral loads and are susceptible to opportunistic infections*”. This was echoed by **P44**, who indicated that “*Most of the children who missed appointments do develop virological failure and also have opportunistic infections.*”
- 2) **Leads to the development of Drug Resistance (DR).** This was indicated by **P94**, who said: “*Patient can develop resistance to treatment and viral load will go up*”. Whereas **P105** added and said: “*If prolonged, missing appointments will lead to resistance and illness and the result is regimen change*”. This was in agreement with what **P107** also said: “*The viral load will not be suppressed, and the child is at risk of developing resistance*”. This view was also emphasised by P108, who mentioned that when missing scheduled appointment dates: “*There is a risk of developing viral resistance and hence lead to virologic failure*”.
- 3) **Causes Opportunistic Infections (OIs).** This was echoed by the responses such as the one from **P51** who indicated that “*When the child misses the appointment date treatment gets finished, and as a consequence, they default and this may cause the viral load to be high and opportunistic infections*”. This was further explained by **P7**, who indicated that when a child miss scheduled appointments, nurses are: “*Unable to monitor progress and unable to identify opportunistic infection on time, poor viral load suppression.*”

Generally, studies (for example, Arrivé, Anaky, Wemin, Diabata, Rouet, *et al.*, 2005; Bikaako-Kajura, Luyirika, Purcell, Downing, *et al.*, 2006; Davies, Boulle, Fakir, Nuttall & Eley, 2008; Biressaw, Abegaz, Abebe, Taye & Belay, 2013; Eyassu, Mothiba, & Mbambo-Kekana, 2016 as well as Martelli, Antonucci, Mukurasi, Zepherine, & Nöstlinger, 2019) concur with the emergent theme in this study in that they too have observed that adherence to antiretroviral treatment is a crucial challenge for HIV care in children. Furthermore, among children and

adolescents living with HIV, lower levels of adherence have been reported across rural settings in Côte d'Ivoire (Arrivé *et al.*, 2005); Uganda (Bikaako-Kajura *et al.*, 2006); Ethiopia (Biressaw *et al.*, 2013); South Africa (Davies *et al.*, 2008 as well as Eyassu, Mothiba & Mbambo-Kekana, 2016) and Malawi (Martelli, 2019). In most of the cases listed here, this has been associated mainly with missing scheduled appointments for the monthly collection of ART refills. In addition, most cases lament the issue of caregiver factors that have been shown to impact the outcomes of child patients, especially in resource-limited settings.

Looking at the findings presented above, it is evident that the nurses understood the fact that missing scheduled appointments is a sign of non-adherence, and if prolonged and left unchecked, it may result in children presenting with poor clinical outcomes such as high VLs, leaving the children prone to Drug Resistance (DR) development which will, in turn, open leeway for the development of OIs.

Indeed, other findings from similar studies looking into the effects of HIV non-adherence in children show a similar pattern to the themes that emerged in this study. For example, a cross-sectional research study conducted among 210 children on ART and their caregivers in Addis Ababa by Biressaw *et al* (2013) found that the level of adherence was unacceptably low. The researcher also reported that this was due to children missing appointments and consequently missed doses. Similar to the finding in this study, the primary reason for missing appointments was related to caregivers' forgetfulness. Reporting on adherence to antiretroviral therapy among children in Cape Town, Reddi, Leeper, Grobler, Geddes, France, *et al* (2007) indicated that 10 percent of children missed clinic appointments which led to non-adherence. Similarly, in Côte d'Ivoire and Uganda, approximately one-third of caregiver-children were reported to have missed ART doses due to missed clinic visits resulting in non-adherence (Davies, *et al.*, 2008).

Studies further indicate that the quality of HIV outcomes depends upon patients' adherence to recommended treatment regimens. However, this does not mean that the researcher in this study disregards that adherence is highly dependent on their caregivers for most children. It is, therefore, noted that patient non-adherence can be a pervasive threat to the health and wellbeing of patients on ART, and it can result in debilitating consequences when OIs have a chance for proliferation (Kacanek, Angelidou, Williams, Chernoff, Gadow, *et al.*, 2015). It has

also been revealed by several studies elsewhere (for example, Reddi *et al.*, 2007; Davies *et al.*, 2008 and Martelli, 2019) that for patients on ART, more than 20% of patients sustain significant risks by misunderstanding, forgetting, or missing appointments.

The responses from the NIMART-trained PNs in this study also indicated their knowledge and understanding of this challenge. For instance, the themes presented above reveal that the nurses were concerned that non-adherence among children on ART could lead to a high viral load which, according to the nurses, is a clear sign of viral unsuppression. The nurses also indicated that non-adherence leads to the development of DR and causes fertile conditions for OIs. Similar to these findings, earlier research by Kalichman, Kalichman, & Cherry (2017) also revealed that ART non-adherence among patients threatens viral suppression, provides a conducive environment for high viral replication and poses a substantial risk for developing the resistant virus.

In the next section, the theme deals with findings to an inquiry of the NIMART-trained PNs' views on monthly monitoring.

Theme 8: Nurses Views on Monthly Weight Monitoring

To further elicit responses on the nurses' views, the question: "*Do you think it is necessary to ensure that the amount of ARVs dispensed is going to last the child until the next appointment date?*" During the analysis, the following codes emerged: Weight-based dosing, Useful growth monitor, Monitor treatment success, Proper child management, Helps with quantity determination, and Help with dose determination. Taken together, the codes indicate that most of the NIMART-trained PNs have an understanding of the importance of monthly weight monitoring for children on ART. This understanding is best summed up in **Figure 5.33** below.

Codes

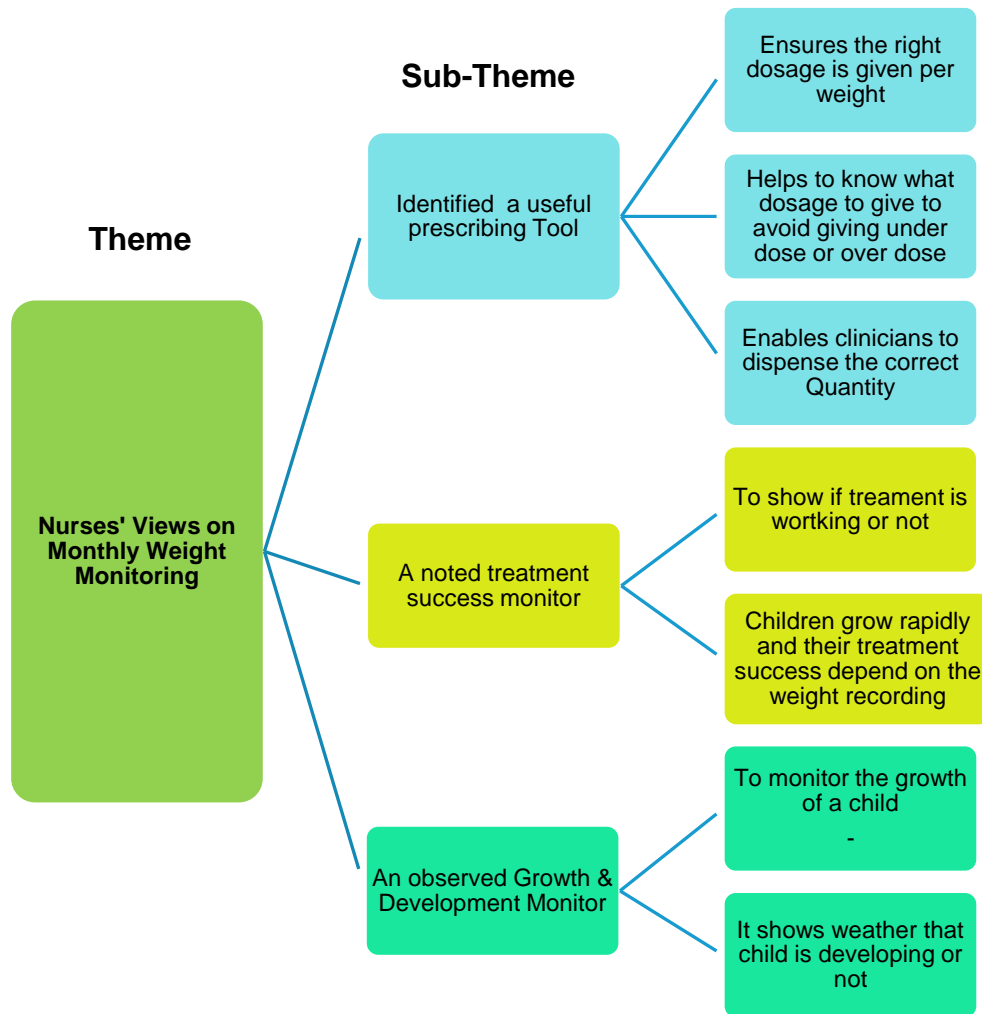


Figure 5.33: Emergent theme, sub-themes and codes - Nurses' views on weight monitoring

The **theme** that emerged from this question is the Nurses' knowledge and understanding of monthly weight monitoring in children on ART. This theme had three **Sub-themes** linked to it as follows;

Firstly, a sub-theme noted is that monthly weight monitoring in children on ART is that most NIMART-trained PNs have identified monthly weight monitoring in children on ART as a **useful prescribing tool** in that it helps the nurses with the correct **Dose Determination**. For instance, **P18** said that "*It is important [to do weight-based dosing] as it allows us as clinicians to monitor a child's growth and give the right dosage of treatment*". **P21**, on the other hand, indicated that "*It helps and ensure the right dosage is dispensed according to the weight of a child*". In addition, **P54** indicated that "*Weight*

[dosing] helps the nurse know what dosage to give to a child and also calculate how much to dispense". Furthermore, it helps the nurses determine **a correct monthly treatment supply**. Where **P103**, for example, mentioned that 'when doing weight-based dosing', *"You get the exact amount of medication to give to a patient"*. On the other hand, **P104** said that through this, *"One can know how much of what to give"*. **P108** mentioned that *"You know exactly how much of what to dispense"*.

The second sub-theme that emerged from the nurses' responses was that **monthly weight monitoring in children is noted by the NIMART-trained PNs as a good treatment success monitor**. According to **P8**, it shows the nurses *"whether treatment is working or not"*. Furthermore, **Participant 20** mentioned that monthly weight monitoring is necessary *"because children's weight increases rapidly and their treatment success depends on the weight recording"*.

A third sub-theme that emerged was that monthly weight monitoring in children on ART has been observed by the nurses to be **a useful Growth and Development (GD) monitor**. In this regard, **P8** had this to say: *Weight-based dosing is essential "to determine if the child is losing weight or gaining and showing to us if the treatment is working"*. Meanwhile, **P11** indicated that *"It allows clinicians to monitor growth and development of a child"*. Another participant (**P87**) mentioned that *"Monthly weight determines the dosage of medication that children should take daily; by monitoring, we want to see whether the child has gained weight or not. If the child gains weight, we will have to increase the dose. If the child loses weight, we decrease."*

The responses in **figure 5:34** below from the NIMART-trained PNs highlight a clear understanding of the importance of weight monitoring in children on ART because the treatment for children is weight-based. Most of the nurses' responses showed that monthly weight monitoring is a valuable growth development and treatment success monitor or tool. For instance, Participant 19 had this to say: *"Because children weight increase rapidly and their doses are based on their weights"*. Doing this helps determine the correct dose and the correct monthly supply for children on ART.

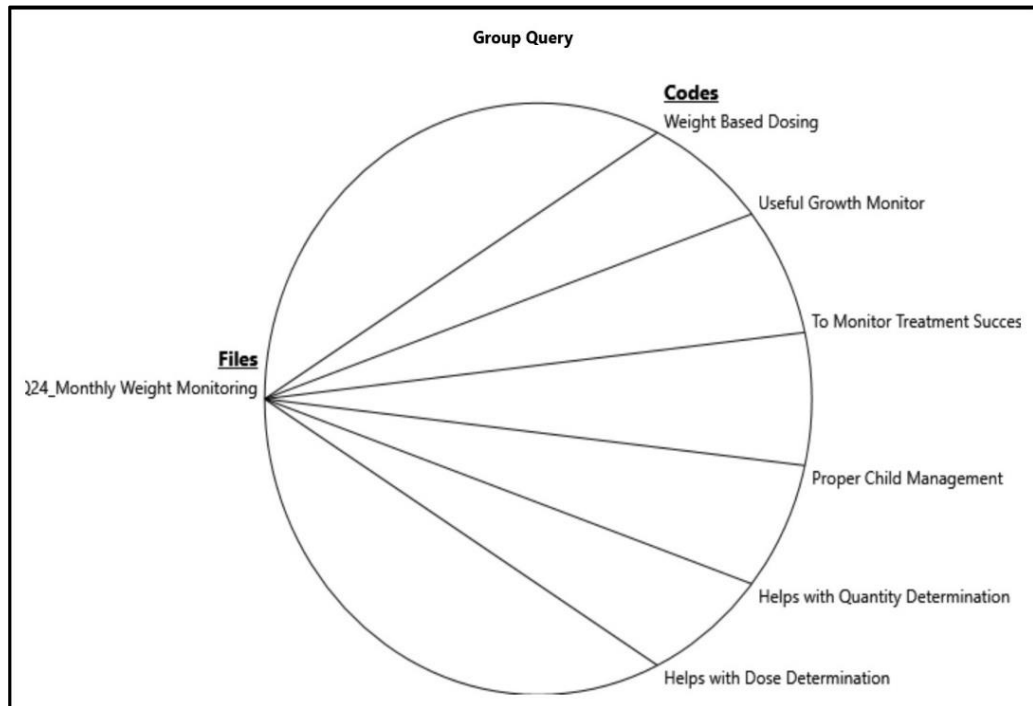


Figure 5.34: Emergent codes - Exploration of nurses' views on weight monitoring

It is important to note that, weight monitoring promotes child health and serves as a service delivery strategy to enhance coverage for crucial ARV-specific interventions (Agbozo, Colecraft, Jahn, & Guetterman, 2018). Hence, Nyavani, Xikombiso and Fhumudzani (2016) concur with the nurse's views in this study. They assert that adequate monitoring of children's weight while on a programme such as ART enables nurses and other caregivers to track changes in the children's weight, thus enabling them to associate the child's weight with overall weight health status. It raises awareness of the importance of growth charts (Nyavani, Xikombiso & Fhumudzani, 2016) and their interpretation (Roberfroid, Pelto, & Kolsteren, 2007). Moreover, optimum focus on weight monitoring increases the ability of healthcare workers to make interventions such as regimen switching when necessary promptly (Ashworth, Shrimpton, & Jamil 2008) and provides avenues for education on medication, nutrition and health (Prado, Jimenez, Vosti, Stewart, Stewart, *et al.*, 2019). It is evident from the forgoing discussion that the NIMART-trained PNs' responses indicate an excellent possession of knowledge and understanding of the importance of weight monitoring in ART child care.

In the next section, the findings of the NIMART-trained PNs' understanding of ART dispensing in children are presented and discussed.

Theme 9: Nurses' Views on ART Dispensing in children

The participant nurses were asked to share their knowledge of whether or not in their understanding it is necessary to ensure that the amount of ARVs dispensed monthly to a child is enough to last until the next scheduled appointment date. The question that guided this part of the inquiry was: 'Do you think it is necessary to ensure that the number of ARVs dispensed will last the child until the next appointment date?'

A majority of the participant's responses to this question highlight a very high level of knowledge and understanding of ART dispensing in children, which is however contrary to the quantitative findings wherein most children were dispensed an inadequate amount of treatment. Several codes emerged from the participants in the responses to this question (See **Figure 5.35** below). These included the following, ranked in order of predominance. To avoid 1) missing doses, 2) viral load unsuppression, 3) to prevent the development of opportunistic infections, to promote 4) treatment adherence, 5) viral suppression, to prevent 6) resistance development, 7) unnecessary transport costs, and the promotion of 8) adherence & viral suppression.

However, of all eight categories of the responses, the most prominent reflected that NIMART-trained PNs understand that they ought to dispense treatment that will last the children until the next appointment date, as this is a useful way to avoid a situation where the children on ART are faced with incidences of 1) missing ART doses, 2) viral load unsuppression, and further assist with 3) preventing the development of opportunistic infections. This is shown through the illustration (**Figure 5.36**), which follows below:

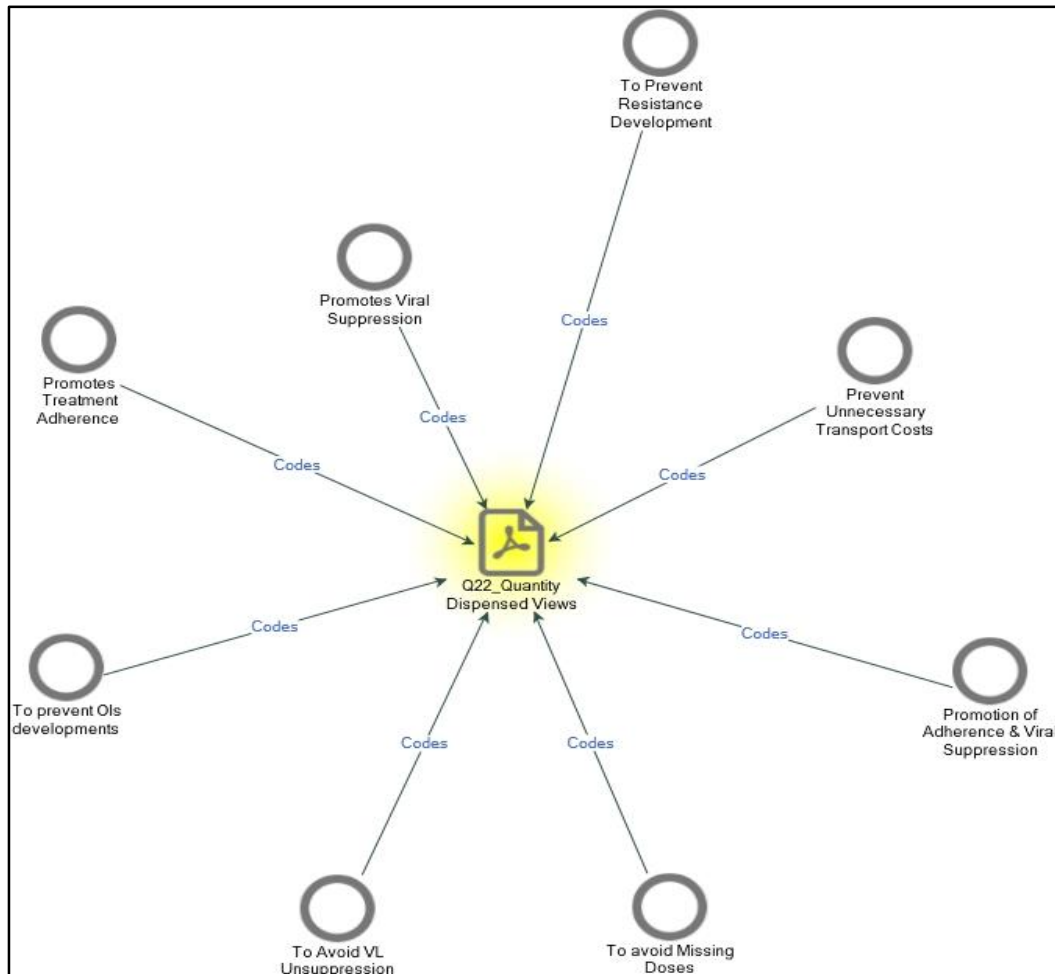


Figure 5.35: Nurses’ ART dispensing views

The Subthemes that emerged from this theme, indicated the nurses’ understanding of the importance of dispensing enough treatment to last the children until the next appointment date, which is contrary to the quantitative results where most children did not receive enough treatment to last them until the next appointment date. Some of the responses that indicate this understanding are as follows:

In substantiation of the reason **‘to avoid missing doses’**, **P7** has this to say: *“No missed doses to be encountered therefore improved viral suppression”*. In addition, **P8** mentioned that *“The child is not supposed to miss the dose, they must take every day on prescribed treatment”*. In the meantime, **P42** added, *“To avoid missing doses before the return date.”*

Another response indicative of the participant's views was **'to avoid viral load unsuppression'**. In this case, **P60** mentioned that *"It is essential to issue enough treatment for the patient because it should be taken daily. Missing treatment may have effects, e.g. unsuppressed viral load ..."*. While another participant (**P90**) responded: *"If they do not have treatment their viral load will be elevated"*.

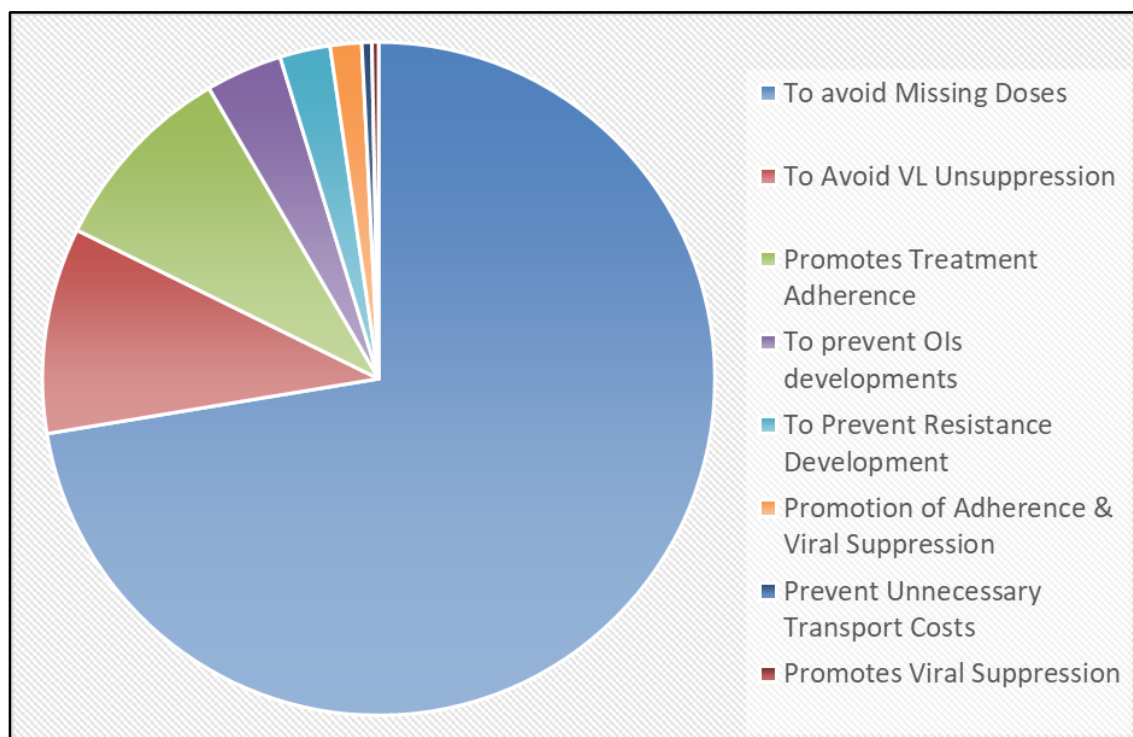


Figure 5.36: Most prominent nurses' ART dispensing views

The nurses also collectively contributed that it is necessary to ensure that enough ARVs are dispensed to patients **'to help prevent opportunistic infections'**. For example, this was evident in the responses of **P10**, who mentioned that *"It is necessary, to avoid unsuppressed viral load and opportunistic infections. Do pill counting."* as well as **P60**, who believed that *"It is crucial to issue enough treatment for the patient because it should be taken daily. Missing treatment may have effects ... and the patient may become prone to opportunistic diseases once viral load rise."*

Similarities exist between this study and other studies. For example, a qualitative study was conducted with patients in Care and Treatment Centre (CTC) clinics located in three

rural and one urban hospital of the Tanzania Kilimanjaro Region (Lyimo, de Bruin, van den Boogaard, Hospers, van der Ven, *et al.*, 2012). The researcher in the study sought, through in-depth interviews, to identify the most relevant determinants of adherence in northern Tanzania. The study found that the CTC clinics run short of medication. In such cases, patients are given an insufficient quantity of their medication. In addition, sometimes the health workers make mistakes and give them a next appointment date that does not correspond with the quantity of ARV medication dispensed. The study concluded similarly to the NIMART-trained PNs in this study that it is necessary to dispense treatment that will last until the next appointment date to avoid missing doses, improve the suppression VLs, and prevent the development of opportunistic infections.

Other studies also provide insight into the detrimental effects of the provision of insufficient ART to last patients until the following appointment dates. These include, for example, (Ridgeway, Dulli, Murray, Silverstein, Dal Santo, *et al.*, 2018), who indicate that this leads to poor ART adherence among children in low-and middle-income countries; Foster, Ayers & Fidler (2020), who mention that this amongst children leads to a high frequency of discontinuation of the prescribed medication. Hence, following Foster *et al.* (2020), the nurses who responded to this issue are correct since it is believed that poorer adherence to ART is possible in children. For children living with HIV infection, poor adherence that may result from insufficient supply of medication may cause two significant challenges: poor health, but also the specific additional burden of onward transmission to future partners (Lowenthal, Bakeera-Kitaka, Marukutira, Chapman, Goldrath, *et al.*, 2014). Worse of all, this may be significantly associated with mortality among children on ART (Foster, Ayers & Fidler, 2020).

The following subsection presents the findings of this study on NIMART-trained PNs' competence in the management of children on ART.

Theme 10: Determining the Nurses Competency in Managing Children on ART

To explore the competency of the NIMART-trained PNs in managing children on ART, the participants were further probed through a case scenario that sought to discover the nurses' comprehension of the implications of ARV under-dosing and the issuing out of an incomplete regimen. It also sought to determine whether or not the nurses have an idea of appropriate strategies to deal with ARV stockouts. Hence, the case scenario was phrased as follows:

Case Scenario: A 23.5kg boy is rightfully on an EFV containing ART regimen and is due for treatment that; according to the 2013 Paediatric Dosing Chart, the boy requires an EFV 300mg Nocte dosage. Whilst assisting the boy, you realise that you only have EFV 200mg in stock, and EFV 50mg, which is also required to make up the 300mg required dose, is out of stock.

This case scenario was followed by the question: *'What will you do to handle this situation?'*

A thematic analysis of the participants' responses revealed two major themes. These are an **observed non-compliance to treatment guidelines** and contrary an identified element of **compliance to treatment guidelines**. Each of the significant subthemes further yielded two sub-themes. These were classified as follows: 'irrational medication prescribing' and 'lack of formulation consideration' for non-compliance to guidelines and 'Do not Issue out treatment' and 'seek advice' for compliance to guidelines. In the analysis conducted, it became evident that the majority of the participants showed a high level of non-compliance to guidelines when faced with a scenario such as the one narrated above. This level of non-compliance is elaborated on through the following **Figure 5:37** below.

From the Figure below, it is evident that the nurses were largely aware that half of EFV 600mg can be given. This was followed by an equal percentage (7.59) indicating that the caregiver can be referred to the Hospital for the out of stock treatment and those who thought that EFV 50mg could be requested from nearby clinics.

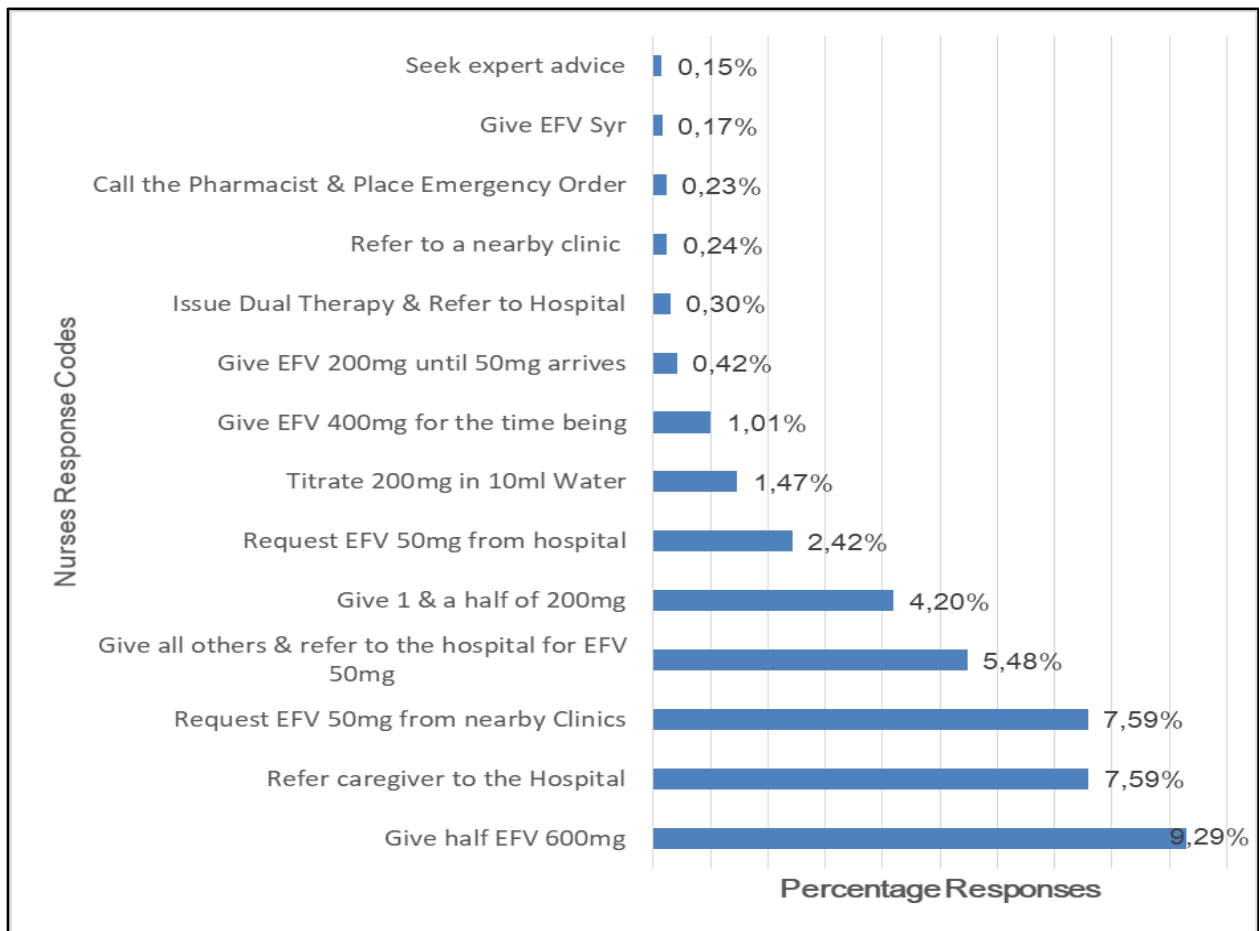


Figure 5.37: Nurses most prominent ART knowledge response codes

The following two options to make the top five were those who opted to give what is available and refer to the hospital to collect what is not available and those who indicated that they would give one and half of 200mg EFV.

Table 5.13 below summarises the classification of the findings from the analysis conducted. It presents the findings in a logical approach that list first the non-compliance issues found to be predominant among the NIMART-trained PNs in this study. Thereafter, the Table presents the subthemes that reflect the issues of compliance to guidelines. Table 16 is preceded by a selection of good responses that were elicited through the instrument administered to the participants in the study.

Table 5.13: Themes, sub-themes, and codes obtained from the case scenario data analysis

Theme	Sub-Theme	Codes
NIMART-trained nurses' non-compliance to guidelines	Observed lack of formulation consideration during prescribing	<ul style="list-style-type: none"> • Issue EFV 600mg & request the caregiver to cut it in half to make 300mg. • Give 1 ½ EFV 200mg • Titrate EFV 600mg or 200mg in 10ml of water & advise the caregiver to give the child 5ml • Titrate EFV 600mg or 200mg in 2ml of water & advise the caregiver to give the child 1ml
	Identified irrational medication prescribing practice	<ul style="list-style-type: none"> • Give ABC+3TC+EFV 200mg & refer to a nearby clinic or hospital • Refer child & caregiver to the hospital for treatment collection • Give Dual Therapy ABC + 3TC & give a referral to take EFV at a nearby clinic or the hospital.
NIMART-trained nurses' compliance to treatment guidelines	Observed non-dispensing of incomplete monthly treatment.	<ul style="list-style-type: none"> • Request missing stock from nearby Clinics • Request stock from the feeder Hospital • Order Emergency Stock from the Hospital
	Identified seeking of expert advice	<ul style="list-style-type: none"> • Consult the Pharmacist • Seek expert advice

Whereas in the subtheme where participants 'knowledge was reflective of 'lack of consideration for formulations', the following are examples of the responses nurses gave:

P92: Said that whenever faced with the above scenario in the clinic, *“I will use EFV 600mg break it into halves, 300mg each half as EFV 200mg is a capsule it cannot be broken into half”*. Whereas **P61** indicated that *“I’ll issue 1 and a half tablet of 200mg of Efavirenz. Discuss with the patient fully that you are going to take 1 and a half tabs of EFV nocte and also count the tabs to ensure that they are enough”*. Another respondent, **P94**, had this to say: *“I will give the child EFV 200mg and discuss with the caregiver to take 200mg and break it into two pieces to make 100mg and take one and a half tablet nocte”*. Furthermore, **P96** indicated that *“If I have EFV 200mg, I will tell the patient to give 200mg and take the other 200mg half then it will make 300mg”*. **P43** said, *“Give 200mg capsule and the other 200mg capsule dissolved in 10 ml of water, the child will drink 5mls of the dissolved capsule plus full 200mg capsule”*. Whereas, **P103** said: *“I will encourage the caregiver to give 200mg EFV in full and dissolve 200mg EFV in 2ml and give 1ml of it to supplement the 200mg to make 300mg dosage.”*

The above responses from NIMART-trained PNs depict a very low understanding of Efavirenz (EFV) drug formulation. Efavirenz is a potent, once-daily Non-Nucleoside Reverse Transcriptase Inhibitor (NNRTI) and the preferred ‘third agent’ in many first-line ARV triple-drug regimens (Coffey, & Volberding, 2012). What is important to note with this drug clinically is that the resistance pattern of EFV overlaps that of other drugs in this class. Hence, even single mutations, especially K103N and Y181 C or Y181 I, can result in a high resistance level (Finch, Greenwood, Whitley, & Norrby, 2010). These are practices that took place in the era of the 2013 Paediatric Dosing Chart in South Africa (SA), which clearly stated that;

*“Currently available formulations of Efavirenz must be swallowed whole and **NOT** chewed, divided or crushed” ~ see **Figure 5.38** below*

EFV is a drug manufactured in the concentrations of 50mg, 200mg capsules and 600mg tablets, respectively. The nurses’ responses above do not show knowledge and understanding of this information nor consideration of the caution or warning given on the dosing chart. EFV 600mg is a film-coated tablet, making halving this type of tablet impossible because it is not scored. In contrast, EFV 200mg is a gelatine coated capsule

which advising a caregiver to half it at home might make the 100mg dose dispersion impossible for them (see **Figures 5.38** below).

