

Perceptions of professional nurses about the barriers and enhancers to the implementation of isoniazid preventative therapy amongst HIV positive adults

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DECLARATION

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ABSTRACT

Background: Tuberculosis (TB) and the Human Immunodeficiency Virus (HIV) are the two infections that have the highest mortality in the world. The prevention of TB among persons infected with HIV is crucial. One of the ways to prevent TB disease among the HIV-infected population is to provide TB preventative therapy. Despite good evidence that isoniazid preventative therapy (IPT) reduces the incidence of TB among people living with HIV, the implementation of IPT is low. This study was done to explore the perceptions of professional nurses about the enhancers and barriers to the implementation of IPT amongst HIV positive adults in the Matzikama sub-district of the West Coast, South Africa.

Methods: A descriptive qualitative design was applied. Ten professional nurses who were responsible for prescribing IPT in rural primary health care clinics, as well as professional nurses in management positions in the sub-district, were purposefully selected. The data was collected through individual interviews. Data was analysed using the six steps described by Creswell. Trustworthiness was enhanced by adhering to the principles of credibility, conformability, transferability and dependability.

Results: Enhancers included clear protocols and availability of stock, especially isoniazid. TB screening on all patients, regular training of healthcare workers, monitoring of registers and folders to improve IPT statistics, and counsellors that identified eligible patients for IPT, were health system and provider-related enhancers.

Barriers that related to leadership and governance were frequent changes of protocols and lack of communication. Stock outs of Mantoux tests and pyridoxine and problems with reading the Mantoux test within 72 hours were health system barriers. Healthcare providers' fear of INH resistance and side effects, uncertainty about the duration of treatment and inadequate knowledge of IPT were identified. Patient adherence was a major problem that could be attributed to a lack of knowledge or the difficulty of attending clinic appointments. The rural context made it difficult to provide a regular service to farm communities, monitor adherence and trace defaulters.

Participant recommendations included one standard protocol, service integration and regular training. On-going patient support and engaging communities and employees may improve implementation of IPT.

Conclusion: IPT has been shown to be beneficial for HIV positive adults. The study revealed several leadership, health system, provider-related and patient-related enhancers and barriers, some which are specific to the rural context. Addressing barriers and promoting enhancing strategies could improve the quality of life for people living with HIV.

Key words: latent tuberculosis infection, isoniazid preventive therapy, barriers, enhancers.

OPSOMMING

Agtergrond: Tuberkulose (TB) en die menslike immuuniteitsgebrekswirus (MIV) is die twee infeksies met die hoogste sterftesyfer in die wêreld. Die voorkoming van TB onder persone met MIV, is van kardinale belang. Een van die maniere om TB te verhoed onder die MIV-geïnfekteerde bevolking is om TB voorkomende terapie te verskaf. Ten spyte van goeie bewyse dat isoniasied voorkomende terapie (IPT) die voorkoms van TB verminder onder mense wat met MIV leef, is die implementering van hierdie behandeling laag. Hierdie studie is gedoen om die persepsies van professionele verpleegkundiges oor die versterkers en hindernisse tot die implementering van hierdie behandeling onder MIV-positiewe volwassenes te verken in die Matzikama sub-distrik, Weskus.

Metode: 'n Beskrywende kwalitatiewe benadering is gevolg. Tien professionele verpleegkundiges wat verantwoordelik is vir die voorskryf van IPT in primêre gesondheidsorg klinieke asook professionele verpleegkundiges in bestuursposte in die sub-distrik is doelbewus gekies. Die data is ingesamel deur middel van individuele onderhoude. Data is geanaliseer met behulp van die ses stappe beskryf deur Creswell. Betroubaarheid van die studie is verseker deur die beginsels van objektiwiteit, bevestiging, veralgemening en neutraliteit.

Resultate: Versterkers wat geïdentifiseer was, was duidelike protokolle en die beskikbaarheid van voorraad, veral isoniasied. TB sifting op alle pasiënte, gereelde opleiding van gesondheidswerkers, monitering van registers en leers om IPT statistieke te verbeter en beraders wat pasiënte identifiseer vir IPT, was gesondheidstelsel en verskaffer verwante versterkers.

Hindernisse wat geïdentifiseer was, was gereelde verandering van protokolle en die gebrek aan kommunikasie. Mantoux toetse en piridoksien wat nie in voorraad was en die lees van die Mantoux toetse binne 72 uur was hindernisse. Die vrees vir INH weerstandheid en nuwe-effekte, onsekerheid oor die duur van die behandeling en onvoldoende kennis van IPT is geïdentifiseer onder gesondheidsorgwerkers. Die behandeling nakoming van pasiente was 'n groot probleem wat toegeskryf kan word aan onvoldoende kennis of probleme om kliniekbesoeke na te kom. Die landelike konteks het dit moeilik gemaak om 'n gereelde diens te lewer aan plaasgemeenskappe, behandeling te monitor en versuimers op te spoor.

Deelnemer aanbevelings sluit in 'n standaard protokol, diensintegrasie en gereelde opleiding. Deurlopende ondersteuning en betrokkenheid van gemeenskappe en werknemers sal implementering van IPT verbeter.

Slotsom: Dit is bewys dat MIV-positiewe volwassenes baat vind by IPT. Die studie het etlike leierskap, gesondheidstelsel, verskaffer-verwante en pasiënt-verwante versterkers en hindernisse aan die lig gebring, waarvan sommige spesifiek in 'n landelike konteks van toepassing is. Die aanspreek van hindernisse en die bevordering van versterking strategieë kan die kwaliteit van lewe vir mense wat met MIV leef verbeter.

Sleutelwoorde: latente tuberkulose-infeksie, isoniasied voorkomende terapie, hindernisse, versterkers.

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ABBREVIATIONS

AIDS	Acquired immune deficiency syndrome
ART	Anti-retroviral therapy
CNP	Clinical nurse practitioner
DOH	Department of Health
DOTS	Directly observed treatment short-course
ETR.net	Electronic tuberculosis register
HIV	Human immunodeficiency virus
IPT	Isoniazid preventative therapy
LPA	Line probe assay
LTBI	Latent tuberculosis infection
NGO	Non-governmental organization
NIMART	Nurse-initiated management of antiretroviral therapy
NTP	National Tuberculosis Programme
PCR	Polymerase chain reaction
PHC	Primary health care
PN	Professional nurse
TB	Tuberculosis
TST	Tuberculin skin test
UNAIDS	United Nations Programme on HIV/AIDS
WHO	World Health Organization

CHAPTER 1:

FOUNDATION OF THE STUDY

1.1 INTRODUCTION

Tuberculosis (TB) and the Human Immunodeficiency Virus (HIV) are the two infections that have the highest mortality in the world (Swaminathan, Menon, Gopalan, Perumal, Santhanakrishnan, Ramachandran, Chinnaiyan, Iliayas, Chandrasekaran, Navaneethapandian, Elangovan, Pho, Wares & Ramalyengar, 2012:e47400). There are still nine million new TB cases identified each year with one million whom are also living with HIV (Tudor, 2015:10). TB is the leading cause of death in South Africa (Tudor, 2015:10). The prevention of TB among persons infected with HIV is crucial. HIV compromises the human immune system, leaving persons vulnerable to develop TB disease, especially if they have latent TB infection. One of the ways to prevent TB disease among the HIV-infected population is to provide TB preventative therapy. Isoniazid tablets are the TB preventive measure given to adults with latent TB, once any symptoms of active TB is excluded. While TB preventive therapy may not reduce the incidence of tuberculosis in the community, it can prevent morbidity and mortality attributable to TB at an individual level (Swaminathan *et al.*, 2012:e47400).

Despite good evidence that isoniazid preventative therapy (IPT) reduces the incidence of TB among people living with HIV, the implementation of IPT is low (Wood & Bekker, 2014:174). A study conducted in Thailand found that nurses were unclear of the direction of national policy and feared that patients would develop isoniazid (INH) resistance due to poor adherence (Moolphate, Lawpoolsri, Pungrassami, Sanguanwongse, Yamada & Kaewkungwal, 2013:61). Furthermore, a study conducted by the Aurum Institute in South Africa found that nurses reported a lack of knowledge and experience as the primary barrier of IPT implementation (Lester, Hamilton, Charalambous, Dwadwa, Chandler, Churchyard & Grant, 2010:S45).

1.2 BACKGROUND AND RATIONALE

South Africa has the third highest number of incident cases (after China and India) and the fifth highest number of undiagnosed active TB (Churchyard, Mametja, Mvusi, Ndjeka, Hesseling, Reid, Babatunde & Pillay, 2014:244). In 2010, 60% of TB cases were also infected with HIV (Oni, Tsekela, Kwaza, Manjezi, Bangani, Wilkinson, Coetzee & Wilkinson, 2012:e52489). Furthermore, South Africa is ranked amongst the worst afflicted countries in the world for both TB and HIV, despite having just 0.7% of the world's population (Karim,

Churchyard, Karim & Lawn, 2009:921). Statistics indicate that approximately 760 000 HIV positive adults have been screened for TB in 2010, but only 120 000 of these adults were started on IPT (Chebab, Vilakazi-Nhlalpo, Vranken, Peters & Klausner, 2013:e57791). According to the IPT guidelines, all HIV positive adults that do not have active TB should be started on IPT.

The World Health Organization (WHO) recommends the three I's strategy to combat HIV/TB: intensified case finding of TB, IPT and infection control for TB (Sculier & Getahun, 2011:18). Sculier and Getahun (2011:18) found that prescribing IPT reduces the risk of TB by 74% in adults that have a positive tuberculin test and deaths from TB by 49% in HIV positive adults. The standard regimen for IPT is Isoniazid 300mg per day in adults living with HIV and should be taken for at least 36 months, according to the Department of Health, Western Cape (Republic of South Africa, DoH, Circular H169/2012:1).

South Africa has a very high burden of HIV and TB. The effective implementation of IPT is needed in order to reduce morbidity and mortality of TB in HIV infected patients. Despite clear guidelines, IPT implementation remains low (Wood & Bekker, 2014:174). Therefore, it is important to identify barriers and enhancers to the implementation of IPT in the South African context in order to recommend strategies to improve the current situation.

In the South African context, professional nurses are responsible for the TB program as well as the implementation of IPT. Anti-retroviral therapy (ART) has been scaled up rapidly, (Lawn & Wood, 2012:995) but the implementation of IPT has been very poor. The tuberculin skin test (TST), which tests for TB infection, has been recognised as an obstacle to IPT implementation (Lawn & Wood, 2012:995). A tuberculin skin test is done by injecting 0.1 ml of liquid under the skin of the left forearm. The liquid contains a protein derivative, which causes the patient to develop a palpable, raised and hardened area at the inoculation site. The reaction is read by measuring the diameter of induration across the forearm (perpendicular to the long axis) in millimeters. If there is no induration, the result should be recorded as "0 mm". Erythema (redness) should not be measured (Cox, de Azevedo, Stinson, Wilkinson Rangaka & Boyles, 2015:1301). TST indurations must be read between 48-72 hours after it was administered. The requirement to return to the clinic within this time frame is impractical for many patients living in rural, low-resource settings and could potentially result in loss to follow-up (Cox *et al.*, 2015:1300). The use of TST requires well-trained and experienced staff to interpret the results (Modi & Dave, 2012:172).