	Abacavir (ABC)	Lamivudine (3TC)	Efavirenz (EFV)	Lopinavir/ritonavir (LPV/rtv)	Ritonavir boosting (RTV)	Stavudine (d4T)	Didanosine (ddI)	Nevirapine (NVP)	Zidovudine (AZT)	Target Dose
Target Dose	8mg/kg TWICE daily OR ≥10kg: 16mg/kg ONCE daily	4mg/kg TWICE daily OR ≥10kg: 6mg/kg ONCE daily	By weight band ONCE daily	300/75mg/ml/dose LPV/rtv TWICE daily	ONLY as booster for LPV/rtv when on Rifampicin TWICE daily (0.75xLPV dose bd)	1mg/kg/dose TWICE daily	180-240mg/ml/dose ONCE daily	160-200 mg/ml/dose TWICE daily (after once daily lead-in x 2 wks)	180-240mg/ml/dose TWICE daily	Target Dose
Available Formulations	Sol 20mg/ml Tabs 60mg (scored dispersible), 300mg (not scored), ABC/3TC 600/300mg	Sol 10mg/ml Tabs 150mg (scored), 300mg, ABC/3TC 600/300mg	Caps 50,200mg Tabs 50,200, 600mg (not scored)	Sol 80/20mg/ml Adult Tabs 200/50mg Paeds Tabs 100/25mg	Sol 80mg/ml	Sol 1mg/ml Caps 15,20,30mg	Tab 25,50,100mg (dispersible in 30ml water) Caps 250mg EC	Sol 10mg/ml Tabs 200mg (scored)	Sol 10mg/ml Caps 100mg Tabs 300mg (not scored), AZT/3TC 300/150mg	Available Formulations
Wt. (kg)	Currently available tablet formulations of abacavir (except 60mg), efavirenz, LPV/rtv and AZT must be swallowed whole and NOT chewed, divided or crushed									Wt. (kg)
<3	Consult with a clinician experienced in paediatric ARV prescribing for neonates (<28 days of age) and infants weighing <3kg									<3

Figure 5.38: Efavirenz formulation instruction to healthcare providers

The tablet halving referred to by the nurses in the responses above comes from a pharmacological concept referred to as tablet splitting, a practice where higher strength tablets are broken in half or quarters to provide the patient with the correct dose. This exercise is considered compounding by the pharmacist and is mainly used to make the titration of the required dose possible (Mosen, & Van der Merwe, 2009; Melo, Pereira, Soares, Silva, Taveira, *et al.*, 2020). However, only splitting scored tablets is approved by the FDA as productive and safe. Furthermore, certain types of tablets are generally not suitable for splitting, for example, extended-release formulations and film or enteric-coated tablets (Qi-hua, Xiao-bo, & Shu-jie, 2007, Crawford, 2011).

However, the findings are in agreement with recent observations that nurses are poorly equipped in the dose calculation of EFV in the management of HIV infected children in public clinics (Long, Brennan, Fox, Ndibongo & Jaffray, 2011).

In the subtheme where the participants' knowledge was deemed to be *'irrational medication prescribing'*, the following responses were made:

P84: I will issue "ABC 300mg + 2x60mg ABC, and refer to hospital for collection of EFV 50mg" to this child. Whereas, **Participant P86** said whenever faced with such a scenario, they will "Give what is available and refer to the hospital pharmacy to collect EFV 50mg

tabs". On the other hand, **P87** indicated that *"I will refer the patient to collect treatment at the hospital"*.

In the subtheme where participants were concerned with the fact that 'treatment should not be issued out', the following examples constituted the findings:

Some participants indicated requesting the missing stock from a nearby facility/ clinic. For example, **P52** had this to say: *I will request EFV 50mg around nearby facilities, and if we fail, I will refer to the hospital for collection.* Similarly, **P57** said: *"I will ask the patient to wait while I shop around nearby clinics and pharmacy to give the correct dose"*.

P107: *"I will phone the hospital pharmacy and inform them (the Pharmacist) of the situation, and if they have stock, I will write a referral letter for them to assist the patient with treatment"*. Similarly, **P4** responded that *"I refer to other facilities and order emergency drugs"*. Other participants had this to say: **P19** mentioned that *"I still call other clinics asking if they are having R/X also doing emergency order"* and **P105** mentioned that *"I will call the pharmacy and arrange for emergency order on the same spot, send a driver to go and collect the medication for us to ensure that the client does not leave the facility without medication."*

In the subtheme where participants were concerned with the fact that 'advice has to be sought', the following examples constituted the findings:

P93 indicated that *"I will consult an expert for a suitable alternative"*. **P101** also indicated that *"I will ask treatment to the nearest clinic if not getting will arrange with Pharmacist at the nearest hospital. The mother will come and collect treatment the next day"*. Lastly, **P102** indicated that *"We usually call pharmacist at the hospital if the medication is available we send a driver with a nurse for collection. They deliver for us immediately."*

Stock-outs of ARVs are a huge problem here because of the huge number of patients that keeps swelling all the time at our ART clinic. So the consumption rate of drugs is very high. A Ugandan study with a similar concern revealed that ART clinic managers conceded that stock-outs of ARVs resulted from factors internal to health facilities and drivers from the

external environment. Placing timely orders for ARV medicines was described as critical to ensuring adequate stocks and a regular supply of ARVs (Zakumumpa, Kiweewa, Khuluza & Kitutu (2019).

Zakumumpa *et al.* (2019) reveal that even in other settings, the sharing or 'borrowing' of drugs within peer-provider networks during stock-out events was a frequently reported strategy across health clinics. Hence, they strongly recommend the borrowing of anti-retroviral medicines from peer providers. This is indicative of the fact that the nurses' views are closer to best practice.

Another important point related [to the nurses' views] point from the Ugandan study (Zakumumpa, *et al.*, 2019) is making upward referrals/ referring the patient to the hospital. This is considered a better option because the hospital is often better stocked with ARVs than the clinics (Fonner, Geurkink, Chiwanga, Amiri & Likindikoki, 2021). This means that the nurses view on this should be commended since this action is highly recommended to enable patients' optimum access ARVs.

Nurses' collaboration or consultation with pharmacists in the care and treatment of patients on ART is said to have the potential to improve medication use and reduce adverse drug events (Celio, Ninane, Bugnon & Schneider, 2018). It can promote adherence amongst patients perceived to be at risk of defaulting due to lack of medicines caused by stock-outs in the clinic environments (Rouleau, Richard, Côté, Gagnon & Pelletier (2019). Similarly, though to a smaller extent, some nurses in this study indicated the importance of seeking expert advice and consulting the pharmacist during periods of stock-outs.

5.3 Integration of the Results and Findings

This study used an explanatory sequential design to evaluate the use of ART in children managed by NIMART-trained PNs at public clinics located in the Mopani District of Limpopo Province. This design requires that different datasets obtained from both quantitative and qualitative be collected, mixed and merged after analysis. This approach enabled the researcher in this study to paint a picture of more than what was observed through the quantitative or qualitative inquiries. After this, Creswell (2014) recommends using meta-

analysis to identify areas of convergence or discordance a more comprehensive overview and understanding of the critical themes that linked the NIMART-trained PNs' knowledge, perceptions, and competency.

The merging of the results and findings in this study was achieved through compiling a summary of both sets of inquiry observations in a tabular format to allow for comparison where the quantitative and qualitative aspects were brought together to determine the extent to which corroborations, expansions and or discrepancies, could be made. Hence, this study employed a mixed-methods joint display to present the integration of the results and findings within a single study (Creswell, 2014). The summary was then used to prepare joint displays from which discussions on each of the study objectives ensued (**See Tables 5.14 – 5.17**)

Table 5.14: Summary of the quantitative constructs and qualitative themes that emerged from the study

QUANTITATIVE STRAND	QUALITATIVE STRAND
Results	Findings from self-reported inquiry
Assessment of Baseline Clinical Outcomes	Knowledge and Understanding of NIMART
<ul style="list-style-type: none"> • Very Low Viral Suppression Rate (n=151, 29.26%) • Very High Unsuppression Rate (n=365; 70.74%) • (n=47; 12.88%) of children were excluded from the study due to a lack of information in their medical records. • Poor Recordkeeping. • Switched from the regimen at initiation to another in the first 4 years of treatment (n=357; 97.80%). 	<p>The NIMART-trained PNs reported themselves good the general knowledge and understanding of...</p> <ul style="list-style-type: none"> • NIMART. • ART management in children. • ART dosing in children using the 2013 Paediatric Dosing Chart. • ART dispensing in children. • Monitoring of viral load in children as per HIV/AIDS Guidelines. • Monthly monitoring of children on ART as per HIV/AIDS treatment guidelines. • The recognition of Opportunistic Infections (OIs) in children on ART. • Management of opportunistic Infections in children on ART.
PRESCRIBING PRACTICES	
<p style="background-color: #00AEEF; color: white; margin: 0;">Demographics</p> <ul style="list-style-type: none"> • (n=153; 60%) of the cohort were children of school-going age • (n=20; 8%) of the children NOT clinically staged. 	

QUANTITATIVE STRAND Results	QUALITATIVE STRAND Findings from self-reported inquiry
On-Time Pill Pickup Results <ul style="list-style-type: none"> From 7105 analysable visits only (n=3134; 44.11%) visits were honoured, (n=2828;39.80%) of visits were missed appointments (n=294;4.14%) next appointment date not documented 	
Monthly Weight Monitoring <ul style="list-style-type: none"> Of 7351 clinic visits, body weight only monitored in (n= 5761; 78.4%). (n=1590; 21.6%) of body weights not monitored. (n=1267; 17.2%) body weights not monitored because treatment was CBO (n= 323; 4.4%) body weight not recorded during visits. 	Competency levels on ART Management in Children The NIMART-trained PNs reported themselves good competency level in... <ul style="list-style-type: none"> Regiment Switching ✎ ART regimen selection. Monthly weight monitoring. 😊 Determination of monthly ART supply. Management of missed appointment dates. Recognition of treatment failure. Management of unsuppressed viral loads in children. ART dispensing in children. ART dosing in children on ART.
Correct Regimen?	Perceptions and experiences in the management of children on ART
<ul style="list-style-type: none"> (n= 7045; 95.84%) prescriptions Triple Regimen was prescribed (n=65; 0.89%) were prescribed dual therapy 	<ul style="list-style-type: none"> The management of children on ART is more stressful than the management of other patients. Nurses agreed to have children who miss scheduled appointment dates in their public clinics. Factors associated with children missing scheduled appointment(s) <ul style="list-style-type: none"> Lack of support from caregivers Stigma

QUANTITATIVE STRAND Results	QUALITATIVE STRAND Findings from self-reported inquiry
<ul style="list-style-type: none"> • (n=15; 0.20%) Mono-therapy • 223 prescriptions (3.03%) had no drug prescribed • 0.04% (n=3) cases of 4 drugs having been prescribed 	<ul style="list-style-type: none"> • Lack of disclosure • Poor treatment literacy • School attendance • Uninformed caregiver and child • Over-commitment • Forgetfulness
Dosage Form? <ul style="list-style-type: none"> • (n=15502; 93%) of the prescriptions with correct dosage form • (n=1192;7%) of the dosage forms incorrectly prescribed 	
Correct Strength/Dose?	Views and perceptions of the implications of missed appointment dates
<ul style="list-style-type: none"> • correct dose (strength) in only (n=9539; 76.51%) of the prescriptions. • (n=903; 7.24%) of children received a sub-optimal dose (under-dose) • (n=2025; 16.24%) prescriptions an overdose of the prescribed ART regimen. 	<ul style="list-style-type: none"> • Non-adherence • Poor clinical outcomes
Factors associated with incorrect dosage measurements	<ul style="list-style-type: none"> • Nurses Views on Monthly Weight Monitoring
over-dosing & under-dosing <ul style="list-style-type: none"> • (n=928; 77, 85%) without indicating either prescribed dose or dosing frequency and/or the quantity issued. • (n=106;8.89%) of incorrect doses prescribed, • (n=102; 8.56%) illegible/unclear prescriptions due to bad handwriting. • (n=37; 3.10%) cases of ARV stockouts. 	<ul style="list-style-type: none"> • Ensures the correct dosage is given per weight • It helps to know what dosage to give to avoid giving under/overdose. • Enables clinicians to dispense the correct quantity. • To show if treatment is working or not.

QUANTITATIVE STRAND Results	QUALITATIVE STRAND Findings from self-reported inquiry
(n=16;1.34%) strength was not indicated because the patient still had treatment at home	<ul style="list-style-type: none"> • Children grow rapidly and their treatment success depends of the weight recording. • To monitor the growth of a child. • It shows whether the child is developing or not.
Correct Dosing Frequency? <ul style="list-style-type: none"> • Total of 15 502 prescriptions - (n=12467; 80%) had a dosing frequency, • (n=3035; 19.58%) of prescriptions without an indication of the dosing frequency. 	Nurses' understanding of ART Dispensing in children <ul style="list-style-type: none"> • Lack of formulation consideration • Irrational medication prescribing • Non-dispense treatment • Seek advice
Correct Quantity Supplied <ul style="list-style-type: none"> • Total of 15 502 prescriptions only (n=7449; 48%) indicated the amount/quantity of ART issued, • (n=8053; 52%) did not indicate the amount dispensed. • Only (n=2883; 38.70%) children received an adequate amount of treatment to last them until the next appointment date, • (n=2927; 39.30%) prescriptions were undersupplied, • (n=1195; 16%) prescriptions received over-supply. 	
Regimen Switching <ul style="list-style-type: none"> • The findings revealed the NIMART-trained PN's regimen switching practices in this cohort of children. • 293 (82.07%) regimen switches took place, 	

QUANTITATIVE STRAND	QUALITATIVE STRAND
Results	Findings from self-reported inquiry
<ul style="list-style-type: none"> Of 293 switches, only (n=21; 7.17%) were really switched from the regimen at initiation to another one; (n=272; 76.19%) were regimen hopping. 	

The following **Table 5.15** provides a joint display of the results derived from Phase 1A of the study.

This phase of the project sought to achieve the following objective:

- To conduct a four year (01 January 2015 to 31 December 2018) desktop baseline assessment to determine the clinical outcomes of children initiated on ART in public clinics of Mopani District in the year 2015.

The data integration shows where quantitative and qualitative data are consistent and where they have a discordance or discrepancies. The baseline clinical outcomes results for this cohort indicated that in terms of VLS rate, the district was sitting at a mere 29.26% (n=151) by the 31st of December 2018. Furthermore, the TIER.Net data highlighted that a total of (n=357; 97.80%) of children were in the four-year understudy regimen switched, with (n=20; 8%) not clinically staged. These results contradict the qualitative findings as depicted in the nurses' self-ratings in terms of their good knowledge and understanding of NIMART, ART management in children, and their ability to monitor viral loads in children as per the treatment guidelines.

Table 5.15: Joint displays comparing results of baseline assessment and qualitative findings

QUANTITATIVE STRAND	QUALITATIVE STRAND	Outcomes
Results	Findings from self-reported inquiry	
Assessment of Baseline Clinical Outcomes	Knowledge and Understanding of NIMART	Discrepancies

QUANTITATIVE STRAND Results	QUALITATIVE STRAND Findings from self-reported inquiry	Outcomes
<ul style="list-style-type: none"> • Very Low Viral Suppression Rate (n=151, 29.26%) • Very High Unsuppression Rate (n=365; 70.74%) • (n=47; 12.88%) of children were excluded from the study due to lack of information in their medical records. • Switched from the regimen at initiation to another in the first 4 years of treatment (n=357; 97.80%). 	<p>The NIMART-trained PNs reported themselves good the general knowledge and understanding of...</p> <ul style="list-style-type: none"> • NIMART. • ART management in children. • ART dosing in children using the 2013 Paediatric Dosing Chart. • Monitoring of viral load in children as per HIV/AIDS Guidelines. • Monthly monitoring of children on ART as per HIV/AIDS treatment guidelines. • The recognition of Opportunistic Infections (OIs) in children on ART. • Management of Opportunistic Infections in children on ART. 	
PRESCRIBING PRACTICES	Competency levels on ART Management in Children	Discrepancies
Demographics <ul style="list-style-type: none"> • (n=20; 8%) of the children NOT clinically staged 	<ul style="list-style-type: none"> • Recognition of treatment failure. • Management of unsuppressed viral loads in children. 	

This also contradicts their high competence level rating in recognition of treatment failure and the management of unsuppressed viral loads in children.

The following **Table 5.16** provides joint displays of the study's results derived from Phase 1B. This phase sought to achieve the following objectives:

- To explore and describe the prescribing practices of NIMART trained professional Nurses when managing children with unsuppressed VLs on ART in public clinics

of Mopani District, Limpopo Province,

- To assess the NIMART-trained PNs' compliance with the 2015 South African HIV/AIDS guidelines for the treatment of children on ART,
- To identify the factors associated with regimen switching in children on ART managed at public clinics across the Mopani District, Limpopo Province,

Similarly, the data integration shows where quantitative and qualitative data are consistent and where they have a discordance or discrepancies.

Table 5.16: Joint displays comparing quantitative results and qualitative findings

QUANTITATIVE STRAND Results	QUALITATIVE STRAND Findings from self-reported inquiry	Outcomes
Assessment of Baseline Clinical Outcomes	Knowledge and Understanding of NIMART	
<ul style="list-style-type: none"> • Very Low Viral Suppression Rate (n=151, 29.26%) • Very High Unsuppression Rate (n=365; 70.74%) • (n=47; 12.88%) of children were excluded from the study due to lack of information in their medical records. • Switched from the regimen at initiation to another in the first 4 years of treatment (n=357; 97.80%). 	<p>The NIMART-trained PNs reported themselves good the general knowledge and understanding of...</p> <ul style="list-style-type: none"> • ART management in children. • ART dosing in children using the 2013 Paediatric Dosing Chart. • ART dispensing in children • Monthly monitoring of children on ART as per HIV/AIDS treatment guidelines. 	Contradiction
PRESCRIBING PRACTICES	Competency levels on ART Management in Children	
On-Time Pill Pickup Results <ul style="list-style-type: none"> • From 7105 analysable visits only (n=3134; 44.11%) visits were honoured, 	<p>The NIMART-trained PNs reported themselves with high competency levels in...</p> <ul style="list-style-type: none"> • Regimen switching • ART regimen selection 	Contradiction

QUANTITATIVE STRAND Results	QUALITATIVE STRAND Findings from self-reported inquiry	Outcomes
<ul style="list-style-type: none"> (n=2828;39.80%) of visits were missed appointments (n=294;4.14%) next appointment date not documented <p>Monthly Weight Monitoring</p> <ul style="list-style-type: none"> Of 7351 clinic visits, body weight only monitored in (n= 5761; 78.4%). (n=1590; 21.6%) of body weights not monitored. (n=1267; 17.2%) body weights not monitored because treatment was CBO (n= 323; 4.4%) body weight not recorded during visits. 	<ul style="list-style-type: none"> Monthly weight monitoring The determination of monthly ART supply The management of missed appointment dates ART dispensing in children ART dosing in children 	
	<p>Perceptions and experiences in the management of children on ART</p>	<p>Confirmation/Expansion</p>
	<ul style="list-style-type: none"> The management of children on ART is more stressful than ART management in other patients. 	
<p>Correct Regimen?</p> <ul style="list-style-type: none"> (n= 7045; 95.84%) prescriptions Triple Regimen was prescribed (n=65; 0.89%) were prescribed dual therapy (n=15; 0.20%) Mono-therapy 223 prescriptions (3.03%) had no drug prescribed 0.04% (n=3) cases of 4 drugs having been prescribed 	<p>Factors associated with children missing scheduled appointment(s)</p>	<p>Expansion</p>
<p>Dosage Form?</p> <ul style="list-style-type: none"> (n=15502; 93%) of the prescriptions with correct dosage form (n=1192;7%) of the dosage forms incorrectly prescribed 	<ul style="list-style-type: none"> Lack of support from caregivers Stigma Lack of disclosure Poor treatment literacy School attendance Uninformed caregiver and/child Over-commitment Forgetfulness 	

QUANTITATIVE STRAND Results	QUALITATIVE STRAND Findings from self-reported inquiry	Outcomes
Correct Strength/Dose? <ul style="list-style-type: none"> • correct dose (strength) in only (n=9539; 76.51%) of the prescriptions. • (n=903; 7.24%) of children received a sub-optimal dose (under-dose) • (n=2025; 16.24%) prescriptions an overdose of the prescribed ART regimen. 		
Factors associated with incorrect dosage measurements	Nurses understanding of ART dispensing in children	Confirmation/Expansion
over-dosing & under-dosing <ul style="list-style-type: none"> • (n=928; 77, 85%) without indicating either prescribed dose or dosing frequency and/or the quantity issued. • (n=106;8.89%) of incorrect doses prescribed, • (n=102; 8.56%) illegible/unclear prescriptions due to bad handwriting. • (n=37; 3.10%) cases of ARV stockouts. • (n=16;1.34%) strength was not indicated because the patient still had treatment at home 	<ul style="list-style-type: none"> • Lack of formulation consideration • Irrational medication prescribing • Non-dispensed treatment 	

QUANTITATIVE STRAND Results	QUALITATIVE STRAND Findings from self-reported inquiry	Outcomes
<p>Correct Dosing Frequency?</p> <ul style="list-style-type: none"> Total of 15 502 prescriptions - (n=12467; 80%) had a dosing frequency, <p>Correct Quantity Supplied</p> <ul style="list-style-type: none"> Total of 15 502 prescriptions only (n=7449; 48%) indicated amount/quantity of ART issued, (n=8053; 52%) did not indicate the amount dispensed. Only (n=2883; 38.70%) children received adequate amount of treatment to last them until the next appointment date, (n=2927; 39.30%) prescriptions were undersupplied, (n=1195; 16%) prescriptions received over-supply. <p>Regimen Switching</p> <ul style="list-style-type: none"> The findings revealed the NIMART-trained PNs' regimen switching practices in this cohort of children. 293 (82.07%) regimen switches took place, Of 293 switches, only (n=21; 7.17%) were really switched from the regimen at initiation to another one; (n=272; 76.19%) were regimen hopping. 		

The nurses' knowledge and understanding ratings contradict baseline results that show poor clinical outcome performance in the cohort under study. Regarding the attempts to reach the 90% VL suppression target, the district is at (n=151; 29.26%) for this cohort, with over 70% of children virally unsuppressed. Moreover, the nurses' self-reported high competence level ratings in terms of ART regimen switching and the recognition of treatment failure is contradictory to the observations made through the baseline results and the results of the medical record. Firstly, the study established that in 4yrs while on therapy, a total of (n=357; 97.80%) were switched regimens. This result contradicts the finding from the qualitative part of the study that showed nurses' good knowledge and understanding of ART management in children as well as the good competence level in regimen switching. The medical records also add/expand knowledge (through the observed result that clarified that out of all 357 children who were switched from the regimen at initiation, only (n=21; 7.17%) were correctly switched), about the nurses lack of knowledge, because in most of the cases, (n= 272; 76.19%) what was thought to be switching was identified by the researcher as regimen hopping cases. This also expands knowledge about NIMART-trained PNs' ability to manage children on ART.

A closer look at the prescribing practices also reveal contradictory observations between the quantitative results and the qualitative findings, for instance;

- ***On-Time Pill Pickup*** – when looking at the quantitative finding that only (n=3134; 44.11%) of 7105 clinic visits were honoured with (n=2828;39.80%) of visits missed, it is confirmed through the baseline result that (n=153;60%) of the children were of school-going age. This, therefore, proves to be true the issue raised by the nurses in their views about issues affecting children honouring appointments, namely, the nurses' view that 'most children miss scheduled appointment dates due to school attendance'.
- ***Monthly weight monitoring*** – since children's treatment is dosed per weight, it requires monthly weight monitoring, and therefore the qualitative finding that only (n=5761;78.4%) of 7351 analysable clinic visits had body weights monitored contradicts the qualitative finding from the nurses' responses that indicated a good knowledge and understanding of monthly weight monitoring. The same is the case

with the observed high competence level of monthly weight monitoring rating as well as the nurses' views on monthly weight monitoring where they depicted a clear understanding that monthly weight monitoring ensures that: the correct dosage is given; helps them to know what dose to give to avoid under/over-dosing the children and, enables them to dispense the correct quantity of treatment, e.t.c.

- **Correct Regimen** – in this case, the quantitative finding highlights that (n=7045; 95.84%) have prescribed a triple regimen therapy as per the guideline and recommendations. These results confirm the qualitative findings wherein nurses gave themselves a good rating on knowledge and understanding of ART management in children and a high competency level on ART regimen selection.
- **Dosage Form** – the fact that a total of (n=15502; 93%) prescriptions were quantitatively found to have been prescribed the correct dosage form confirms the self-rated good knowledge & understanding and high competence level rating in the qualitative phase.
- **Correct Strength/Dose** – the quantitative discovery that only (n=9539; 76.51%) of the prescriptions were prescribed the correct dose, and (n=2025; 16.24%) of prescriptions were over-dosed, whereas (n=903;7.24%) of prescriptions were under-dosed, contradicts the nurses self-rating of having a good knowledge and understanding of ART management in children, as well as a high competence level of ART dosing in children. Instead, this could also confirm and expand the nurses' perception that the management of children on ART is more stressful than the management of other patients.
- **Correct Dosing Frequency** – in the quantitative results from a total of (n=15 502;80%) prescriptions that had a dosing frequency, inconsistencies were noted in the daily, nocte and bd dosing frequencies. This contradicts the nurses' self-rating of good knowledge and understanding of ART dosing in children.
- **Correct Quantity Supplied** – the quantitative finding that only (n=2883;38.70%) prescriptions were dispensed the correct amount of treatment to take home, with more prescriptions (n=2927;39.30%) dispensed showing an under-supply of treatment, contradicts the nurses' self-rating of good knowledge and understanding of ART dispensing, as well as their self-reported high competence level in the determination of monthly ART supply.

- **Regimen Switching** – it was noted that in a total of (n=293; 82.07%) of regimen switches, only (n=21;7.17%) were correct/real regimen switches with (n=272;76.19%) identified as regimen hopping cases. This contradicts the qualitative findings wherein nurses indicated a good knowledge and understanding and high competence of ART management in children and ART regimen switching, respectively.

In the following **Table 5.17**, a joint display of the findings of the qualitative phase (Phase 2) of the explanatory sequential mixed methods inquiry that sought to achieve the goals set by the following objectives are presented:

- To determine the knowledge, understanding, and competence of NIMART-trained PNs in managing children on ART in public clinics of Mopani District, Limpopo Province,
- To establish the perceptions of NIMART-trained PNs regarding the effective management of children on ART in public clinics,

Similarly, the data integration shows where quantitative and qualitative data are consistent and have a discordance or discrepancies.

Table 5.17: Joint displays comparing findings of qualitative and quantitative results

QUALITATIVE STRAND Findings from self-reported inquiry	QUANTITATIVE STRAND Results	Outcomes
Knowledge and Understanding of NIMART	PRESCRIBING PRACTICES	
<p>The NIMART-trained PNs reported themselves good the general knowledge and understanding of...</p> <ul style="list-style-type: none"> • ART management in children • ART dosing in children using the 2013 Paediatric Dosing Chart. • ART dispensing in children. 	<p>Demographics</p> <ul style="list-style-type: none"> • (n=153; 60%) of the cohort were children of school-going age <p>Correct Dosing Frequency?</p> <p>(n=3035; 19.58%) of prescriptions without an indication of the dosing frequency.</p>	Contradiction/ Expansion

QUALITATIVE STRAND Findings from self-reported inquiry	QUANTITATIVE STRAND Results	Outcomes
Competency levels on ART Management in Children	Correct Quantity Supplied <ul style="list-style-type: none"> • Total of 15 502 prescriptions only (n=7449; 48%) indicated amount/quantity of ART issued, • (n=8053; 52%) did not indicate the amount dispensed. • Only (n=2883; 38.70%) children received adequate amount of treatment to last them until the next appointment date, • (n=2927; 39.30%) prescriptions were undersupplied, • (n=1195; 16%) prescriptions received over-supply. 	Contradiction
<p>The NIMART-trained PNs reported themselves good competency level in...</p> <ul style="list-style-type: none"> • Regiment Switching • ART regimen selection. • Monthly weight monitoring. • Determination of monthly ART supply. • Management of missed appointment dates. • Recognition of treatment failure. • Management of unsuppressed viral loads in children. • ART dispensing in children. • ART dosing in children on ART. 		Confirmation
Perceptions and experiences in the management of children on ART		Expansion
<ul style="list-style-type: none"> • The management of children on ART is more stressful than the management of other patients. • Nurses agreed to having children miss scheduled appointment dates in their public clinics. 		
Factors associated with children missing scheduled appointment(s)		
<ul style="list-style-type: none"> • Lack of support from caregivers • Stigma 		

QUALITATIVE STRAND Findings from self-reported inquiry	QUANTITATIVE STRAND Results	Outcomes
<ul style="list-style-type: none"> • Lack of disclosure • Poor treatment literacy • School attendance • Uninformed caregiver and child • Over-commitment • Forgetfulness 		
Views and perceptions of the implications of missed appointment dates		Confirmation
<ul style="list-style-type: none"> • Non-adherence • Poor clinical outcomes 		Contradiction/Confirmation
<ul style="list-style-type: none"> • Nurses Views on Monthly Weight Monitoring 		
<ul style="list-style-type: none"> • Ensures the correct dosage is given per weight • It helps to know what dosage to give to avoid giving under/overdose. • Enables clinicians to dispense the correct quantity. • To show if treatment is working or not. • Children grow rapidly and their treatment success depends of the weight recording. • To monitor the growth of a child. • It shows whether the child is developing or not. 		

QUALITATIVE STRAND	QUANTITATIVE STRAND	Outcomes
Findings from self-reported inquiry	Results	
Nurses' understanding of ART Dispensing in children		Expansion
<ul style="list-style-type: none"> • Lack of formulation consideration • Irrational medication prescribing • Non-dispense treatment • Seek advice 		

Generally, the nurses' noted perception indicated by (n=62; 57.41%) of the responses to this question that *"the management of children on ART is more stressful than managing other patients on ART"* is, in essence, a confirmation for most noted irrational prescribing practices in the management of children. Furthermore, demographic data from the quantitative phase also show that a total of (n=153; 60%) of the children initiated on ART in 2015 were of school-going age. The nurses' view confirms this in the qualitative findings that school attendance contributed to children missing scheduled appointment dates. The nurses mention in their responses that; *"Most of them (children) are at school and their school programme clashes with their appointments at the clinic"* [P95]. This is supported by the view of **participant 99**, who stated that children miss scheduled appointment dates because the *"school schedule is against clinic dates"*.

Monthly Weight Monitoring – the nurses' reported a good understanding of the importance of monthly weight monitoring as depicted in their responses wherein they mentioned that;

- Monthly weight monitoring in children on ART is a **useful prescribing tool** in that it helps the nurses with the correct **Dose Determination**. For instance, **P18** said that *"It is important [to do weight-based dosing] as it allows us as clinicians to monitor a child's growth and give the right dosage of treatment"*.
- Furthermore, they mentioned that it helps them with the **Determination of a correct monthly treatment supply**. Where **P103**, for example, mentioned that 'when doing weight-based dosing', *"You get the exact amount of medication to give to a patient"*. On the other hand, **P104** said that through this, *"One can know how much of what to give"*. **P108** mentioned that *"You know exactly how much of what to dispense"*. Furthermore, it is regarded as **a treatment success monitor, in that according to**

P8, it shows the nurses *“whether treatment is working or not”*.

- Moreover, the nurses mentioned that monthly weight monitoring is a **useful Growth Development (GD) monitor** wherein **P11** indicated that “It allows clinicians to monitor growth and development of a child”. Another participant (**P87**) mentioned that *“Monthly weight determines the dosage of medication that children should take daily; by monitoring, we want to see whether the child has gained weight or not. If the child gains weight, we will have to increase the dose. If we lose weight, we decrease.”*

These responses contradict that in practice, as shown in the quantitative results, only (n=5761; 78.4%) of clinic visits were weight monitored. Hence, their understanding of treatment being weight-based is questionable. However, on the other hand, this could be clarifying the nurses' perception that “the management of children on ART is more stressful than managing other patients on ART”.

Furthermore, the nurses' lack of understanding of ART dispensing in children as depicted in their responses to the case scenario, which highlighted their lack of formulation consideration in cases of EFV 50mg stockouts as well as their irrational prescribing practices, confirms the high rate of viral unsuppression noted in the baseline results as well the medical records results highlighting that only (n=9539;76.51%) of the prescriptions were correctly dosed, with some notable cases of over-and under-dosing practices. The nurses' inability to indicate in the prescriptions the prescribed dose, dosing frequency, or the ARV quantity supplied in (n=928; 77.85%) of the prescriptions is not only against the nursing care principle, which states that *“if it is not written down, then it did not happen”* (Andrews, & St Aubyn, 2015). This follows the understanding that in nursing good records promote continuity of care through clear communication; it also demonstrates the quality of care delivered; and further provides the evidence necessary for any legal proceedings. Similarly, Mutshatshi, Mothiba, Mamogobo, and Mbombi (2018) lament that patients' records provide a trace for the care processes that took place and are further used as communication amongst nurses and other healthcare professionals for continued management of patients. Hence nurses are tasked with ensuring that medical records are kept accurate and complete to manage their patients effectively. Since poor record-keeping has a negative impact on the care delivery system and clinical decision-making (Inan & Dinc, 2013; Wilson, Woollands, & Barrett, 2018).

These findings also contradict the nurses' high esteem in terms of knowledge and understanding of ART management in children and their high competence level self-rating. Their views on the factors associated with children missing scheduled appointments are in agreement / confirm the nurses' acknowledgement of having children who miss scheduled appointments and further clarify the very thin line (n=3234; 44.11%) of honoured visits as well as (n=2828; 39.80%) of missed visits.

The nurses' views and perceptions on the implications of missing scheduled appointments that it is a sign of non-adherence and can lead to poor clinical outcomes confirm the quantitative results, that missing scheduled appointment visits is a form of non-adherence to treatment and can lead to poor clinical outcomes if left unchecked. However, as observed in the study, these views contradict what happens in practice, in that only 44.11% of clinic visits were honoured. However, this lack of on-time pill pick-up noticed in the quantitative phase clarifies the poor treatment literacy and the lack of information noticed with the caregivers and the children, leading to treatment non-adherence.

5.4 Interpretation and Discussion of Merged Results and Findings

This section presents the study's findings observed from the merging/ mixing the quantitative and qualitative strands. The discussion outlined by the section focuses on similarities drawn from both the quantitative and qualitative first. The section then wraps up, highlighting the divergences observed in the study. This is because the researcher sought to focus more on the merged results. According to Othman, Steen and Flee (2021), integrating the quantitative and qualitative results means interrelating both sets of results and generating relationships between the two.

5.4.1 Demographic Information

The demographic findings revealed that many nurses were females. These findings indicate that nursing is still a female-dominated profession. The study further identified that most NIMART-trained PNs professional nurses were in their middle age. These findings presume that the nursing profession is dominated by middle-aged nurses with a few young nurses. Many NIMART-trained PNs had a nursing Diploma, a nursing degree, Advanced Diploma in Nursing Certificate, a College Certificate, an Honours, and a Master's Degree.

There were no nurses who had a Doctoral Degree. NIMART-trained PNs involved in the study have experience in nursing and the management of children on ART. Moreover, most unsuppressed children under 15 yrs were of school-going age when ART was initiated.

5.4.2 Similarities between Quantitative Results and Qualitative Findings

The baseline clinical outcomes results for this cohort indicated that in terms of VLS rate, the district was sitting at a mere 29.26% (n=151) by the 31st of December 2018. Furthermore, the TIER.Net data highlighted that a total of (n=357; 97.80%) of children were in the four-year understudy regimen switched, with (n=20; 8%) not clinically staged. These results contradict the qualitative findings depicted in the nurses' self-ratings regarding their excellent knowledge and understanding of NIMART, ART management in children, and their ability to monitor viral loads in children as per the treatment guidelines. This also contradicts their high competence level rating in recognising treatment failure and the management of unsuppressed viral loads in children. Only 93% of the prescriptions prescribed the correct dosage form. Moreover, the nurses agreed to have children who miss scheduled appointment dates in their public clinics. From 7105 analysable visits, only 44.11% were honoured, with 39.80% of missed appointments and 4.14% the next appointment date not documented.

5.4.3 Quantitative results without qualitative correspondence

Poor medical record keeping was found very prevalent throughout the data analysis. The researcher has experienced unavailable information wherein 47 medical records were excluded from the study because they only contained the patient's demographic details without any medical history. The following results were found when coming to the explored data for answering the study's aim and objectives, the following results were found; 1) in terms of the WHO clinical staging, this was recorded in only 64.71% of children initiated on ART in 2015; 2) the presence of concomitant diseases on admission was only recorded in 20% of the children; 3) monthly weight monitoring, and this was recorded in only 78.4% of the visits; 4) from 16669 prescriptions, only 12467 prescriptions had a strength prescribed; 5) there were also cases of drug omissions during prescriptions wherein mono- and dual-

therapies were prescribed; 6) Furthermore, 77.85% were prescribed without indicating the dose, dosing frequency, or quantity issued; 7) with a total of 19.58% of prescriptions without an indication of the dosing frequency for the prescribed drugs, and 8) 52% of the prescriptions without an indication of the quantity of ART dispensed.

Nursing practice necessitates meticulous record-keeping that is thorough, timely, and accurate. There is no way to establish that care was given to the patient without a thorough record, and there is a saying in nursing that "what is not recorded has not been done" (Mutshatshi, Mothiba, Mamogobo, & Mbombi, 2018).). Furthermore, poor record-keeping not only jeopardises patient care, but also exposes nurses to legal claims arising from a breakdown in communication caused by incomplete or insufficient data (Marinic 2015). A nurse must keep clear and correct records of all nursing acts done to the patient at all times, according to the South African Nursing Council (SANC) Rules and Regulation R387 pertaining to Acts and Omissions. Failure to do so is considered professional misconduct.

5.4.4 Qualitative Results without Quantitative

From the nurses responses in the qualitative phase, some clarity was established from the nurse's experience that the factors associated with children missing scheduled appointment(s) were; lack of support from caregivers; stigma; lack of disclosure; poor treatment literacy; school attendance; lack of information about the treatment or the condition to the caregiver and child; over-commitment of parents or caregivers; as well as forgetfulness.

5.5 Conclusion

The results and findings of the study clearly demonstrate a gap in knowledge, understanding and competence level of the NIMART-trained PNs managing children on ART in public clinics of Mopani District, Limpopo Province. Further investment in nurse capacity building is needed to bridge the gaps and prepare more nurses to provide high-quality, comprehensive HIV care and treatment services to children managed in public clinics.

The nurse's prescribing practices described above demonstrate an irrationality in management for this cohort of children. Most prescriptions did not entirely comply with the

2014/15 HIV/AIDs treatment recommendations in that children were managed without following all the necessary follow-up processes. The children were prescribed treatment without record of their body weight, and in some instances treatment was consecutively issued to the parents/caregiver for three to five consecutive months in the absence of the child, there has been drug omission cases, and notable cases of mono and dual therapy, incidences of under- and overdosing as well as incorrectly supplied quantities. The study findings clarify that the irrational use of ARVs in children impacts their clinical outcomes negatively in that baseline findings demonstrated that over 70% of these children were virally unsuppressed ($VL \geq 400$ copies/ml). These findings of the study further demonstrate that, for children under 15 years, adherence to antiretroviral therapy is alone not enough for obtaining good clinical outcomes. These findings are similar to prior study findings (Liedtke, Tomlin, Skrepnek, *et al.*, 2016; Chiampas, Kim, Badowski, 2015; Li & Foisy, 2014; Yehia, Mehta, Ciuffetelli, *et al.*, 2012).

In this study, a cascade of gaps emerged between HIV competency as self-reported by the NIMART trained nurses and their practice. Not all the trained nurses were found competent when presented with scenarios relating to the care and management of HIV positive children under the age of 15. Similar findings from other studies (for Example, Smith, Odera, Chege, Muigai, Patnaik, Michaels-Strasser, ... & Dohrn, 2016) indicated a need to examine each step along the nurse capacity-building cascade, from policy to training, training to competency, and competency to practice, in order to identify barriers and opportunities to bridge the gaps.

A gap was also noted between training and the self-perceived competency of nurses in HIV care and treatment. Although all the nurses had been trained in HIV care and treatment tasks, only about 60 percent felt competent to perform those tasks. These findings suggest that training alone has not been sufficient to ensure self-perceived HIV competency in NIMART trained nurses in settings similar to the one described in this study.

Finally, because the dosages of medicines depend on a patient's weight, it is essential to make sure that the NIMART trained nurses have updated information children's weight and age. Too little medicine can be ineffective and too much could be harmful. Also,

different medicines have different concentrations of ingredients. So it is always important to ensure that regimen hopping is avoided at all times.

CHAPTER 6

A CONTEXT-SPECIFIC ART DOSING AND DISPENSING TRAINING PROGRAMME FOR NURSES

6.1 Introduction

Chapter Five above presented the results and the findings of this study. Before this section, Chapter three gave a comprehensive overview of the study's theoretical frame, where two theories; medicine Utilisation Research Concept and Clinical Pharmacy Concept, have been utilised to direct the research and to develop and implement an instructional programme to refine the dosing and dispensing of ART in children managed in primary health care clinics. The activities to endorse the development of this training programme for the NIMART- trained professional nurses aimed toward refining the knowledge and understanding of ART dosing and dispensing in children under 15 years managed in public primary healthcare settings. These activities involve the facilitator, participant, setting, dynamics, process, and thus the terminus was utilised in this study.

The interpretation of the results and findings, and also the outcome of the findings based on integrating the qualitative and quantitative data, were the inspiration for the development of this setting-specific training programme for the NIMART- trained professional nurses, who are initiating and managing children on ART in public primary healthcare clinic settings. This chapter is envisaged to explain the training programme that might guide, aid to enhance the knowledge and expertise of NIMART- trained professional nurses during the ART dosing and dispensing process in public clinics during the routine monthly ART clinic visits.

6.2 Summary Results and Findings Guiding the Training Programme

Following the analysis of both the quantitative results and, therefore, the qualitative findings. Phase 3 of the study was set to determine the training demands of NIMART- trained professional nurses regarding the effective management of children on ART in public clinics and additional develop a training programme for the appropriate use of antiretrovirals and management of ART by NIMART- trained professional nurses in Mopani public clinics. The research results and findings on assessing the utilisation of ARVs in children on ART

managed in public clinics of Mopani District: towards dosing and dispensing training programme for nurses shaped the content for the training and implementation of the training programme. The NIMART-trained PNs were also of assistance in identifying strategies that would improve the implementation of the training programme in their context. The final objective for the study was to implement the educational training programme for the appropriate use of antiretrovirals and ART management by NIMART-trained PNs within the Mopani District public clinics.

6.2.1 Training Development Guiding Results and Findings

6.2.1.1 Quantitative Phase

In summary, this phase of the study aimed at establishing the rationality of the nurses' prescribing practices when managing virally unsuppressed children on ART, establishing their regimen switching patterns as well as determining the NIMART-trained PNs' compliance to the HIV Treatment guidelines when dosing and dispensing ART in children under 15 years. The identified training needs noted in this phase were in the following areas;

Prescribing Practices – The primarily identified irrationality prevalent across the district whilst working with the data for this cohort revolved around poor medical record-keeping noted with the unavailability of medical records, which frustrated the analysis of most indicators for the study. This need for training was identified to enhance the importance of keeping proper medical records and understanding that medical records are the basis of medical data. Since the precise safekeeping of medical records is decisive to providing quality treatment to patients. Therefore, the inappropriate keeping of medical records can influence patient management and, the endurance of medical care, leading to inadequate health care (Britz, 2018).

Other noted areas of concern that required training were on the **irrational prescribing practices** noted whilst analysing data.

- a) Aspects of incomplete prescription writing
- b) Poor WHO clinical staging practices at ART initiation
- c) Poor monthly weight monitoring practices, with (n=1590; 21.6%) of body weights not monitored.

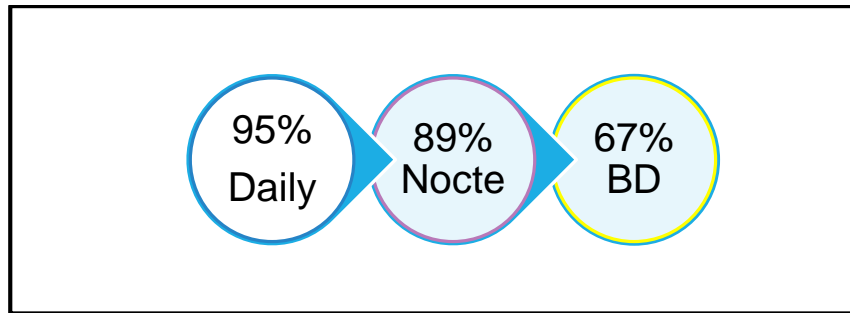


Figure 6.2: Summary of dosing frequencies

- v) **Inadequate monthly supplies of treatment issued.** Only in 48% of the prescriptions did the nurses indicate the amount/quantity of ART given, and in 52% of the prescriptions, the nurses did not show the amount dispensed or issued out to the patient. Those with an indication of the quantity supplied, in 39.30% of the prescriptions, the children their treatment were undersupplied. At the same time, 16% of the prescriptions received an over-supply of their prescribed ARVs.
- vi) **Irrational regimen switching practices.** Only 7.17% of children correctly switched from the regimen at initiation to another one & 76.19% incorrectly switched from one regimen to as often as five times.

6.2.1.2 Qualitative Phase

Generally, the nurses' perception when coming to the management of children on ART was that this is more stressful than caring for other patients on ART. Furthermore, the nurses agreed to have children who miss scheduled appointment dates in their public clinics. The following themes and subthemes emerged from the data analysis;

1) **Factors associated with children missing scheduled appointment(s):**

- The absence of support from parents and caregivers
- Observed fear of stigma
- Lack of HIV disclosure
- Poor treatment literacy
- School attendance

- Uninformed caregiver or child
- Over-commitment
- Forgetfulness

2) Nurses' understanding of ART Dispensing in children assessed from their responses to the cases scenario given to them depicted the following subthemes;

- Lack of formulation consideration. E.g. the doubling of twelve hourly formulations to promote treatment adherence.
- Irrational medication prescribing. The dispensing of incomplete ARVs practised during stockouts with the instruction for the caregivers to collect the missing item either from the nearest clinic or the hospital.
- Non-dispense treatment – promotes treatment adherence and protects the patient from developing single or dual drug-resistant mutations that may lead to treatment failure.
- Seek advice – this show adherence to HIV/AIDS treatment guidelines.

The results and findings of this study suggested the need for constant monitoring of rational prescribing of ARVs and the consolidation of factors to support the appropriate use of ARVs in children initiated on ART and managed by NIMART-trained PNs in resource-limited public primary healthcare clinics.

6.3 The rationale for the Training Programme

The stimulus for developing this training programme follows an observation of the shared practices and, therefore, the inadequate training needs observed from the participants required to reinforce the standard of ART management in children. More poignantly, the researcher identified that there are not any training programmes specifically designed to reinforce the nurses' knowledge, understanding of ART dosing and dispensing in children either as a mentoring programme or a Continuous Professional Development (CPD) programme for the NIMART-trained PNs within the Limpopo Province for improving

HIV/AIDS treatment indicators within the public clinics. This programme is thus developed in order to address the identified knowledge and understanding gaps. The findings of this study revealed the necessity for the programme to focus on the sensible implementation of the steps of ART management in children as stipulated or outlined within the HIV/AIDS treatment guidelines, with much emphasis on the implications of identified irrational prescribing practices. The context-specific ART dosing and dispensing training sessions will be conducted according to the South African Qualifications Authority (SAQA) requirement for accreditation in public clinics within the Limpopo Province.

6.3.1 Benefits of the Developed Training Programme

The researcher envisages both the short and long-term benefits of the ART dosing and dispensing training programme. Hence, it is expected that the training programme will bring a new angle to the management of HIV in children by promoting rational antiretroviral use at primary healthcare facilities and antiretroviral therapy stewardship. This angle has not yet been explored in HIV/ AIDS management and care. Hence, the researcher in this study anticipates that outcomes of the training programme will contribute knowledge towards the establishment of improvement strategies and the strengthening of systems in the management of HIV/ AIDS in children living in rural areas as follows;

- **Benefits of the Training to Participants**

The NIMART-trained PNs will acquire additional knowledge and expertise to persuade them to provide good quality ART care to enhance the clinical outcomes of children under 15 years. Improving nurses' constant learning will also stimulate participants' interest in managing children on ART. The nurses no longer see the management of children on ART as more "stressful" than managing other patients on ART. The training will assist the nurses in structuring their daily work activities to accommodate the school going child and, therefore, the overly committed parent/caregiver.

- **Benefits to the Department of Health**

Outcomes of the training programme are envisaged to bring a new angle to managing HIV in children by promoting rational antiretroviral use at primary healthcare clinics and antiretroviral stewardship. This angle has not yet been explored in HIV/ AIDS management and care. The training provides information to pharmacy managers about their role in managing HIV/AIDS for children in primary healthcare clinics, informing HIV/ AIDS guidelines for health workers. The strategies brought by the training programme will hopefully be adopted by the department of health, implementing partners and other relevant stakeholders within the management of HIV/AIDS. Hopefully, the strategies will be of positive effect in the treatment and care and assist in preventing the development of an "antiretroviral era", as this will be a detrimental effect on the lives of children living with HIV/AIDS.

- **Benefits to the community**

The nurses are well informed and skilled on ART's practical dosing and dispensing in children under 15 years. The benefits of the training to the community will include the overall improvement within the monthly monitoring of the children on ART. Therefore, the quality of ART care rendered to patients. This may cause an improved quality of life for the youngsters who are the community's future and therefore the country. The programme also will profit the community by securing high patient and family care whilst being pleased with the interaction with their nurses. The advantage of this training to community also includes meeting the expectations and health demands of the patients in care.

- **Benefits to the profession (body of knowledge)**

From a research perspective, the training programme is expected to be of use in formulating the basis for further research into the development of pharmacist-initiated training and mentorship programmes for the NIMART-trained PNs involved in the management of ART in children treated in public primary healthcare settings may also ensue.

Furthermore, this ART dosing and dispensing training programme will be the first of its kind to focus on quality improvement strategies following a four years evaluation of the nurses prescribing patterns and practices in the management of virally unsuppressed children on ART.

Since the training programme covers the necessary to note ART dosing and dispensing aspects that were gathered through a valuable and dense explorative project that is expanding the body of knowledge in the nursing as well as the pharmacy profession, as it not only improves the knowledge and skills but will also ensure continuous professional development as well as an improved quality health care in public clinics of Mopani District for the children on ART programmes. This training programme further sheds light on the pharmacy profession on how nurses in public clinics require their support through mentorship, further in-service training and coaching.

6.3.2 Adult Learning Theory by Malcolm Knowles

In the first chapter of this study, the researcher acknowledged that the implementation of the training programme should use Malcolm Knowles' adult learning theory. The adult learning theory was thought of as an appropriate option considering that the target participants are the nurses, in this case, and they are adult nurses. Malcolm Knowles' "andragogy" explains the significance of tailoring adult education differently from children and young people in general. In support of this stance, Beder and Darkenwald, 1982 in Knowles (2015) argue that adult learning is different from the traditional learning given to children or adolescents. Hence, Knowles laments in Kurt (2017) that being an effective educator involves understanding how adults learn best. Kurt (2017) then made the following assumptions that describe adults in the learning terrain: adults are;

- **practical and more results-oriented people:** who appreciate learning issues that directly impact their work and private life. Furthermore, when he theorises adult learners, he found them willing and prepared to learn if the conditioning they are learning about during training are of support to them and might be applied in their working environment and not just theory they can not apply. Therefore the literacy

activities selected during the implementation of the training during this project would clearly show the learners (NIMART- trained professional nurses) how the training would advantage them within the management of children on ART and the way which will effectively assist them whilst dosing and dispensing ART to children once they're in their respective area of work.

- **self-directed learners:** Knowles has observed that adult learners are self- oriented. They take accountability for their lives, they make and own their decisions, and that they like having control over their learning. Hence, they ought to be involved in developing and assessing their knowledge. Likewise, mature learners delight learning activities that address their needs. Consequently, during the implementation of the training during this study, the nurses were allowed to work in groups to insure active participation in aspects found with knowledge and understanding gaps during the study phases.
- **less open-minded:** grown-up learners are considered less open-minded and may thus oppose new changes due to their deep life experiences. This occasionally acts as a barrier and a contender towards their education. However, they also enjoy learning subjects that directly influence their lives and working environments. Considering this issue, the researcher during this study kept this uniqueness in mind and, as a result, continuously encouraged the participants to be more open-minded during the training sessions. This was done to stimulate critical thinking and make the training sessions a platform to accentuate the nurses' knowledge and skills in ART management.
- **slower learners:** conformable with this theory, grown-up learners are considered steady in learning new things than youthful ones. Still, they're purported to possess have additional integrative knowledge since they link their acquired knowledge with their experiences. Thus, Knowles (2015) argues that the integrative understanding of adult learners' experiences and mistakes in practice form a foundation of their learning activities. Hence, during this study, the researcher kept in mind that she got to be persevering and work at a pace that adult learners can follow, permitting them to integrate the training to their existing knowledge, and encouraged the participants

to share their experiences and former mistakes.

- **use their personal experience(s) as a helpful resource:** Most adult learners have acquired work experiences from different working environments. Therefore, it's encouraged (Knowles, 2015) to accommodate these experiences. It has to be applicable to their daily duties and aimed towards developing them professionally. During this study, the training programme focused on the pharmaceutical activities, ART management that the nurses perform daily when managing children in their clinics.
- **motivated to learn:** It is observed that adult learners enjoy learning about issues that have direct relevance and are authoritative to their daily duties and private life.. They are further considered enthusiastic about external and internal motivation factors that spur them to learn with interest and enthusiasm. Hence the researcher, who was also a facilitator during this study, ensured outside motivating factors to the training and encouraged the participants to keep up an eagerness to learn.

More specifically, the researcher also ensured that the programme's design also adhered to the principles laid by Knowles (2015) pedagogical principles.

6.4 The Design of the Training Programme

6.4.1 The Model Adopted for the Training Programme

The Paediatric dosing and dispensing training programme developed and enforced during this study espoused the ADDIE model. This educational design model is a methodical approach of developing teaching and training programmes for enriched learner performance. The ADDIE is meant explicitly for setting up operative teaching and training in five phases Analysis, Design, Development, Implementation, and Evaluation (see **Figure 6.3** below).

These phases supplied a foundation for a straightforward training in determining the areas in practice that require advancements (Branch, 2009; Watson, 1981). Furthermore, Almomen, Kaufman, Alotaibi, Al-Rowais, Albeik, *et al* (2016) alludes to the employ of a structured

educational design model for creating professional development programmes for nurses' productive, noteworthy proficiency in primary healthcare. Because;

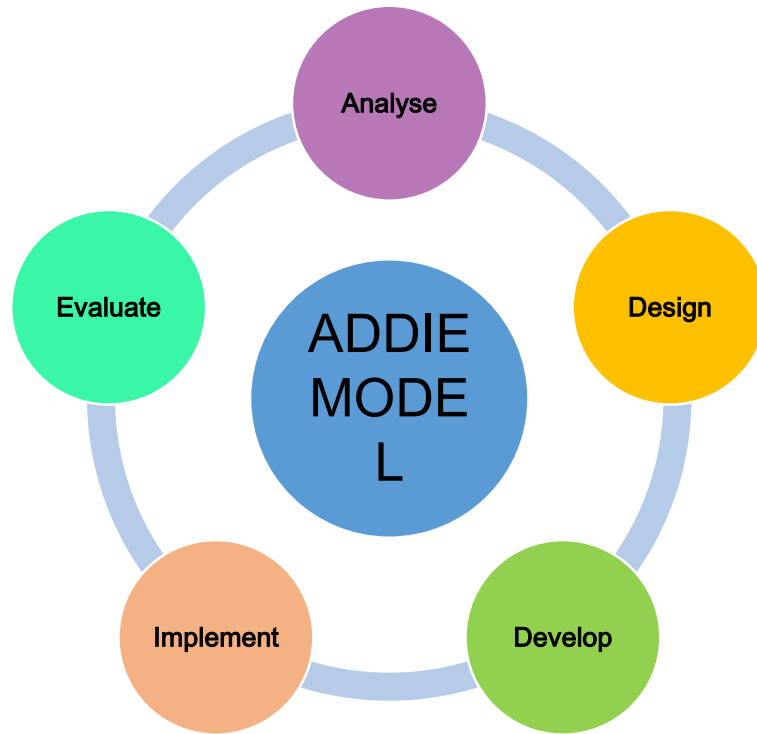


Figure 6.3: Training development phases ~ adopted from the ADDIE model

- 1) Continuing Professional Development (CPD) is a crucial system to assist nurses and other healthcare professionals conserve and further evolving knowledge and proficiency;
- 2) The ADDIE model (analysis, design, development, implementation, evaluation) provides a long- time and valuable structure for creating productive CPD programs;
- 3) The ADDIE process ensures that nurses' applicable literacy requirements are met effectively;
- 4) The researcher acknowledges that although this is frequently not a part of this study, the ADDIE model's evaluation phase provides feedback that will beget enhancement within the CPD program's future iterations.

The reason for choosing the ADDIE model was to direct developing the ART dosing and dispensing training programme intended to supply NIMART- trained professional nurses 'with knowledge and proficiency on the rational use of ARVs during child care.

It's important to note that in clinical practice, CPD is central to the nurses' constant learning and institutes an imperative phase for keeping nurses' knowledge and proficiency up-to- date. As professionals, nurses are, consistent with the South African Nursing Council (SANC), indebted to stay up-to- date on developments and trends in health provision (Mlambo, Silén, & McGrath, 2021).

This is frequently attained through engagement in various activities that organise CPDs. Likewise, Towle (1998) in Almomen *et al.* (2016) described professional development because the process of enhancing staff qualifications through access to education and training opportunities within the workplace, frequently supplied by an external organisation or by observing others perform on the work. It also helps set up and conserve training staff members' morale, therefore yielding and attracting higher quality staff for an organisation.

6.4.1.1 The Analysis Phase

This phase involved a situational analysis, which looked at the objectives for phases 1 and 2 and is reflected in the 3rd phase of the study. This was meant to detect the prescribing practices and training needs of NIMART-trained PNs to improve the pharmaceutical management of children on ART. The identified knowledge gaps and potential sources for training solutions were explored through a sequential mixed-method approach. They were led to the development of the educational training programme. A purposive sampling technique guided by study results and findings was used to identify and select a relevant target group of NIMART-trained PNs who revealed a poor understanding of the ART dosing and dispensing in children and a low competence level in the effective management of children on ART in public clinics. The embraced sampling technique aimed at making sure that the developed training programme is applicable for the targeted group of participants (Branson, Rayner, Cox, Furman, & King, 1975; Watson, 1981).

6.4.1.2 The Design Phase

This phase included the drawing out of a plan for the training programme. The phase helped with detailing the knowledge outcomes, the training content, educating methodology, educational strategy, training activities, and the evaluation measures to meet the training demands of the programme. Moreover, this phase of the model served as a figure of the training result, and it helped shape the training. The integrated findings of the qualitative and quantitative phases guided the development of an educational training programme grounded on the Rational Medicine Use (RMU) theory.

6.4.1.3 The Development Phase

This phase included the conception and documentation of the training programme, the development of the training program, as well as resources to be used for training purposes. The training content included the aim of training, results, objectives, pre-requisites, educational strategies, training environment, learning activities, assessment methods, and procedures for the effective implementation of this training programme for the NIMART-trained PNs (Branson et al., 1975; Watson, 1981).

6.4.1.4 The Implementation Phase

This is the definite employment of training, and its effectiveness depends on how well set all the other phases are. The NIMART- trained professional nurses who partook in the study were invited to attend a briefing session aimed at confirming whether or not the findings of the implementation phase addressed their training demands during the implementation of the dosing and dispensing training. This also provided a chance for these nurses to give their voice before the training programme was ultimately presented in the Mopani District public clinics (Branson et al., 1975; Watson, 1981).

6.4.1.5 The Evaluation Phase

Conferring to Hannum (2005), this phase of evaluation is a retrospection of how the rest of all the four phases were conveyed and aims at attaining feedback from the training

participants. This phase is the assessment of the efficiency of the training programme. Furthermore, this model phase also intended to confirm whether or not the training programme achieved its envisioned goals. Thus, all participant nurses were anonymously provided an assessment instrument to rate the training programme. Furthermore, participants were similarly involved in small group discussions of three (03) to four (04) people to gather their inputs to the training. Nonetheless, for this study, the attained feedback was only used to detect whether or not the programme accomplished its intended goals and to further gauge whether there is a need for adjustment and further improvement to the training programme.

6.4.2 The Purpose of the Training Programme

The sole purpose of the training programme in this study was to bring a new angle to the management of HIV in children through the promotion of rational antiretroviral use and to empower nurses at primary healthcare clinics in the public clinics located in rural areas. The training is also intended to promote the idea of an antiretroviral stewardship programme. This angle has not yet been explored in paediatric HIV/AIDS management and care. Hence, the researcher in this study anticipates that the outcomes of the programme will contribute knowledge towards the establishment of improvement strategies and the strengthening of systems in the management of HIV/ AIDS in children living in rural areas, particularly but not limited to those of Mopani District, in the Limpopo Province. During the data analysis, in both phases of the study.

The study results and findings indicated gaps in knowledge, understanding, and competence of the NIMART-trained PNs involved in the management and care of children on ART. The researcher theorised that these shortcomings would best be covered through an in-service training programme. It was also believed that professionals would share the knowledge gained from participating in this study and throughout the training with the rest of the other nursing categories in their areas within the district. Therefore, in order to achieve this purpose, the NIMART-trained PNs were empowered through the customised training programme as leaders of ART management and care.

6.4.3 The specific Outcomes of the Programme

The results of the training programme were set to be directly interlinked to the study's primary objectives, and that the study purpose, expected goals and objectives are accomplished. The end-product of the training programme was set as a competent professional nurse who can rationally manage a child on ART from initiation and in all monthly follow-up clinic visits. The programme's product had to be empowered to work as an independent NIMART-trained nurse when managing children on ART, leading to personal and professional growth and development.

6.4.4 Pre-requisites for Attending the Programme

The following pre-requirements or inclusion criteria were considered before any nurse can be allowed into the training programme:

- The participant nurses should have knowledge, skills and experience, in the management of children on ART;
- All newly appointed NIMART-trained PNs should be included in the training programme to familiarise them with the rational ART dosing and dispensing principles;
- The participant nurses should have undergone a NIMART training or an equivalent programme;
- The participant nurses should be employed in a Mopani District public primary healthcare clinic; also be
- Registered with SANC as a nurse.

The above-listed inclusion measures were used to ensure that all participant nurses were implementing the ART dosing and dispensing training programme in their clinics. This training is envisaged to help them in improving the quality of care given to children on ART.

6.4.5 Adopted Strategies to Implement the Training Programme

Several approaches were embraced for the effectiveness of the training of these NIMART-trained PNs on the rational use of ARVs, which focused on addressing the irrational prescribing

practices of ARVs. The researcher used a variety of teaching and learning methods for this programme, and these are as follows:

The Contextual Learning Approach: This learning method was guided by the study's findings in this training programme. In this study, a setting-specific training programme was suggested for the implementation of the training programme. The rolling out of the training programme was conducted in public clinic settings because that is where these NIMART-trained PNs are managing children on ART. For the setting influences learning and can therefore foster change (Killen, 2010). Some of the challenges identified during the implementation phase of the study were therefore addressed in real-life clinic settings where they occur.

The Problem-Grounded Learning Approach: this type of approach was utilised in this training to allow participants to resolve work-related challenges. Prescriptions and case scenarios were developed in the training programme and were presented in the learning activities to bring work-related challenges into action. The participants were motivated to acquire problem-solving skills and therefore resolve work-related challenges presented in either prescriptions or scenarios during the training process. The Problem-grounded learning permitted the participants in the training programme to diligently engage in their professional development sessions instead of being tolerating participants during the training process (Matlala, 2021).

The Lecture Method Approach: this method of learning is considered a long-lived and out-dated face-to-face training technique. Here in this method of learning, the facilitator conveys facts to the participants. The benefit of this form approach in teaching and learning is that it encourages and influences adult learners to make additional investigations on the subject matter (Amberkar, Mohan, Kumari, & Bairy, 2011). It further enables the facilitator the opportunity to clarify some stereotypes. Moreover, it also provides the participants with an opportunity to intermingle and share more details based on their work experiences. However, this form of learning technique requires some creativity from the facilitator to make the subject exciting and thought-provoking to the learners (Kloppers, 2011). Therefore, the lecture learning approach was elected for this training programme since it is considered an efficient method of presenting new information.

The Small Group Discussion Approach: this form of learning style was adopted for the training following the understanding that the participants are grown-up learners and are said to learn best when they intermingle in manageable small groups as it enhances their experience and relates their knowledge. In these small group conversation session, the training facilitator functioned as a central-person for the participants' discussion of relevant issues to their clinical problem-solving proficiency. In this case, small group discussions were elected to inspire adult learners and encourage live participation (Hadimani, 2014).

The Experiential Learning Approach: This method of learning guided by the study results and findings in the medical records focused on simulating a day to day replica of a realtime working environment for providing more insight for the learners in their practice work settings. In this format of learning, participants' benefit by developing additional abilities as they are involved in various activities in a realtime working environments. The nurses gain more insight and expertise from their peers' experiences. Additionally, experiential learning afforded the participants a chance to participate and learn from each other guided by individual experiences (Fenske, Freeland, Price & Brough, 2015). Experiential learning was opted to encourage NIMART-trained PNs to use their work experience and share such experiences.

The Facilitation Approach: through this learning approach, adult learners acquire knowledge through active interrelating with colleagues and facilitators during training. During the learning process, each learner needs to be guided by someone, and the facilitator has to play the role of being a guide but not reinforcing learners what they are not willing to learn. According to Meyer and Van Niekerk (2008), the facilitator has to simplify the learning material for learners to understand. Thus, the training programme in the ART dosing and dispensing training programme was facilitated by an individual with appropriate qualifications and skills. The facilitator should also reassure and motivate the NIMART-trained PNs throughout the programme to assist NIMART- trained nurses in effectively managing children on ART.

6.4.6 The Learning Environment

The learning environment for this training programme was the public primary healthcare clinics in Mopani District, Limpopo Province. This is where the NIMART- trained nurses are managing children on ART. The ART dosing and dispensing programme is implemented in these clinics, with the NIMART-trained PNs actively participating in the implementation process. All the learning activities planned indicate how the participants benefit from the training programme because adult learners need the motivation to learn. The facilitator considered external factors to encourage the participants' willingness to learn.

According to Killen (2010), a positive learning environment motivate learners and create conditions where learners will be able to maximise their full potential through the following:

- Creation of an environment that is safe both physically and psychologically;
- Structuring of the learning experiences to guide learners towards long term goals;
- Develop trust in the learners and allow their active participation during the training implementation sessions.