Two other obstacles are that the South African policy limits the impact of scale-up by not setting targets for the implementation of IPT and advocates the use of IPT for a relatively

short duration (Lawn & Wood, 2012:995). The South African guidelines first recommended IPT for six months for asymptomatic HIV positive adults with a TST of more than 5mm (Oni *et al.*, 2012:E52489). In 2013, the IPT guidelines were included as part of the revised ART guidelines to recommend at least 36 months of IPT for those whose TST is positive or 6 months of IPT for those whose TST status is unknown (Churchyard *et al.*, 2014:245).

In South Africa, an assessment done by Wood and Bekker, found that IPT may overburden the health system and that drug resistance can be increased where there is already a high resistance to INH (2014:174). According to Modi and Dave (2012:172), healthcare workers' lack of experience and knowledge and not knowing the benefits of IPT, were important barriers to IPT implementation.

The Matzikama sub-district is a rural district where nurses working in primary health care clinics render preventative services to the community. IPT is one of the prescribed preventative services that should be rendered to the community and all HIV positive patients should be screened and if eligible, initiated on IPT. The researcher is a clinical nurse mentor in the Matzikama sub-district (West Coast, Western Cape, South Africa) and has observed that the implementation of IPT remains low in the clinics despite training and guidelines that recommends the implementation of IPT.

Figure 1.1 shows the number of patients eligible for IPT and the number initiated on IPT from 1 April 2015 to 31 May 2016. It can be seen in the statistics that not all HIV positive adults who were eligible for IPT were initiated. The statistics were collected from the following clinics: Vredendal North, Vredendal Central, Klawer and Vanrhynsdorp Clinics (Republic of South Africa Sinjani Statistics Vredendal Hospital, 2016). There are three other clinics in the Matzikama sub-district, but they were not included in the study. Vanrhynsdorp clinic initiated one more patient that was previously eligible, but did not commence on IPT.

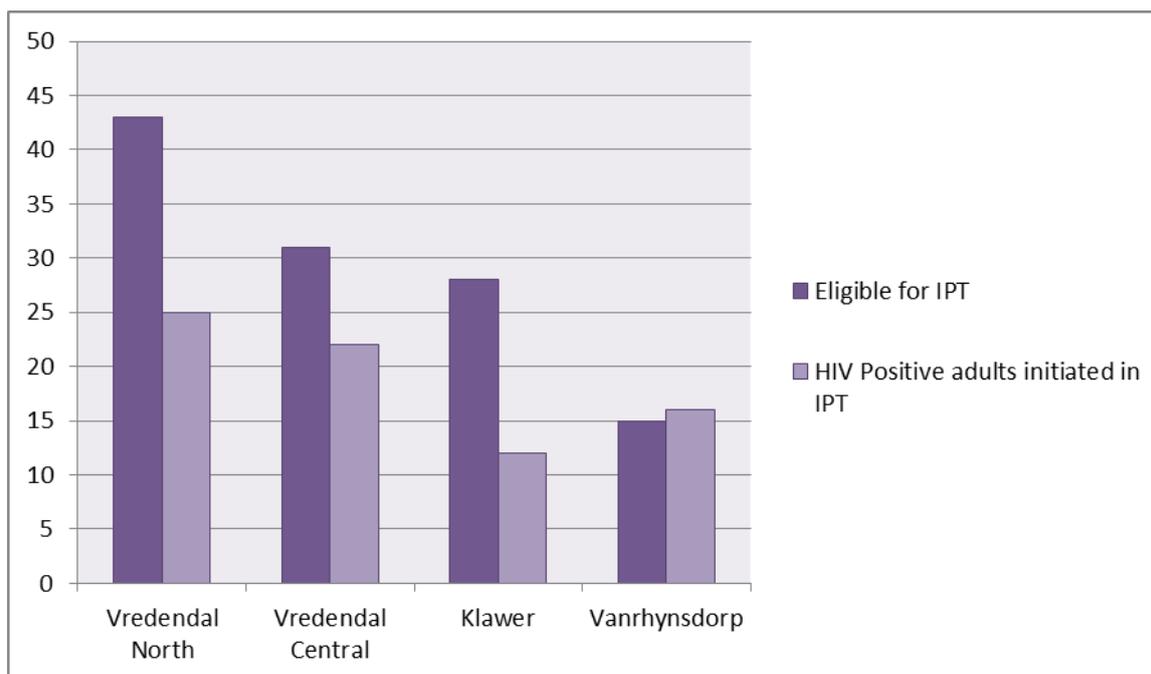


Figure 1.1: Number of patients eligible and initiated on IPT in Matzikama (Sinjani-Vredendal Hospital)

It is critical to understand what barriers and enhancers professional nurses (PNs) experience in the implementation of IPT. There is little evidence regarding the perceptions of professional nurses about the barriers and enhancers to the implementation of IPT amongst HIV positive adults in the rural areas of the West Coast District of the Western Cape.

1.3 RESEARCH PROBLEM

Very few studies have been conducted on the barriers and enhancers to the implementation of IPT and no evidence could be found specifically for rural areas. It was therefore critical to investigate the barriers and enhancers of IPT in the clinics where the PNs are the main prescribers of IPT. In addition, the perspectives of nurses in Primary Health Care (PHC) management positions in the district would be valuable since they play a key role in the monitoring and evaluation of implemented guidelines. In this study, the barriers and enhancers to the implementation of IPT are described from the unique perspective of these professional nurses (PNs and nurses in PHC management positions).

1.4 RESEARCH QUESTION

The study was guided by the following research question: What do professional nurses perceive to be barriers and enhancers to the implementation of IPT amongst HIV positive adults in the West Coast District of the Western Cape?

1.5 RESEARCH AIM

The aim of the study was to explore the barriers and enhancers to the implementation of IPT amongst HIV positive adults, from the perspective of professional nurses in the West Coast District of the Western Cape.

1.6 RESEARCH OBJECTIVES

The objectives were to:

- Explore the perceptions of professional nurses about the enhancers to the implementation of IPT amongst HIV positive adults.
- Explore the perceptions of professional nurses about the barriers to the implementation of IPT amongst HIV positive adults.

1.7 CONCEPTUAL FRAMEWORK

A conceptual framework is a logical structure or explanation of a theory, which guides a research study and assists the researcher to link the findings to nursing's body of knowledge (Burns & Grove, 2011:238). For the purpose of this study, the barriers and enhancers to the implementation of IPT as described by Getahun, Granich, Sculier, Gunneberg, Blanc, Nunn and Raviglione (2010:S61) were used as a conceptual framework (Figure 1.2). Getahun *et al.* (210:S61) used this framework, namely, the pillars of the health system to present the key health system-related barriers and enhancers. The researcher used the conceptual framework as a guide when conducting interviews and analysing the data.

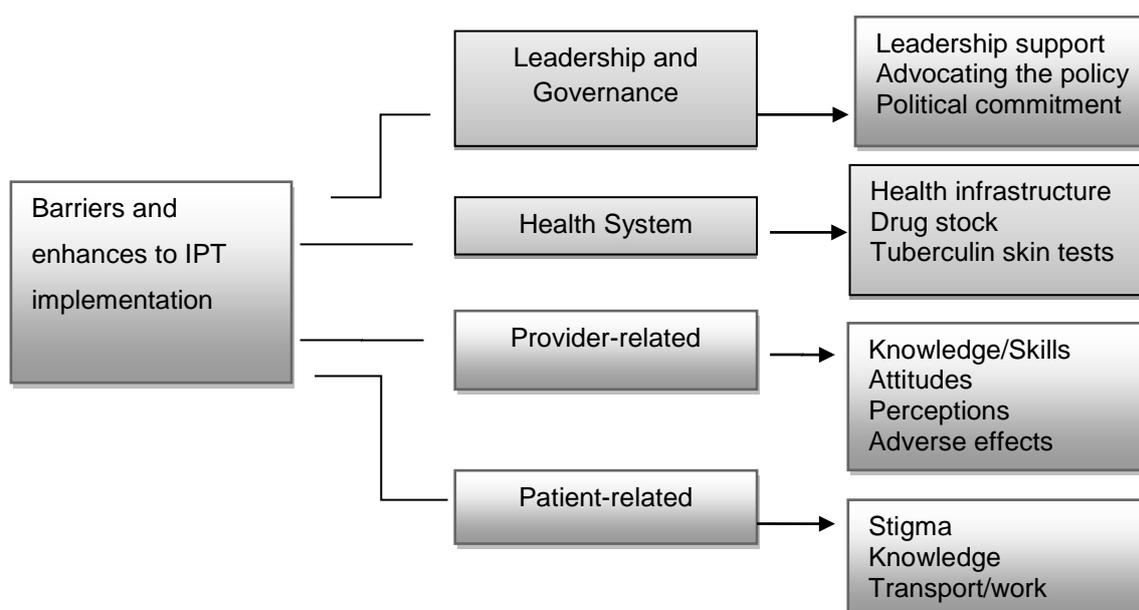


Figure 1.2: Conceptual framework

Adapted from Getahun et al. (2010:S61)

1.7.1 Leadership and governance

There may be a gap between the existence of a policy and the actual implementation of IPT (Getahun *et al.*, 2010:S57). South Africa has a national IPT policy, but it may be that in certain provinces or districts the leadership is still not advocating the policy. Although there may be enough funding for IPT, the lack of political commitment could constrain implementation (Getahun *et al.*, 2010:S62).

1.7.2 Health system

Lester *et al.* (2010: S46) reported that a critical barrier to the implementation of IPT is to exclude active TB prior to initiating IPT. Most of the investigations for TB, for example chest radiography and sputum tests are performed offsite. In addition, false-negative sputum tests, chest radiography and atypical presentation of TB among HIV positive adults may make the exclusion of active TB difficult.

The monitoring and evaluation of IPT for quality and effectiveness can be challenging (Getahun *et al.*, 2010:S61). Patients need to be followed-up over a period of 36 months and accurate monitoring systems are needed to ensure that these patients remain on treatment for the full time period.

Shortage of supplies such as isoniazid, HIV tests, tuberculin skin tests and the unavailability of laboratory services could be a further barrier to service delivery (Getahun *et al.*, 2010:S61).

1.7.3 Provider-related

The lack of experience, knowledge and the clarity of guidelines are important barriers to IPT provision (Getahun *et al.*, 2010:S61). Prescribers may be unaware of the benefits of IPT, unclear about the guidelines and believe that existing screening tools are inaccurate (Lester *et al.*, 2010:S46). A study conducted by Moolphate *et al.* (2013:64) found that nurses are concerned about a higher workload, difficulty with the administration of the tuberculin skin test and cold chain management. Another reported barrier to prescribing IPT is the belief that the high prevalence of TB meant that starting empirical courses of full TB treatment offered greater benefit and is safer (Lester *et al.*, 2010:S46).