6.4.7 The Content of the Training Programme

The training programme's content is based on the study results and findings that revealed the knowledge gap during the management of virally unsuppressed children on ART in 94 public primary healthcare clinics in the Mopani District of Limpopo Province. The challenges related to poor medical record-keeping, irrational prescribing practices that included incomplete prescriptions, medication omissions, medication errors such as under/overdosing, undersupply and oversupply of medication. The inconsideration of drug formulations was identified during the analysis. These were therefore reflected upon in the content map (denoted **Figure 6.4**) of the training programme as follows:

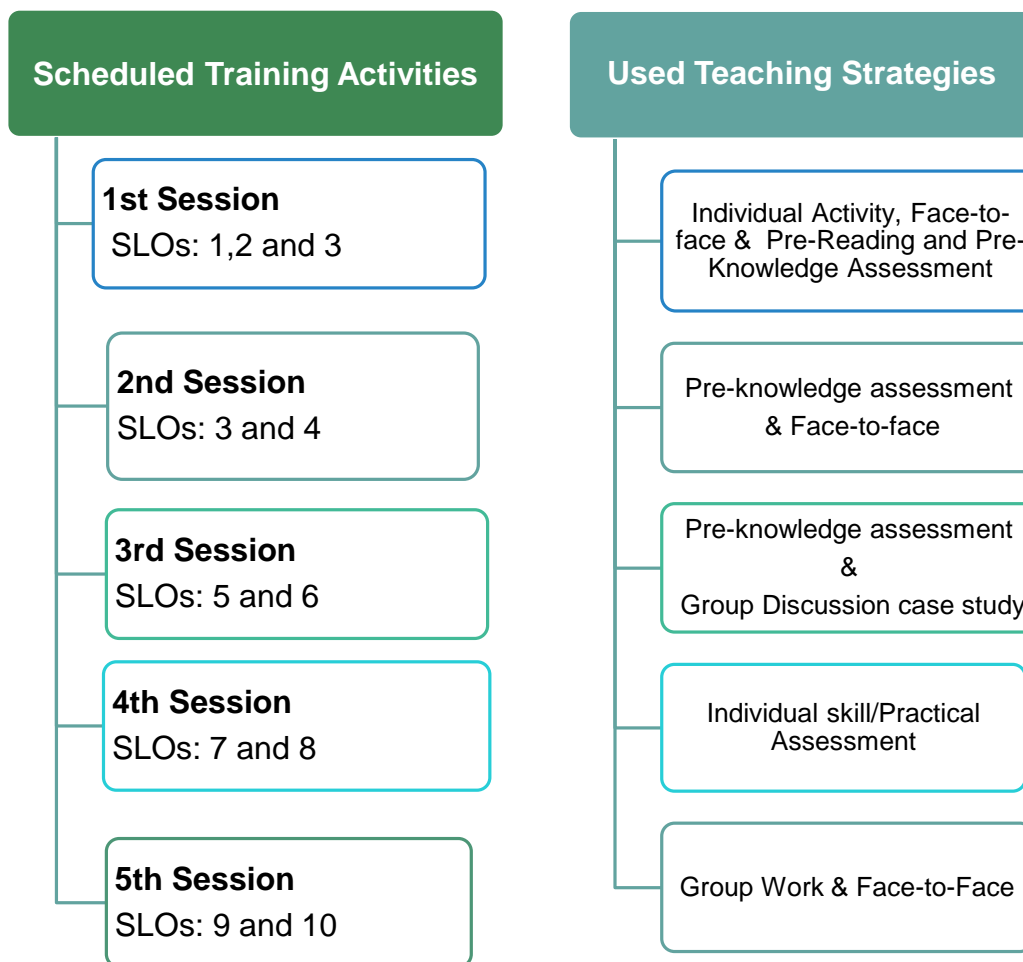


Figure 6.4: Training content process map

6.5 The Outline of the Training Programme for Nurses

This ART dosing and dispensing training programme is developed according to the SAQA (SAQA) Criteria and Guidelines for Short Courses and Skills Programmes. According to the SAQA (2004) criteria, a credit-bearing short learning programme refers to a variety of short learning programmes for which credits are awarded concerning the course's contribution to a unit standard or part-qualification, are awarded (SAQA, 2004).

The context-specific training programme was structured as a short training programme for NIMART-trained PNs in nursing care units grounded on the SAQA requirements for National Qualification Framework (NQF) Level five accreditation. The workshop will be conducted over five days, eight hours per day. Therefore, the training programme in this study will be a credit-bearing short course conducted over five days in the form of a workshop lasting forty (40) hours

equivalent to five credits. This short learning programme aims to update learners on new developments and insights in their professions, earn credits towards formal programmes, and intend for personal enrichment.

The planned training programme is aligned with the research findings. It will contribute to the SANC (2015) proposal, in line with the provisions of the Nursing Act, 2005 (Act No. 33 of 2005), in the process of developing Continuing Professional Development (CPD) System when it is approved for implementation. The CPD proposal stipulates that a professional nurse accumulate 15 CPD points per year that will be eventually linked to the Annual Practice Certificate (APC) renewal. Still, currently, the SANC is not yet ready for a full roll-out of CPD. The specific learning outcomes will assist the facilitator in taking into account the latest aspects so that the NIMART-trained PNs will obtain the latest and up-to-date information on the ART dosing and dispensing training programme.

6.5.1 The SAQA Unit Standard Format

The SAQA unit standard format for the context-specific training programme was adhered to. This includes the name of the programme/unit standard, NQF level, credits, the purpose of the unit standard, duration of the programme, learning assumed to be in place, specific outcomes and assessment criteria, unit standard or programme assessment; and the critical cross-field outcomes.

6.5.1.1 Name of the programme or unit standard

The Rational Use of Antiretrovirals (ARVs) in Children on Antiretroviral Therapy.

6.5.1.2 The NQF level

This programme will be offered at NQF Level 5.

6.5.1.3 The credits

The programme will be awarded five (05) credits.

6.5.1.4 The purpose of the programme/unit standard

This programme is for NIMART-trained PNs working in public clinic settings who initiate and manage children on ART. The programme describes the rational use of ARVs, to promote the idea of an antiretroviral stewardship programme.

The training programme explains the rational and irrational medicine use concepts, the role of ARVs in HIV/AIDS management, good ART prescribing and dispensing practices, the pharmacokinetic and pharmacodynamic principles of ARVs, regimen switching principles, as well as the psychosocial and cultural factors that affect children and their parents/caregivers.

6.5.1.5 The Duration of the Training Programme

The programme would be offered over five consecutive days (40 hours).

6.5.1.6 Learning Assumed to be in Place

The pre-requisites for attending the programme were outlined, including a specified expected educational qualification outlined in **Table 6.1** below.

6.5.1.7 Specific Learning Outcomes and Assessment Criteria of the Training Programme

The specific learning outcomes and assessment criteria were established, focusing on the merged results and findings of the quantitative and qualitative phase, as discussed in Chapter five of this study. The subjects are based on the results from the conducted medical records evaluations in the 94 public clinics and findings from the self-administered questerviews completed by various NIMART-trained PNs in the public clinics of Mopani District in the Limpopo Province.

Table 6.1: Summary of the specific learning outcomes content and assessment criteria of the training programme

Learning Outcomes	Study Units and Content	Assessment Criteria
<p>1. Demonstrate knowledge and understanding of the role of ARVs in the management of HIV/AIDS.</p>	<p>Study Unit 1: Describing the role of antiretrovirals in ART management</p> <p>Study Unit 1.1: Discuss the goal (s) of ART in children</p> <p>Study Unit 1.2: Explain the aim of a combination of ART triple regimen</p>	<ul style="list-style-type: none"> • Discuss the Goals of Antiretroviral Therapy in Children • ARVs are explained as a combination of medicines that limit the replication of the HI Virus. • The benefits and implications of treatment are explained as a life-long programme for the children on ART. • ART is defined regarding the benefits of adherence and the consequences of non-adherence to the treatment plan.
<p>2. Demonstrate an understanding of psychosocial and cultural factors affecting children who receive ART, their parents/caregivers, family, and community.</p>	<p>Study Unit 2: Address Psychosocial and cultural barriers to treatment adherence</p> <p>Study Unit 2.1: Facilitate treatment support systems for children on ART and their parents/caregivers</p>	<ul style="list-style-type: none"> • Identify local Treatment support systems • Cultural and traditional beliefs are explained in terms of their effect on the treatment of HIV&AIDS. • Effects of Stigma on the Non-disclosure of the HIV status to children • Explain factors that promote ART adherence
<p>3. Demonstrate a clear understanding of the Rational and Irrational Medicine use</p>	<p>Study Unit 3: Rational and Irrational ART use concept</p>	<ul style="list-style-type: none"> • Discuss the aims & objectives of the Rational Medicine Use concept • Understand the advantages of Rational

Learning Outcomes	Study Units and Content	Assessment Criteria
<p>concepts</p>	<p>Study unit 3.1: ART Adherence</p>	<p>Medicine Use</p> <ul style="list-style-type: none"> • Explain the Irrational Medicine Use concept • Understand the implications of Irrational Medicine use in the management of children on ART • Discuss the importance of adherence to the HIV/AIDS treatment Guideline in ART Management • Discuss the effects of non-adherence to HIV/AIDS treatment Guidelines
	<p>Study unit 3.2: Good ART Prescribing Practices</p>	<ul style="list-style-type: none"> • Differentiate between Rational Prescribing & Irrational Prescribing • Identify the components of a Rational Prescription
	<p>Study unit 3.3: Good ART Dispensing Practices</p>	<ul style="list-style-type: none"> • Demonstrate self-competence to determine the correct quantity of ARVs to dispense • Discuss how to determine the correct quantity to dispense • Aspects to consider when dispensing ART in children
	<p>Study unit 3.4: Viral Load Monitoring</p>	<ul style="list-style-type: none"> • Familiarisation with clinical ART guideline recommendations for VL monitoring • Discuss the importance of on schedule VL

Learning Outcomes	Study Units and Content	Assessment Criteria
		<p>monitoring</p>
<p>4. Demonstrate knowledge and understanding of pharmacokinetics and pharmacodynamics of ARVs</p>	<p>Study Unit 4: Pharmacokinetic and Pharmacodynamics of ARVs</p>	<ul style="list-style-type: none"> • Discuss Regimen Switching • Explain the role of Regimen Switching in ART • Discuss factors associated with “Regimen Hopping.”
<p>5. Demonstrate an understanding of good medical record-keeping in HIV/AIDS management</p>	<p>Study Unit 5: Good Medical Record Keeping</p>	<ul style="list-style-type: none"> • Discuss the importance of ARV formulation considerations. • Explain the benefits of ART formulation considerations in treatment. • Discuss the disadvantages of the lack of ART formulations consideration. • Explain the formulation aspects to consider during ART prescribing and management.

6.5.1.8 Unit Standard or Programme Assessment

This unit standard will be assessed in the context where the training is conducted in both written and practical assessments. The participants will be informed about the assessment methods used in this training, which was also indicated in the programme to prepare them. Formative and summative assessment approaches were to assess the level of competency in peer assessment, self-assessment, group presentation feedback, written test, and practical. A practical evaluation tool, written test, marking guide was created, and a test was set to assess the training participants.

6.5.1.9 The Critical Cross-Field Outcomes

The critical cross-field outcomes are essential in the training programme as they provide a basis upon which the implementation of the training programme is directed. The participants were expected to know the critical cross-field outcomes to achieve specific learning outcomes above. The critical cross-field outcomes are indicated below in **Table 6.2** below.

6.5.2. Learning Content of the Training Programme

The learning content of the training programme will be divided into study units aimed at achieving the specific learning objectives. The programme has five study units which are presented in the course covering the following aspects: Antiretroviral Therapy Goals of ART in children, On-time pill pickup and treatment adherence, dealing with monthly follow-up visits, principles of good medical record-keeping, the explanation of the concept “Rational Medicine Use”, historical background of the Rational Medicine Use concept, advantages of Rational Medicine Use during ART management and patient care, the Irrational Medicine Use concept, Types of Irrational Medicine Use, Implications of Irrational Medicine use in the management of children on ART, dealing with stockouts, Viral suppression vs viral non-suppression, ARVs and Drug Resistance, Predictors of Drug Resistance. Participants were engaged in learning activities outlined in **Table 6.2** below throughout the training sessions.

6.5.3 The Designed Training Programme

Table 6.2: Context-specific training programme design

Course Details: A Short Training Course on the Rational Use of ARVs in Children Course Towards their Effective Dosing and Dispensing Practices.	
Contact Hours:	40 Hours
Course Credits:	5
NQF Level:	5
Venue:	
Duration of the training sessions	The course will be conducted in five days. NB: Each session will have learning activities with interactive facilitation and some practical exercises which are patient file-based.
Pre-requisites Learning assumed to be in place	The pre-requisites for this course are: <ul style="list-style-type: none"> • The participant nurses should have knowledge, skills and experience, in the management of children on ART; • All newly appointed NIMART-trained PNs should be included in the training programme to familiarise them with the rational ART dosing and dispensing principles; • The participant nurses should have undergone a NIMART training an equivalent; • The participant nurses are employed in a public primary healthcare clinic; and • Registered with SANC as a nurse.

<p>Co-Requisites</p> <p>Units of learning to contribute during the course</p>	<p>The co-requisites for the system are:</p> <ul style="list-style-type: none"> • A professional nurse registered with the South African Nursing Council. • English as a medium of instruction and communication. • Ability to write and read in English.
<p>Course Facilitator</p>	<ul style="list-style-type: none"> • Mabila LN (Clinical Pharmacology Lecturer & PhD candidate) during the study and training of the trainers and participants.
<p>Purpose of the Course</p>	<ul style="list-style-type: none"> • The sole purpose of this training programme is to bring a new angle of ART management in children by promoting rational antiretroviral use at primary healthcare clinics and empowering nurses in public clinics of antiretroviral stewardship. This angle has not yet been explored in the area of paediatric HIV/AIDS management and care.

Critical Cross-Fields Outcomes (CCFOs)

Course participants will be able to:

- Identify and use problem-solving skills to solve problems related to ART dosing & dispensing in children.
- Work effectively with others as a team member, group, organisation, community to achieve learning objectives.
- Organising, managing oneself responsibly and effectively.
- Collect, analyse and critically evaluate information.
- Reflect and explore learning strategies that are effective during the training.
- Use science the technology effectively and responsibly towards achieving the set goals.
- Communicate effectively using visual, mathematical or language skills, both oral and written persuasion.
- Recognise that the problem-solving contexts do not exist in isolation and work as a team member of the multidisciplinary healthcare team.

Course outline:

On completion of this training, the NIMART-trained PNs as learners should be able to have achieved the following Specific Learning Outcomes (SLOs):

Specific Learning Outcome 1

Demonstrate fundamental knowledge and understanding of ARVs and their role in HIV/AIDS management.

ASSESSMENT CRITERIA**Assessment Criterion 1**

Discuss the Goals of Antiretroviral Therapy in Children

Assessment Criterion 2

ARVs are explained as a combination of medicines that limit the replication of the HI Virus.

Assessment Criterion 3

The benefits and implications of treatment are explained as a life-long programme for the children on ART.

Assessment Criterion 4

ART is defined regarding the benefits of adherence and the consequences of non-adherence to the treatment plan.

Assessment Criterion 5

The link between treatment non-compliance and drug resistance is described in terms of the risks to the patient.

Specific Learning Outcome 2

Explain the psychosocial and cultural factors that affect the children who receive ART, their parents/ caregivers, their family and the community.

Assessment Criterion 1

Cultural and traditional beliefs are explained in terms of their effect on the treatment of HIV&AIDS.

Assessment Criterion 2

Effects of Stigma on the Non-disclosure of the HIV status to children

Assessment Criterion 3

Explain factors that promote ART adherence

Specific Outcome 3

Facilitate treatment support systems for the children on ART

Assessment Criterion 1

Facilitate local support systems for the parents and caregivers of children receiving ART.

Assessment Criterion 2

Local community support groups for the parents and caregivers of children receiving ART are identified in their ability to support, help and motivate the parents.

ASSESSMENT CRITERION RANGE

Support systems include counsellors, team members, community resources and treatment support groups.

Specific Learning Outcome 4

Explain the Concept of Rational & Irrational Medicine Use

Assessment Criterion 1

The aims & objectives of the Rational Medicine Use concept is discussed

Assessment Criterion 2

The advantages of Rational Medicine Use are discussed

Assessment Criterion 3

Explain the Irrational Medicine Use concept

Assessment Criterion 4

Implications of Irrational Medicine use in the management of children on ART

Assessment Criterion 5

Discuss the importance of adherence to the HIV/AIDS treatment Guideline in ART Management

Assessment Criterion 6

Discuss the effects of non-adherence to HIV/AIDS treatment Guidelines

Specific Learning Outcome 5

Demonstrate an understanding of medical record keeping in HIV/AIDS management

Assessment Criterion 1

Discuss Good Medical Record Keeping

Assessment Criterion 2

Explain the Importance of Good Record Keeping in ART management

Specific Learning Outcome 6

Demonstrate an understanding of Rational Regimen Switching Practices in Children

Assessment Criterion 1

Discuss Regimen Switching

Assessment Criterion 2

Explain the role of Regimen Switching in ART

Assessment Criterion 3

Discuss factors associated with "Regimen Hopping."

Specific Learning Outcome 7

Demonstrate an understanding of Good Prescribing Practices

Assessment Criterion 1

Discuss Rational Prescribing

Assessment Criterion 2

Discuss a Rational Prescription

Specific Learning Outcome 8

Demonstrate an understanding of Good ART Dispensing

Assessment Criterion 1

Show the competence to determine the correct quantity of ARVs to dispense

Assessment Criterion 2

Discuss how to determine the correct quantity to dispense

Assessment Criterion 3

Aspects to consider when dispensing ART in children

Specific Learning Outcome 9

Demonstrate an understanding of Viral Load Monitoring

Assessment Criterion 1

Familiarisation with clinical ART guideline recommendations for VL monitoring

Assessment Criterion 2

Discuss the importance of on schedule VL monitoring

Specific Learning Outcome 10

Demonstrate knowledge and understanding of the pharmacokinetic & pharmacodynamics of ARVs

Assessment Criterion 1

Demonstrate an understanding of the importance of ARV formulations

Assessment Criterion 2

Benefits of ART formulation considerations in the treatment

Assessment Criterion 3

Disadvantages of lack of ART formulation

Assessment Criterion 4

Formulation Aspects to consider during ART prescribing and management

Specific Learning Outcome 1

Demonstrate fundamental knowledge and understanding of ARVs and their role in HIV/AIDS management.

At the end of this outcome, participant nurses should be able to:

1. Discuss the Goals of Antiretroviral Therapy in Children.
2. Discuss the role of ARVs in ART management.
3. Explain the benefits of ART in children
4. Discuss the implications of long-term ART in Children.
5. Explained the benefits of ART in terms of adherence and the consequences of non-adherence to the treatment plan.
6. Relate treatment non-compliance and drug resistance by looking at the risks to the patient.



Activity 1: Individual Activity

NB: Use the latest South African ART Clinical Guidelines for the Management of HIV in Adults, Pregnancy, Children, Infants & Neonates, as well as your personal experience to do this activity. **On the provided worksheet:**

- 1.1 Make a note of what you understand the goal(s) of ART in children.
- 1.2 Explain what ARVs are and their role in ART management.
- 1.3 Discuss the benefits of ART to children.
- 1.4 Discuss the implications of long-term ART in Children.
- 1.5 Discuss individual answers with a colleague sitting next to you.
- 1.6 Each participant will be given time to report on their partner's answers.
- 1.7 Assessment of individual answers.
- 1.8 Consolidate all answers and reflect.
- 1.9 The facilitator summarises the concepts and adds input.

1. National Department of Health South Africa., 2019. 2019 ART Clinical Guidelines for the Management of HIV in Adults, Pregnancy, Adolescents, Children, Infants and Neonates.
2. Hudelson, C. and Cluver, L., 2015. A systematic review is associated with adherence to antiretroviral therapy among adolescents living with HIV/AIDS in low- and middle-income countries. *AIDS care*, 27(7), pp.805-816.

Specific Learning Outcome 2

Explain the psychosocial and cultural factors that affect the children who receive ART, their parents/ caregivers, their family and the community.

At the end of this outcome, participant nurses should be able to:

1. Explain the caregivers' cultural and traditional beliefs and their effects on the adherence of children to ART.
2. Discuss the effects of Stigma on the Non-disclosure of the HIV status to children
3. Explain factors that promote ART adherence in children



Activity 2: Face-to-Face

2.1 The facilitator explains the psychosocial and cultural factors that affect on;

- the children who receive ART,
- their parents/ caregivers,
- their family and the community.

2.2 The facilitator will also discuss with the participants the effects of parental/caregiver stigma on non-disclosure

2.3 The facilitator will also explain the factors for ART adherence promotion in children to the participants.

2.4 Furthermore, the facilitator will wrap up by consolidating **SLO1 and SLO2,**

2.5 After that, make a summary and give inputs.

Specific Outcome 3

Facilitate treatment support systems for the children on ART

At the end of this outcome, participant nurses should be able to:

1. Facilitate local support systems for the parents and caregivers of children receiving ART.
2. Identify local community support groups to support, help and motivate the parents and caregivers of children receiving ART.



Activity 3: Pre-Reading & Pre-Knowledge Assessment

NB!! Divide yourselves into groups of four and choose a group presenter for the feedback session time.

Read the following documents;

- 3.1 Disclosure Guidelines for Children and Adolescents in the context of HIV, TB and non-communicable diseases (2016 or Latest version).
- 3.2 Identify local community support groups in your area and their role in supporting, motivating, and helping children and their parents/caregivers.
- 3.3 Furthermore, the facilitator will make a summary and give inputs.
- 3.4 After that, the facilitator will wrap up by consolidating all the **SLO3** aspects

Specific Learning Outcome 4

Explain the Concept of Rational & Irrational Medicine Use

At the end of this outcome, participant nurses should be able to:

1. Discuss the aims & objectives of the Rational Medicine Use concept
2. Understand the advantages of Rational Medicine Use
3. Explain the Irrational Medicine Use concept
4. Understand the implications of Irrational Medicine use in the management of children on ART
- 3) Discuss the importance of adherence to the HIV/AIDS treatment Guideline in ART Management
- 4) Discuss the effects of non-adherence to HIV/AIDS treatment Guidelines



Activity 4: Face-to-Face

The facilitator's presentation will address the following ;

- 4.1 Discuss the aims & objectives of the Rational Medicine Use concept
- 4.2 Understand the advantages of Rational Medicine Use
- 4.3 Explain the Irrational Medicine Use concept
- 4.4 Understand the implications of Irrational Medicine use in the management of children on ART
- 4.5 Discuss the importance of adherence to the HIV/AIDS treatment Guideline in ART Management
- 4.6 Discuss the effects of non-adherence to HIV/AIDS treatment Guidelines
- 4.7 After that, the facilitator will wrap up by consolidating all the **SLO4** aspects

Specific Learning Outcome 5

Demonstrate an understanding of medical record keeping in HIV/AIDS management

At the end of this outcome, participant nurses should be able to:

1. Discuss Good Medical Record Keeping
2. Explain the Importance of Good Record Keeping in ART management



Activity 5: Pre-Knowledge Assessment

NB!! On the provided worksheet, use your experience to outline individually the following;

- 5.1 A list of types of records in nursing practice?
- 5.2 Explain to the nurse the importance of record-keeping in nursing practice?
- 5.3 Explain the principles of good record keeping.
- 5.4 Discuss your answers with the person sitting next to you for 5 minutes.
- 5.5 The facilitator summarises **SLO5** and gives inputs.

Specific Learning Outcome 6

Demonstrate an understanding of Rational Regimen Switching Practices in Children

At the end of this outcome, participant nurses should be able to:

1. Discuss Regimen Switching
2. Explain the role of Regimen Switching in ART
3. Discuss factors associated with “Regimen Hopping.”
4. Demonstrate an understanding of Good Prescribing Practices
5. Discuss Rational Prescribing
6. Discuss a Rational Prescription



Activity 6: Group Discussion Case Study

Please Note: Complete all the activities with your group members and nominate one group member to present your feedback to the entire class.

- Each group will present their feedback for 5 minutes per group.
- Analyse the scenario below and use your experience and the latest Clinical ART guideline as a reference to answer questions **6.1 to 6.4** below:

Case Scenario

Risana is an 11 months old girl who has been on ART since birth. During an ART file audit you conducted in your clinic, you discovered that Risana, for the past four months she has received treatment as follows;

	15/03/2020	14/04/2020	15/05/2020	16/06/2020
Body Wt	11kg	11kg	-	11.2kg
Rx	ABC 6ml bd 3TC 6ml bd Kaletra 2ml bd	AZT 20ml bd 3TC 6ml bd Kaletra 2ml bd	ABC 6ml bd 3TC 6ml bd Kaletra 2ml bd	ABC 12ml nocte 3TC 12ml nocte EFV 300mg nocte

Latest VL Results	119 copies/mL taken (15/03/2020)
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Questions

1. Discuss Regimen switching
2. Relate the regimen switching answer above to Risana's received treatment in these four months.
3. Define Risana's treatment prescribing pattern
4. What is the goal of Regimen Switching in children on ART?
5. After all group presentations, the facilitator gives inputs and summarises **SLO6**.

Specific Learning Outcome 7

Demonstrate an understanding of Good ART Prescribing Practices

At the end of this outcome, participant nurses should be able to:

1. Differentiate between Rational Prescribing & Irrational Prescribing
2. Identify the components of a Rational Prescription



Activity 7: Individual Skill/Practical Assessment

- 7.1 Each participant is expected to come to the training with one medical record of a virally unsuppressed child under 10 years on ART for over 24 months.
- 7.2 Participants will be given 30-45 minutes to conduct a six-month medical record audit of one medical record.
- 7.3 Thereafter, each participant will be given 10 minutes to present their audit findings to the entire group. The feedback should answer the following questions;
 - a. The child's age and ART initiation date
 - b. A record of the latest
 - c. Did the child honour the scheduled appointment dates in all 4 visits? **Explain**
 - d. Was the child's weight recorded in all 6 visits? **Explain**

- e. Was the child prescribed the correct regimen for age/weight in the 6 months? **Explain**
- f. Was the child prescribed the correct strength for all the prescribed ARV drugs? **Explain**
- g. Was the child prescribed the correct dosing frequencies in the 6 months?
Explain
- h. After all presentations, the facilitator summarises SLO7 and gives inputs.

Specific Learning Outcome 8

Demonstrate an understanding of Good ART Dispensing

At the end of this outcome, participant nurses should be able to:

1. Show the competence to determine the correct quantity of ARVs to dispense
2. Discuss how to determine the correct quantity to dispense
3. Aspects to consider when dispensing ART in children



Activity 8: Individual Skill/Practical Assessment

- Using the same file used for activity 7.
- The latest Paediatric ART Dosing Chart, and
- The latest Clinical ART Guidelines.
- Each participant will be given 30 minutes to conduct a 6 consecutive month's audit to answer question **8.1** below;
- With the help of the provided Paediatric ART Dosing Chart. Determine the correct quantities to supply the children in **Qs 8.2 to 8.4**
- All participants will be **given 5 minutes** to discuss their answers with the whole group

8.1 Was the child issued correct quantities in the 6 months? **Explain**

8.2 Strawberry is a very clever*big girl* who does not take syrups anymore. Her body weight is 19.9kg, and she is on an AZT, 3TC and LPV/r containing regimen. **How much of each prescribed item will you issue out to Strawberry to last 28 days?**

8.3 Bubbles is a 3yrs old boy with a bodyweight of 14kg on an Efavirenz containing regimen. **How much**

EFV will you issue out to last him 30 days?

8.4 Lollipop is a 2 years old boy with a bodyweight of 11kg and on ABC 120mg Bd, 3TC 60mg Bd and Lopinavir/ritonavir 160/40mg Bd. **How many bottle(s) of ABC, 3TC and LPV/r are you going to issue out to Lollipop to last him 30 days?**

8.5 After all group presentations, the facilitator gives inputs and summarises **SLO7** and **SLO8** by presenting the concept of Rational Prescribing and aspects to consider during the dispensing of ART.

Specific Learning Outcome 9

Demonstrate an understanding of Viral Load Monitoring

At the end of this outcome, participant nurses should be able to:

1. Familiarisation with clinical ART guideline recommendations for VL monitoring
2. Discuss the importance of on schedule VL monitoring



Activity 9: Group Work

NB!! Complete all the activities with your group members and then one group member to present on the provided worksheet to the class.

Use the following documents;

- The latest Clinical ART Guideline.

9.1 Discuss the recommendations for VL monitoring.

9.2 Using your knowledge and understanding of ART management, discuss the importance of on-time VL monitoring

9.3 One group member to present your discussion.

9.4 The facilitator summarises **SLO9** and gives inputs.

Specific Learning Outcome 10

Demonstrate knowledge and understanding of the pharmacokinetic & pharmacodynamic principles of ARVs

At the end of this outcome, participant nurses should be able to:

1. Demonstrate an understanding of the importance of ARV formulations.
2. Benefits of ART formulation considerations in treatment.
3. Disadvantages of lack of ART formulation.
4. Formulation Aspects to consider during ART prescribing and management.



Activity 10: Face-to-Face

The facilitator explains the importance of ARV formulation consideration in ART management

10.1 The facilitator will present the benefits of ART formulation considerations in treatment to the participants.

10.2 The facilitator will also explain the disadvantages of the lack of ART formulation consideration.

10.3 Furthermore, the facilitator discusses the formulation aspects to consider during ART prescribing and management.

10.4 After that, the facilitator summarises **SLO10** and gives inputs.

Extra activities to enhance the participants' ART dosing and dispensing competence level.



Activity 11: Group Work Case Scenario

Please Note: Complete all the activities with your group members on the provided worksheet.

Select one group member to present your feedback to the entire group.

Use the following documents;

- The latest Clinical ART Guideline to answer questions **11.1 to 11.3**.

Case Scenario: Milo is rightfully on ABC 2ml Bd, 3TC 2ml Bd and LPV/r 1.5ml Bd. Her next review date will be a month (28 days).

11.1 How much ABC are you going to dispense to **Milo**?

11.2 How much 3TC are you going to dispense to **Milo**?

11.3 How much LPV/r are you going to dispense to **Milo**?

The evaluation tool for the participants to rate the implementation of the training process as well as the training programme.



Activity 12: Evaluation of the Training Programme

Each learner is allowed to evaluate the training programme.

- Kindly complete an individual evaluation tool anonymously to evaluate the training programme.
- To open click on this link: <https://forms.gle/8DfYa8oGPjKQG8M27>

6.6 Details of the implementation process of the training programme

The development of the training programme includes the description of guidelines for the accomplishment of the programme. According to Everett-Murphy, Mash, and Malan (2015), guidelines are important because they serve as a guide and a standard to best practices for directing the implementation of the programme exertion (Rosenfeld & Shiffman, 2009).

Hence, the following guidelines were developed to direct the implementation process of the training programme:

6.6.1 Guidelines for the Facilitator

The following guidelines are meant for the facilitator of the training programme

- The facilitator should make a prior arrangement to execute the training programme with the Sub-district managers to give times and venues for the facilitator to conduct the programme.
- The facilitator who could be the programme coordinator should be aware of their knowledge and proficiency about ART dosing and dispensing programme.
- The facilitator should bring a favourable setting for NIMART- trained professional nurses to learn how to enhance the implementation of the ART dosing and dispensing training programme during HIV/ AIDS management processes.
- The facilitator must be practical and hold the comprehensive experience and information necessary to support NIMART- trained professional nurses and help them implement the ART dosing and dispensing training programme in ART management.
- The facilitator's functions in empowering NIMART- trained professional nurses in implementing the ART dosing and dispensing training programme should be clear so that each one is conscious of the arrears of self and the other to avoid discording ideas.
- It's the responsibility of the facilitator to seek further information about the ART dosing and dispensing training programme so that during the implementation part, the facilitator demonstration the uppermost degree of knowledge and understanding of the ART dosing and dispensing training programme.
- Provide support to the participators during the accomplishment of all programme exertion.

6.6.2 Guidelines for the Participants

The following are the guidelines for the participators

- The participants, in this case, are NIMART- trained professional nurses who need to concede the knowledge gap they've about the implementation of the ART dosing and dispensing training programme during patient care in the wards.
- Active participation in each exercise must be encouraged to acquire the experience during interaction with the facilitator.

- The participator should achieve all anticipated knowledge outcomes for the programme.
- NIMART- trained professional nurses have to take responsibility for their professional growth and development and learn during empowerment.
- The participator should negotiate with colleagues about group discourses to complete given group activities.
- The participants should record each exercise in each study unit to help them during the completion of the programme evaluation tool.

6.6.1 Guidelines for the Context

The following guidelines were formulated grounded on the data analysis as discussed in Chapter five of the study.

- The context is the public primary healthcare clinics of Mopani District in the Limpopo Province, where NIMART- trained professional nurses manage children on ART.
- The clinics should cooperatively probe the latest information on the ART dosing and dispensing training programme to keep abreast of the rearmost developments within the nursing profession.
- To strengthen the programme and secure sustainability, clear guidelines should be set and promoted to nurse experts during workshops to gain further up-to- date knowledge on executing the ART dosing and dispensing training programme.
- Encouragement of the collaboration with the pharmacists as ART dosing and dispensing experts at the hospital level could be valuable resource support to nurses managing children on ART and enforcing the training programme.
- The clinics should also partake in the district, provincial, and national activities related to the ART dosing and dispensing training programme to manage children on ART effectively.

6.6.3 Guidelines regarding the dynamics of the programme

The programme dynamics include the facilitator's and participators' responsibility, accountability, willingness, effective communication, participation, and commitment. The guidelines to operationalise these dynamics are described as follows

Responsibility and accountability.

- NIMART- trained professional nurses have to be willing to be responsible for their literacy and empowerment by the facilitator as an expert in the field.
- NIMART- trained professional nurses should be responsible for their conduct and elisions during empowerment.

Willingness and commitment.

The facilitator should commit their own time and energy to empower and capacitate the participators through varied activities.

- NIMART- trained professional nurses should be willing and committed to being directed and empowered by the facilitator.
- The participators, NIMART- trained professional nurses, should also be prepared to work towards self- growth and development through the support of experts and ready to seek clarity when the need arises.
- The facilitator and the participators should all be willing and committed to the process.

Active participation

- The facilitator and the participators should be eager to diligently share in the empowerment activities to achieve the desired results.
- Participation in the facilitator demands an understanding of their professional and moral responsibility towards the professional development of NIMART- trained professional nurses enforcing the ART dosing and dispensing training programme during patient care.
- Both the facilitator and the participators should share in conversations and feedback on the ART dosing and dispensing training programme.

6.6.4 Guidelines Regarding the Training Procedure

The training programme aims to refine the implementation of the ART dosing and dispensing training programme during patient care through situational analysis, design, development perpetration, and evaluation. These activities are talked over as follows:

Situational analysis:

- The programme's first step is attaining the NIMART- trained professional nurses' prescribing practices and training needs when managing children on ART in their clinics. Their perceptions are concerning the ART management process and their self-rating of their knowledge, understanding, and competence levels in terms of the management of children on ART.

Design, plan, and development:

- The facilitator prepares for the programme grounded on the knowledge gaps and training requirements as identified in the situational analysis leading to the development of a training programme to ameliorate perpetration of the ART dosing and dispensing training programme.
- The facilitator will define and transfer facts regarding the ART dosing and dispensing training programme accomplishment and set goals for its implementation.
- The planning aims to impact individual and professional growth for NIMART- trained professional nurses on how they will deal with the dynamics.

Implementation:

- At this level, active participation is observed in the workshop conducted for NIMART- trained professional nurses on enforcing the ART dosing and dispensing training programme.
- Sharing information is constituted in a complimentary context to evolve contemplative, cognitive, and psychomotor chops.

Evaluation:

- The NIMART- trained professional nurses undertake professional valuations through feedback to enhance alteration of conduct for appreciative results, and feedback may enhance the performance of NIMART- trained professional nurses.

6.6.5 Guidelines in Terms of the Results of the Training Programme

- There's an expectancy that the outcomes of the facilitator, participator, and training contexture will be
- A capable NIMART- trained nurse in ART dosing and dispensing when managing children on ART.
- Cultivating lifelong training, mentoring proficiency on the part of the facilitator will allow them to be accountable and capable health professionals.
- The environment could refine quality patient care since NIMART- trained professional nurses will effectively treat children on ART during patient care.

6.6 Conclusion

Chapter six discussed developing a context-specific training programme for the NIMART- trained professional nurses in public primary healthcare clinics. The development of the training programme was grounded on the study results and findings as derived from the data analysis and merging of both the qualitative and quantitative phases. The study showed that for NIMART- trained professional nurses to manage children on ART in the clinics effectively, they required a training programme that would help them to enhance the dosing and dispensing practices of ART in virally unsuppressed children. The development of a training programme comported of distinct literacy outcomes that solidified the study units to empower NIMART- trained professional nurses with knowledge and expertise to enhance the ART management process. The guidelines for implementing the training programme were described based on rational drug use theory.

CHAPTER 7

IMPLEMENTATION OF THE PAEDIATRIC ART DOSING AND DISPENSING TRAINING PROGRAMME

7.1 Introduction

Chapter six described the development of the ART dosing and dispensing training programme for NIMART-trained PNs and the guidelines for the implementation in public primary healthcare clinics of Mopani District, in Limpopo Province, South Africa. Chapter seven focuses on addressing the last phase of the study (Phase 4), which aimed at implementing the developed Paediatric ART dosing and dispensing training programme for NIMART-trained PNs managing children on ART in resource-limited public primary healthcare clinics.

7.2 The Implementation Process of the Training

The implementation process was a way of operationalising the developed ART dosing and dispensing training programme and evaluating if the programme activities produced the intended results to make amendments in the programme if required. Furthermore, the implementation of the training programme intended to confirm if the study results were still the same as what the participants explained during the phase 2 data collection processes. The participants were allowed to verify whether the training programme addressed their training and learning needs in the appropriate management of children on ART. However, the implementation phase was conducted with NIMART-trained PNs in the Ba-Phalaborwa and Greater Letaba Sub-district due to the COVID-19 restrictions.

7.2.1 The Implementation Process

The implementation was conducted with few available participants due to the need to abide by the Covid-19 restrictions to ensure safety measures are adhered to as outlined in the WHO guidelines for preventing infections. The South African government collaborated with the National Department of Health. During the

implementation phase, all safety measures were adhered to, including maintaining social distance where the sitting arrangements were about 1.5 to 2 meters apart, the compulsory wearing of facemasks at all times in the session, frequent handwashing, and use of sanitisers. The operational managers of the used training facilities also ensured that thorough cleaning of the environment and surfaces took place. The training participant's further minimised close contact throughout the sessions. The implementation was conducted in two separate sessions. The first session was in Greater Letaba with three participants, and the second session took place in Ba-Phalaborwa and had nine participants. These sessions of implementing the training programme were conducted in two and a half days and not the five days as planned. This was mainly due to a shortage of nurses in the training facilities, which warranted the plea to minimise the time spent with participants as much as possible.

Before the training, arrangements were made with Sub-district and clinic operational managers to request a suitable date for NIMART-trained PNs to participate in the in-service training programme. On the first few hours of the first day, the whole training programme was introduced, training materials were given, and pre-training assessments (**Appendix XI**) were conducted with all participants on both occasions. The pre-training evaluation aimed to assess current training needs, knowledge, and skills gaps of the NIMART-nurses managing children on ART. Furthermore, the researcher wanted to confirm whether the scores obtained would yield similar findings as those obtained during the situational analysis phase of the study project in the results and findings.

On the second day, the participants were introduced to the activities in the training programme by the researcher, who was the programme facilitator. A total of twelve NIMART-trained PNs were accessed at different intervals to implement the ART dosing and dispensing training programme. Post-training assessments (**Appendix XI**) were conducted again to assess the knowledge and skills that the NIMART-trained PNs acquired during training compared with the pre-training assessment scores. The post-training assessment scores were analysed to check if there were differences in each participant's pre and post-training scores, and the discrepancies

were noted between the scores. The importance of the post-training assessment was to confirm the difference in the scores before and after the training. The findings indicated that the training programme had improved the participants' knowledge and skills. At the end of all sessions, all participants were given evaluation forms to comment and input the training programme aimed at improving the training programme (**Appendix XII**).

The ADDIE model was used to guide the implementation phase of the training programme, where the last two phases of the model, the implementation, and the evaluation, were adhered to. The participants were given pre-test assessments, followed by activities in the unit standards of the programme. Post-test assessments and individual assessments, using an evaluation tool, evaluate the whole programme. The evaluation of the training programme was the last phase of the ADDIE model, and all professional nurses were included in both the assessments, training and the review of the training programme.

A context-specific training programme for NIMART-trained PNs implementing the management of children on ART started with the situational analysis in Phase one. Then the theoretical framework was developed in Phase two, followed by the development of the training programme with guidelines in Phase three and then the implementation of the training programme in Phase four which was conducted during this phase. The following study units were included in the training programme, i.e. the description of the training programme, knowledge and understanding of the role of ARVs in the management of HIV/AIDS, demonstrated knowledge of the effects of psychosocial and cultural factors on ART adherence, demonstrated knowledge of the rational and irrational ART use concepts, demonstrated understanding of pharmacokinetics and pharmacodynamics of ARVs as well as the understanding of good medical record keeping.

7.2.2 Training Resources

The training materials were developed in advance. The manuals included the facilitator manual, the 2019 Clinical ART Treatment Guideline, and the paediatric dosing chart. All related training materials were developed during the development phase of the programme. All training needs identified as gaps during the analysis phase were included in the topics covered in the training programme. The training material was based on the latest South African Clinical ART treatment guidelines, articles and books on HIV/AIDS management in children, the rational use of medicines and ARVs in particular, antiretroviral stewardship, factors associated with poor clinical outcomes in children on ART, viral suppression and non-suppression, medication errors in children on ART e.t.c. This was done to ensure that recent materials were used to keep nurses abreast of the latest information on the management of children on ART. Writing materials, laptops, overhead projector, worksheets and necessary training stationery were arranged for the training sessions, and all training materials were printed.

The development of the training materials was also verified for quality purposes by the supervisors before the training commenced, and inputs were considered. The simulation skill was prepared before training using a replica of patient medical records used to manage children on ART. Hence, the Paediatric ART dosing and dispensing facilitator's training manual and marking guides were developed to assess the participants' pre-and post-training practical skills for success. The training materials were handed over to the participants on the first training day. This included the pre-training assessment materials and the general information session on the training programme aspects.

7.2.3 Rolling out the Training Programme

The facilitator, an experienced clinical pharmacist, lecturer, assessor, and moderator arranged training dates. The arrangements were made with the participants who were available for the training. The whole training process was thoroughly outlined to

them, given the COVID-19 pandemic restrictions and their consent to participate in the study implementation.

The initially planned sessions were prepared for five consecutive days. The Grater Letaba session had three participants, and the Ba-Phalaborwa session had nine participants. Still, since the current Covid-19 pandemic, each session was consolidated in two days, and there were limited participants in both sessions. Hence a total of 12 participants were trained. The training was conducted in pre-arranged venues to accommodate the small number of participants to avoid overcrowding and strictly adhere to all Covid-19 precautionary measures to prevent infections. The training-introduction was briefed on the first few hours, and pre-training assessments were conducted on the first day. These were followed by some activities and training by the facilitator to sum up, the unit standard activities. This was after that concluded on the second day with the post-training assessments.

7.2.4 Evaluation of the Training Programme

The participants were throughout the training process continuously evaluated and engaged to ensure that the objectives of the training were accomplished. The immediate evaluation was guided by Kirkpatrick's evaluation models, which are comprised of four levels as follows; 1) the first level is the training reaction level; 2) the second level which encapsulates the learning process; 3) the third level is known as the behaviour; and 4) the fourth and last as the level is known as the results level (Kirkpatrick, & Kirkpatrick, 2016; Kurt, 2017; DeSilets, 2018). This study, however, only focused on the first two levels of the evaluation from this model, which are reaction, and learning levels.

- **Reaction Level**

According to this model, the reaction evaluation can be done immediately after training. This is deemed a simple way to obtain reaction feedback. This can also be conducted post-training through surveys or questionnaires. The reaction evaluation revealed how the delegates felt, their reactions to the training or learning experience, such as whether the trainees liked or enjoyed the training? Did they reflect the training

as relevant? This evaluation of the complete training measured how the exercise achieved the learning objectives. The feedback after the programme was attained by encouraging written comments in an open-ended questionnaire to generate immediate responses. An evaluation tool was developed to guide the participants about what was interesting in the training programme, what they disliked, what can be improved, and any other comment they think the facilitator should consider (**see Appendix XII**).

The knowledge and skills of NIMART-trained PNs were assessed using a written test and the evaluation tool for a skill that was done pre-training and post-training. The participants evaluated the training through pre-training and post-training assessments. An immediate evaluation of the whole training was conducted using an evaluation tool to measure how the training achieved the learning objectives. An open-ended question evaluation tool was prepared to guide the participants about what was interesting in the training programme, what they disliked, what could be improved. Thus, including any other comment, they think the facilitator needs to consider. All the participants felt that the training would be helpful in their daily work activities.

Positive Training Aspects	Training Challenges	Suggestions for Improving
<ul style="list-style-type: none"> • 1. The training was an eye opener • 2. The training addressed real issues • 3. The facilitator was very knowledgeable • 4. Real file audits made us see the mistakes we are making in practice & it was helpful • 5. Learned the proper way of using the dosing chart • 6. Learned how to properly determine the amount to issue out • 7. Outlined the importance of monthly weight monitoring • 8. Made me see how as clinicians we contribute to poor clinical outcomes. • 9. Learned proper ways to prescribe and writing every detail, 	<ul style="list-style-type: none"> • The time was a bit short and certain topics needed more time • The time was not enough to nicely complete certain activities with the facilitator because it was helpful doing them with her. 	<ul style="list-style-type: none"> • Pharmacists in the hospitals in the management of ART programmes in the clinics. • Pharmacists' involvement in training the nurses on the safe use of ARVs. • Recommendation for the adoption of the training programme by the Provincial Department of Health, so that all NIMART-trained nurses are trained • The book clinical stationery contributes to some point to the poor keeping of records, so if this can be addressed it will help.

Figure 7.1: Summary of the training evaluations

All the NIMART-trained PNs had positive views about the training programme. They alluded that the training was an eye-opener and met their expectations about ART management in children. The participants were satisfied with how the facilitation was conducted. Additionally, they commended how the file audits helped them see their mistakes while managing children on ART. They liked this process in such a way that most nurses alluded that this is one of the things they are going to implement in their clinics as a quality improvement strategy towards the improvement of the management of children on ART, as well as a way to ensure that the antiretroviral stewardship process is adhered to at the clinic.

What came out as recommendations were that the training helped them identify a lot of mistakes they make unaware and feel that if the pharmacists from their feeder hospitals can be more proactive in ART management programmes in the public clinics that fall under them and give them coaching and mentorship on the proper use of ARVs more especially when guidelines are updated or new drugs are introduced into the

guideline. Furthermore, some of the nurses mentioned that some of the medical records omissions made whilst prescribing, such as the poor weight monitoring records, apart from the fact that parents/caregivers collect treatment without their children. These result from the fact that the new booklet paediatric clinical stationery, which is not user-friendly in that it does not have enough space to effectively record all the necessary monthly monitoring data since it allows for the recording of three prescriptions per page and depending on the other colleagues' handwriting this prevents them as nurses from recording any changes observed in terms of weight gain or the development of OIs for the next two months.

Some participants alluded that the NIMART-training they attended focused mainly on adult treatment. Hence they feel that this training could assist them as NIMART-trained PNs if the department of Health can adapt the training programme. Furthermore, the nurses highlighted that the training time was insufficient to cover all aspects and wished more time was allocated for learning since they enjoyed working on the activities and getting feedback from the facilitator.

- **The Learning Level**

The learning evaluation tool measured the extent to which training has to increase the knowledge or intellectual capability and skills before and after the learning experience. This included whether the training provided what the participants had expected to learn. It also measured the extent of improvement or change needed to meet the participant's knowledge and skills after the training. In this study, this was attained through pre-training and post-training assessments. **Table 7.1** below reveals the NIMART-trained PNs' performance scores following the pre-and post-training assessments conducted.

Table 7.1: Summary of the pre- and post-training assessments

Participants' #	Pre-training scores		Post-Training Scores	
	Score	(%)	Score(n)	(%)
Participant 1	15	38	24	60
Participant 2	29	73	34	85
Participant 3	18	45	24	60

Participants' #	Pre-training scores		Post-Training Scores	
	Score	(%)	Score(n)	(%)
Participant 4	15	35	30	75
Participant 5	26	65	33	83
Participant 6	20	50	26	65
Participant 7	19	48	27	68
Participant 8	18	45	28	70
Participant 9	21	53	26	65
Participant 10	18	45	24	60
Participant 11	16	40	23	58
Participant 12	25	63	35	88
Average	20	50	28	70

Twelve (12) NIMART-trained PNs who attended the training programme participated in the assessment sessions. The findings revealed that in the pre-test written assessment, two participants obtained a mark < 40%, the majority of the participants (n=5) got a performance mark between 40%- 49%, with four of the participants obtaining a mark between 50%-65% with only one person who obtained a 73% mark. These findings prove to the researcher that there was a knowledge gap in the management of children on ART because the average performance of the participants improved from a 50% average mark to a 70% average performance. For the post-training test, no participant performed < 50%, with the majority of the participants (n=6) obtaining a performance mark between 60-69%, followed by three participants who got a performance mark of 81-90%, and two participants who obtained a 70-80% performance and only one participant scoring less than 60%.

Following the revealed knowledge gap amongst the NIMART-trained PNs in the dosing and dispensing ART in children. The post-test findings suggest that after the training sessions, participants' knowledge has improved. The completed assessment results before and after the training were compared. The post-training performance scores

were higher than the pre-training assessment scores. Therefore, the pre-training scores confirmed knowledge and skill gaps, while the post-training scores showed improved knowledge and competence in dosing and dispensing ART whilst managing children on ART. Thus, the number of scores in the post-training assessments posits that the training of NIMART-trained PNs on the dosing and dispensing of ART in children was essential to improve their knowledge and competence levels. Therefore, this would aid in enhancing the implementation of rational Paediatric ART dosing and dispensing principles in public primary healthcare clinics in Mopani District and hopefully the whole of Limpopo Province.

7.2.5 Training Manual

Introduction

The Designed Training Programme is designed and outlined as follows in Chapter 6.

Course Details: A Short Training Course on the Rational Use of ARVs in Children Course towards their Effective Dosing and Dispensing Practices.

Contact Hours: 40 Hours

Course Credits: 5

Duration of the training sessions: The course will be conducted in five days.

NB: Each session will have learning activities with interactive facilitation and some practical exercises which are patient file-based.

Learning assumed to be in place

 **The Training pre-requisites for this course are:**

- The participant nurses should have knowledge, skills and experience, in the management of children on ART;
- All newly appointed NIMART-trained PNs should be included in the training

programme to familiarise them with the rational ART dosing and dispensing principles;

- The participant nurses should have undergone a NIMART training an equivalent;
- The participant nurses are employed in a public primary healthcare clinic and Registered with SANC.

Co-Requisites Units of Learning to Contribute during the Course:

- A professional nurse registered with the South African Nursing Council.
- English as a medium of instruction and communication. Ability to write and read in English.

Course Facilitator

- Mrs LN Mabila (Clinical Pharmacology Lecturer & PhD candidate) during the study and training of the trainers and participants.

Purpose of the Course:

- The sole purpose of this training programme is to bring a new angle of ART management in children by promoting rational antiretroviral use at primary healthcare clinics and empowering nurses in public clinics of antiretroviral stewardship. This angle has not yet been explored in paediatric HIV/AIDS management and care.

Critical Cross-Fields Outcomes (CCFOs)

Course participants will be able to:

- Identify and use problem-solving skills to solve problems related to ART dosing & dispensing in children.
- Work effectively with others as a team member, group, organisation, community to achieve learning objectives.
- Organising, managing oneself responsibly and effectively.
- Collect, analyse and critically evaluate information.
- Reflect and explore learning strategies that are effective during the training.

- Use science the technology effectively and responsibly towards achieving the set goals.
- Communicate effectively using visual, mathematical or language skills, both oral and written persuasion.
- Recognise that the problem-solving contexts do not exist in isolation and work as a team member of the multidisciplinary healthcare team.

Course outline:

- On completion of this training, the NIMART-trained PNs as learners should be able to have achieved the following Specific Learning Outcomes (SLOs):

SPECIFIC LEARNING OUTCOME 1

Demonstrate fundamental knowledge and understanding of ARVs and their role in HIV/AIDS management.

ASSESSMENT CRITERIA

Assessment Criterion 1

Discuss the Goals of Antiretroviral Therapy in Children

Assessment Criterion 2

- ARVs are explained as a combination of medicines that limit the replication of HIV.

Assessment Criterion 3

- The benefits and implications of treatment are explained as a life-long programme for the children on ART.

Assessment Criterion 4

- ART is defined regarding the benefits of adherence and the consequences of non-adherence to the treatment plan.

Assessment Criterion 5

- The link between treatment non-compliance and drug resistance is described in terms of the risks to the patient.

SPECIFIC LEARNING OUTCOME 2

Explain the psychosocial and cultural factors that affect the children who receive ART, their parents/ caregivers, their family and the community.

Assessment Criterion 1

- Cultural and traditional beliefs are explained in terms of their effect on the treatment of HIV&AIDS.

Assessment Criterion 2

- Effects of Stigma on the Non-disclosure of the HIV status to children

Assessment Criterion 3

- Explain factors that promote ART adherence

SPECIFIC OUTCOME 3

Facilitate treatment support systems for the children on ART

Assessment Criterion 1

- Facilitate local support systems for the parents or caregivers of children receiving ART.

Assessment Criterion 2

- Local community support groups for the parents and caregivers of children receiving ART are identified in their ability to support, help and motivate the parents.

ASSESSMENT CRITERION RANGE

- Support systems include counsellors, team members, community resources and treatment support groups.

SPECIFIC LEARNING OUTCOME 4

Explain the Concept of Rational & Irrational Medicine Use

Assessment Criterion 1

- The aims & objectives of the Rational Medicine Use concept is discussed

Assessment Criterion 2

- The advantages of Rational Medicine Use are discussed

Assessment Criterion 3

- Explain the Irrational Medicine Use concept

Assessment Criterion 4

- Implications of Irrational Medicine use in the management of children on ART

Assessment Criterion 5

- Discuss the importance of adherence to the HIV/AIDS treatment Guideline in ART Management

Assessment Criterion 6

- Discuss the effects of non-adherence to HIV/AIDS treatment Guidelines

SPECIFIC LEARNING OUTCOME 5

Demonstrate an understanding of medical record keeping in HIV/AIDS management

Assessment Criterion 1

- Discuss Good Medical Record Keeping

Assessment Criterion 2

- Explain the Importance of Good Record Keeping in ART management

SPECIFIC LEARNING OUTCOME 6

Demonstrate an understanding of Rational Regimen Switching Practices in Children

Assessment Criterion 1

- Discuss Regimen Switching

Assessment Criterion 2

- Explain the role of Regimen Switching in ART

Assessment Criterion 3

- Discuss factors associated with "Regimen Hopping."

SPECIFIC LEARNING OUTCOME 7

Demonstrate an understanding of Good Prescribing Practices

Assessment Criterion 1

- Discuss Rational Prescribing

Assessment Criterion 2

- Discuss a Rational Prescription

SPECIFIC LEARNING OUTCOME 8

Demonstrate an understanding of Good ART Dispensing

Assessment Criterion 1

- Show the competence to determine the correct quantity of ARVs to dispense

Assessment Criterion 2

- Discuss how to determine the correct quantity to dispense

Assessment Criterion 3

- Aspects to consider when dispensing ART in children

SPECIFIC LEARNING OUTCOME 9

Demonstrate an understanding of Viral Load Monitoring

Assessment Criterion 1

- Familiarisation with clinical ART guideline recommendations for VL monitoring

Assessment Criterion 2

- Discuss the importance of on schedule VL Monitoring

SPECIFIC LEARNING OUTCOME 10

Demonstrate knowledge and understanding of the pharmacokinetic & pharmacodynamics of ARVs

Assessment Criterion 1

- Demonstrate an understanding of the importance of ARV formulations

Assessment Criterion 2

- Benefits of ART formulation considerations in the treatment

Assessment Criterion 3

- Disadvantages of lack of ART formulation

Assessment Criterion 4

- Formulation Aspects to consider during ART prescribing and management

Specific Learning Outcome 1

Demonstrate fundamental knowledge and understanding of ARVs and their role in HIV/AIDS management.

At the end of this outcome, participant nurses should be able to:

7. Discuss the Goals of Antiretroviral Therapy in Children.
8. Discuss the role of ARVs in ART management.
9. Explain the benefits of ART in children
10. Discuss the implications of long-term ART in Children.
11. Explained the benefits of ART in terms of adherence and the consequences of non-adherence to the treatment plan.
12. Relate treatment non-compliance and drug resistance by looking at the risks to the patient.



Activity 1: Individual Activity

NB: Use the latest South African ART Clinical Guidelines for the Management of HIV in Adults, Pregnancy, Children, Infants & Neonates, as well as your personal experience to do this activity. **On a piece of paper;**

- 1.1 Make a note of what you understand the goal(s) of ART in children.
- 1.2 Explain what ARVs are and their role in ART management
- 1.3 Discuss the benefits of ART to children
- 1.4 Discuss the implications of long-term ART in Children.
- 1.5 Discuss individual answers with a colleague sitting next to you.
- 1.6 Each participant will be given time to report on their partner's answers.
- 1.7 Assessment of individual answers.
- 1.8 Consolidate all answers and reflect.
- 1.9 The facilitator summarises the concepts and adds input.

TRAINING RESOURCES

Evaluation at ART Initiation

The study reported a noticeable percentage of children being initiated on ART without vital baseline records like the WHO clinical staging and the presence of other concomitant diseases the child had at the time of ART initiation.

The nurses are reminded of the need to note that.

- At the time of ART initiation, a patient's CD4 count and plasma viral load should be measured to establish a baseline for monitoring the patient's response to ART.
- To set the baseline for monitoring ART toxicity, a complete blood count (CBC), urinalysis, and serum chemistry panel (including levels of electrolytes,

creatinine, glucose, and hepatic transaminases) should be performed.

- The serum lipids (cholesterol and triglycerides) levels should also be measured.
- A CBC allows clinicians to monitor Zidovudine-associated anaemia, leukopenia, and macrocytosis.

References

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Available Online:

<http://aidsinfo.nih.gov/contentfiles/lvguidelines/pediatricguidelines.pdf>

Accessed Online: 30 November 2021

Monthly weight monitoring

Children who have recently received an HIV diagnosis should;

- Have their CD4 counts and plasma viral loads measured,
- Their growth and development should be evaluated for signs of HIV-associated abnormalities.
- Testing should also be performed to assess for HIV-associated conditions, including;

Clinical and Laboratory Monitoring After Initiating or Changing an Antiretroviral Regimen

- Children who start ART or change to a new regimen should be monitored to assess the effectiveness, tolerability, and Adverse Effects (AEs) of the regimen and evaluate medication adherence.
- Clinicians should schedule frequent clinic visits and monitor patients closely during the first few months after initiating a new ART regimen.

- These visits are an opportunity for clinicians to provide support and discuss adherence with patients and their caregivers.
- The first few weeks of ART can be challenging for children and their caregivers; they must adjust their schedules to allow consistent and routine administration of medication doses.
- Children may also experience AEs of medications. Both children and their caregivers need assistance to determine whether the effects are temporary and tolerable or more severe or long-term and require a visit to the clinician.
- This promotes interactive reporting and ensures that providers can have a productive dialogue with both children and their caregiver(s), even in situations where medication adherence is reported to be inconsistent.

Differences between Adults and Children

- Viral Loads
- CD4 counts
- Response to therapy
- Pharmacokinetics and Lack of Trial Data
- Adherence issues
- Drug formulations
- Taste issues
- Immune reconstitution

Viral Suppression

- To achieve sustained viral suppression throughout a child's lifetime, both short-term and long-term ART toxicities must be anticipated.
- Clinicians must consider potential AEs and issues with medication palatability (e.g. Abacavir and Kaletra Syr) when selecting an ARV regimen and the individual child's comorbidities, concomitant medications, and history of drug intolerance or viral resistance.
- The AEs caused by ARV drugs can vary from mild, more common symptoms (e.g., gastrointestinal intolerance, fatigue) to infrequent but severe and life-threatening illnesses.

- Drug-related toxicity can be;
 - **Acute** (occurring soon after a drug has been administered),
 - **Sub - Acute** (occurring within 1 to 2 days of administration),
 - **or Late** (occurring after prolonged drug administration).



It is **very important for children on ART** to be present for clinic visits.

Paediatric Drug Dosing

- Increase Doses as the child grows
- Body Surface Area (BSA) and weight
- Always refer to the Dosing Chart for guidance

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6. Van Dyke, R.B., Lee, S., Johnson, G.M., Wiznia, A., Mohan, K., Stanley, K., Morse, E.V., Krogstad, P.A., Nachman, S., Pediatric AIDS Clinical Trials Group Adherence Subcommittee and Pediatric AIDS Clinical Trials Group 377 Study Team, 2002. Reported adherence as a determinant of response to highly active antiretroviral therapy in children who have human immunodeficiency virus infection. *Paediatrics*, 109(4), pp.e61-e61.
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The Cornerstone of ART Management

- After selecting a suitable regimen for a child
- Have to master the use of this chart to treat the child accordingly
- These are timeously updated
- Therefore necessary to ensure you have the latest copy in your clinic

ANTIRETROVIRAL DRUG DOSING CHART FOR CHILDREN 2021

Compiled by Child and Adolescent Committee of SA HIV Clinicians Society in collaboration with the Department of Health

	Abacavir (ABC)	Lamivudine (3TC)	Abacavir + Lamivudine (ABC + 3TC)	Zidovudine (AZT)	Lopinavir/ritonavir (LPV/r)	Lopinavir/ritonavir when on rifampicin (and for 2 weeks after stopping rifampicin)	* Atazanavir (ATV) + Ritonavir (RTV)	Dolutegravir (DTG)	Dolutegravir when on Rifampicin	Efavirenz (EFV)	
Target dose	8 mg/kg/dose TWICE daily OR If ≥ 10 kg: 16 mg/kg/dose ONCE daily	4 mg/kg/dose TWICE daily OR If ≥ 10 kg: 8 mg/kg/dose ONCE daily	As for individual medicines ONCE daily	180-240 mg/m ² /dose TWICE daily	300/75 mg/m ² /dose LPV/r TWICE daily	LPV/r std dose + super-boosting with ritonavir (RTV) powder TWICE daily ($\geq 0.75 \times$ LPV dose bd) OR Double-dose LPV/r tabs ONLY if able to swallow whole LPV/r tabs TWICE daily	By weight band ONCE daily	By weight band ONCE daily	By weight band TWICE DAILY	By weight band ONCE daily	Target dose
Available formulations	Sol. 20 mg/ml Tabs 60 mg (scored, dispersible), 300 mg (not scored), FDC: see column on Abacavir + Lamivudine	Sol. 10 mg/ml Tabs 150 mg (scored), FDC: see column on Abacavir + Lamivudine	Dispersible tablet FDC: ABC/3TC 120/60 mg Tablets FDC: ABC/3TC 600/300 mg	Sol. 10 mg/ml, Tabs 100, 300 mg (not scored), FDC: AZT/3TC 300/150 mg	Sol. 80/20 mg/ml Adult tabs 200/50 mg, Paed tabs 100/25 mg TABLETS MUST BE SWALLOWED WHOLE Pellets 40/10 mg per capsule ONLY FOR USE IF NOT TOLERATING LPV/r SOLUTION CAPSULES ARE NOT RECOMMENDED < 6 MONTHS OF AGE CAPSULES MUST NOT BE SWALLOWED WHOLE	Oral powder 100 mg/packet Adult tabs 200/50 mg, Paed tabs 100/25 mg	ATV caps 150, 200 mg; RTV tabs 100 mg; FDC: ATV/RTV 300/100 mg ATV CAPSULES, RTV TABLETS AND FDC TABLETS MUST BE SWALLOWED WHOLE	Tab 50mg, FDC: TLD 300/300/50 mg	Tab 50 mg	Caps/tabs 50, 200, 600 mg; FDC: TEE 300/200/600 mg TABLETS MUST BE SWALLOWED WHOLE	Available formulations
Wt. (kg)	Consult with a clinician experienced in paediatric ARV prescribing for neonates (<28 days of age) and infants weighing <3kg										Wt. (kg)
	CHOOSE ONLY ONE OPTION:										
3-3.9	2 ml bd	2 ml bd	1 x 120/60 mg tab od	6 ml bd	* 1 ml bd OR 2 capsules bd	LPV/r std dose (see purple column) + oral ritonavir powder 100 mg (1 packet) bd	Do not use double-dose LPV/r tabs	Not currently recommended: dosing & formulations not available	Not currently recommended: dosing & formulations not available	Avoid using when <10 kg or <3 years	3-3.9
4-4.9					* 1.5 ml bd OR 2 capsules bd						4-4.9
5-5.9	3 ml bd	3 ml bd		9 ml bd	* 1.5 ml bd OR 3 capsules bd						5-5.9
6-6.9											6-6.9
7-7.9	4 ml bd	4 ml bd	1.5 x 120/60 mg tabs od	12 ml bd							7-7.9
8-8.9											8-8.9
9-9.9							9-9.9				
10-10.9	Choose only one option		Choose only one		OR	2 ml bd OR 4 capsules bd OR 2 x 100/25 mg paed tabs am + 1 x 100/25 mg paed tab pm	3x100/25 mg paed tabs bd	Not currently recommended: dosing & formulations not available	Not currently recommended: dosing & formulations not available	Avoid ATV capsules when <15 kg or <6 years	10-10.9
11-13.9	6 ml bd OR 2x60 mg tabs bd	12 ml od OR 4x60 mg tabs od	6 ml bd	12 ml od	2 x 120/60mg tabs od						1x100 mg tab bd
14-14.9	8 ml bd OR 2.5x60 mg tabs bd	5x60 mg tabs od OR 1x300 mg tab od OR 15 ml od	1/2x150 mg tab bd OR 8 ml bd	1x150 mg tab od OR 15 ml od	2.5 x 120/60 mg tabs od	2x100 mg tabs am + 1x100 mg tab pm OR 15 ml bd	4x100/25 mg paed tabs bd OR 2x200/50 mg adult tabs bd	Not currently recommended: dosing & formulations not available	Not currently recommended: dosing & formulations not available	1x200 mg cap/tab + 2 x 50 mg caps/tabs nocte	14-14.9
15-16.9											15-16.9
17-19.9											17-19.9
20-22.9	10 ml bd OR 3x60 mg tabs bd	1x300 mg tab + 1x60 mg tab od	1x150 mg tab bd OR 15 ml bd	2x150 mg tab od OR 30 ml od	3 x 120/60 mg tabs od	2x100 mg tabs bd OR 20 ml bd	2x200/50 mg adult tabs bd	1x50 mg tab od	1x50 mg tab bd	ATV 1x200 mg cap od + RTV 1x100 mg tab od	20-22.9
23-24.9		1x300 mg tab + 2x60 mg tabs od									23-24.9
25-29.9						1x300 mg tab bd	6x100/25 mg paed tabs bd OR 3x200/50 mg adult tabs bd	1x50 mg tab od	1x50 mg tab bd	1xATV/RTV 300/100mg FDC od	25-29.9
30-34.9	1x300 mg tab bd	2x300 mg tabs od	1x150 mg tab bd	2x150 mg tabs od	1x600/300 mg tab od	OR					8x100/25 mg paed tabs bd
35-39.9						1xAZT/3TC					35-39.9

A. NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS (NRTIs)

- These are mainly used as a backbone for most ARV Regimens
- These are;
 - 1) **Abacavir (ABC; Ziagen®)**
 - 2) **Zidovudine (AZT)**
 - 3) **Lamivudine (3TC)**
 - 4) **Tenofovir (TDF)**
 - 5) Stavudine (d4T; Zerit®)
 - 6) Didanosine (ddl; Videx®)
- We will only address those highlighted in bold for the benefit of this training since they are currently used to manage children on ART in South Africa.

1) **Abacavir (ABC)**

Available in the following formulations;

✚ **Abacavir 60mg 12 hourly formulations scored tablets**



- Dispersible *Dissolves* in water
- One dispersible tablet = 3ml of Abacavir solution

✚ **Abacavir 300mg Tablet**

- Twice daily (12 hourly) dosing formulation



ABC 300mg Tablets are a Twice Daily (BD) formulation.

Not for Once daily dosing

+ Abacavir 600mg Tablet

- Once-daily (24 hourly) dosing formulation
- Primarily used in combinations with Lamivudine (3TC) 300mg ~ Dumiva®

FAQ: Can tablets be split/crushed if the child cannot swallow?



Answer: Yes – you can split the 60mg or the 120/60mg fixed dose or dissolve it in water. But NOT the ABC 300mg or ABC 600mg formulation. They must be swallowed whole.

+ Dumiva® Tablets



- Fixed dose Combination tablet (FDC)
- 3TC 300mg & ABC 600mg
- Very large 24 hourly formulation tablet
- Dose: 1 tablet once a day
- Wise to use from 25kg if the child can swallow big tablets

FAQ: Can tablets be split/crushed if the child cannot swallow?



No the tablet must be swallowed whole

B. NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS (NNRTIs)

- These agents are commonly used as first-line ART regimens
- Namely;
 - 1) **Efavirenz (EFV; Stocrin®)**
 - 2) Emtricitabine (FTC)
 - 3) Nevirapine (NVP; Viramune®)

1) Efavirenz (EFV)

Available in the following three formulations;

- i. 50mg Capsule
- ii. 200mg Capsule, and
- iii. 600mg Coated Tablet

FAQ: Can tablets be split/crushed if the child cannot swallow?



EFV 600mg tablets CANNOT be split, divided, chewed or crushed into half to make 300mg or it must be swallowed whole.

However, the capsules can be opened and the entire powder added to a small amount of soft food and ingested at once

Never advise patients or their caregivers to take or give half a capsule of EFV 200mg.