Alcohol abuse needs to be excluded before the initiation of IPT (Republic of South Africa, DoH, Circular H169/2012:1). Serious adverse reactions such as hepatotoxicity may occur in patients who abuse alcohol. Providers may therefore not initiate IPT if they suspect alcohol use (Getahun *et al.*, 2010:S61).

A further concern from the perspective of providers is that using isoniazid without other TB drugs will induce drug resistance, particularly in South Africa with its high multidrug and extensive drug-resistance (Lester *et al.*, 2010:47). Durovni, Cawalconte, Saraceni, Velloza, Israel, King, Cohn, Efran, Pacherco, Moulton, Chraisson and Golub (2010:S55) reported that the adverse effects of IPT are a barrier to the prescription of IPT.

1.7.4 Patient-related

Evidence on patient-related barriers to the implementation of IPT is limited. However, some studies relate provider perceived patient-derived barriers such as the lack of money for transport to the clinic, the high pill burden (Lester *et al.*, 2010:S47) and poor adherence (Moolphate *et al.*, 2013:64). One of the reasons patients may not adhere to their treatment is because they are not adequately prepared and educated (Getahun *et al.*, 2010:S61).

Mental health issues may also affect the understanding of the regimen and the instructions given (Mindachew, Deribew, Memiah & Biadgilign, 2014:26). Furthermore, HIV positive adults may not be willing to disclose their HIV status to their family members, because they are afraid of losing the relationships. They may therefore lack the courage to take IPT (Mindachew *et al.*, 2014:26).

1.8 RESEARCH METHODOLOGY

In this chapter a brief discussion on the research methodology applied is described; a more in-depth discussion follows in chapter 3.

1.8.1 Research design

In this study, a descriptive qualitative approach was used to explore the barriers and enhancers to the implementation of IPT amongst HIV positive adults, from the perspective of professional nurses.

1.8.2 Study setting

The Western Cape Province is divided into six districts. Five of these districts are rural areas, namely the West Coast, Cape Winelands, Eden, Overberg and Karoo, with the Cape Metropole being the only urban area. The Matzikama sub-district in the West Coast rural district was the focus of this study (Figure 1.3).



Figure 1.3: Map of Western Cape, West Coast district with Matzikama (Images for Western Cape districts with sub districts)

1.8.3 Population and sampling

The population for this study were all professional nurses (PNs) that were responsible for prescribing IPT in the clinics of Matzikama as well as nurses in PHC management positions in the this sub-district. The total population was 21.

Purposive sampling was used to select and identify three clinics with high (49% of IPT implementation), middle (26% of IPT implementation) and low (12% of IPT implementation) implementation rates of IPT. The researcher purposively chose seven PNs and three PNs in management positions to participate.

1.8.3.1 Inclusion criteria

- All PNs responsible for prescribing IPT and
- PNs in PHC management positions in Matzikama.

1.8.4 Interview guide

An interview guide (Appendix 4) with open-ended questions based on the objectives, the literature review and the researcher's experience was used. The interview guide consisted of Section A: Demographic data; and Section B: Perceptions of barriers and enhancers to IPT. There were no predetermined responses and being a semi-structured interview the researcher was free to probe and explore within these inquiry areas. The guide made the process of interviewing more systematic and kept the interactions focused.

1.8.5 Pilot interview

The pilot interview was done prior to the initiation of the main study so that the researcher could become familiar with some of the practical aspects of conducting the interview, as well as becoming alert to her level of interviewing skills (de Vos, Strydom, Fouché & Delpont, 2011:349). The researcher conducted one interview with a PN who was from the Cederberg sub-district to identify whether the questions were clear as well as to refine the researcher's interviewing skills. The study supervisors assessed the interviewing skills of the researcher and provided feedback. The interview was recorded. The pilot interview was excluded from the analysis.

1.8.6 Trustworthiness

Polit and Beck (2014:323) use four criteria to describe the trustworthiness and evaluate the quality of research, namely, credibility, confirmability, transferability, dependability and authenticity. These criteria will be discussed in detail in chapter three.

1.8.7 Data collection

Data collection took place in the form of individual interviews with the utilization of a semi-structured interview guide (Appendix 4). One open-ended question and additional probing questions were asked of the nurses and PNs in management positions to explore the barriers and enhancers about the implementation of IPT.

The researcher personally approached each participant, explained the study and the participant and researcher agreed on a convenient time and place for the interview. A private environment was provided. The interviews were audio-recorded and permission was obtained from the participants. Interviews lasted 20 to 30 minutes. The researcher went back to the participants to verify with them the transcriptions and no changes were made. The data was collected in the clinic over a period of three weeks and field notes were taken during the interview. These notes helped the researcher to remember and reflect back on the interview, including the non-verbal actions by the participants and were used in the analyses (de Vos *et al.*, 2011:359). The interviews were transcribed by a transcriber after all 10 interviews were conducted.

1.8.8 Data analysis

The processing and analysis of data began after the researcher received the transcribed data. The researcher then analyzed the data according to the six steps of Creswell (2014:197) namely: the organization and preparation of the data for analysis; reading through all the data; gaining a general sense of the information and reflecting on the overall meaning; conducting the analysis based on the specific theoretical approach and method

which involves coding or organizing related segments of data into categories; the generation of a description of the setting or people and the categorization of themes for analysis; representing the data within the research report and interpreting the larger meaning of the data.

1.9 ETHICAL CONSIDERATIONS

Permission to conduct this study was obtained from the Health Research Ethics Committee (HREC) at Stellenbosch University (Appendix 1) and the Western Cape Department of Health (Appendix 2). The ethics reference number is S14/04/094. Permission was also obtained from the area managers and district managers in the Matzikama sub-district. The researcher abided by all the ethical guidelines of the ethics committee.

There are three fundamental ethical principles that guide research (Brink, van der Walt & van Rensburg, 2007:31).

1.9.1 Autonomy

Participants had the right to decide whether they wanted to participate in the study and had the right to withdraw from the study at any time or refuse to provide information (Brink *et al.*, 2007:32), the right not to answer a question or to say more than they are comfortable with (Richie, Lewis, Nicholls & Ormston, 2014:83). The researcher applied autonomy to inform the participants that they were participating in the study voluntarily with no coercion and that if they wanted to withdraw from the study at any stage they were allowed to do so with being penalized in any way.

1.9.2 Beneficence

The principle of beneficence includes the researcher protecting the well-being of the participants by protecting them from any discomfort or harm (Brink *et al.*, 2007:32). The study adheres to the principles of the Declaration of Helsinki (World Medical Association, 2013:2191).

The ethical principle of voluntary participation and protecting the participants from harm are formalized in the concept of informed consent (Burns & Grove, 2011:118). The participants were informed about the scope of the study and the benefit of their participation. The participants were given adequate information to enable them to make a decision about whether or not they wanted to take part in the study (Richie *et al.*, 2014:87). The consent form was in English since all the participants were comfortable with English. The content of the informed consent form was explained to the participants before they signed and verbal

consent was obtained for tape recording of their responses. An information form was given to all the participants to keep and there was opportunity for them to ask questions.

The participants were reassured about confidentiality and anonymity of their responses. Confidentiality and anonymity are guaranteed by ensuring that data obtained are used in such a way that no one other than the researcher knows the source (LoBiondo-Wood & Harber, 2010:252). The participant's names and the names of the clinics, including personal identifiers such as rank and management were not recorded.

The benefit-risk ratio indicated minimal risk to participants. The participants experienced no distress, but counseling services were available at clinics, in the unlikely event that a participant experience emotional distress. No reimbursements were provided other than refreshments.

1.9.3 Justice

All data were handled confidentially. As mentioned before, participants were informed regarding the confidentiality of their responses and their names were not written or mentioned anywhere on the interview sheet. Furthermore, justice alludes to privacy, which was ensured by anonymity and confidentiality procedures (Brink *et al.*, 2007:33). Privacy refers to the freedom an individual has to determine the time, extent and general circumstances under which private information will be shared with or withheld from others (Burns & Grove, 2011:114). The consent forms will be stored in a locked cupboard (Brink *et al.*, 2007:36). The transcribed interviews will be stored on the researcher's personal computer, which is password protected, and only the study supervisor will be given access to the data. The data will be securely stored for five years after completion of the study. Table 1.4 presents a structural outline of the methods used in the study to ensure ethical practice.

Table 1.1: A participant map of research ethics

Before the interview	During the interview	After the interview
Unpressured decision-making – nobody pressurized the participant	Right not to answer a question	Right to privacy and anonymity
Research is independent and legitimate – researcher obtained permission from HREC	Unpressurised pace and time to think	Unbiased and accurate reporting
Knowing why they were selected – the participants were provided with an information leaflet about the study	Feeling comfortable and respected	Opportunity for feedback on findings
Clear and worthwhile objectives	Opportunity for own views to be recorded	Research used for social benefit
Knowing what to expect, being prepared – especially in terms of questioning. The study objectives were explained. to the participants	Questions are relevant and clear	
Openness, honesty and being able to correct misunderstandings – The researcher explained the study to the participants and gave them the opportunity to ask questions.	Left without negative feelings	

Source: Ritchie et al., 2014:83

1.10 OPERATIONAL DEFINITIONS

Adherence: The National Tuberculosis Management Guidelines of the Department of Health (Republic of South Africa, 2009:47) defines adherence as “following the recommended course of treatment by taking all the medication, as prescribed, for the entire length of the time necessary”. For this study, patient adherence is defined as the completion of 36 months of isoniazid preventative treatment, taking IPT as prescribed and returning for follow up.

Adverse effect: It is an unwanted reaction to medication and in this research setting, isoniazid is the drug that is used. The predictable side effects of isoniazid are nausea, vomiting, abdominal pain, peripheral neuropathy and a rash (Dreyer, 2007:32).

Perceptions: George (2010:198) defines perception as the interpretation of a sensory impression. In this study the participants’ perceptions about the barriers and enhancers to IPT were explored by asking participants to voice their views on a topic and using probes to help them filter through their previous experience.

Professional nurse: According to the South African Nursing Act No. 33 of 2005, the definition of a nurse is a person registered as a nurse under section 31(1), in order to practice nursing or Midwifery (Republic of South Africa, 2005:5). The professional nurse can function in the capacity of a manager.

Resistance: According to Dreyer (2007:144) the development of resistance by micro-organisms against certain anti-microbial occurs by the formation of mutations during treatment that by some means resist the action of the drug.

Tuberculin skin test (TST): The test is used to identify previous or current Mycobacterium tuberculosis infections. The test shows hypersensitivity to proteins of the TB bacillus. It indicates infection and not TB disease (Republic of South Africa, 2009:107).

1.11 DURATION OF THE STUDY

Ethics approval was obtained on the 29 August 2014 (Appendix 1) and approval from the Department of Health on the 19 December 2014 (Appendix 2). The data were collected in March 2015 and analysed from June 2015 to July 2016. The thesis was submitted for examination in December 2016.

1.12 CHAPTER OUTLINE

Chapter 1: Foundation of the study

This chapter describes the background and rationale of the study. A brief outline of the objectives and methodology are also described.

Chapter 2: Literature review

A literature review related to the barriers and enhancers to the implementation of isoniazid preventive therapy amongst HIV positive patients is described in this chapter.

Chapter 3: Research methodology

An in-depth description of the research methodology applied in the study, which includes the design, population and data analysis is discussed.

Chapter 4: Results

The findings are discussed, interpreted and analysed based on the data collected.

Chapter 5: Discussion, conclusions and recommendations

The findings according to the study objectives are concluded and recommendations are made based on the scientific evidence obtained in the study.

1.13 SIGNIFICANCE OF THE STUDY

This study explored the perceptions of professional nurses about the barriers and enhancers to the implementation of IPT amongst HIV positive adults, specifically in a rural context. Recommendations based on the scientific evidence obtained will be made to the Department of Health and could be used in health clinics to improve IPT implementation. This could ultimately decrease the morbidity and mortality of TB, especially in patients living with HIV. The benefits of IPT to the health of patients living with HIV are clear and one of these benefits is that it is more cost effective to prevent TB than to treat it.

1.14 SUMMARY

TB has emerged as a major opportunistic infection with the advent of HIV infection. HIV infection is the greatest risk factor for the reactivation of latent mycobacterial infection.

This study aimed to explore the perceptions of nurses about the barriers and enhancers to the implementation of IPT using a qualitative descriptive approach. The research methods, trustworthiness and ethical considerations were discussed.

1.15 CONCLUSION

The uptake of the implementation of IPT is a challenge and nurses must become part of the solution to implement it. Successful implementation of IPT within the Matzikama district will depend on identifying and overcoming the barriers that nurses experience in the clinics. This study has identified factors influencing the implementation of IPT, which could lead to interventions that may improve the current situation.

CHAPTER 2: LITERATURE REVIEW

2.1 INTRODUCTION

The focus of this literature review is on the barriers and enhancers to the implementation of IPT amongst HIV positive adults. There is a plethora of literature on TB, HIV/AIDS and IPT. This review has been limited to the barriers and enhancers to the implementation of IPT and the challenges of TB prevention.

2.2 ELECTING AND REVIEWING THE LITERATURE

The purpose of reviewing the literature was to identify sources that would add value to the topic and improve understanding of the field to be researched. For this study, the following databases were searched over the period 2005-2016: EBSCO HOST, Science-Direct, Google Scholar, Biblioline, CINAHL, MEDLINE and PubMed. To conduct the literature search, the following keywords were used: latent tuberculosis infection, isoniazid preventive therapy, implementation of isoniazid preventive therapy, barriers and enhancers to isoniazid preventive therapy.

A background to the research topic is provided under the following headings: TB epidemiology; HIV/TB co-infection; and The National Tuberculosis Programme; and TB prevention strategies. The barriers and enhancers to IPT implementation are discussed under the following headings: leadership and governance; health system; provider-related; health workforce; and patient-related.

2.3 TB EPIDEMIOLOGY

TB remains a global threat and the World Health Organizations Global Tuberculosis Report (WHO) records that an estimated 9.6 million people developed TB in 2014. An estimated 1.5 million people, of whom 1.1 million were HIV-negative, died of TB in the same year (WHO, 2015:1). The WHO estimates, that one third of the population is infected with latent tuberculosis infections (LTBI) (Kapoor, Gupta & Shah, 2016:85). New infections of HIV have increased by 400% in the last 15 years (Jassat, de Kock, Page-Shipp & Conradie, 2015:1). Less than two-thirds (63%) of these were reported to WHO, which means that 37% of new cases went undiagnosed or were not reported (WHO, 2015:1). To reduce this burden, early case detection and treatment gaps must be addressed.

The Global Tuberculosis Report of 2015, further records that from 2000 to 2014, TB treatment saved 35 million lives among HIV negative adults and 8 million lives among HIV positive adults on anti-retroviral therapy (ART) and TB treatment (WHO, 2015:8). Globally in 2013, the treatment success rate for people diagnosed with TB was 86%, a level that has been sustained since 2005 (WHO, 2015:2). This is not the case in all countries, especially low resource countries, such as the African Region with a success rate of 79%, and some regions of America and Europe with a success rate of 75% (WHO, 2015:36). Of the estimated 9.6 million people diagnosed with TB globally, the African region had 28% of cases, the most severe burden relative to the population (WHO, 2015:2).

An estimated 450 000 new cases of TB were diagnosed in South Africa in 2014 (Jassat *et al.*, 2015:1). Despite the fact that TB is curable, it is a major cause of death in South Africa and internationally. South Africa has a high burden of TB and one of the highest numbers of undiagnosed active TB cases in the world (Churchyard *et al.*, 2014:244).

Numerous factors have converged to create this TB epidemic in South Africa, including: social conditions such as migrant labour, poor health infrastructure, and economic conditions such as poverty and unemployment. Furthermore, environmental conditions such as overcrowded informal settlements contribute to the epidemic (Jassat *et al.*, 2015:1).

The West Coast District, Western Province of South Africa, specifically the Matzikama sub-district, shows similarities to the Global TB report. Between 2013 and 2015, averages of 968 patients per year were initiated on drug sensitive TB treatment. The percentage of patients with HIV/TB co-infection that were initiated was between 20-25% of all TB cases in the same period. The average number of patients initiated on drug resistant TB medication was 52 per year during this period (Medical Research Council, 2013:68).

2.4 HIV AND TB CO-INFECTION

TB is the most life threatening opportunistic disease among HIV positive adults and remains a leading cause of mortality even in patients receiving anti-retroviral treatment (ART) (Date, Vitoria, Granich, Banda, Fox & Gills, 2010:253). According to the 2015 WHO TB Report (2015:1,8), TB ranks, with HIV, as the world's most deadly infectious disease. Globally, the HIV death rate was an estimated 1.2 million, including 0.4 million TB deaths amongst HIV positive adults. The African region accounted for almost three-quarters of these cases. Southern Africa was found to have more than 50% of newly co-infected TB/HIV cases in the world (Rangaka, Wilkinson, Boule, Glynn, Fielding, van Cutsem, Wilkinson, Goliath, Mathee, Goemaere & Maartens, 2014:682). In South Africa, TB is the leading cause of death in people living with HIV causing 25% of HIV-related deaths (Kapoor *et al.*, 2016:85).

In autopsy studies done on HIV positive adults, findings revealed a high proportion of undiagnosed TB (WHO, 2015:83). This shows the importance of increasing efforts to screen HIV positive adults for TB. Those without TB symptoms must be offered IPT.

According to Kapoor *et al.* (2016:85), evidence suggests that women of childbearing age are particularly vulnerable to TB during their pregnancy. TB potentially accounts for 6% to 15% of global maternal mortality, with women in their early postpartum period twice more likely to develop TB. Furthermore, the authors evince that HIV/TB co-infection has shown to increase the risk of mother-to-child transmission by an estimated 2.5% and has contributed to poorer birth outcomes, such as premature birth and miscarriage

Southern Africa has the highest rates of TB among HIV infected pregnant women. A study conducted in Lesotho found that as a result of TB/HIV co-infection, the mortality rate amongst pregnant HIV-positive women contributed significantly to the increased risk of HIV transmission from mother to child (Tiam, Machekano, Gounder, Maama-Maime, Ntene-Sealiete, Sahu, Isavwa, Oyebanji, Ahimbisibwe, Mokone, Barnes, Chaisson, Guay & Kassaye, 2014:e5).

Scale-up of TB prevention, diagnosis and treatment of TB, as well as early initiation of ART are needed to prevent TB deaths among HIV positive adults (WHO 2014:99).

South Africa has one of the worst HIV/AIDS epidemics in the world. Approximately 11%, of the South African adult population (5.6 million people) are now living with HIV (Bogart, Chetty, Giddy, Sypek, Sticklor, Walensky, Losina, Katz & Bassett, 2013:3). In South Africa, 61% of newly diagnosed TB cases were co-infected with HIV (WHO, 2015:13) and South Africa was one of the countries where the uptake of IPT increased significantly (WHO, 2015:3). Furthermore, South Africa is ranked amongst the worst afflicted countries in the world for both TB and HIV, despite having just 0.7% of the world's population (Karim *et al.*, 2009:921).

Similar findings are shown in the Western Cape Mortality Profile for 2012 (2015:65). For Matzikama sub-district, the leading causes of death are firstly TB at 20% of all deaths and secondly HIV at 9.5% (Table 2.1).

Table 2.1 Leading causes of mortality, West Coast 2012

Rank	Matzikama	Cederberg	Bergrivier	Saldanha bay	Swartland	West coast
1	Tuberculosis (20%)	Tuberculosis (12.8%)	Tuberculosis (10.1%)	HIV/AIDS (14.4%)	HIV/AIDS (12.2%)	Tuberculosis (12.3%)
2	HIV/AIDS (9.5%)	Interpersonal violence (10.2%)	Ischaemic heart disease (8.2%)	Tuberculosis (9.1%)	Tuberculosis (9.6%)	HIV/AIDS (11.0%)
3	Interpersonal Violence (8.1%)	HIV/AIDS (8.7%)	HIV/AIDS (8.0%)	Ischaemic Heart disease (8.4%)	Ischaemic Heart disease (7.6%)	Ischaemic Heart disease (7.5%)

Source: Western Cape Mortality Profile, 2015:65

2.5 THE NATIONAL TUBERCULOSIS PROGRAMME

South Africa has a National TB Programme that consists of four management levels: national, provincial, district and sub-district level. The national level coordinates, facilitates and evaluates the TB programme. The provincial level is responsible for the implementation of the programme as well as the funding of the TB programme. Districts work according to the District Health Programme. Each district is divided into sub-districts providing care at community level. The TB programme is coordinated on district level and ensures good communication between provincial level and sub-district level. At sub-district level, the TB programme forms part of the primary health care service delivered at each healthcare facility (Republic of South Africa, 2009:13).

The core function of the National Tuberculosis Programme as published in the South African National TB Management Guidelines (Republic of South Africa, 2014:56) is to strengthen the implementation of the directly observed treatment short course (DOTS), through political commitment with increased and sustained financing. DOTS mean that patients are directly observed by a treatment supporter to ensure that they swallow their tablets. Close monitoring, support and supervision ensures treatment compliance and early detection of any side effects that may occur due to the medication (Republic of South Africa, 2014:56). Although the DOTS strategy is still advocated in the South African National TB Management Guidelines, research that was done between 1995 and 2008 around DOTS, found that the overall success rate in the DOTS and the self-treatment groups were low (Karumbi & Garner, 2015:1). The systematic review done by Karumbi and Garner (2015:3) found that direct observation has little or no effect on the successful completion of treatment and that there was probably no difference in the outcomes when the patient was directly observed at

home or at the clinic. This indicates the need for more research into alternative strategies to support patient adherence to preventative and curative treatments.