C. PROTEASE INHIBITORS (PIs)

- 1) **Lopinavir/ritonavir (LPV/r; Kaletra®; Aluvia®)**
- 2) **Ritonavir' Boosting' (RTV; Norvir ®)**
- 3) **Nelfinavir (NFV; Viracept®)**

4) Saquinavir (SQV; Invirase®)

1) Lopinavir/ritonavir (LPV/r; Kaletra®; Aluvia®)

- This is a Fixed-Dose Combination (FDC) of Lopinavir (LPV) & Ritonavir (r)
- Like other ARVs, this is used with other HIV medications to help control the replication of the HIV infection.
- Resulting in a robust immune system & improved quality of life
-

Dosage Forms & Strengths

Lopinavir/ritonavir is available in the following 12 hourly formulations and strengths;

1. Tablet

- 100mg/25mg
- 200mg/50mg
- LPV/r 100mg/25mg are heat-stable tablets
- They come in packs of 60 tablets and 120 tablets
- They are formulated in a "melt extrusion" matrix ~ meaning that they **MUST** be swallowed whole and **MUST NEVER** be broken, crushed, chewed or dissolved before administration.
- These tablets can be taken with or without food and are suitable for children over > 10kg who can swallow tablets whole.
- These tablets are **NOT** suitable for infants or younger children that are unable to swallow tablets whole

2. Oral Solution

- 80mg/20mg/ml oral liquid
- is supplied in a pack of 5 bottles, each containing 60ml
- or one bottle containing 160ml (not part of the current Government formulary).
- This formulation contains 42% ethanol and 15% propylene glycol
- It further has an unpleasant taste.

- It is **NOT** heat stable and requires cold chain transport.
- LPV/r oral liquid should be kept at 2 to 8°C at least up to the point of dispensing.
- Once dispensed and outside the refrigerator, LPV/r oral liquid is stable at **25° C** for 42 days (6 weeks).
- LPV/r oral liquid should be taken with food.

3. Oral Pellets

- 40 mg/10 mg

LPV/r 40mg/10mg heat-stable oral pellets (in a capsule)

They received FDA approval in 2015 for use in children above 14 days of age and over > 5kg.

The CHAPAS 2 Trial^{4,5} was an open-label, randomised control crossover trial of the LPV/r 40mg/10mg oral pellets, 80mg/20mg/ml oral liquid, and 100mg/25mg tablets in Ugandan infants and children ages 3 months to < 13 years old and found that **LPV/r oral pellets** provided **similar therapeutic levels** to both oral liquid and tablets when taken with food.

- LPV/r oral pellets are administered twice daily (every 12 hours).



LPV/r SHOULD NOT be administered once daily (every 24 hours) to children
The capsules containing LPV/r oral pellets MUST NOT be swallowed whole.

Table 7.2: Simplified Weight Band Dosing Schedule for LPV/r oral pellets 40mg/10mg

Weight Band (Kg)	Number of LPV/r oral pellets 40mg/10mg		LPV/r 80mg/20mg/ml Solution	
	Am	Pm	Am	Pm
3 – 4.9kg	2	2	1	1
5 – 5.9kg	2	2	1	1
6 – 9.9kg	3	3	1.5	1.5
10 – 13.9kg	4	4	2	2
14 – 19.9kg	5	5	2.5	2.5
20 – 24.9kg	6	6	3	3
25 – 29.9kg	7	7	*NR	*NR
30 – 34.9kg	8	8	*NR	*NR
≥ 35kg	10	10	*NR	*NR

Adapted from the Cipla package insert approved by USFDA and WHO 2013 dosages of recommended antiretroviral drugs. NR = Not Recommended

Directions for Infants and Young Children Older than 6 months of Age Who Can Take Soft Foods:

- i) Open the bottle, count and remove the exact number of capsules required for the immediate dose as prescribed.
- ii) Place these on a clean surface and close the bottle.
- iii) Hold the capsule on both ends and, twisting in the opposite direction and pull apart to deliver pellets over a small amount of soft food such

as porridge at room temperature.

- iv) The pellets **MUST NOT** be stirred, crushed, dissolved/dispersed in water, or chewed.
- v) Administer the entire dose of pellets with food to the child immediately.
- vi) It is crucial to make sure the child has taken the entire dose of pellets by limiting the food used to an amount the child can easily consume in one swallow (e.g. 1 teaspoon), followed by additional food to ensure the full dose is ingested.
- vii) No mixture of the pellets and food is to be stored for later use.
- viii) Dispose of the capsule shell as waste.

For Infants NOT Yet Taking Solid Food, i.e. less than 6 months of Age:

- i) There is currently no experience administering pellets to infants < 3 months.
- ii) In the youngest infants of the CHAPAS 2 study (3-6 months of age), oral pellets were added to a small volume of expressed breastmilk in a spoon and given to the infant or put directly on the infant's tongue before breastfeeding.
- iii) Since oral pellets **CANNOT** be stirred, dissolved/dispersed or crushed in liquids before administration.
- iv) It is essential to ensure that infants are developmentally able to swallow them.
- v) Open the bottle, count and remove the exact number of capsules required for the immediate dose as prescribed.
- vi) Place these on a clean surface and close the bottle.
- vii) Hold the capsule on both ends and pull the capsule apart by twisting in the opposite direction.
- viii) Pellets can be added to a small volume of expressed breast milk or formula

in a spoon and given to the infant or put directly on the infant's tongue before breastfeeding.

- ix) Administer the entire dose of pellets to the infant immediately.
- x) It is vital to make sure the infant has taken the entire dose of pellets by limiting the breastmilk (or formula) used to an amount the infant can easily consume in a few swallows (e.g. two or three teaspoons), which may be followed by additional breastmilk (or formula) to ensure the full dose is ingested.
- xi) Dispose of the capsule shells in routine waste.

INFORMATION FOR HEALTHCARE PROVIDERS CONCERNING THE USE OF PELLETS:

- i) Adequate instructions must be provided to the caregiver or older child regarding the administration of the oral pellets to ensure the correct number of capsules is opened, and the entire dose is administered as required.
- ii) It may be helpful to **DEMONSTRATE** how to administer the **FIRST dose** to the caregiver.
- iii) If giving LPV/r pellets to infants < 6months **WHERE POSSIBLE**, it may also be helpful to **OBSERVE** administration of the first dose to ensure the infant swallows the full dose.
- iv) Infants should be carefully observed for signs of aspiration, which may include coughing, choking, gagging or eye reddening.
- v) The pellets should not be broken, crushed, chewed, or allowed to dissolve to maintain the integrity of this dosage form, which is a melt-extrusion matrix similar to LPV/r 100mg/25mg heat-stable tablets, which, when crushed or broken, may significantly decrease drug exposure.
- vi) The recommended soft food should be one that does not require chewing to minimise the chances of the child chewing or crushing the pellets.

- vii) Consider using LPV/r oral liquid, as per the Table below, for infants who cannot swallow solid particles such as pellets.
- viii) Consider using LPV/r 100mg/25mg tablets, as per the treatment guidelines and dosing charts, for older children who can swallow tablets to avoid the need to open and administer a high number of LPV/r pellet capsules.

SUPPLY AND RECOMMENDED STORAGE AND HANDLING OF LPV/r oral pellets:

- Lopinavir/Ritonavir oral pellets 40mg/10mg per capsule are supplied in bottles containing 120 capsules.
- It should:
 - Be transported and stored in the original container.
 - Be transported and stored at temperatures **NOT EXCEEDING** 30°C
 - Not be exposed to high humidity outside the original container for longer than two weeks



With the understanding of the **high temperatures** experienced in Mopani. Clinicians need to advise parents and caregivers of children to store medication away from children, in a cool dry place.

2) Ritonavir' Boosting' (RTV; Norvir ®)

- Indicated in combination with other antiretroviral agents for the treatment of HIV-infection
- Not typically used as sole protease inhibitor (PI), but as a pharmacokinetic enhancer of other PIs such as Lopinavir, Saquinavir, Atazanavir e.t.c.



The Department of Health recently sent out a notice reminding practitioners that double dosing of LPV/r (as we do for adults) in *children* on rifampicin-containing TB treatment is *not* recommended.

- The notice was sent out after the third line antiretroviral committee raised concerns regarding the number of cases of protease inhibitor resistance that have been observed, possibly as a result of unboosted or double dosing of LPV/r in young children on rifampicin-containing TB treatment.
- Current LPV/r formulations consist of LPV to ritonavir in the ratio of 4:1.
 - Double dosing does not maintain adequate levels of LPV in young children on rifampicin-containing TB regimens;
 - however, increasing the dose of ritonavir so that the ratio of LPV to ritonavir is 1:1 can result in adequate levels of LPV.
- The STGs and EML recommend additional ritonavir of 0.75 times the LPV dose, 12 hourly, for the duration of rifampicin containing TB treatment. This should be continued for two weeks after completion of rifampicin-containing TB treatment

Table 7.3:Ritonavir boosting (ONLY if on rifampicin) 80 mg/ml ritonavir solution

Weight Band (Kg)	In addition to LPV/r dose
3 – 4.9kg	1ml Bd
5 – 13.9kg	1.5ml Bd
14 – 19.9kg	2ml Bd
20 – 24.9kg	2.5ml Bd
25 – 34.9kg	3ml Bd
≥ 35kg	4ml Bd

The Table is extracted from the Paediatric Hospital Level STGs and EML

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5. World Health Organization, 2015. Fact sheet on lopinavir and ritonavir (LPV/R) oral pellets: 40 mg/10 mg per capsule bottle pack containing 120 capsules.

D. OTHER PIs

These are;

- 1) **Atazanavir (ATV; Reyataz®)**
- 2) Indinavir (IDV; Crixivan®)
- 3) Darunavir (DRV; Prezista®)

Atazanavir (ATV; Reyataz®)

- Atazanavir is always used in combination with other HIV medicines.
- To treat HIV infection in adults and children 3 months of age and older who weigh at least 5 kg.

Dosage Forms & Strengths

- Atazanavir is available in a capsule form and has the following strengths;
 - 100mg
 - 150mg
 - 200mg
 - 300mg
- Swallow the capsules whole. **Do not open the capsules.**
 - Oral powder (50 mg of atazanavir per packet)
- Atazanavir oral powder must be mixed with food or liquid.
- If atazanavir oral powder is mixed with water, your child must eat the food right after taking the oral powder and water mixture.
- Give ritonavir right after your child has taken atazanavir oral powder mixed with food or liquid.
- For information about the correct way to mix and give your child a dose of atazanavir oral powder, see the "Instructions for Use" that comes with the medicine.

E. INTEGRASE STRAND TRANSFER INHIBITORS (ISTIs)

These are;

- 1) **Dolutegravir (DTG; Tivicay®)**
- 2) Raltegravir (Isentress®)
- 3) Cabotegravir (Vocabria®)
- 4) Elvitegravir (Vitekta®)

1) Dolutegravir (DTG)

- This is an Integrase strand transfer inhibitor (ISTI)
- They act by blocking the action of integrase, a viral enzyme of the human immunodeficiency virus type 1 (HIV-1).
- Like all other ARVs, Integrase strand transfer inhibitors is not a cure for HIV or AIDS
- It is used to prevent the human immunodeficiency virus from multiplying in the host.

FAQ: Can tablets be split/crushed if the child cannot swallow?



Tablets **CANNOT** be split, divided, chewed or crushed **it must be swallowed whole** or dissolved in a small amount of water. Allow the tablet to disperse (it will not dissolve completely)
Stir and give the mixture to the child right away.

References

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SPECIFIC LEARNING OUTCOME 2

Explain the psychosocial and cultural factors that affect the children who receive ART, their parents/ caregivers, their family and the community.

At the end of this outcome, participant nurses should be able to:

1. Explain the caregivers' cultural and traditional beliefs and their effects on children's adherence to ART.
2. Discuss the effects of Stigma on the Non-disclosure of the HIV status to children
3. Explain factors that promote ART adherence in children



Activity 2: Face-to-Face

9.5 The facilitator explains the psychosocial and cultural factors that affect on;

- the children who receive ART,
- their parents/ caregivers,
- their family and the community.

9.6 The facilitator will also discuss with the participants the effects of parental/caregiver stigma on non-disclosure

9.7 The facilitator will also explain the factors for ART adherence promotion in children to the participants.

9.8 Furthermore, the facilitator will wrap up by consolidating **SLO1 and SLO2**,

9.9 After that, make a summary and give inputs.

Facilitator's Feedback Session:

- The process of disclosure is a complex one
- Caregivers of HIV positive children should be supported emotionally and psychologically to facilitate disclosing HIV status to their children.
- There is evidence to suggest that it is beneficial to disclose HIV status to infected children before they reach adolescence as;
 - it fosters ART adherence
 - participation in ongoing care, and

- psychological resilience,
- while lessening the risk of horizontal transmission due to risky sexual behaviour
- However, the parent/caregiver's decision determines when this happens.
- ✚ A Study conducted closer to home in Vhembe amongst caregivers of children on ART, and the findings indicated that;
 - Participants demonstrated their understanding of ARV treatment being dispensed according to the children's weight, and they needed to accompany the children for monthly follow-ups.
 - Furthermore, the majority of the caregivers indicated that they were allowed to collect ARV drugs in the absence of children in their care, which was said to be less expensive.
 - However, The majority of participants mentioned **financial burdens** that they experienced.
 - The burden was said to originate from **transport costs during follow-up visits** and insufficient money for food and clothing for the child in need of care.



Clinicians need to keep this in mind when they dispense part of the monthly treatment and request the caregivers to collect the missing treatment either from a nearby clinic or the hospital

- This study revealed that **caring for children on ARV medication often resulted in caregivers borrowing money**, accumulating and living in debt, **footing or hiking for lifts to get access to the health clinics for follow-up.**
- Some of the caregivers also pointed out that they did not have access to the Child Support Grants (CSG) for those children,
- It was controlled by the eldest child, who does not prioritise the child's needs on ARV medication.

- In addition, caregivers indicated that sometimes the money that parents leave behind could only be accessed at the age of 18, leaving the children with nothing to support them.
- Often, children would be stealing money from others and neighbours, which was evident in the comments:

SPECIFIC OUTCOME 3

Facilitate treatment support systems for the children on ART

At the end of this outcome, participant nurses should be able to:

1. Facilitate local support systems for the parents and caregivers of children receiving ART.
2. Identify local community support groups to support, help and motivate the parents and caregivers of children receiving ART.



Activity 3: Pre-Reading & Pre-Knowledge Assessment

NB!! Divide yourselves into groups of four and choose a group presenter for the feedback session time.

Read the following documents;

1. Disclosure Guidelines for Children and Adolescents in the context of HIV, TB and non-communicable diseases (2016 or Latest version).
2. Identify local community support groups in your area and their role in supporting, motivating, and helping children and their parents/caregivers.
3. Furthermore, the facilitator will make a summary and give inputs.
4. After that, the facilitator will wrap up by consolidating all the **SLO3** aspects

Facilitator's Feedback Session:

- Clinicians need to remember that children depend solely on caregivers for adherence. That is;

- Treatment administration,
- Presenting to the clinic for a collection of their antiretroviral treatment (ART),
- Caregivers can be their primary parents, guardians, older siblings, aunts, uncles or grandmothers.
- As clinicians, you can support the parents/caregivers as they suffer emotional strain in caring for children on ART.
- Give information of support groups in the community of your facility
- The emotional wellbeing of a parent/caregiver plays a huge role towards the child's adherence to treatment.

References

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SPECIFIC LEARNING OUTCOME 4

Explain the Concept of Rational & Irrational Medicine Use

At the end of this outcome, participant nurses should be able to:

1. Discuss the aims & objectives of the Rational Medicine Use concept
2. Understand the advantages of Rational Medicine Use
3. Explain the Irrational Medicine Use concept
4. Understand the implications of Irrational Medicine use in the management of children on ART
5. Discuss the importance of adherence to the HIV/AIDS treatment Guideline in ART Management
6. Discuss the effects of non-adherence to HIV/AIDS treatment Guidelines



Activity 4: Face-to-Face

The facilitator's presentation will address the following ;

1. Discuss the aims & objectives of the Rational Medicine Use concept
2. Understand the advantages of Rational Medicine Use
3. Explain the Irrational Medicine Use concept
4. Understand the implications of Irrational Medicine use in the management of children on ART
5. Discuss the importance of adherence to the HIV/AIDS treatment Guideline in ART Management
6. Discuss the effects of non-adherence to HIV/AIDS treatment Guidelines
7. After that, the facilitator will wrap up by consolidating all the **SLO4** aspects

Facilitator's Feedback Session

What is Rational Medicine Use

- Rational medicine use occurs when patients' receive medications appropriate to their clinical needs,
 - in doses that meet their requirements (individually),
 - for an adequate period,
 - and at the lowest cost to them and their community

The Importance of Rational Medicine Use in the context of HIV/AIDS

- ART is complex because it is comprised of a combination of many drugs.
- Moreover, it is taken for a lifetime.
- Hence there's a recent and constant development of these agents.
- Rational medicine use strategies enhance the effective, safe, and cost-effective use of medicines,
- Further, preserving the effectiveness of ARVs, and
- Contribute to good health outcomes.

What is Irrational ARV Prescribing

- This is the opposite of RMU
- This is when children are prescribed ARVs inappropriate to their clinical needs,
- in doses that do not meet their requirements, i.e. Age & weight,
- for an inadequate period, e.g. undersupply of medication,
- At a cost to them and their community
 - When given an undersupply, they will have to spend money and come back to the clinic before their actual clinic visit
 - Going to a nearby clinic or the hospital can also be costly to them

Why ARVs in Children Have to be used rationally?

- Children have limited ARVs suitable and safe for them
- ARVs, if incorrectly used, the child is at risk of resistance development
- Due to viral replication & mutations
- Treatment failure – limits the choice of ARVs for them
- The future challenge that might have adverse effects on them living longer, healthier lives
- 2nd and 3rd line regimens are expensive

Aspects that lead to Irrational Prescribing in ART Management

We will only discuss the two types of factors that emerged during data analysis for this training programme. These are;

1) Clinical Factors

2) Pharmaceutical Factors

Clinical Factors

✚ The clinical factors that mainly contribute to **irrational prescribing** in the management of children on ART are;

- **Inadequate examination of the patient** – like what mostly happens in Public Clinics with caregivers timeously collecting monthly supplies of treatment in



"You are responsible for the prescriptions that you sign.

Only prescribe ARVs when you have adequate knowledge of your patient's health need" ~ GMC 2013

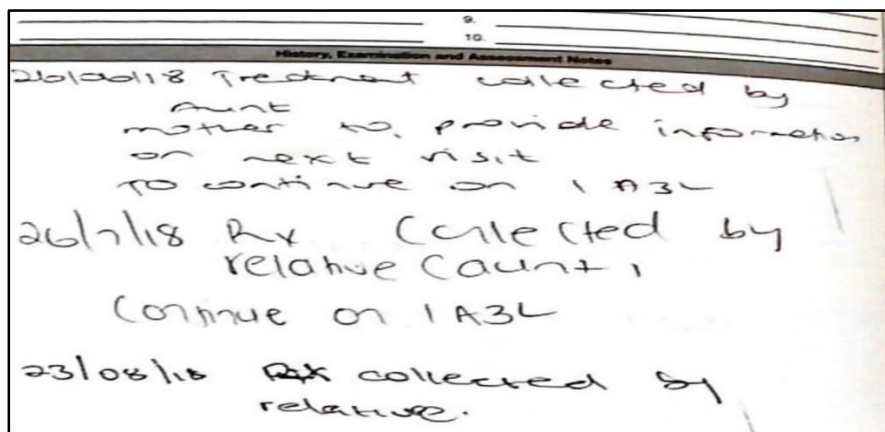
Be satisfied that the drugs serve the patient's

- The prescription or prescriber related factors that contribute towards irrational medicine use are;
- **Under-prescribing of medicine**
 - E.g. the prescription of dual and monotherapy drugs (see attached figures).
- **Over-prescribing of ARVs**
 - E.g. prescribing a quadruple therapy when the guideline requires only three drugs.

Incorrect Prescribing of the ARVs.

Examples;

1. Prescribing without a child's weight



2. A wrong regimen selection,
3. Prescribing an incorrect dose – see attached

TB Screen <input type="checkbox"/> Current TB <input type="checkbox"/> TB Exposure If on treatment, how many months: <input type="text"/>		<p style="color: red; font-family: cursive;">According to the 2013 ART Dosing Chart ; weight = 21kg ABC = 10ml 12Hly OR 300+60mg OD 3TC = 150mg 12Hly EFV = 300mg Nocte</p> <p style="text-align: right; color: red;">23/1/18</p>					
Monitor ARV Treatment Assess Development (Birth - 5 years) <input type="checkbox"/> Developing well <input type="checkbox"/> Some delay <input type="checkbox"/> Losing milestones School Progress (5-15 years) <input type="checkbox"/> Progressing well <input type="checkbox"/> Not progressing <input type="checkbox"/> Not applicable <input type="checkbox"/> Rash <input type="checkbox"/> Diarrhoea <input type="checkbox"/> Dizziness <input type="checkbox"/> Other, specify: _____ <input type="checkbox"/> Occasionally misses a dose <input type="checkbox"/> Not taking medication							
Investigations							
ALT: <input type="text"/> TG: <input type="text"/> LDL Chot: <input type="text"/> TB M/C/S: <input type="text"/>		Test should be done according to current policy Date of current bloods taken: dd / mm / yy <input type="checkbox"/> CD4 count: <input type="text"/> cells/mm ³ % <input type="checkbox"/> Viral Load: <input type="text"/> <input type="checkbox"/> HB / WCC / PLT <input type="checkbox"/> Creatinine clearance <input type="checkbox"/> Other investigation results (including XFR): _____					
Medication							
Medication	Dosage	Frequency	Duration	Pill In	Pill C	dd / mm / yy	dd / mm / yy
ARV 1	ABC	12Hly	1/12				
ARV 2	3TC	12Hly	1/12				
ARV 3	EFV	Nocte	1/12				
ARV 4							
Multivitamin							
Continoususe							

4. Prescribing an incorrect dosing frequency that does not consider the drug formulation

- E.g Lamivudine 150mg 2 tabs nocte, or
- EFV 200mg take 1½ capsule at night or ABC 300mg 2 tabs nocte.
- The aim to improve adherence results is good, but the prescription does not consider the pharmaceutical aspects of the 12 hourly 3TC and ABC formulations. How will the patient break even an EFV capsule to make up the 300mg?

5. Multiple Prescribing

- E.g. prescribing four drugs instead of the required three drugs recommended by the treatment guidelines.

6. Extravagant Prescribing

- Prescribing ARVs in the same class ~ will not serve the purpose of treatment

Dispensing Related Pharmaceutical Factors

- Incorrect interpretation of the prescription
- Dispensing incorrect
- Issuing inadequate supply of ARVs
- Incorrect labelling of medication, and
- Poor packaging

Implications of Irrational Medicine Use

The **irrational use of ARVs** in children leads to;

- An increased risk of toxicities and adverse effects,
- The rapid development of drug resistance,
- Treatment failure, and
- Wastage of the pharmaceutical budget
 - Hence the need for the promotion of Rational Medicine Use (RMU) or Rational Drug Use (RDU) in the management of children on ART.

How do we ensure Rational Prescribing in practice?

- Adherence to treatment guidelines regarding ARV selection, dosing, route and duration of treatment
- This will improve clinical outcome and treatment duration and thus improve quality of life.
- To ensure adherence, users should be involved in developing the guidelines
- Be educated through audits of ART use through in-service medical record reviews.

Adherence Predictors

- Important to speak to caregivers and children in a supportive, non-judgmental manner
- Use layman's terms for comprehension ~ creates trust
- Clinicians must consider potential Adverse Effects (AEs).
- and issues with medication palatability when selecting an ARV regimen
 - E.g Abacavir and Kaletra Syr

- As well as the individual child's comorbidities, concomitant medications, and history of drug intolerance or viral resistance.

SPECIFIC LEARNING OUTCOME 5

Demonstrate an understanding of medical record keeping in HIV/AIDS management

At the end of this outcome, participant nurses should be able to:

1. Discuss Good Medical Record Keeping
2. Explain the Importance of Good Record Keeping in ART management



Activity 5 Pre-Knowledge Assessment

NB!! On a piece of paper, use your experience to outline individually the following;

- 1) A list of types of records in nursing practice?
- 2) Explain to the nurse the importance of record-keeping in nursing practice?
- 3) Explain the principles of good record keeping.
- 4) Discuss your answers with the person sitting next to you for 5 minutes.
- 5) The facilitator summarises **SLO5** and gives inputs.

Facilitator's Feedback

5.1 List types of records in nursing practice

- Patients' clinical records,
- Clinic records, and
- Administrative records

5.2 Explain the importance of record-keeping in nursing practice

- It provides clear evidence;
 - of the care planned,
 - the decisions made,
 - the care delivered, and
 - the information shared
- It is a means of communication with members of the multidisciplinary team

- the patient's progress and continuity of care
- Recording of assessment, nursing intervention implemented, the outcome and the patient's response to interventions
- It indicates that the nurse provided care.
- Enhances professional growth ~ nurses can later evaluate the effectiveness of their interventions.
- Serves as a legal document during lawsuits by patients and relatives

5.6 Explain the general principles of record-keeping

5.3.1 Accuracy

- entails the correct information

The image shows a handwritten medical record on a grid. The left side contains the text: 'Treatment given', 'ABC not available', and 'to go to hospital to collect'. The right side contains 'Treatment given'. Below this, there are columns labeled 'IN', 'OUT', and 'E'. The 'E' column contains the handwritten text 'ABC', '3TC', and 'EeV'. A red arrow points from the 'E' column to a thought bubble containing the word 'How?'.

	IN	OUT	E
Treatment given			ABC
ABC not available			3TC
to go to hospital to collect			EeV

5.3.2 Completeness

- E.g. name of the patient, folder number, ART initiation date, child's DoB, WHO staging, regimen at initiation, reasons for switching regimens e.t.c.

5.3.3 Legibility ~ must be tidy and neat

5.3.4 Tidiness ~ records must be legible & visible

Case Scenario

Milo is an 11 months old girl who has been on ART since birth. During an ART file audit you conducted in your clinic, you discovered that Milo, for the past four months she has received treatment as follows;

	15/03/2020	14/04/2020	15/05/2020	16/06/2020
Body Wt	11kg	11kg	-	11.2kg
Rx	ABC 6ml Bd 3TC 6ml Bd Kaletra 2ml Bd	AZT 20ml Bd 3TC 6ml Bd Kaletra 2ml Bd	ABC 6ml Bd 3TC 6ml Bd Kaletra 2ml Bd	ABC 12ml Nocte 3TC 12ml Nocte EFV 300mg Nocte
Latest VL Results	119 copies/mL taken (15/03/2020)			

Questions

- 6.1 Discuss Regimen Switching
- 6.2 Relate the regimen switching answer above to **Milo's** received treatment these four months.
- 6.3 Define **Milo's** treatment prescribing pattern
- 6.4 What is the goal of Regimen Switching in children on ART?
- 6.7 After all group presentations, the facilitator gives inputs and summarises **SLO6**.

Facilitator's Feedback Session

Antiretroviral Therapy in Children



An important motto in treating Children on ART is;
"The first regimen is your best chance for success"

~ Dr Leon J Levin

- Recent data show that children's response to antiretroviral therapy (ART) overseas and locally has been phenomenal.

- **Yes**, inevitably, increasing numbers of children will require a second-line regimen at some point
- **However**, aim to get it right the first time.

Why Change Regimen(s)

- There are two main reasons for changing ART
 - viz toxicity or intolerance, and
 - Failure of the current regimen.
- Other reasons include poor adherence (often improved with alternative antiretroviral (ARVs)), and
- The emergence of more effective or safer regimens.



Questions for Discussion in class

What about stockouts?

Do we switch every month an ARV is out of stock?

ARV Toxicity or Intolerance

- **See the latest Guidelines for Antiretroviral Therapy in Children**
 - Effective antiretroviral therapy (ART) results in viral suppression and improved immune function.
 - However, Adverse Effects have been reported using all ARV drugs.
 - In the mid-1990s, when combination ART was introduced, AEs were among the most common reasons for switching or discontinuing therapy and medication non-adherence.
 - Currently recommended ARV regimens are associated with fewer serious and intolerable AEs than regimens used in the past.

When to switch?

- There's little paediatric data on when is the perfect time to change ART
- See pages 13 to 17 of the 2019 South African Clinical ART Guidelines for details of **when and how**.



- Intervention does not necessarily mean a change of regimen.
- It may involve resolving adherence issues

How to Switch?

- When a patient exhibits intolerance to or toxicity from a single drug, the offending drug can often be replaced, e.g. replacing zidovudine (AZT) with Abacavir (ABC) for bone marrow toxicity caused by AZT.
- Rarely, a reduction in dosage may be considered as long as the reduced dose is still in the therapeutic range.
- All ART should be stopped for severe toxicity such as ABC hypersensitivity reaction until the patient recovers.
- Only then can one cautiously restart ART
- The offending drug should be switched for one that does not cause the same reaction.



Never become ashamed to consult for expert advice

The monthly changing of one drug identified in the medical records is not regimen switching.

✚ Failure of Current Regimen

- Ideally, one should not switch regimens based on a single viral load or CD4 count

✚ Before Switching Regimens;

- 1) A thorough assessment of adherence issues should be made
 - This is important in determining the cause of failure, as frequently, the same issues will be a barrier to the success of a subsequent regimen.

✚ Assessing Adherence

- Adherence is the most crucial factor determining the success of an ART regimen.
 - Virological failure often follows poor adherence
 - Therefore, adherence issues must be resolved before changing therapy.
- 2) Do a medical record audit to verify if the child;
 - Is on a correct regimen
 - Receives the correct dose
 - The dosing frequencies are also correct
 - The quantity of ARVs dispensed is also correct and will last until the next visit.
- This will help you determine if the child is appropriately managed
 - Because adhering to an irrational regimen may also contribute to poor clinical outcomes.



Changing ART is never an emergency, and is useless if the root cause to the failure of the first regimen is not addressed

~ Dr Leon Levin, 2009

3) Exclude Inadequate Drug Exposure

- There is always a possibility that the child might not be receiving treatment as expected due to the following;
 - i) **Drug not being ingested** - e.g. poor adherence, vomiting, or spitting up of

an unpalatable drug such as ritonavir.

- ii) **Poor absorption** - often in children with chronic diarrhoea or malabsorption
 - iii) **Increased drug metabolism** – children beyond the neonatal age have markedly increased drug metabolisms compared with adults.
 - iv) **Drug interactions** – investigate all patient medications (including over-the-counter drugs and 'herbal' products) for possible drug interactions. ARV agents commonly implicated drugs, including rifampicin, anti-epileptics, antimalarials and St John's Wort.
- 4) Exclude other causes of a raised VL and a lower CD4 count, such as;
- i) Inter-current infections
 - ii) Opportunistic infections, and
 - iii) Immunisations
- All these can temporarily drop the CD4 count or raise the VL.
 - Therefore, it is advisable to repeat the CD4 count and VL tests a month later to ensure a return to baseline.

Factors to Consider when Changing ART

a. Expert advice

- There is no substitute for expert advice when changing ART.
- The Paediatric ART management field is fraught with pitfalls for the careless.
- Many children's futures have been compromised by poor choices when switching regimens.



There is always **enough time to consult** with an expert **before switching a regimen.**

This is **NOT** a promotion for procrastination or ignorance

b. At least two drugs

- Always try to include at least two new drugs when switching regimens

- Always refer to the guidelines or consult an expert if unsure
- Be aware of cross-resistance - since what may look like a 'new drug' may be ineffective as the virus is already resistant to it.
- Genotyping may help select which drugs in the current regimen can be re-used.
- This does not apply to drugs in the previous regimen – resistance mutations may be below the detectable level.

5) **Do Not Add one drug to a Failing Regimen**

- Adding one drug to a failing regimen will predispose the child to the rapid development of resistance.
- This practice is = monotherapy and should be avoided at all costs

6) **Consider Drugs Used for the Prevention-of-Mother-to-Child Transmission (PMTCT)**

- Several studies have demonstrated resistance to NVP where mothers and their children received a single dose of Nevirapine.
- Please, consult the treatment Guidelines for reference on the management of children when other ARVs have been used for prevention.

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SPECIFIC LEARNING OUTCOME 7

Demonstrate an understanding of Good ART Prescribing Practices

At the end of this outcome, participant nurses should be able to:

1. Differentiate between Rational Prescribing & Irrational Prescribing
2. Identify the components of a Rational Prescription



Activity 7: Individual Skill/Practical Assessment

- Each participant is expected to come to the training with one medical record of a virally unsuppressed child under 10 years on ART for over 24 months.
- Participants will be given 30-45 minutes to conduct a six-month medical record audit of one medical record.
- After that, each participant will be given 10 minutes to present their audit findings to the entire group. The feedback should answer the following questions;
 - 7.1 The child's age and ART initiation date
 - 7.2 A record of the latest VL results
 - 7.3 Did the child honour the scheduled appointment dates in all 4 visits? **Explain**
 - 7.4 Was the child's weight recorded in all 6 visits? **Explain**
 - 7.5 Was the child prescribed the correct regimen for age/weight in the 6 months? **Explain**
 - 7.6 Was the child prescribed the correct strength for all the prescribed ARV drugs? **Explain**
 - 7.7 Was the child prescribed the correct dosing frequencies in the 6 months? **Explain**

Facilitator's Feedback Session

- This activity is aimed at assisting the nurses to **self-identify what they're doing** well in their respective clinics, as well as **to identify the mistakes** they are making during ART management.
- They will then be given a chance to discuss their audit findings
- This activity aims at helping them identify the areas requiring improvement in their respective clinics.

A Rational Prescription writing

ARVs should only be prescribed when necessary for treatment following a precise diagnosis like all other medicines.

In all cases, carefully consider the expected benefit of a prescribed medication against potential risks.