The diagnosis of TB in a person with TB symptoms is dependent, in most cases, on a good sputum sample or specimen. The stained sputum is examined through a microscope to identify TB bacilli or through molecular testing (Republic of South Africa, 2014:20). In South Africa, molecular testing can be done through two different polymerase chain reaction (PCR) technologies that provide different information, namely, the Gene Xpert and Line Probe assay (LPA). The Gene Xpert is useful for rapidly diagnosing TB and to exclude rifampicin resistance, while LPA is useful for drug resistance confirmation and detects resistance to both rifampicin and isoniazid (Republic of South Africa, 2014:22).

In order to ensure the success of the National TB Programme, good management, no stock outs of medication and a good reporting and recording system is important. Training and the regular update of policies, guidelines and training materials for all health care workers will strengthen collaboration between TB disease and HIV infection (Republic of South Africa, 2009:11). TB prevention is also an essential component of the National TB Programme.

2.6 TB PREVENTION STRATEGIES

The WHO recommends the three I's strategy to combat HIV/TB, which are: intensified case finding of TB, IPT and infection control for TB (Sculier & Getahun, 2011:18).

2.6.1 Intensified case finding

Intensified case finding is the screening of all HIV patients for TB symptoms, which includes cough, fever, weight loss and drenching night sweats, at each clinical encounter (van Griensven, Choun, Chim, Thai, Lorent & Lynen, 2015:1823). HIV-positive adults diagnosed with TB must start treatment within five days of diagnosis.

2.6.2 Isoniazid preventative treatment

Should an HIV-positive adult present with no signs of TB, the healthcare worker should commence IPT. The standard regimen for IPT is isoniazid 300mg per day in adults living with HIV and is prescribed according to the duration stated in Table 2.2 (Republic of South Africa, DOH, Circular H57/2014, 2014:2).

Although it is best practice to commence IPT in all HIV positive patients with no active TB, there are eligibility criteria for IPT, namely, screening for liver dysfunction, history of allergy to INH or alcohol abuse. Obtaining this history is required before commencing IPT (van Griensven *et al.*, 2015:1823).

According to the current South African IPT guidelines (Republic of South Africa, DoH Circular H57/2014), all HIV positive adults that do not have active TB, but a positive tuberculin skin test (TST) of more than 5mm should be commenced on IPT for 36 months. The tuberculin test shows hypersensitivity to TB bacillus proteins (Republic of South Africa, 2014:24). If the TST is negative and the patient is on ART, they should be commenced on IPT for 12 months. The duration of IPT is based on the TST as depicted in Table 2.2.

Table 2.2: Duration of IPT based on TST

	Pre-ART	On ART
TST not done	IPT for 6 months**	IPT for 12 months
TST negative	No IPT	IPT for 12 months
TST positive	IPT for 36 months	IPT for 36 months

**Important to do TST within 6 months while on IPT

Source: Western Cape Government, Circular H57/2014

The WHO strongly recommends that HIV adults with no active TB should continue with IPT for up to 36 months in high TB incidence settings (Sumner, Houben, Rangaka, Maartens, Boulle, Wilkinson & White, 2016:1280). Sumner *et al.* (2016:1279) also found that IPT together with ART provides additional protection against TB. The continuous use of IPT together with improved infection control efforts can reduce exposure to TB infections and may provide long-term protection against TB (Sumner *et al.*, 2016:1283).

It was found by Swaminathan *et al.* (2012:e47400) that six months of isoniazid and ethambutol or 36 months of isoniazid alone were equally effective in preventing active TB among HIV positive adults in India. The six-month regimen of IPT was sufficient to reduce the TB risk for as long as seven years in a study in Rio de Janeiro (Swaminathan *et al.*, 2012:e47400). However, the study also showed that failing to complete IPT might yield a high TB risk (Golub, Cohn, Saraceni, Cavalcante, Pacheco, Moulton, Durovni & Chaisson, 2015:63).

Another study conducted in Botswana comparing six months with 36 months of treatment, reported a significantly greater efficacy with the longer regime (Swaminathan *et al.*, 2012:e47400). In a later study in Botswana, the efficacy of 36 months versus six months IPT, in Botswana also found that the TB incidence was higher in the first year after 36 months of IPT, but then subsequently declined (Samandari, Agizew, Nyirenca, Tedla, Sibanda, Mosimaneotsile, Motsamai, Shang, Rose & Shepherd, 2015:353).

Studies in South Africa reported an added benefit of IPT with ART (Swaminathan, *et al.*, 2012:e47400). The combination of IPT and ART reduced the risk of TB by 80-97% and death by up to 50% (Churchyard *et al.*, 2014:340). A study among HIV-positive adults in Cape Town receiving ART with 12 months of IPT, led to a 37% reduction in TB (Samandari *et al.*, 2015:358).

The reduction in mortality with IPT is significant in HIV adults who had a positive TST (Briggs, Emerson, Modi, Taylor & Date, 2015:S299). Briggs *et al.* (2015:S299) also found that the continuing of IPT for 36 months resulted in a decrease in mortality when compared with 6 months of IPT.

Although there is strong evidence that IPT reduces TB morbidity and mortality, implementation remains challenging. Rubin (2014:375) stated in an article 'Trouble with Tuberculosis Prevention', based on a study done by Churchyard, that IPT had no effect on the high rate of TB. Two factors were implicated in this study: firstly the patient taking IPT was only protected during treatment, because protection disappeared rapidly after IPT was stopped; and secondly the uptake of IPT was unimpressive. A study conducted by Churchyard in South African gold mines, with co-infected HIV positive adults, showed that IPT had no effect on the high rate of tuberculosis (Rubin, 2014:375).

Statistics indicate that globally approximately 933 000 HIV positive adults received IPT in 2014. This is approximately a 60% increase compared to 2013. Over half of the people resided in South Africa (Republic of South Africa, 2015:78). Co-infection of TB and HIV in patients is a challenge, therefore complete integrated care is a necessity (Aung, Moolphate, Paudel, Jayathunge, Duangrithi, Wangdi, Aung, Lorga & Higuchi, 2013:199).

2.6.3 Infection prevention and control

The need for infection prevention and control is important to minimize the spread of TB. The National Infection Prevention and Control Guidelines for TB, MDR-TB and XDR-TB, report that TB is usually spread from person to person by air droplets. After inhalation of the droplet, the nuclei are carried down the trachea and bronchi to the lungs (Republic of South Africa, 2015:5).

Furthermore, the Guidelines instruct that each facility must have a written TB infection and control plan that recognizes, separates and makes provision for TB investigation and treatment. Training of health care workers on the infection prevention and control plan, as well as community education and awareness is important. Surveillance of TB disease among health workers includes the screening and testing of staff every six months (Republic of

South Africa, 2015:10). Moreover, personal risk reduction where people know their HIV status and the provision of IPT to HIV positive adults is necessary. Health care workers in high risk areas, must be trained to recognize TB symptoms and wear a recommended respirator that covers the mouth and nose and is fitted with a specific small particulate filter (N95 respirator) (Jassat *et al.*, 2015:99; Republic of South Africa, 2009:95).

It is recommended that environmental controls are used to prevent the spread and reduce the concentration of droplet nuclei in the air. The type of controls implemented may vary from one facility to another. These include natural ventilation e.g. open windows and doors to allow the air to move in and out of the room and high efficiency particulate air filters that clean air and recirculate air in the room. Another method of control is ultraviolet germicidal irradiation that is dependent on room air mixing to be effective (Republic of South Africa, 2015:13-15).

2.7 ENABLERS AND BARRIERS TO THE IMPLEMENTATION OF IPT

The conceptual framework adapted from Getahun *et al.* (2010:S61) guided the researcher in structuring and understanding the barriers as well as the enhancers to IPT implementation. The researcher has alluded to these factors in chapter one when the conceptual framework was described. The factors are discussed under the following headings: Leadership and governance; the health system; provider and health workforce related; and patient-related.

According to Moolphate *et al.* (2013:64), the most common reasons why IPT is not implemented includes: no clear direction in national policy, fear of isoniazid resistance, poor adherence, toxicity, administration of TST and the workload of health care workers.

2.7.1 Leadership and governance

According to the WHO (2010:86) leadership and governance in building a health system involves ensuring that strategic policy frameworks exist and are combined with effective oversight, coalition-building, regulation, attention to system design and accountability. Getahun *et al.* (2010:S62) reported that IPT should be a priority for the National AIDS control program. Training modules and efforts need to include IPT in providing HIV care and treatment. Policies with time bound targets are necessary to scale-up the implementation of IPT.

The widespread implementation of IPT programs prove to be difficult, due to the complexities involved in the coordination of national TB/HIV programs e.g. supply chain management, monitoring and evaluation (Briggs *et al.*, 2015:S302). A study conducted in

Upper Northern Thailand showed that the main barrier to the implementation of IPT could be related to governance and leadership, because the national policy was not clearly stated (Moolphate *et al.*, 2013:60). Only 33% of the staff members had seen the WHO guidelines for IPT.

Factors that may have influenced IPT uptake in South Africa are guideline changes and the use of the TST. In South Africa, guidelines first recommended IPT for 6 months continuously or if interrupted, over 9 months (Lawn & Wood, 2012:996). In 2013, the IPT guidelines changed and the duration of IPT was determined according to the TST result. The reintroduction of TST into the guidelines creates a barrier to implementation of IPT (Churchyard *et al.*, 2014:246).

South Africa has a national IPT policy, but it may be that in certain provinces or districts the leadership is still not advocating the policy. Although there may be enough funding for IPT, the lack of political commitment could constrain implementation (Getahun *et al.*, 2010:S62).

2.7.1.1 Policy

Cloete and Wissink (2005:3) define policy as “a statement of intent”. Policy specifies the principles to be pursued in attaining goals. Policies should advocate integrated care. Patients requiring HIV care must receive IPT to benefit fully (Ait-Khaled, Alarcon, Bissell, Boillot, Caminero, Chiang, Clevenbergh, Dlodlo, Enarson, Enarson, Ferroussier, Fujiwara, Harries, Heldal, Hinderaker, Kim, Lienhardt, Rieder, Rusen, Trébuq, Van Deun, & Wilson, 2009:930). There is an expectation that government should take responsibility for IPT distribution, because interrupted drug supplies were a barrier reported in a study done by Mindachew *et al.* (2014:26) in Addis Ababa, Ethiopia.

A review of policies in 23 high-burden countries (Gupta, Granich, Date, Lepere, Hersh, Gouws & Samb, 2014:1150) found that the issuing of national policy guidance is a critical step in ensuring quality HIV/TB coordination and program implementation. However, despite the prevention benefits, implementation of the WHO 2010 and 2013 guidelines continue to pose significant challenges and policy adaption can be a complex and lengthy process, which needed additional efforts (Gupta *et al.*, 2014:1154-1155).

According to Modi and Dave (2012:173), a clear global policy is needed that is part of the TB/HIV national programme. The number of HIV positive adults provided with IPT in Cambodia increased dramatically when the WHO revised the guidelines, based on TB screening that relies on the absence of the four clinical symptoms, namely: cough, night

sweats, fever and weight loss to rule out active TB. With this revised guidelines Chest X-rays and TST were no longer a requirement for initiation of IPT (Modi & Dave, 2012:173).

It was noted that the coverage and implementation of IPT has been slow in many countries, due to numerous factors, for example: INH resistance, drug side effects, attitude of providers, shortage of drug supplies and TB screening. These factors may affect both the attitude and perception of policy makers towards TB prevention therapy (Assebe, Reda, Wibeneh, Lerebo & Lambert, 2015:346).

Policies amongst provinces in South Africa differ, resulting in varying methods of implementation. This suggests the need to identify factors that contribute to these differences as well as efforts to align provincial policy with national policy (Bristow, Larson, Vilakazi-Nhlapo, Wilson & Klausner, 2012:1021).

The WHO and United Nations Programme on HIV/AIDS (UNAIDS) recommended that governments should provide information about TB and IPT to all HIV positive adults. It is important to exclude active TB and ensure appropriate monitoring and follow up. Staff must ensure that IPT is part of the package of care for HIV positive adults and voluntary counselling and testing are provided to everyone visiting the facility. It is important that policies are clear and dissemination of accurate information is required (Modi & Dave, 2012:172).

2.7.2 Health system

For the scale-up of IPT implantation, clear, simple guidelines; the use of algorithm screening tool with IPT provision; client monitoring and education; effective INH access and supply system; engagement of affected communities; and monitoring and evaluation system are required (Getahun *et al.*, 2010:S62). Modi and Dave (2012:171) identified the following prerequisites, which should be in place before an IPT service is considered: adequate capacity for HIV counselling, trained health care staff, linkage between HIV and TB services and TB treatment services with a high probability of curing TB cases. Screening of all people should be implemented in all healthcare facilities.

2.7.2.1 Clinical algorithms

The implementation of clinical algorithms is important to enhance health services to play an active role in diagnosing TB (Sculier & Getahun, 2011:S5). Introduction and adaption of the Gene Xpert into these algorithms, on a large scale in health services, will improve early detection of TB, and identification of patients in need of IPT. Gene Xpert can detect drug susceptibility and rifampicin resistant TB in less than two hours.

Lester *et al.* (2010: S46) reported that a critical barrier to the implementation of IPT is to exclude active TB prior to initiating IPT. Some investigation methods for TB, for example, chest radiography are performed offsite. There is currently no international evidence-based tool to screen people living with HIV with TB symptoms. The signs and symptoms of TB among people with and without HIV are different. An example of this is that many HIV patients do not have a prolonged cough, which is one of the standard TB screening questions (Modi & Dave, 2012:172). Sputum smear microscopy or chest X-rays have been used to diagnose TB in some cases. However, most HIV positive patients have a negative smear or extra pulmonary TB, which is difficult to diagnose if these investigation methods are not on site. X-ray findings have been reported to be normal in 14% to 23% of these patients. Weight loss is commonly mistaken for “HIV wasting syndrome”.

2.7.2.2 Supplies and INH resistance

Getahun *et al.* (2010:S61) found that a shortage of supplies such as INH, HIV tests, TST and the unavailability of laboratory services could be a barrier to service delivery. The unavailability of INH at a health facility was the reason for non-adherence in South Africa (Behre, Demise & Tesfate, 2014:1). Ensuring supplies of INH are available for HIV care programs are vital. The adult dosage of 300mg should be available for adults, including pregnant women and patients receiving ART (Getahun *et al.*, 2010:S62).

In Ethiopia the uptake of IPT has been limited due to difficulties in excluding TB and the concern about drug resistance despite the strong recommendations globally (Yirdaw, Jerene, Gashu, Edginton, Kumar, Letamo, Feleke, Teklu, Zewdu, Weiss & Ruff, 2014:e104557).

As was found in an ART Clinic in Cape Town, INH is an important component of standard TB treatment, drug-resistance is already high and the widespread use of antibiotics is inevitably followed by increasing drug resistance (Wood & Bekker, 2014:176).

They also suggest that ART plus IPT may not be adequate to control TB in the population. An operational perspective is whether the drug toxicity leading to IPT discontinuation was due to INH or ARV's (van Griensven *et al.*, 2015:1829).

2.7.2.3 Administration of TST

In sub-Saharan Africa, ART has been scaled up rapidly, but the implementation of IPT remains poor. The tuberculin skin test was an obstacle for the implementation of IPT (Lawn & Wood 2012). TST is especially an obstacle in the rural areas where patients cannot return to the facility in time to read the TST (Cox *et al.*, 2015:1300). In a literature review, Briggs *et*

al. (2015:S302) found that facilities have not routinely incorporated TST due to a number of challenges, for example, adequate available supplies; staff trained to administer and interpret the TST; and missed opportunities for treatment when patients do not return to have their TST results read.

Reducing the problems surrounding the use of TST will help to improve the implementation of IPT. In a study done in Khayelitsha Cape Town, patients were educated to read their own results, and report it to the nurse (Cox *et al.*, 2015:302).

2.7.2.4 Integrated services

The WHO encourages decentralization of HIV and TB services, as studies conducted have demonstrated improvements in outcomes, even in rural settings where services are decentralised (Charles, Lindegren, Wester, Blevins, Sterling, Dung, Dusingize, Avit-E, Durier, Castelnuovo, Nakigozi, Cortes, Ballif & Fenner, 2016:2). Furthermore, they found that IPT was offered routinely to 42% of patients that enrolled on the HIV programme or commenced ART in integrated sites, versus only 9% of patients enrolled in non-integrated sites.

Integration of HIV and TB services to deliver collaborative TB/HIV activities is important in settings where TB patients are also HIV positive and in need of ART (Sculier & Getahun, 2011:S5). The integration of HIV and TB services in primary health care, as well as mother and child health care, will improve IPT uptake. IPT together with ART have additive efficacy with respect to the prevention of TB and it is suggested that the two therapies should be given concomitantly (Danel, Moh, Gabillard, Badje & le Carrou, 2015:817).

Mindachew *et al.* (2014:26) found decentralization of the health care system where the patient is seen holistically and appropriate counselling and support is provided, may lead to good adherence.

2.7.2.5 Engagement of affected communities

Community awareness of TB symptoms and early HIV detection will reduce delay in the initiation of TB, IPT and HIV care (Sculier & Getahun, 2011:S5). The innovation and decentralization of services closer to the community to prevent, diagnose, and treat TB is crucial. Changing the site of service delivery e.g. providing IPT outside the clinic, such as in an HIV support group, or in the household through home-based care, would be a solution to up-scale IPT (Adams, Talbot, Orator, Blunt & Steinhart, 2014:281).

2.7.2.6 Monitoring and evaluation system

The monitoring and evaluation of IPT for quality and effectiveness can be challenging (Getahun *et al.*, 2010:S61). Patients need to be followed-up for 36 months and accurate monitoring systems are needed to ensure that these patients remain on treatment for the full period. The integration of reporting formats, e.g. folders and pre-ART or ART registers to cross check the accuracy of data and to identify reporting gaps, are important (Sculier & Getahun, 2011:S5). This will ensure recording of assessment of TB screening on a monthly basis or with every visit during IPT (Getahun *et al.*, 2010:S63). Changes in the medical recording system e.g. changing from paper to computerized records and the use of patient-tracking systems can be a solution for better adherence and treatment outcomes (Adams *et al.*, 2014:281).

Recording and reporting errors that were found in a study done in Brazil included the lack of registration; incomplete assessment; incorrect remarks of latent tuberculosis infection contra-indication; and whether a TST or any examination was done or not (Wysocki, Villa, Arakawa, Brunello, Vendramini, Monroe & Kritski, 2016:e0155348).

The National Tuberculosis Program (NTP) in South Africa has an electronic recording and reporting system for drug-susceptible TB (ETR.net) and drug-resistant TB (EDR.web). There are challenges with the electronic recording and reporting system, due to the high turnover of data capturers and poor-quality data entry. Problems occur with the tracking of patients who move between sub-districts or districts and across programs (Churchyard *et al.*, 2014:247).

2.7.3 Provider or health workforce

The IPT programme is implemented primarily on PHC level. Healthcare workers on PHC level in the SA context who are part of IPT implementation include professional nurses, doctors, pharmacists, pharmacist assistants and lay health workers.

2.7.3.1 Roles, responsibilities and workload

A study that was done in lower income countries to assess the implementation of the Three I's found that only one quarter of all sites had specialized clinics with dedicated staff that performed TB screening for HIV patients (Charles *et al.*, 2016).

A systematic review that was done by Ait-Khaled *et al.* (2009:928) found that it is unclear who is supposed to take responsibility for the implementation of IPT. The PNs, responsible for the TB programme, felt they simply did not have the time or capacity to undertake this additional task alongside their regular duties (Ait-Khaled *et al.*, 2009:928).

A study in Brazil found that in the PHC sector, there is a high staff turnover and the large work overload leads to the failure to diagnose and treat latent TB (Wysocki *et al.*, 2016). In South Africa, with the on-going risk of TB infection, the healthcare system may be overburdened by the implementation of IPT (Wood & Bekker 2014:175). A study conducted by Moolphate *et al.* (2013:64) found that nurses are concerned about a higher workload, difficulty with the administration of the TST and cold chain management.

Goswami, Gadkowski, Piedrahita, Bisette, Ahearn, Blain, Ostbye, Saukkonen and Stout (2012:468) found that initiating, rather than completing treatment was the major challenge in the latent tuberculosis infection programme. This was also found in a study done in Botswana where the screening and evaluation of patients was often incomplete and physical examinations were not conducted (Maboe, Bengtsson & van Rensburg, 2015:135). Health providers reported that these patients might be overlooked, because they went to other facilities, were defaulting or collected their INH from the pharmacy without seeing a doctor or nurse. Involvement of pharmacists in prescribing and distribution of isoniazid may help to improve IPT implementation and adherence (Adams *et al.*, 2014:281).

2.7.3.2 Attitudes and perceptions

Attitude is a feeling or opinion about something and perception a belief or an image people have because of how they see or understand something (George, 2010:198). Health worker attitudes may influence IPT implementation. Their attitudes may affect how they recognize patient decision-making abilities, understand patient concerns and encourage patients to participate in decisions about their medications (Jiehui, Munsiff, Tarantino & Dorsinville, 2010:295).

There was a strong belief amongst health workers in Rio (Durovni *et al.*, 2010:553) that the complexity of HIV treatment and HIV patients' lifestyles adversely affected TB prevention in these patients.

Durovni *et al.* (2010:S55) reported that the adverse effects of IPT is a barrier to prescribing IPT.

A reported barrier to prescribing IPT is the belief that the high prevalence of TB meant that starting empirical courses of full TB treatment offered greater benefit and is safer than prophylaxis (Lester *et al.*, 2010:S46; Churchyard, 2011:88). Churchyard (2011:88) also found that doctors had heard of IPT, but were unaware of its efficacy in preventing TB. Another perception was that using isoniazid would induce drug resistance, especially in the South African context of multidrug-resistance.