All prescriptions should:

- be written legibly in ink by the prescriber with the full name and address of the patient,
- be signed with the date on the prescription in the clinical stationery form;
- specify the date of birth of the child and,
- the weight of the child;
- signature of the prescriber;

In all prescription writing, the following should be noted:

- i) The name of the medicine or preparation should be written in full using the generic name.
- ii) No abbreviations should be used due to the risk of misinterpretation.
 - Avoid the Greek mu (μ): write mcg as an abbreviation for micrograms.
- iii) Avoid unnecessary use of decimal points and only use where decimal points are unavoidable.
 - A zero should be written before the decimal point where there is no other figure, e.g. 2 mg, not 2.0 mg or 0.5 mL and not .5 mL.
- iv) **Frequency:** Avoid Greek and Roman frequency abbreviations that cause

considerable confusion (qid, qod, tds, tid, etc.). Instead, either state the frequency in terms of hours (e.g. 8 hourly) or times per day in numerals (e.g. 3 times daily).

v) State the treatment regimen in full as follows:

- medicine name and strength,
- route of administration,
- dose or dosage,
- dosing frequency,
- duration of treatment,

• e.g. **Lamivudine, oral, 150 mg 12 hourly for 28 days.**

vi) Most monthly outpatient scripts for chronic medication are for 28 days; check that the patient will access a repeat before the 28 days are completed.

vii) After writing the prescription, check that the dose, dose units, route, frequency, and duration for each item is stated to avoid a situation like this below;

The image shows a handwritten table with the following structure:

	IN ▼	OUT ▼	E
ABC			
3TC			
Efv			

viii) Consider whether the number of items is too great to be practical for the patient, and

ix) Check that there are no redundant items or potentially essential drug interactions.

- x) Check that the script is dated and that the patient's name and folder number are on the prescription form.
- xi) Only then sign the script (print your name, use a stamp, or use your institution issued prescriber number).

SPECIFIC LEARNING OUTCOME 8

Demonstrate an understanding of Good ART Dispensing

At the end of this outcome, participant nurses should be able to:

1. Show the competence to determine the correct quantity of ARVs to dispense
2. Discuss how to determine the correct quantity to dispense
3. Aspects to consider when dispensing ART in children



Activity 8: Individual Skill/Practical Assessment

- We are using the same file used for activity 7.
- The latest Paediatric ART Dosing Chart, and
- The latest Clinical ART Guidelines.
- With the help of the provided Paediatric ART Dosing Chart. Determine the correct quantities to supply the children in **Qs 8.2 to 8.4**
- All participants will be **given 5 minutes** to discuss their answers with the whole group.

8.1 Was the child issued correct quantities in the 6 months? **Explain**

With the help of the provided Paediatric ART Dosing Chart. Determine the correct quantities to supply the following children

- 8.2 **Strawberry** is a very clever*big girl* who does not take syrups anymore. Her body weight is 19.9kg, and she is on an AZT, 3TC and LPV/r containing regimen. **How much of each prescribed item will you issue out to Strawberry to last 28 days?**
- 8.3 **Bubbles** is a 3yrs old boy with a bodyweight of 14kg on an Efavirenz containing regimen. **How much EFV will you issue out to last him 30 days?**
- 8.4 **Lollipop** is a 2 years old boy with a bodyweight of 11kg and on ABC 120mg Bd, 3TC 60mg Bd and Lopinavir/ritonavir 160/40mg Bd. **How many bottle(s) of ABC, 3TC and LPV/r are you going to issue**

out to Lollipop to last him 30 days?

- 8.5 After all group presentations, the facilitator gives inputs and summarises **SLO7** and **SLO8** by presenting the concept of Rational Prescribing and aspects to consider during the dispensing of ART.

Facilitator's Feedback Session:

8.1 Was the child issued correct quantities in the 6 months? **Explain**

- This activity aims at getting the participants to identify their practices at their respective clinics so that they live the training knowing their strengths and weakness as well as areas requiring improvement in their clinics
- Talking about it with their peers helps make this activity exciting and memorable.

8.2 **Strawberry** is a very clever*big girl* who does not take syrups anymore. Her body weight is 19.9kg, and she is on an AZT, 3TC and LPV/r containing regimen.

How much of each prescribed item will you issue out to Strawberry to last 28 days?

For AZT

- Strawberry requires the following dose for both drugs: 1x 300mg Tabs Bd = 2 tablets per day
- Treatment for 28 days should be;
- 2 tablets x 28 days = 56 Tablets
- **So Strawberry should be given 56 AZT tablets**

For 3TC

- Strawberry requires the following dose for both drugs: 1x 150mg Tabs Bd = 2 tablets per day
 - Treatment for 28 days should be;
 - 2 tablets x 28 days = 56 Tablets
 - **So Strawberry should be given 56 3TC tablets**
- If you have the Fixed-Dose Combination (Lamzid®) in stock, which is a combination of AZT 300mg & 3TC 150mg

- Strawberry requires the following dose for both drugs: 1xLamzid 300/150mg Tabs Bd = 2 tablets per day
- Treatment for 28 days should be;
- 2 tablets x 28 days = 56 Tablets
- **So Strawberry should be given 56 of a combination of AZT (300mg) and 3TC(150mg) tablets**

 **For LPV/r**

- Strawberry requires the following dose of LPV/r: 5 Pellets Bd = 10 Pellets per day.
Treatment for 28 days should be;
10 Pellets x 28 days = 280 Pellets

What is the pack size of LPV/r Pellets?

- It comes in a pack of 120 Pellets
 - **So Strawberry should be given how many pellets?**



Bearing the manufacturer's instructions in mind, **the pellets should be stored in their original container.** And, they **should not be exposed to high humidity** outside the original container **for longer than 2-weeks.**

OR

- Strawberry can be given LPV/r: 2x 100/25mg Tabs Bd = 04 Tablets per day
Treatment for 28 days should be; 04 Tablets x 28 days = 112 Tablets
- **So Strawberry should be given 112 of the 100/25 Aluvia Tablets to last for 28 days**

8.3 Bubbles is a 3yrs old boy with a bodyweight of 14kg on an Efavirenz containing regimen. **How much EFV will you issue out to last him 30 days?**

- Bubbles should be given EFV 300mg nocte for his weight.
- There's no EFV 300mg Tablet or capsule. EFV is available in 50mg and 200mg

formulations. **So Bubbles** requires;

- 1 x 200mg EFV Capsule at night and 2 x EFV 50mg Capsule
- **Treatment for 28 days should be;**

01 Tablets x 28 days = 28 EFV 200mg Tablets, and

- 2 x 50mg EFV Capsule at night = 56 Capsules
 - **So Strawberry should be given 56 of EFV 50mg to last for 28 days**

8.4 **Bubbles** is a 3yrs old boy with a bodyweight of 14kg on an Efavirenz containing regimen. **How much EFV will you issue out to last him 28 days?**

✚ **Bubbles** should get the EFV as follows;

The required dose for a 14kg is 300mg Nocte

So, EFV is available in 200mg and 50mg Capsules

- Bubbles are expected to come back for review in 28 days, and he needs per day 1 x 200mg + 2 x 50mg capsules to make the 300mg.

Quantity to dispense for 200mg Capsule = Dose per day x 28 days
= 1 capsule x 28 days
= 28 capsules

Quantity to dispense for 50mg Capsule = Dose per day x 28 days
= 2 capsules x 28 days
= 56 capsules

For a child to have enough treatment until the next appointment date in 28 days, he should get 28 x 200mg EFV Capsules + 56 x 50mg EFV Capsules.



Remember EFV 200mg comes in a pack size of 84 capsules, enough for three months in this case. You therefore need a strategy of how you effectively manage the dispensing of the 3 months' supply.

8.5 **Lollipop** is a 2 years old boy with a bodyweight of 11kg and on ABC 120mg Bd, 3TC 60mg Bd and Lopinavir/ritonavir 160/40mg Bd. **How many bottle(s) of ABC, 3TC and LPV/r are you going to issue out to Lollipop to last him 30 days?**

ABC and 3TC

Lollipop requires the following dose for both drugs: 6 ml Bd = 12ml per day

LPV/r : 2ml Bd = 4ml per day

So,

For ABC and 3TC since the dose and frequency are the same;

Amount Required = 6ml x 2

= 12ml per day

- The child will come back for review in 28 days
- But to cover the child for a possibility of spillages during administration, I will determine the quantity to issue out by 30 days.

i.e. Quantity to dispense = Dose per day x The number of days to next visit

= 12ml x 30 days

= 360ml

For a child to have enough treatment until the next appointment in 28 days, they need 360ml of ABC and the same amount for 3TC syrup.

How many bottles am I going to give?

- You need to know how many millilitres a bottle of 3TC and ABC contains to get the answer.
- Each bottle of ABC and 3TC contain 240ml

So this is how you determine the number of bottles to give Lollipop;

- 360ml ÷ 240ml = 1,5 bottle
- Since you cannot open the bottle
Lollipop should be given **2 Bottles of ABC and 2 Bottles of 3TC solution.**

You do the same for LPV/r

Amount Required = 2ml x 2

= 4ml per day

- The child will come back for review in 28 days
- But to cover the child for a possibility of spillages during administration, I

will determine the quantity to issue out **by 30 days**.

I.e. **Quantity to dispense** = Dose per day x The number of days to next visit
= 4ml x 30 days
= **120ml**

- Each bottle of LPV/r contain 60ml, and therefore the patient should be given **120ml ÷ 60ml = 2 Bottles**

Specific Learning Outcome 9

Demonstrate an understanding of Viral Load Monitoring

At the end of this outcome, participant nurses should be able to:

1. Familiarisation with clinical ART guideline recommendations for VL monitoring
2. Discuss the importance of on schedule VL monitoring



Activity 9: Group Work

NB!! Complete all the activities with your group members and then one group member to present to the class on a piece of paper.

Use the following documents;

- The latest Clinical ART Guideline.
 - 9.1 Discuss the recommendations for VL monitoring.
 - 9.2 Using your knowledge and understanding of ART management, discuss the importance of on-time VL monitoring
 - 9.3 One group member to present your discussion.
 - 9.4 The facilitator summarises **SLO9** and gives inputs.

Specific Learning Outcome 10

Demonstrate knowledge and understanding of the pharmacokinetic & pharmacodynamics principles of ARVs

At the end of this outcome, participant nurses should be able to:

1. Demonstrate an understanding of the importance of ARV formulations.
2. Benefits of ART formulation considerations in treatment.

3. Disadvantages of lack of ART formulation.
4. Formulation Aspects to consider during ART prescribing and management.



Activity 10: Face-to-Face

The facilitator explains the importance of ARV formulation consideration in ART management

- 10.1 The facilitator will present the benefits of ART formulation considerations in treatment to the participants.
- 10.2 The facilitator will also explain the disadvantages of the lack of ART formulation consideration.
- 10.3 Furthermore, the facilitator discusses the formulation aspects to consider during ART prescribing and management.
- 10.4 After that, the facilitator summarises **SLO10** and gives inputs.

Facilitator's Feedback

- ✚ Benefits of ART formulation considerations in treatment.
 - Improved clinical outcomes
- ✚ The disadvantages of the lack of ART formulation consideration.

The inconsideration of formulation details in the management of children on ART can lead to;

 - Irrational prescribing practices such as underdosing and overdosing wherein 12 hourly formulations can be prescribed for daily administrations a practice that
 - Irrational storage practices.
- ✚ Formulation Aspects to Consider during ART Prescribing and Management.



Activity 11: Group Work Case Scenario

Please Note: Complete all the activities with your group members on the provided worksheet.

Select one group member to present your feedback to the entire group.

Use the following documents;

- The latest Clinical ART Guideline to answer questions 11.1 to 11.3.

Case Scenario: Milo is rightfully on ABC 2ml Bd, 3TC 2ml Bd and LPV/r 1.5ml Bd. Her next review date will be a month (28 days).

11.1 How much ABC are you going to dispense to **Milo**?

11.2 How much 3TC are you going to dispense to **Milo**?

11.3 How much LPV/r are you going to dispense to **Milo**?

Facilitator's Feedback Session:

11.1 How much ABC are you going to dispense to **Milo**?

For ABC: Milo's weight requires a 2ml Bd dose.

That is, $2\text{ml} \times 2 \text{ Times a day} = 4\text{ml/day}$

This means that Milo requires to get this much treatment to last a month

That is, $4\text{ml} \times 30 \text{ days} = 120\text{ml}$

ABC Syrup Bottle contains how many mls?

- 240ml

How many MLs does she need for a month?

- 120ml for a month

Therefore, since you cannot half the bottle, you will have to give her a 1 x 240ml Bottle of ABC Syr

11.2 How much 3TC are you going to dispense to **Milo**?

For 3TC: Milo's weight requires a 2ml Bd dose.

That is, $2\text{ml} \times 2 \text{ Times a day} = 4\text{ml/day}$

This means that Milo requires to get this much treatment to last a month

That is, $4\text{ml} \times 30 \text{ days} = 120\text{ml}$

3TC Syrup Bottle contains how many mls?

- 240ml

How many MLs does she need for a month?

- 120ml for a month

Therefore, since you cannot half the bottle, you will have to give her a 1 x 240ml Bottle of 3TC Syr.

11.3 How much LPV/r are you going to dispense to **Milo**?

For LPV/r, Milo's weight requires a 1.5ml Bd dose

This means that Milo requires to get this much treatment to last a month

That is, $1.5\text{ml} \times 2 \text{ Times a day} = 3\text{ml/day}$

Milo requires to get this much treatment to last a month

That is, $3\text{ml} \times 30 \text{ days} = 90\text{ml}$



Why 30 Days and not 28 Days?

To cover for the child's spillages or any event of wasted dosages during administration.

It is recommended to calculate the quantity to dispense



Activity 12: Evaluation of the Training Programme

Each learner is allowed to evaluate the training programme.

- Kindly complete an individual evaluation tool anonymously to evaluate the training programme.
- To open click on this link: <https://forms.gle/8DfYa8oGPjKQG8M27>

7.3.6 Discussion of Findings

This study aimed to investigate the development and implementation of a training programme to improve the paediatric ART dosing and dispensing practices in the management of children on ART by NIMART-trained PNs in public clinics. This process was guided by the ADDIE model, implement, and evaluate phases. The implementation was done successfully, and the immediate evaluation of the training followed Kirkpatrick's four levels of the evaluation model. However, only the first two model levels were conducted for this study. According to the researcher, the overall training programme implementation was successful since the training objectives were met. The evaluation findings show that the training generated some positive reactions and matched the results of studies conducted by Bernardino and Curado (2020) and Curado and Teixeira (2014). Similarly, the training programmes conducted had a positive impact at the evaluation level in these studies.

It was noticed that during the implementation of the training programme, most NIMART-trained PNs struggled with the determination of the monthly amount of treatment to dispense even though they had the official dosing chart.

The NIMART-trained PNs were satisfied with the training programme's content, the topics covered, activities, the facilitator, facilitation methods, and the training programme has in this regard also achieved its intended objectives. The findings of the reaction level of the participants during evaluations show a positive response that confirms that the implementation of the training programme was of high quality. These findings agree with those of a study conducted by Al-Khaldi, Al-Dawwod, Al-Khudeer, and Al-Saqqaf (2017). They revealed that learners articulated an excellent level of satisfaction following their training, and this reflected that most of their learning needs were met and were successfully achieved.

The study's learning findings revealed that NIMART-trained PNs obtained high scores in the post-training assessment, compared to the pre-training assessment, which is an indication that the training improved their knowledge and skills in the management of children on ART. In support of these findings, other studies reveal that adequate training

results in improved understanding of HIV management, greater confidence and clinical competence. However, in these studies, this was seen to work well if accompanied by continuous mentorship (Georgeu, Colvin, Lewin, Fairall, Bachmann, Uebel, Zwarenstein, Draper, & Bateman, 2012; Davies, Homfray, & Venables, 2013; Naude, Van Aswegen, & Havenga, 2017; Esterhuizen, Solomons, Van der Merwe, & Crowley, 2019).

Furthermore, appropriate training and support given to the nurses have been witnessed in practice to lead to an increased quality of patient care, confidence and professional development (Green, de Azevedo, Patten, Davies, Ibeto, & Cox, 2014). Moreover, a study conducted by Mabelane, Marincowitz, Ogunbanjo, and Govender (2016) at Dr CN Phatuti District Hospital in Mopani has also noticed these benefits and laments that appropriately trained nurses experience work satisfaction because of the difference they are making in patients' lives. A study by Motlokoa (2016) in the North West province noticed that training warrants the nurses' ability to work independently, which boosted nurses' self-esteem and self-worth. Similarly, in a study conducted in Vhembe District, Limpopo Province, after training, some nurses reported that they felt proud that they were appropriately contributing to the NIMART programme (Rasalanavho, 2016).

The feedback from the evaluations suggests that the participants found the training programme attractive. Even though challenges were encountered by the participants, which included stress they experienced before, during, and after the training assessments and the insufficient contact time due to the adherence to Covid-19 restrictions. This is compatible with the findings of a study conducted by Lavoie-Tremblay, Sanzone, Aubé, and Paquet (2021), which indicated that academic stressors are common in testing and evaluation. This results from the participant's fear of failure in training. The NIMART-trained PNs also suggested that the facilitator recommends to the Department of Health that this Paediatric ART dosing and dispensing training programme be adopted as a CPD or a mentorship training to support NIMART-trained PNs in public primary healthcare clinics because *“really the NIMART training we received brushed on these Paediatric issues”* [P3 & P7].

Furthermore, most nurses' suggests that it would be of great help to them if the pharmacists in their feeder hospitals (i.e. hospitals supporting their clinics) could come on board and support them at the clinics because this training has made them realise that pharmacists have an essential role to play in their ART management programmes.

7.4 Summary

The summary details the sequence followed in conducting the whole study from the beginning to its final stage and are outlined as follows:

7.4.1 Purpose of the Study

The purpose of this study was to evaluate the use of ART in children managed by NIMART-trained PNs at public clinics located in resource-limited settings in the Mopani District of Limpopo Province. The study evaluated the use of ART against the 2015 South African HIV treatment guidelines to develop and implement a paediatric antiretroviral therapy dosing and dispensing training programme for the NIMART trained nurses who manage children on ART in public clinics.

The purpose was achieved in four phases; in the **first phase**, the researcher conducted a four year (01 January 2015 to 31 December 2018) desktop baseline assessment to determine the clinical outcomes of children initiated on ART in public clinics of Mopani District in the year 2015. A journey then followed this wherein the medical records of children who met the study inclusion criteria were explored to describe the prescribing practices of NIMART trained professional Nurses when managing children with unsuppressed VLs on ART in public clinics Mopani District, Limpopo Province. The researcher also assessed in this phase the NIMART-trained PNs' compliance with the 2015 South African HIV/AIDS guidelines for the treatment of children on ART. After that, the factors associated with regimen switching in these children on ART were managed at public clinics across the Mopani District, Limpopo Province. After this phase was concluded, the obtained data were analysed. The identified knowledge and competence gaps were used to shape the **second phase** of the study to determine the knowledge, understanding, and competence of NIMART-

trained PNs in managing children on ART in public clinics of Mopani District, Limpopo Province, and to establish the perceptions of NIMART-trained PNs regarding the effective management of children on ART in public clinics.

The study objectives were obtained through adopting a mixed-method, explanatory sequential research design. The development of the framework for the training programme was grounded on the merged findings of the study. After that, the training programme and the guidelines for implementing the training programme were developed in **phase 3** of the study to operationalise the training programme in **phase 4**.

7.4.2 Completion of the Study Phases

A preliminary literature review was conducted that confirmed the components of the role of NIMART in HIV/AIDS management and clinical pharmacy and the Rational Medicine Use theory. The first phase of this study was the situational analysis to explore and describe the NIMART-trained PNs' ART prescribing practices when managing virally unsuppressed children on ART in their primary healthcare clinics. The researcher distributed one-on-one self-administered semi-structured questerviews using ample open and closed-ended questions to collect data from NIMART-trained PNs at public primary healthcare clinics in the Limpopo Province. Due to Covid-19 restrictions, the questerviews were a paperless google form. After giving consent to participate in the study, the participants received a Google Form link, and the researcher had to hotspot the participants to complete the form online. The researcher succeeded in carrying out all the study phases and can say that all the study phases were carried out successfully. Field notes were written to capture non-verbal cues transcribed verbatim was made of the audio records, and the qualitative data was analysed using Nvivo Pro 12 software. The data coding was conducted guided by Tesch's open coding method for analysis. The themes, subthemes and codes that emerged from the analysis were developed and presented narratively with the support of the literature.

Measures to ensure the study's trustworthiness, credibility, conformability, dependability, and transferability were all considered, and how they were guaranteed were detailed. The merged findings of the study revealed that even though the NIMART-trained PNs rated themselves very well in terms of their knowledge and understanding of ART dosing and dispensing in children on ART. Their prescribing practices in the management of virally unsuppressed children were found irrational. This was emphasised by their responses to the given EFV 50mg stockout case scenario, which revealed a lack of competence in management and a knowledge gap in ART management. This indicated to the researcher a need to develop a training programme for NIMART-trained PNs to improve the ART prescribing practices in public primary healthcare clinics of Mopani District in the Limpopo Province.

The study's second phase was guided by the clinical pharmacy and rational medicine use theories. Whereas the merged findings of the study in Tables 5.11 to 5.14 in Chapter 5 regarding the ADDIE model framework guided phase 3 of the study, which is the development of the Paediatric ART dosing and dispensing training programme. The developed training guidelines in line with the SAQA guidelines directed its implementation, which is phase four. The final phase, presented in this chapter, was the implementation of the Paediatric ART dosing and dispensing training programme and was immediately followed by the participants' evaluation of the training programme aimed at verifying whether or not the training programme has been achieved intended objectives.

CHAPTER 8 CONCLUSIONS, LIMITATIONS & RECOMMENDATIONS OF THE STUDY

8.1 Introduction

This is the last chapter of this thesis. It sums up the entire project that its purpose was to evaluate the use of ART in children managed by NIMART-trained PNs at public clinics located in resource-limited settings in the Mopani District Limpopo Province. The aim and objectives of this study were therefore achieved in the following phases;

Phase1: A four-year (01 January 2015 to 31 December 2018) desktop assessment was conducted on the TIER.Net system to determine the clinical outcomes of children initiated on ART in public clinics of Mopani District in the year 2015. After which, the researcher determined in the medical records of identified children the rationality of the NIMART-trained PNs' prescribing practices when managing virally unsuppressed children on ART, established their regimen switching patterns and determined their compliance to the HIV Treatment guidelines when dosing and dispensing ART in children under 15 years.

Phase 2: Determined the knowledge, understanding, and competence levels of NIMART-trained PNs in managing children on ART in public clinics of Mopani District, Limpopo Province, and further established the perceptions of NIMART-trained PNs regarding the effective management of children on ART in public clinics.

Phase 3: established the training needs of NIMART-trained PNs regarding the effective management of children on ART in public clinics and developed a training programme for the appropriate use of antiretrovirals and management of ART by NIMART-trained PNs in Mopani public clinics.

Phase 4: Implemented the training programme for the appropriate use of antiretrovirals and ART management by NIMART-trained PNs in the Mopani public clinics.

8.2 Conclusions

From the findings of this ARV utilisation review and the implementation of the developed ART dosing and dispensing training programme. The study concludes that the nurse's prescribing practice was irrational in this cohort of children, and most prescriptions did not entirely comply with the 2014/15 HIV/AIDS treatment recommendations. The study findings clarify that the irrational use of ARVs in children impacts their clinical outcomes negatively. The findings of the study further demonstrate that, for children under 15 years, adherence to antiretroviral therapy is alone not enough for obtaining good clinical outcomes. The study findings also reveal that this cohort of children was susceptible to medication related errors such as; Drug omissions in ARV regimens; Incorrect dosing & dosing frequencies; as well as incorrectly supplied quantities. These findings are similar to prior study findings (Liedtke, Tomlin, Skrepnek, et al., 2016; Chiampas, Kim, Badowski, 2015; Li & Foisy, 2014; Yehia, Mehta, Ciuffetelli, et al. 2012)

The study concludes that for children initiated on ART to obtain viral suppression, they must be prescribed their ART rationally from the onset. This means that for viral suppression in children, there's a need for monthly prescriptions to contain;

- 1) a triple regimen as recommended in the HIV/AIDS treatment guidelines;
- 2) the correct dosage form mindful of their age and drug administration properties;
- 3) the correct strength suitable for their body weight that avoids cases of underdosing or overdosing;
- 4) correct dosing frequency that takes into consideration the pharmacokinetics (PK) and pharmacodynamics (PC) aspects of the ARVs prescribed to empower them with the knowledge of which tablets to swallow whole and which ones cannot be crushed, divided or chewed. Which ARVs are 12hourly and 24hourly formulation, and what is the meaning of that, and
- 5) the correct quantity of all prescribed ARVs enough to last them until their next scheduled appointment to ensure that they do not run out of treatment as this might predispose the children to viral mutations, which might lead to the development of drug resistance and ultimately treatment failure. Since 60% of children enrolled on ART in public primary healthcare clinics of Mopani District in 2015 were of school-going age. The finding that children miss scheduled appointments due to school

attendance clarifies that the approach used for the ART management programme in Mopani district in the years under review was not child-centred and thus did not offer age-appropriate care to this cohort of children.

8.3 Study Limitations

Even though the objectives of this study were successfully met, there have been limitations experienced. The study was only conducted in public primary healthcare clinics of Mopani District, Limpopo Province. The findings are only limited to the 94 of the 108 public primary healthcare clinics in Mopani District accredited to rollout ART to children by 2015. Therefore, the findings of this study cannot be generalised to all public primary healthcare clinics in the Limpopo Province or other provinces in South Africa. The implementation phase of the training programme was planned to include all NIMART-trained PNs in all five Sub-Districts of Mopani, but it was only conducted in two sub-districts due to the global COVID-19 pandemic. Furthermore, the study was cross-sectional and thus could not evaluate the relationship between incorrect ARV dosing and virological outcomes or whether treatment discontinuations or adverse effects were associated with overdosing.

Moreover, the study only focused on a cohort of virologically unsuppressed children ($VL \geq 400$ copies/ml) initiated on ART in 2015 in public primary healthcare clinics and not elsewhere. However, despite all these limitations, the results and findings of the study are deemed valuable to trigger other researchers to explore further the use of ARVs in children on ART in public primary healthcare clinics. They can be used as a reference for future research evaluating the appropriate use of ARVs in children.

8.4 Recommendations

The recommendations outlined in this chapter are based on the following; 1) the quantitative results; 2) the themes and sub-themes that emerged from qualitative findings; 3) the observations made during the training implementation.

The recommendations from this study will be helpful for the NIMART-trained PNs in that it will assist them with the appropriate dosing and dispensing of ARVs whilst managing children on ART in public primary healthcare clinics. They also shed light on the nursing and clinical pharmacy education and research gaps.

Themes that emerged in the Study requiring intervention

The themes that emerged in this study that required attention were as follows;

Theme 1: Non-adherence to HIV/AIDS Treatment Guidelines

The results and findings of this study demonstrated a lack of adherence to the 2015 HIV/AIDS treatment guidelines. The NIMART-trained PNs were dispensing ART without the patient's body weight; some prescriptions only contained ARV names. Some were prescribed mono-and dual therapies; there were also identified cases of underdosing and overdosing, and an undersupply of monthly treatment.

Recommendations

The researcher understands that ever since the rolling out of the NIMART programme in South Africa. Nurses play a central role in HIV care and ART management, such as initiation, support, and monthly monitoring. This is believed to be one of the core competencies for nursing practice in HIV management mentions that treatment guidelines are essential to adhere to in that they contain endorsements that help describe professional expectations, knowledge, and competencies that NIMART-trained PNs should have to provide evidence-based care supporting both ART adherence and their own decision making. Continuous training, support supervision, and improved relationships with colleagues need to be enhanced to enable NIMART trained nurses to adhere to treatment guidelines.

The study recommends continuous Paediatric HIV/AIDS management training that focuses on ART dosing and dispensing and pharmacist-led support supervision and mentorship. All need to be provided, promoted and enhanced to efficiently and effectively reach the desired clinical outcomes in children on ART. The inclusion of NIMART-trained PNs in developing treatment guidelines is also recommended. This might promote their use of guidelines as well as their adherence. Support supervision from pharmacists as supervisors and trainers should be made available constantly and debriefing sessions conducted with NIMART-trained PNs regularly. The development of a child policy on the frequency of a child's visits and ART prescribing is needed. Documentation of a child's body weight and a review of ARV doses should be made mandatory for every clinic visit and ARV collection visit. NIMART-trained PNs and other healthcare professionals who prescribe and dispense ARVs need to be adequately trained to monitor a child's bodyweight and recognise when the ARV dose needs to be adjusted. Further research in this practice could evaluate improvements in the implementation of HIV/AIDS treatment guidelines and the impact.

Theme 2: The Irrational Prescribing Practices

The study demonstrated the following irrational aspects that hinder the appropriate use of ARVs in virally unsuppressed children in public clinics of Mopani District. These were the incomplete prescription writing practices. The NIMART-trained PNs would prescribe ARVs without the monthly monitoring bodyweight that was seen to go as far as NIMART-trained PNs issuing monthly treatment to parents and caregivers in the absence of children for three to five consecutive months even though the nurses depicted an excellent knowledge and understanding of the importance of monthly weight monitoring. Furthermore, the study demonstrated a lack of indication of the availability of concomitant diseases and WHO clinical staging at ART initiation.

Prescribing and prescription errors are the major problems among medication errors. They occur both in general practice, hospitals and clinics. And although they are rarely fatal, they can affect patients' safety and quality of healthcare. These errors occur when there is a significant unintentional reduction in the probability of timely and

effective treatment or increased risk of harm compared with generally accepted practice. However, prescription errors encompass those related to the act of writing a prescription, whereas prescribing errors encompass irrational prescribing, inappropriate prescribing, underprescribing, overprescribing, and ineffective prescribing, arising from inaccurate medical decisions or decisions concerning treatment or treatment monitoring. Appropriate prescribing results when errors are minimised and when the prescriber actively endeavours to achieve better prescribing: both actions are required.

Recommendations

The prevalence of irrational prescriptions in this cohort of children is high. There is a need to make NIMART-trained PNs aware of the importance of rational prescribing in children on ART since the failure to prescribe ART according to treatment guidelines is observed as an irrational use of ARVs (Holloway & Van Dijk, 2011). The WHO recommends the appropriate use of ARVs as a strategy to improve patient outcomes, lessen the incidences of adverse drug reactions and reduce health care costs (WHO, 2012). The study recommends that NIMART-trained professional nurses perform their ART dosing and dispensing roles as guided by the HIV/AIDS guidelines to ensure the rational use of ARVs in the management of children.

The study further recommends that knowledge gaps amongst NIMART-trained PNs be addressed through quality improvement strategies such as mentorship, clinic medical record audits, and automated prescribing systems where possible. A Pharmacist led ART dosing and dispensing continuous professional development training program promoting the rational use of ARVs in children on ART in resource-limited public primary healthcare clinics could be an ideal intervention since special attention should be given to the rational use of ARVs since antiretroviral resistance is currently becoming a significant public health problem in children living with HIV. The promotion of the rational use of ARVs will require effective policies and efficient collaboration between health professionals, patients, and the entire communities. An adequate understanding of the relevant aspects of ARV use on all stakeholders is essential to drive collaborative efforts to address irrational ARV use. The tackling of

irrational ARV use should be prioritised to improve healthcare delivery towards ensuring patient safety and allowing for optimal utilisation of the ARVs. Irrational prescribing most often derives from a wrong medical decision because of a lack of knowledge or inadequate training. Adverse clinical outcomes can be related to a lack of knowledge or skill. Even the simple act of transcribing previous medications and collecting information as part of the medication history requires knowledge of pharmacotherapy and adequate information about the patient's clinical condition. Equally, the choice of dose requires information about the patient's clinical status and immediate verification of the appropriateness of treatment.

Clinical Pharmacists and Pharmacists in feeder hospitals supporting these public clinics should provide training on rational use of ARVs for the NIMART-trained PNs and other health care professionals. In addition, the hospital's Drug and Therapeutics Committee should regularly evaluate ARV usage patterns in these clinics (Melku, Wubetu, & Dessie, 2021).

Theme 3: Medication Errors

The study revealed the prevalence of medication errors in this cohort of children. These included; i) cases of ARV omissions in most prescriptions; ii) incorrectly prescribed dosage forms; iii) Incorrectly prescribed doses; iv) Incorrectly prescribed dosing frequencies; as well as v) inadequately supplied monthly treatment issues. In this cohort, only 48% of the prescriptions indicated the number of ARVs dispensed, and in 52% of the prescriptions, the nurses did not indicate the amount dispensed or issued out to the patient. Those with an indication of the quantity supplied, in 39.30% of the prescriptions, the treatment for the children was undersupplied, with 16% of the prescriptions that received an over-supply of their prescribed ARVs. These findings were similar to an observation made by a study in Uganda that noted that the prevalence of irrational prescriptions is high among children under 15 years in Uganda (Mulema, Lukabwe, Niyonzima, Akena, & Elyanu, 2017).

Both errors in the act of writing (prescription errors) and prescribing errors due to erroneous medical decisions were found in this study. The prescribing errors in this study were mainly related to inappropriate doses and inadequate monitoring, and

these need attention as they can harm patients. Junior staff members are said to more frequently make medication errors, mainly ascribed to inadequate knowledge or training, which often trigger inappropriate prescribing and other faults. Medication errors are common in public and private practice, hospitals and clinics. Inadequate staffing, lack of skills and knowledge of relevant rules, tasks outside the routine, or taking care of another clinician's patient have also been identified as conditions associated with prescribing faults. Furthermore, inadequate knowledge or competence and incomplete information about clinical characteristics and previous treatment of patients also can result in prescribing errors, including the use of potentially inappropriate medications. Strenuous working conditions, complex or unclear guidelines, and inadequate communication among healthcare personnel, particularly between healthcare professionals such as nurses and doctors, have been identified as critical underlying factors contributing to prescription and prescribing errors.

Recommendations

Like many other studies, this study acknowledges that the irrational use of ARVs in children is a severe global problem that is harmful and wasteful. Moreover, it acknowledges that nurses identify the prescription of ART in children as a complex process. Hence, when asked in the qualitative whether they thought the management of their perceptions concerning the management of children on ART, most of them mentioned that it was stressful. This study, however, recommends that attention be given to the age of the child on ART, their weight bands, CD4 counts, WHO staging, and the presence of concomitant diseases at ART initiation. Similar to (Turkova, Webb, & Lyall, 2012; Ponnet, Frederix, Petdachai, Wilson, Eksaengsri, & Zachariah, 2005), the researcher in this study is of the firm opinion that if all these factors can be considered in the ART management process, the room for error will be considerable. NIMART-trained PNs need coaching and mentorship support to help them understand that overdosing children on ART may increase the children's risk of developing drug-related adverse effects. At the same time, under-dosing may increase their risk of virological failure and further promote the development of drug resistance, both of which could impact their long-term treatment outcomes.