Communication between healthcare providers and patients are important. A cross-sectional study in Addis Ababa found that doctors appear insensitive, view patients as complainers or do not provide clear messages about the reasons for treatment (Mindachew *et al.*, 2011:916).

2.7.3.3 Knowledge and skills

The lack of experience, knowledge and the clarity of guidelines are significant barriers to IPT provision (Getahun *et al.*, 2010:S61). Prescribers may be unaware of the benefits of IPT, unclear about the guidelines and believe that existing screening tools are inaccurate (Lester *et al.*, 2010:S46).

Health care workers must have on-going training. Opportunities for sharing experiences and continuous support will improve implementation of IPT (Denegetu & Dolamo, 2014:52). The risk of serious isoniazid-related toxicity will be reduced by educating and monitoring the patient. Patients must be warned about symptoms of toxicity and about alcohol consumption while on IPT (Getahun *et al.*, 2010:S62).

Namuwenge, Mukonzo, Kiwanuka, Wanyenze, Byaruhanga, Bissell and Zachariah (2012:87) found that patients stop taking IPT within the first month. The need to improve adherence counselling and education are important. Counselling should be focused on the first two months of treatment and the use of reminders such as cellular phone alarms and watches for remembering treatment times (Behre *et al.*, 2014). Maboe *et al.* (2015:143) recommended that all health care workers had increased training.

2.7.4 Patient-related

Adherence is important for HIV positive adults. To have the full benefit of IPT, they must complete their treatment. If they stop their course, it does not have the same benefits (Getahun *et al.*, 2010:S61). Adherence rates for IPT vary significantly due to e.g. side effects, knowledge and socio-economic problems (Gust, Mosimaneotsile, Mathebula, Chingapane, Gaul, Pals & Samandari, 2011:E18435).

The National Tuberculosis Management Guidelines of the Department of Health (2009:47) defines adherence as “following the recommended course of treatment by taking all the medication, as prescribed, for the entire length of the time necessary.”

Successful implementation of the IPT programme hinges on patient adherence and completion of the IPT regimen.

In Asia, IPT completion rates were acceptable, comparable with other studies, but poor adherence was common amongst patients not yet on ART (Van Griensven *et al.*, 2015:1827). A study that compared urban and rural South Africa, reported that IPT, in combination with ART, had a significantly higher level of effectivity (Wood & Bekker, 2014:176). Kabali, von Reyn, Brooks, Waddell, Mtei, Bakari, Matee, Pallangyo, Arbeti and Horsburgh (2011:1520) found that patients who default on their IPT also do not take their other medication e.g. antiretroviral drugs.

In Ethiopia, Yirdaw *et al.* (2014:e104557) found that only 24% of patients started on IPT completed their treatment.

2.7.4.1 Knowledge

Patient treatment adherence is important and should be promoted. Education is an effective strategy for increasing adherence (Getahun *et al.*, 2010:S62). They also suggested that patients be provided written information about adverse effects of the medications and the importance of taking medication at the same time each day.

A barrier to adherence is also the patient's failure to follow the advice or recommendations of the healthcare provider and is often misunderstood or carried out incorrectly (Berhe *et al.*, 2014:2).

2.7.4.2 Treatment regimen

The use of the 300mg INH that reduces pill burden might furthermore improve adherence. A study that was conducted in New York City by Jiehui *et al.* (2010:295) suggested that an evaluation of a shorter regimen may provide an important strategy to improve completion rates.

An observational study that was conducted by Menzies, Dion, Francis, Parisien, Rocher, Mannix and Schwartzman (2005:1346) found that patients who took pills at different hours of the day were less likely to complete their treatment successfully than those who took their doses at the same time each day. They also found that patients feel threatened by pill counts and direct questioning of how many doses they have taken.

2.7.4.3 Side effects

A treatment side effect is an unwanted reaction to the medication. The predictable side effects of isoniazid are nausea, vomiting, abdominal pain, peripheral neuropathy and a rash (Dreyer, 2007:32). The most important adverse event is the development of hepatotoxicity, which can be caused by isoniazid. The occurrence of liver tenderness, an enlarged liver or jaundice should lead to urgent referral (Republic of South Africa, 2009:68)

In a study done in Tanzania, stigma and the fear of side effects of the medication were the best predictors of non-adherence. Further reasons for missing pills such as forgetfulness and being away from home were factors that played a role in non-adherence (Kabali *et al.*, 2011:1517)

Studies from Malawi, Zambia and South Africa have shown that adherence varies from 24% to 59% and that it is a great challenge for health care workers on how they can help to improved adherence (Sculier *et al.*, 2011:S5). The feasibility and monitoring of IPT toxicity is also of concern, although South African patients have very low rates of adverse events (0.07% hepatotoxicity) as found by Sculier and Getahun (2011:S5). Side effects were one of the reasons for patients defaulting, according to Kwara, Herold, Machan and Carter (2008:866). .

Serious adverse reactions such as hepatotoxicity may occur in patients who abuse alcohol. Providers may therefore not initiate IPT if they suspect alcohol use (Getahun *et al.*, 2010:S61). Hepatotoxicity may occur with no symptoms and therefore clinical monitoring; including a liver function test, at least during the first three months of treatment is recommended (Miyazawa, Matsuoka, Hamana, Nagai, Nakamura, Nirei & Moriyama, 2014:594).

A study amongst Latino immigrants found that side effects play a significant role in adherence (Allinger, Black, Nguyen & Lasus, 2007:194). Miyazawa *et al.* (2014:594) reported in a study conducted in the United States that eight deaths occurred due to hepatitis among patients taking isoniazid. Furthermore, hepatotoxicity was reported in patients over 35 years of age and patients with a history of alcohol consumption, especially those drinking on a daily basis.

In a study conducted in Botswana, patients reported difficulties with taking INH, such as nausea, weight loss, dizziness, tiredness or body ache (Gust *et al.* 2011:e18435).

In the Thibela TB study, done in the South-African gold mines with 24 221 participants, sixty-one participants reported side effects such as a rash, fifty participants reported peripheral neuropathy in approximately 34 days after IPT started and seventeen participants reported symptoms associated with hepatotoxicity (Grant, Mahdi, van Alsea, Lottie, Fielding & Churchyard, 2010:S31,S32).

2.7.4.4 Socio economic factors

Lavigne, Rocher, Steensma and Brassard (2006:66) found that males might be less compliant with latent tuberculosis treatment for economic reasons. In many cultures, they

are the main contributors to the family income and cannot afford to take time off from work to visit a clinic. Absences from work and travel time are reasons cited for less money earned. Another finding by Lavigne *et al.* (2006:66) is that males are less likely to adhere to healthy behaviours including prevention messages such as smoking cessation and adherence to treatment.

A study done in the United States of America by Allinger, Black, Nguyen and Lasus (2007:194) found that being foreign-born from a high endemic country such as Central and South America, Mexico and Cuba, are also a major risk factor for adherence. This indicates that culturally relevant measures need to be addressed.

The findings in a study done in Rhode Island show certain patient groups: those who were young; postpartum; and with no health insurance, are at an increased risk of poor adherence. Other factors associated with poor adherence were lower socio-economic status, poor health knowledge and unidentified barriers to routine preventive care such as lack of transportation (Kwara *et al.*, 2008:866).

The number of bus trips played a role in a study that was done by Machado, Finkmoore, Emodi, Takenami, Barbosa, Tavares, Reis, Arruda and Riley (2009:723). The bus fare in Salvador, Brazil was high and users had to pay the full fare again when transferring to another bus. The number of bus trips and not the distance was the problem for not completing the treatment.

Mental health issues may also affect the understanding of the treatment and the instructions given (Mindachew *et al.*, 2014:26). Furthermore, HIV positive adults may not be willing to disclose their HIV status to their family members, because they are afraid of losing the relationships. They may therefore lack the courage to take IPT (Mindachew *et al.*, 2014:26).

In Uganda a study by Namuwenge *et al.* (2012:87) it was observed that patients under 30 years of age, were at risk for poor adherence. The majority of Ugandan youth are unemployed. No education or only primary education also played a role. Namuwenge, Mukonzo, Kiwanuka, Wanyenze, Byaruhanga, Bissell and Zachariah (2012:87) also found that travelling relatively long distances and transport costs might be a deterrent to IPT compliance. Stigma, no support system and increased household responsibilities have been identified as major drivers for poor adherence. These findings were similar to a study conducted in Botswana, by Gust *et al.* (2011:e18436) were barriers to adherence, were also distance from the clinic including level of education and alcohol use.

Research that was done in a rural area in South Africa by Rowe, Makhubele, Hargreaves, Porter, Hausler and Pronyk (2005:265) found that barriers to adherence were a lack of money for food and transport. Patients believed that it is unhealthy to take medication without food. Women depended on their parents or husbands for financial support. The decisions to attend a clinic were not made by the women themselves. They sometimes did not have the money for transport to go to a clinic and the lack of social and family support were barriers to adherence.

Fear of stigmatization, competition between Western and traditional medicine and a reluctance to take medication in the absence of symptoms are additional barriers to adherence (Rowe *et al.*, 2005:265,266). Stigma and efforts to conceal the condition and its treatment could interfere with adherence. Some of the HIV positive adults take their medication or share or sell the medication to others who are at risk (Szakacs, Wilson, Cameron, Clark, Kocheleff, Muller & McCarthy, 2006:97).

2.8 CONCLUSION

Not many studies were done in South Africa around IPT implementation and few studies were conducted in rural areas. IPT has been shown to be beneficial for the prevention of TB, but uptake has been slow due to a number of barriers as discussed in this chapter.

Prevention of TB through focusing on the enhancers and mitigating the barriers to IPT implementation as discussed will contribute to the overall goal of reducing the TB burden and improve the quality of life in HIV positive adults.

Chapter 3 discusses the research methodology that was used to explore the barriers and enhancers for the implementation of IPT from the perspective of professional nurses.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 INTRODUCTION

The previous chapters provided a background to the study including a literature review regarding the barriers and enhancers of IPT implementation. This chapter describes the methodology used in conducting this study and the measures to provide trustworthiness are discussed.

Research methodology specifies how a researcher may go about practically studying what they believe can be known (Terre Blanche, Durrheim & Painter, 2007:6). According to Brink *et al.* (2007:191) methodology includes the population, approach, data-collection method and data analysis in this study.

3.2 AIM OF THE STUDY

The aim of the study was to explore the barriers and enhancers to the implementation of IPT amongst HIV positive adults, from the perspective of professional nurses in the West Coast District of the Western Cape Province.

3.3 OBJECTIVES

The objectives were to:

- Explore the perceptions of professional nurses about the enhancers to the implementation of IPT amongst HIV positive adults.
- Explore the perceptions of professional nurses about the barriers to the implementation of IPT amongst HIV positive adults.