Theme 4: Non-Adherence to Treatment

The study found that only 44.11% of visits were honoured from this cohort of children, and 39.80% of the visits were missed. In the qualitative phase, the NIMART-trained PNs of Mopani District public clinics mentioned that from their experience, they have realised that the contributing factors to this practice are related to the caregivers' lack of commitment and health illiteracy, the fact that clinic visit days clash with the school attendance schedule, and also that the parents and caregivers do not disclose the HIV status to the children on ART due to the fear of stigmatisation. Furthermore, the nurses confirmed that they do not involve the parents/caregivers when deciding the next appointment date.

Recommendations

These findings suggested a need for intervention since non-adherence to ARV therapy poses a danger to the child. The study recommends the involvement of both the child and the caregiver in remembering appointment dates. Caregivers should be offered all available resources to help them adhere to a sound treatment plan. This should include the involvement of parents and caregivers in deciding a suitable next appointment date as recommended by the Ideal Clinic principles. Nurses need to remember that Mopani is densely populated by farmworkers who cannot be absent from work timeously apart from fighting poverty. This is also coupled with the general fear of stigmatisation.

Furthermore, the NIMART-trained PNs should begin assessing potential adherence barriers and discuss the importance of adherence with the child (where possible), the patients, and caregivers before initiating or changing an ARV regimen. Even though adherence is difficult to assess accurately, the study recommends incorporating a routine adherence assessment into every clinic visit. It will be important that the nurses assess any potential barriers to adherence and discuss the importance of adherence with parents and caregivers of children before initiating or changing an ARV regimen. Moreover, the study recommends that NIMART-trained PNs and parents/caregivers of children on ART make age-specific disclosures to children on ART. This is with the understanding that children who have been disclosed their HIV status have improved

adherence practices to treatment. Furthermore, in partnership with its stakeholders and implementing partners in the District, the Department of Health can make HIV status disclosure guidelines available in all public clinics to make it much easier for them to deliver age-appropriate information to the children on ART and their parents/caregivers. Support services should be available to children who become traumatised and their parents/caregivers.

Theme 5: Irrational Regimen Switching Practices

The study demonstrated a high level of non-compliance to treatment guidelines when coming to the issue of regimen switching in this cohort of children, and this outlined a low level of knowledge and understanding of this aspect, with only 7.17% of children correctly switched from the regimen at initiation to another one, and a total of 76.19% of cases where children were incorrectly switched from the regimen at initiation to another regimen. The study further established that these children were switched regimens to as often as three to five times in the four years, a practice defined as regimen hopping and not regimen switching. These findings were in contrast to the findings of this study that was conducted in Thailand which found that one in five children were switched to a second-line regimen in 5 years of being on ART (Goetghebuer, Hainaut, Van der Kelen, Delforge, Warszawski, Le Chenadec, Ramos, Dialla, Wack, Laurent, & Ait si Selmi, 2018). This practice was clarified during the training implementation process to be resulting from monthly ARV stock-outs that the NIMART-trained PNs face during the management of children on ART in public primary healthcare clinics in Mopani District, Limpopo Province.

Recommendations

The switching of antiretroviral therapy is somewhat unavoidable, considering that HIV treatment is now considered a lifetime therapy. However, this can be delayed if the NIMART-trained PNs can make use of the ART management process as if it is the only opportunity they have even though the treatment guidelines advise the nurses and clinicians, in general, to seek expert advice whenever they are faced with challenges in ART management. Therefore, this study recommends the development of a protocol that the NIMART-trained PNs can follow to assist them in effectively

managing ARV stock-outs. This will therefore prevent the nurses from switching children back and forth regimens whenever ARVs are available and not.

Theme 6: Lack of Consideration of ARV Formulations

The study revealed in the qualitative phase that the NIMART-trained PNs in trying to manage an EFV 50mg stock-out case for children in need of EFV 300mg they do not pay much attention to the drug formulation and thus either irrationally prescribe; 1) EFV 600mg and request the parents and caregivers of children requiring EFV 300mg nocte to give the child half of the coated tablet; or 2) EFV 200mg and request the parent or caregiver to administer one and a half capsule at night irrespective of how complex this instruction is; or 3) EFV 200mg and request the parents or caregivers to titrate the powder of the tablet in either 2ml or 10ml of water and administer half of the mixture.

Recommendations

The study recommends that clinical pharmacists have a crucial role in training NIMART-trained PNs in the ARV pharmacokinetics and pharmacodynamic principles of ARV formulations skills required for them to understand which ARVs can be split, crushed, and crushed, chewed or divided and which ones cannot. This will help them prescribe ARVs rationally with understanding whenever faced with stock-outs. This will further help them effectively care for children on ART and thus eradicate cases of incorrect prescribing due to the lack of knowledge and understanding of ARVs formulations, which can potentially predispose these children to viral mutations due to suboptimal dose administrations. Resolving these issues will increase the number of virally suppressed children receiving antiretroviral therapy in public primary healthcare clinics.

Theme 7: Recommendations to the Nursing Education

The study recommends that the nursing education in clinical pharmacology and pharmacotherapy should be based on the practical needs of nurses as future prescribers. It should include the principles of rational ARV therapeutics, rational ART prescribing and problem-solving. It also ought to immunise the nursing students against the influences they are likely to encounter in their professional life, such as the

irrational prescribing by peers. All categories of nurses are a product of nursing education and training institutions. Thus, the quality of patient care rendered to the patients through the management of children on ART is dependent on the training that nursing education training institution offers. Their students should be equipped to ensure the effective management of children living with HIV. Nursing schools, colleges, and universities are all nursing training institutions. Thus, they are upon the accreditation by SANC and Council of Higher Education. They are also entitled to provide education and training for various nurses in South Africa. Therefore, the researcher recommends that the Paediatric ART Dosing and Dispensing be introduced from the first level of training and be reinforced throughout training to produce highly competent nurses who can effectively manage, dose and dispense ART to children during patient care. Hence, the quality of Paediatric ART management is achieved in public primary healthcare clinics. The researcher also recommends that this short course be included in the curriculum of all undergraduate nursing training programmes. This can create an opportunity to include all critical aspects during learning in all nursing training institutions.

Theme 8: Suggested Solutions for the Improvement of the Implementation of the Paediatric ART Dosing and Dispensing Training Programme

The NIMART-trained PNs suggested during the implementation of the training programme that the development of this training programme is viewed as a possible strategy that can improve the management of children on ART. The training programme's content was suggested based on the aspects of paediatric ART management that were considered problematic based on medical record reviews. The NIMART-trained PNs further suggested a need for reinforcement of similar teaching sessions as they seem neglected and viewed necessary by them as they could assist in empowering them with information, knowledge, and relevant skills on the appropriate dosing dispensing ARVs in children. During the training of the nurses on the paediatric dosing and dispensing of ARVs, the NIMART-trained PNs suggested that all categories of nurses should be included in the training as nurses work as a team, and due to shortage of NIMART- or PC101 trained nurses in specific Clinics and the fact that the clinics make use of the integrated management of HIV

and Non-Communicable Diseases (NCDs) they find themselves managing children on ART.

Recommendations

The researcher recommends continuous in-service training sessions for all nurses managing children on ART to equip them with up to date information to improve their knowledge and skills. Operational managers should provide supervision, monitoring, and evaluation of the teaching sessions that are provided in the units of Paediatric ART dosing and dispensing. This will help to reinforce that continuity and consistency is maintained. Furthermore, the study recommends the development of a paediatric dosing chart that will indicate the correct quantity of ARVs to dispense out.

Theme 9: Recommendations to Pharmacy and Nursing Research

There has not been research on implementing a Paediatric ART dosing and dispensing training programme. Similarly, there was no research conducted in South Africa on developing and implementing the paediatric ART dosing and dispensing training programme in resource-limited public primary healthcare clinics to improve the rational use of ARV in virally unsuppressed children on ART. Further research can, therefore, stimulate other researchers in the future to focus on perceptions of all categories of nurses towards the management of children on ART in public clinics. This will thus also help to develop a model for the effective and rational management of children on ART in public clinics. Furthermore, research can be conducted to assess whether the paediatric ART dosing and dispensing training programme developed can also be implemented elsewhere and yield similar positive results.

Theme 10: Recommendations to Pharmacy Education and Training

The study's findings suggest the need for clinical pharmacists to take initiatives in ARV medicine utilisation reviews to guide other healthcare professionals on ARV usage and assist in designing policies for the promotion of rational ARV use in children on ART. This further suggests a leading role in offering mentorship and support to the NIMART-trained PNs to help improve the rational use of ARVs. Pharmacy training institutions to include in their curriculum a module that will help impart knowledge and

necessary skills for pharmacy students to be stewards and promote the rational use of ARVs as well as to guide pharmacists on conducting medicine reviews in practice and how these can be used to improve the rational use of ARVs.

Theme 11: Recommendations to the Department of Health

The study's findings mainly demonstrated that the prescribing process is intimidating for the NIMART-trained PNs, particularly when faced with stock-out issues, as highlighted by their responses to the Efavirenz case scenario. Furthermore, most children received an undersupply of their monthly treatment, which could not last until their next appointment date. Therefore, the study identified through these findings that the management of children on ART in the four years required an intervention that will help NIMART-trained PNs in public primary healthcare clinics improve their irrational dosing and dispensing of ARVs practices observed.

Moreover, the study established during the implementation of the training programme that the NIMART-trained PNs who participated, even though they were provided with the paediatric dosing chart during the training activities, could not determine the correct monthly supply of treatment to dispense. This observation clarified the study finding wherein over 39% of children were under-supplied their monthly treatment. Another noticed element was that guidelines and dosing charts, especially when newly updated, were unclear or specific to the NIMART-trained PNs.

Since 60% of children enrolled on ART in public primary healthcare clinics of Mopani District were of school-going age. The district needed to implement child-centred approaches to ensure that children receive holistic and age-appropriate care.

The study recommends the development of formal guidelines, training and mentoring healthcare workers on these child-centred approaches, developing child-friendly job aides, and creating child-friendly areas have the potential to marginally improve the quality of HIV services provided to children in low resource settings. This will, in turn, push the Mopani District closer to realising its 95-95-95 goals.

Guided by the study findings, the researcher recommends a shift in the management strategy for children on ART. The study recommends that to accomplish the 2030 95-

95-95 USAID targets, the NIMART-trained PNs should be equipped with continuous training and development sessions. Furthermore, children under 15 years should be considered a key population and their performance indicators reported upon separately from that of adults. By so doing this will be a great way of monitoring the performance in terms of paediatric ART management.

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LIST OF APPENDICES

Appendix I: Faculty Approval Letter



University of Limpopo
Faculty of Health Sciences
Executive Dean
Private Bag X1106, Sovenga, 0727, South Africa
Tel: (015) 268 2149, Fax: (015) 268 2665, Email: kgakgabi.letsolo@ul.ac.za

DATE: 04 March 2019

NAME OF STUDENT: MABILA LN
STUDENT NUMBER: 200014487
DEPARTMENT: PHARMACY
SCHOOL: HEALTH CARE SCIENCE
QUALIFICATION: DOCTOR OF PHARMACY

Dear Student

FACULTY APPROVAL OF PROPOSAL (PROPOSAL NO. FHDC2019/2)

I have pleasure in informing you that your Doctor of Pharmacy proposal served at the Faculty Higher Degrees Meeting on the 04 March 2019 and your title was approved as follows:

Approved Title: "Evaluation of Antiretroviral Use In Children Managed in Public Clinics of Mopani District, Limpopo Province: Towards a Dosing and Dispensing Training Programme for Nurses".

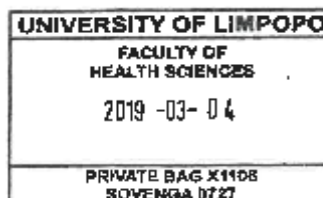
Note the following :

Ethical Clearance	Tick One
Requires no ethical clearance Proceed with the study	
Requires ethical clearance (TREC) (apply online) Proceed with the study only after receipt of ethical clearance certificate	<input checked="" type="checkbox"/>

Yours faithfully


MR K. Letsolo
Chairperson

CC: Supervisor: Prof PH Demana
CO- Supervisor: Prof TM Mofhlba



Appendix II: Ethical Clearance Certificate



University of Limpopo
Department of Research Administration and Development
Private Bag X1106, Sovenga, 0727, South Africa
Tel: (015) 268 3935, Fax: (015) 268 2306, Email: anastasia.ngobe@ul.ac.za

TURFLOOP RESEARCH ETHICS COMMITTEE
ETHICS CLEARANCE CERTIFICATE

MEETING: 5 April 2019

PROJECT NUMBER: TREC/81/2019:PG

PROJECT:

Title: Evaluation of Antiretroviral Use in Children Managed in Public Clinics of Mopani District, Limpopo Province: Towards A Dosing and Dispensing Training Programme for Nurses.

Researcher: LN Mabila
Supervisor: Prof PH Demana
Co-Supervisor/s: Prof TM Mothiba
School: Health Care Sciences
Degree: PhD in Pharmacy


PROF P MASOKO
CHAIRPERSON: TURFLOOP RESEARCH ETHICS COMMITTEE

The Turfloop Research Ethics Committee (TREC) is registered with the National Health Research Ethics Council, Registration Number: REC-0310111-031.

- Note:**
- i) This Ethics Clearance Certificate will be valid for one (1) year, as from the abovementioned date. Application for annual renewal (or annual review) need to be received by TREC one month before lapse of this period.
 - ii) Should any departure be contemplated from the research procedure as approved, the researcher(s) must re-submit the protocol to the committee, together with the Application for Amendment form.
 - iii) PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES.

Finding solutions for Africa

Appendix III: Ethical Clearance Renewal Certificate



University of Limpopo
Department of Research Administration and Development
Private Bag X1106, Sovenga, 0727, South Africa
Tel: (015) 268 3935, Fax: (015) 268 2306, Email: anastasia.ngobe@ul.ac.za

TURFLOOP RESEARCH ETHICS COMMITTEE
ETHICS CLEARANCE CERTIFICATE

MEETING: 10 July 2020

PROJECT NUMBER: TREC/81/2019:PG – Renewed: 10 July 2020

PROJECT:

Title: Evaluation of Antiretroviral Use in Children Managed in Public Clinics of Mopani District, Limpopo Province: Towards A Dosing and Dispensing Training Programme for Nurses.
Researcher: LN Mabila
Supervisor: Prof PH Demana
Co-Supervisor/s: Prof TM Mothiba
School: Health Care Sciences
Degree: PhD in Pharmacy

PROF P MASOKO
CHAIRPERSON: TURFLOOP RESEARCH ETHICS COMMITTEE

The Turfloop Research Ethics Committee (TREC) is registered with the National Health Research Ethics Council, Registration Number: REC-0310111-031

Note:

- i) This Ethics Clearance Certificate will be valid for one (1) year, as from the abovementioned date. Application for annual renewal (or annual review) need to be received by TREC one month before lapse of this period.
- ii) Should any departure be contemplated from the research procedure as approved, the researcher(s) must re-submit the protocol to the committee, together with the Application for Amendment form.
- iii) PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES.

Finding solutions for Africa

Appendix IV: Limpopo Provincial Government - Study Permission Letter



LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH

Ref: LP_20190
Enquiries: Stander SS
Tel: 015 293 6650
Email: research.limpopo@gmail.com

MABILA LM
University of Limpopo
Private Bag x 1106
Sovenga
0727

Greetings,

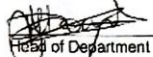
RE: EVALUATION OF ANTIRETROVIRAL USE IN CHILDREN MANAGED IN PUBLIC CLINICS OF MOPANI DISTRICT, LIMPOPO PROVINCE: TOWARDS A DOSING AND DISPENSING TRAINING PROGRAMME

Permission to conduct the above mentioned study is hereby granted.

1. Kindly be informed that:-

- Research must be loaded on the NHRD site (<http://nhrd.hst.org.za>) by the researcher.
- Further arrangement should be made with the targeted institutions, after consultation with the District Executive Manager.
- In the course of your study there should be no action that disrupts the services, or incur any cost on the Department.
- After completion of the study, it is mandatory that the findings should be submitted to the Department to serve as a resource.
- The researcher should be prepared to assist in the interpretation and implementation of the study recommendation where possible.
- The above approval is valid for a 1 year period.
- If the proposal has been amended, a new approval should be sought from the Department of Health.
- Kindly note, that the Department can withdraw the approval at any time.

Your cooperation will be highly appreciated.


Head of Department

02/05/2017
Date

Private Bag X8302 Polokwane
Fidel Castro Ruz House, 18 College Street, Polokwane 0700. Tel: 015 293 6000/12. Fax: 015 293 6211.

The heartland of Southern Africa – Development is about people!

Appendix V: Limpopo Provincial Government - District Permission Letter




LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

Ref: S4/2/2
Enq: Mohatti Isiraele
Tel: 015 811 6543

To **Mabila L.N**
School of Health Care Sciences
Department of Pharmacy
University of Limpopo

Re: PERMISSION TO CONDUCT RESEARCH IN MOPANI HEALTH FACILITIES: YOURSELF

1. The matter cited above bears reference
2. This serves to respond to the request submitted to research on the topic: **"Evaluating the use of Antiretroviral Therapy in children managed in PHC facilities in Mopani District, Limpopo Province, towards the development of a dosing and dispensing training programme."**
3. It is with pleasure to inform you about the decision to permit you to conduct research at PHC facilities within Mopani District with effect from August 2019 to December 2020.
4. You will be required to furnish PHC authorities with this letter for purposes of access and assistance.
5. You are further advised to observe ethical standards necessary to keep the integrity of the facilities.
6. The Mopani District wishes you well in your endeavour to generate knowledge.


Director: Corporate Services

Date: 19.07.2019

Appendix VI: Phase 1 Data Collection Tool

NB: Due to Size of the Excel File, kindly [CLICK HERE](#) to access the full Appendix

PHASE 1B DATA COLLECTION CHECKLIST											
(Patients Regimen Switched and those with low VLs)											
Please do not leave any field in this form unfilled. Every detail is required											
SECTION A: PATIENT DEMOGRAPHIC DATA											
1. Sub-District Name											
2. Facility Name											
3. Facility Type (Please Tick)					Primary Health Care			Community Health Care			
4. Data Collection Date					Year	Month	Day				
					yyyy	mm	dd				
5. Patients' Date of Birth			6. Gender (Please Tick)		7. Race (Please Tick)						
yyyy	mm	dd	Male	Female	A	I	W	C			
* A=African , I -Indian , W= White, C=Coloured											
SECTION B: BASELINE CLINICAL DATA											
8. ART Initiation Date				Year	Month	Date					
				yyyy	mm	dd					
9. Childs WHO Clinical Staging at initiation (P											
Stage 1	Stage 2	Stage 3	Stage 4	Not Staged							
10. Concomitant disease at ART initiation					Yes	No					
10 a) If Yes Above, please Specify											
11. Regimen at Initiation (Please Tick)					A3E	A3L	Z3L	Z3E	Z3N	S3L	S3E

Appendix VII: Phase 2 Consent/Cover Letter

Informed Consent For Nurses Participating in the Study

PROJECT TITLE: Evaluation of Antiretroviral Use In Children Managed in Public Clinics of Mopani District, Limpopo Province: Toward a Dosing and Dispensing Training Programme.

INFORMED CONSENT FORM

I, _____ hereby voluntarily consent to participate in the following project: ***Evaluation of Antiretroviral Use In Children Managed in Public Clinics of Mopani District, Limpopo Province: Toward a Dosing and Dispensing Training Programme.***

I understand that:

1. This study is *"An Evaluation of the use of antiretroviral therapy in children receiving treatment from Public Health Care Facilities: Towards a training programme for professional nurses"*.
2. I was informed of any new information that may become available during the research that may influence my willingness to continue with my participation;
3. Access to the records that pertain to my participation in the study will be restricted to persons directly involved in the research;
4. Any questions that I may have regarding the research, or related matters, will be answered by the researcher at any point in time;
5. If I have any questions about, or problems regarding the study, I may contact the researcher;
6. Participation in this research is voluntary and I can withdraw my participation at any stage during the project.

Signature of Participant

Researcher

Signed at _____ this _____ day of _____ 2019.

c

Appendix VIII: Phase 2 Self-Administered Questerview

NB: Due to Format and Size of the Online Questerview, kindly [CLICK HERE](#) to access full the Appendix

The screenshot shows a survey interface with a title bar: "Evaluation of Antiretroviral Use in Children Managed in Public Clinics of M". The survey content includes a header banner for the "UNAIDS 2020 MISSION" with three "90" targets. The main section is titled "Introduction and Informed Consent" and contains the following text:

Dear Participant

You are hereby invited to take part in a Doctoral Degree Study focusing on Nurses who are NIMART Trained and working Public Primary Health Care Facilities. This study seeks to evaluate the use of ART in children managed by NIMART-trained nurses at public clinics located in resource-limited settings.

The study is of strategic importance given the government's efforts to achieve the WHO's 90-90-90 targets by 2020 and 95-95-95 targets by 2030.

The Researcher is a Doctoral Candidate in Pharmacy at the University of Limpopo.

The study is funded by the Department of Science and Innovation with the support of the National Research Foundation.

I have attempted to keep the time to complete the survey as short as possible. My pilot study has shown that it would take you less than 30 minutes to complete the survey.

Participation in this survey is voluntary, there are no known or anticipated risks.

This study has received formal ethical clearance from the Turfloop Research Ethics Committee (TREC/81/2019-PG) Ethics Committee.

Permission to conduct the study has been obtained from the Provincial Department of Health, the Mopani District Head and Sub-district Heads.

You may decline to answer any of the questions in the survey. Should you feel uncomfortable with the questions at any stage of the survey, you are free to withdraw your participation.

All data collected will be treated as confidential and your anonymity will be protected in any reports or publications produced as a result of the survey.

If you agree to participate, please choose YES, I Agree below and then Proceed with the Questionnaire.

If, at this stage or in future, you have any further queries about the project, please feel free to contact me via e-mail: Nkateko.Mabila@ul.ac.za or by cellphone/WhatsApp - 0839409133.

For queries regarding your rights as a research subject or any research integrity issues, you may contact the UL Ethics Officer Ms Anastasia Ngobe (TREC@ul.ac.za) at the UL Research Office.

Do you agree to participate in this study?

Yes, I agree

Appendix IX: 2013 Paediatric Dosing Chart



ANTIRETROVIRAL DRUG DOSING CHART FOR CHILDREN 2013

Compiled by the Child and Adolescent Committee of the SA HIV Clinicians Society in collaboration with the Department of Health



	Abacavir (ABC)	Lamivudine (3TC)	Efavirenz (EFV)	Lopinavir/Ritonavir (LPV/r)	Ritonavir boosting (RTV)	Stavudine (d4T)	Didanosine (ddI)	Nevirapine (NVP)	Zidovudine (AZT)	Target Dose	
Target Dose	8mg/kg TWICE daily OR a10kg: 16mg/kg ONCE daily	4mg/kg TWICE daily OR a10kg: 8mg/kg ONCE daily	By weight based ONCE daily	300/75mg/m ² /dose LPV/r TWICE daily	ONLY as booster for LPV/r when on didanosine TWICE daily (0.75xLPV dose bd)	1mg/kg/dose TWICE daily	180-240mg/m ² /dose ONCE daily	160-200 mg/m ² /dose TWICE daily (after once daily load in x 2 wks)	180-240mg/m ² /dose TWICE daily	Target Dose	
Available Formulations	Sol 20mg/ml tabs 60mg (scored dispensable), 300mg (not scored), ABC/3TC 600/300mg	Sol. 10mg/ml Tabs 150mg (scored), 300mg ABC/3TC 600/300mg	Caps 50,200mg Tabs 50,200, 600mg (not scored)	Sol. 80/20mg/ml Adult Tabs 200/50mg, Paeds Tabs 100/25mg	Sol. 80mg/ml	Sol. 1mg/ml Caps 15,30,30mg	Tabs 25,50,100mg (dispensable in 30ml water) Caps 250mg EC	Sol. 10mg/ml Tabs 200mg (scored)	Sol. 10mg/ml Caps 100mg Tabs 300mg (not scored), AZT/3TC 300/150mg	Available Formulations	
Wt. (kg)	Currently available tablet formulations of abacavir (except 60mg), efavirenz, LPV/r and AZT must be swallowed whole and NOT chewed, divided or crushed										
<3	Consult with a clinician experienced in paediatric ARV prescribing for neonates (<28 days of age) and infants weighing <3kg										
3-3.9	2ml bd	2ml bd	Avoid using when <10kg or <3 years: dosing not established	*1ml bd	1ml bd	6ml	Avoid	5ml bd	6ml bd	3-3.9	
4-4.9											4-4.9
5-5.9	3ml bd	3ml bd				7.5mg bd: open 15mg capsule into 5ml water: give 2.5ml	100mg od: (2x50mg tabs)				5-5.9
6-6.9				*1.5ml bd	1.5ml bd						6-6.9
7-7.9						10mg bd: open 20mg capsule into 5ml water: give 2.5ml	125mg od: (1x100mg + 1x25mg tabs)				7-7.9
8-8.9	4ml bd	4ml bd						8-8.9			
9-9.9									1 cap bd OR 12ml bd	9-9.9	
10-10.9	Choose only one option: 6ml bd OR 2x60mg tabs bd	Choose only one option: 12ml od OR 4x60mg tabs od		300mg nocte (1x200mg cap/tab)	2ml bd	1.5ml bd	15mg bd: open 15mg capsule into 5ml water	150mg od: (1x100mg + 1x50mg tabs)	10ml bd	10-10.9	
11-13.9										11-13.9	
14-16.9	8ml bd OR 2.5x60mg tabs bd	5x60mg tabs od OR 1x300mg tabs od OR 15ml od		300mg nocte: (2x100mg cap/tab) + 2x50mg cap/tab	Choose one option: - 2.5ml bd - 100/25mg paedie tabs: 2 bd - 200/50mg adult tabs: 1 bd	2ml bd	20mg bd: open 20mg capsule into 5ml water (if the child is unable to swallow a capsule)	175mg od: (1x100mg + 1x75mg)	1 tab am OR 1/2 tab pm OR 15ml bd	2 caps am 1 cap pm OR 15ml bd	14-16.9
17-19.9										17-19.9	
20-22.9	10ml bd OR 3x60mg tabs bd	1x300mg tabs + 1x60mg tabs od OR 1x300mg tabs od		300mg nocte: (2x100mg cap/tab) + 2x50mg cap/tab	Choose one option: - 3ml bd - 100/25mg paedie tabs: 2 bd - 200/50mg adult tabs: 1 bd	2.5ml bd		200mg od: (2x100mg tabs)	7 caps bd OR 20ml bd	20-22.9	
23-24.9										23-24.9	
25-29.9	1x300mg tab bd	2x300mg tabs od OR 1xABC/3TC 600/300mg tab od		400mg nocte: (2x200mg cap/tab)	Choose one option: - 3.5ml bd - 100/25mg paedie tabs: 3 bd - 200/50mg adult tabs: 1 bd + 100/25mg paedie tabs: 1 bd	3ml bd		250mg od: (2x100mg + 1x50mg tabs) OR 1x250mg EC cap od	1 tab bd	1x300mg tab bd OR 1xABC/3TC 300/150mg tab bd	25-29.9
30-34.9					Choose one option: - 4ml bd - 100/25mg paedie tabs: 3 bd - 200/50mg adult tabs: 1 bd + 100/25mg paedie tabs: 1 bd						30-34.9
35-39.9					Choose one option: - 5ml bd - 200/50mg adult tabs: 2 bd	4ml bd					35-39.9
>40				600mg tab nocte							>40

od = once a day
usually at night
bd = twice a day

* Avoid LPV/r solution in any full term infant <14 days of age and any premature infant <14 days after their due date of delivery (40 weeks post conception) or obtain expert advice.
Children 25-34.9kg may also be dosed with LPV/r 200/50mg adult tabs: 2 tabs am; 1 tab pm

Weight (kg)	3-4.9	5-9.9	10-13.9	14-29.9	≥30
Cotrimoxazole Dose	2.5ml od	5ml od	5ml od	10ml or 1 tab od	2 tabs od
Multivitamin Dose	2.5ml od	2.5ml od	5ml od	5ml od	10ml or 1 tab od

Appendix X: Limpopo Province Abacavir Stockout Protocol



LIMPOPO
PROVINCIAL GOVERNMENT
REPUBLIC OF SOUTH AFRICA

DEPARTMENT OF HEALTH

Enq : Dr Robertson 083 635 0535
: Dr Ramavhuya: 082 492 6354
: Maureen Masinge (Pharmacist): ARV Monitor 083 422 5393

ABACAVIR STOCK OUT PROTOCOL

BACKGROUND:

Abacavir is one of the first line drugs in children up to 14 year old adolescents and those with weight below 40kg. The country is currently experiencing Abacavir stock supply challenges.

All patients on Lifelong ART should get a combination of three ART at all times. Switching of a single ART drug in patients with none suppressed viral load encourages resistances.

ABACAVIR TABLETS

All hospital Pharmacists must ensure that Abacavir tablets are available for patients who need them through their District Pharmacists and ARV Monitor.

ABACAVIR SYRUP

ACTION REQUIRED:

1. During Abacavir (ABC) stock out Zidovudine (AZT) can temporarily replace ABC in those patients with suppressed viral load. Discuss with your District Specialist for other options in cases where AZT is contraindicated (such as HB less than 8g/dl) or in patients with none suppressed viral loads.
2. Check HB every 4 weeks x 3 to ensure that the HB remains above 6g/dl.
3. As soon as Abacavir is back, replace AZT unless the patient is more stable on AZT.

See attached articles:

1. Approaches to tenofovir and abacavir drug shortages In South Africa: A guide for clinicians.
2. Antiretroviral drug dosing chart for children 2013

Dr M.W Shilumani
General Manager HAST

Date 22/01/2015

Appendix XI: Pre and Post Training Questionnaire

Paediatric ART Dosing and Dispensing Training Pre-Test Questionnaire

SECTION A: PARTICIPANT'S DEMOGRAPHIC DETAILS

PARTICIPANT No:

Total Marks: 45

Marks Obtained:

DURATION: 45 Minutes

1. Please indicate your age?

	Please Tick (√)
18-20	
21-29	
30-39	
40-49	
50-59	
60 and above	

2. To which gender identity do you most identify?

	Please Tick (√)
Male	
Female	
Transgender Male	
Transgender Female	
Intersex	
Others (Specify)	

3. What is the highest level of nursing education you have completed or received?

	Please Tick (√)
Certificate in Nursing	
Diploma in Nursing	
Bachelor's Degree	
Honours Degree	
Master's Degree	
PhD	

4. Your current Position or Rank?

.....

5. How long have you been caring for children on Antiretroviral Therapy?

	Please Tick (√)
0-3 years	
4-6 years	
7-9 years	
10-12 years	
13-15 years	
More than 15 years	

SECTION B

Kindly use the provided dosing chart to assist you in answering the following questions.

QUESTION 1 (2 Marks)

1.1. What are the goal (s) of ART?

.....
.....

QUESTION 2 (6 Marks)

2.1. Providing quality of care at each follow-up visit is necessary? **Please Tick (√)**

Yes		No	
-----	--	----	--

2.2 Explain your answer to **Q2.1** above. (3 Marks)

.....
.....
.....

QUESTION 3 (6 Marks)

Lebogang is a 2 month old baby with a body weight of 3.7kg. She is HiV +ve and on the following regimen since birth: (6 Marks)

- ABC 20mg/ml po 2ml Bd
- 3TC 10mg/ml po 2ml Bd
- LPV/r 80/20mg/ml po 1ml Bd

Her weight at birth was 3.395kg.

4.2 Which ARV Drugs were issued out to Granny in **Month 1**? **(2 Marks)**

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4.3 Comment on the treatment issued in Month 1? **(2 Marks)**

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4.4 Look at the prescription in **Month 1**. How much of each prescribed drug was issued out to this patient? **(2 Marks)**

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.....

Let us look at Month 2. The Nurse wrote in this visit that, **“Patient Reports to have enough treatment .To come with the treatment next visit, to check adherence”**

4.5 Briefly Comment on this statement from **Month 2** bearing in mind what happened in **Month 1**. **(3 Marks)**

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4.6 Looking at the amount of treatment issued in **Month 1** and the report in **Month 2**, is this patient adherent? **Explain your answer** **(2 Marks)**

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4.7 **Let us look at Month 3.** Who came for treatment collection? **(1 Mark)**

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4.8 What is the Big Question? **(1 Mark)**

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4.9 Name FIVE (05) areas of concern with this case.

(5 Marks)

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4.10 What are the likely outcomes of such a case?

(3 Marks)

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Thank You 😊😊😊 Inkomu 😊😊😊 Kea Leboga😊😊😊

Appendix XII: Training Implementation Evaluation Tool

Evaluation Tool of the Training Session

INSTRUCTION TO PARTICIPANTS

Participants may not write names on the provided evaluation tool. Please share your feedback about the attended training session.

		Fair	Good	Excellent
1.	How will you rate the overall quality of the session			
2.	How was the overall knowledge of the facilitator in terms of the topics covered?			
3.	How well did the facilitator keep the session alive and interesting?			
4.	How effective to your work were the topics covered?			

5. What was the **most interesting** thing you learned from this training session?

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6. What was the **least interesting** thing you learned in this training session?

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7. Was the length of the presentation sufficient for the topics discussed? **Explain**

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8. What would have made the training sessions more effective?

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9. The knowledge and skills gained from this training session will be helpful in my work? **Please Tick (√)**

Yes	No
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10. If **Yes**, above, mention 2 things you will implement and/or review in your Clinic.

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Inkomu😊😊Thank you 😊😊 Kea Leboga😊😊 Ndo Livhuwa😊😊

Appendix XIII: 2021 SASOCP Conference Podium Presentation Letter



Dear Ms Linneth Nkateko Mabila

Abstract submitted for the South African Society of Clinical Pharmacy' conference 2020

Thank you for your submission of the following abstract: "*A Pilot Review of Antiretroviral Therapy Use in Virally Unsuppressed Children Managed by Nurses in Resource-Limited Settings*"

The Abstract Committee has reviewed your abstract, and is pleased to inform you that it has been accepted for podium presentation. The following 10-minute time slot has been allocated to you:

Date: 6th of November 2020

Time: 10:15 -10:30

Academic Session: C

Time allocation: 12 minutes for presentation and 3 minutes for questions.

Please note that your presentation has to be in Microsoft PowerPoint format. Your presentation needs to be pre-recorded and available to the committee the week before conference. Please refer to the guide attached to adhere to the pre-recording requisites.

Please confirm your registration status upon receiving this notice. Should you require any information, please do not hesitate to contact us at sasocclinpharm@gmail.com

Sincerely

Ms Michelle Gijelaar
Chairperson
SASOCP

Finding Solutions for Africa