3.4 STUDY SETTING

The setting is the location where the study is performed. A setting could be: a) natural or uncontrolled, for example, in a real life situation or environment; b) partially controlled where the researcher manipulates the environment to a certain extent; c) highly controlled where the environment is artificially constructed for the purpose of conducting the study (Grove, Burns & Gray, 2013:373).

The research setting in this study was natural as it occurred in a real life setting, in the clinics where the participants were working. The Western Cape Province is divided into six districts. Five of these districts are rural areas, namely the West Coast, Cape Winelands, Eden,

Overberg and Karoo, with the Cape Metropole being the only urban area. The Matzikama sub-district in the West Coast rural district was the focus of this study.

3.5 RESEARCH DESIGN

Grove, Burns and Gray (2013:195) defines a research design as a blueprint for how a study is conducted. It also guides the researcher in planning and implementing the study to achieve accurate results (Grove *et al.*, 2013:195). A descriptive qualitative design was applied, to explore the barriers and enhancers for the implementation of IPT amongst HIV positive adults, from the perspective of professional nurses.

3.5.1 Qualitative research

Qualitative research is valued in the medical field and helps to understand the experiences or perspectives of individuals in the contexts in which these experiences or perspectives are situated (O'Brien, Harris, Beckman, Reed & Cook, 2014:1245).

A qualitative research design was used in the study, as the researcher wanted to focus on the perceptions of the professional nurses. Qualitative design is described by Burns and Grove (2011:73) as an approach to research in which life experiences of participants are described and meaning is given to the real life experiences of participants. It explores human experience through the viewpoint of the participant in the context in which the actions take place (Brink *et al.*, 2007:113).

3.5.2 Descriptive research

Descriptive research refers to research studies that have as their main objective the accurate portrayal of the characteristics of a particular individual or situation (Burns & Grove, 2005:26). Grove *et al.* (2013:215) states that the purpose is to provide a picture of situations as they naturally occur. The descriptive approach was adopted for collecting data on the perceptions of professional nurses involved with IPT.

The qualitative approach is unstructured and therefore more appropriate to explore the nature of the problem (de Vos *et al.*, 2011:65). It allows the researcher to capture the perceptions of the professional nurses in a natural setting (de Vos *et al.*, 2011:65). The descriptive qualitative design allowed the researcher to describe the patterns, which emerged from the data. In this study, the researcher focused on exploring and describing the perceptions about the barriers and enhances to the implementation of IPT held by the participants. The researcher examined the perceptions from the participant's point of view in order to interpret their words.

The researcher was actively involved in the interviews with the participants in order to explore the barriers and enhancers for the implementation of IPT. It is important that the researcher and the participant focus together on a specific topic, think, and reflect on it in a way they had not before (Ritchie *et al.*, 2014:186). According to Ritchie, *et al.* (2014:183), it is important that the researcher and participant have some knowledge of the themes they wish to explore and the interview is based on the topic guide (Ritchie *et al.*, 2014:183). This was done through an in-depth interview where the researcher asked open-ended questions, allowed the participant to answer, and reflected and summarised responses where necessary, to accurately describe what was discovered during the semi-structured interviews.

3.6 POPULATION AND SAMPLING

According to Burns and Grove (2011:51), a study population is all the individuals that meet a certain criteria for inclusion into a specific study. The population for this study were all professional nurses who were responsible for prescribing IPT in the clinics of Matzikama as well as nurses in PHC management positions in the this sub-district. The total population of professional nurses working in Matzikama Sub district was 21.

3.6.1 Sampling strategy

In one-on-one interviews in qualitative research, potential participants should have a common experience that is significant to the research focus. A sample is a subset of the population that is selected for the specific study (Burns & Grove, 2011:51). Sampling defines the process of selecting a group of people, behaviours, events or other elements with which to conduct the study (Burns & Grove, 2011:51). The sample is determined by whatever the researcher wants to know, the purpose of enquiry and what will be useful and feasible within the available time and resources.

For this study the participants recruited were appropriate to answer the research question and had similar roles and experiences according to the stated inclusion criteria. They were chosen specifically because of their knowledge and experience in managing patients with TB and HIV.

In the study purposive sampling was used to select and identify three clinics with high, middle and low implementation rates of IPT to obtain a range of views. Purposive sampling in descriptive qualitative research allows for the inclusion of research participants who are best able to provide the information under investigation (Grove *et al.*, 2013:365). In qualitative research, the focus is on the quality of the information obtained from the participants and not on the size of the sample (Grove *et al.*, 2013:371). The researcher

purposely chose seven PNs working in the clinics and three nurses in management positions to participate. The researcher chose to question PNs and managers for their different perceptions. The perceptions of managers may differ from those of PNs since they view implementation from a different perspective and may have more insights about guidelines and protocols. The PNs work with patients every day and have first-hand knowledge of problems that occur.

The sample size was determined by data saturation. For this study, saturation of data occurred with the sixth interview when the data became repetitive and redundant and subsequent interviews provided no new information (Grove *et al.*, 2013:372). The researcher continued with the initially anticipated ten interviews in order to ensure that the participants from the high, middle and low implementation clinics' perspectives were explored.

3.6.2 Inclusion criteria

Inclusion criteria are qualities that the participant must possess to be part of or qualify to be included in the target population (Grove *et al.*, 2013:353). These criteria included:

- All PNs responsible for prescribing IPT; and
- PNs in PHC management positions in Matzikama.

3.6.3 Gaining access to the study population

Prior to commencing any data collection, the researcher had a meeting with the management of the sub-district. The researcher explained the purpose of the study and presented the approval letter from the Stellenbosch University Health Research Ethics Committee (Appendix 1) and the formal approval letter of the Department of Health (Appendix 2). The Primary Health Care (PHC) manager gave verbal permission to proceed with the data collection. The researcher visited the clinics, met with the operational managers and explained the reason for the study to the participants who were eligible and willing to participate in the research.

3.7 INTERVIEW GUIDE

An interview is an unstructured or structured verbal communication between the researcher and the subject, during which information is obtained for a study (Grove *et al.*, 2013:422). It also allows the researcher to exercise control over the content of the interview to obtain essential data for the study.

In this study, the researcher used semi-structured interviews, which were organized, around the area of particular interest, while still allowing flexibility in scope and depth (de Vos *et al.*, 2011:351). This is the most common measurement strategy used in qualitative and

descriptive studies (Grove *et al.*, 2013:422). The researcher explored the experience of the participants and the semi-structured interviews included open-ended questions.

In order to explore the views of the participants during the interview, an interview guide (Annexure 4) with open-ended questions based on the objectives, literature review and the researcher's experience were used.

Each interview started with a few demographic questions: gender, age, race, professional qualification, current position and years of clinical experience in primary health care. The interview was then followed by questions about their experiences of implementing IPT. Open-ended questions with some probing questions were asked, for example, 'Tell me about your experiences of implementing IPT in your clinic'. All the questions are mentioned in Appendix 4. It was important to hear the participant's views and experiences in their own words.

There were no predetermined responses and being a semi-structured interview the researcher was free to probe and explore within these inquiry areas. Using the interview guide ensured that the limited time was used beneficially. The guide made the process of interviewing more systematic and kept the interactions focused.

3.8 PILOT INTERVIEW

The pilot interview was done prior to the initiation of the main study so that the researcher became familiar with some of the practical aspects of conducting the interview, as well as becoming alert to her level of interviewing skills (de Vos, *et al.*, 2011:349). The researcher conducted one interview with a PN who was from the Cederberg sub-district to identify whether the questions were clear as well as to refine the researcher's interviewing skills. The participant did not have any difficulty in answering the questions. Data from this pilot interview was not included in the study findings. The study supervisor assessed the interviewing skills of the researcher and provided feedback. No problems with the interview guide or audio recording were identified. The interview was audio-recorded.

3.9 SCIENTIFIC RIGOUR OF THE STUDY

Rigour was ensured through trustworthiness. Trustworthiness is concerned with the accuracy and truthfulness of scientific findings (Brink *et al.*, 2007:118). To represent reality or truth in any qualitative study, Polit and Beck (2014:323) used four criteria to describe the trustworthiness and evaluate the quality of qualitative research, namely credibility, confirmability, transferability and dependability.

3.9.1 Credibility

Credibility in qualitative research refers to internal validity (Brink *et al.*, 2007:118). It deals with the accuracy of data to reflect the phenomenon of interest. The researcher must strive to establish confidence in the truth of the findings (Polit & Beck, 2014:323). Suitable participants were identified according to the study inclusion criteria. The researcher introduced the aim of the study to the participants and asked their permission to participate in the study. This was done to build a good trusting relationship (Shenton, 2004:65).

Activities increasing the probability that credible findings will be produced are: prolonged engagement, reflexivity, triangulation, comprehensive recording of information, debriefing and member checks (Polit & Beck, 2014:324). The strategies that were applied to ensure credibility are described below.

3.9.1.1 Prolonged engagement

Prolonged engagement is the investment of sufficient time collecting data to have an understanding of the culture, language and views of the participants. It is also essential for building trust (Polit & Beck, 2014:325-326). The researcher is from Matzikama and has experience in working in the clinics. Enough time was spent with the participants to develop insight into their experiences.

3.9.1.2 Comprehensive recording of information

The researcher interacted with the participants for a prolonged time and this allowed for rich data collection and for the researcher to gain adequate understanding of the study. Thoroughness in record keeping helps readers to develop confidence in data (Polit & Beck, 2014:327). Semi-structured interviews were conducted until data saturation occurred. The interview was audio-recorded and the researcher took field notes to ensure that the information provided was not missed.

3.9.1.3 Member checks

Member checking is used in qualitative methodology and is defined as a quality control process by which a researcher seeks to improve the accuracy and credibility of what has been recorded during the interview (Harper & Cole, 2012:510). Member checks relating to the accuracy of the data may take place “on the spot” during the interview (Shenton, 2004:68). At the end of each question, the researcher summarized her understanding of what had been said so that the participant could validate the data. The participant can either agree or disagree that the summary reflected their views and experiences and if accurate, the study is said to have credibility (Harper & Cole, 2012:511). In addition, the researcher

went back to the participants so that they could verify that what was transcribed in the interviews was what they intended to say as described by Shenton (2004:68).

3.9.1.4 Reflexivity

The researcher explored personal feelings and experiences that might influence the study and integrated this understanding into the study to promote objectivity (Burns & Grove, 2011:95). The researcher made reflective notes. The analysis of the researcher's experience made the researcher aware of possible biases and preconceived ideas.

3.9.1.5 Peer review and debriefing

The researcher had frequent meetings with the study supervisors/peers throughout the research process in order to reflect on the interviews, transcripts, data analysis and interpretation process (Polit & Beck, 2014:330). The study supervisor reviewed the qualitative study so that the findings resonated with a person other than the researcher (Creswell, 2014:202).

3.9.2 Transferability

Pilot and Beck (2014:323) refers to the applicability of findings to other settings. The decision to transfer findings will rest with the reader. In qualitative research generalizing findings may be problematic, but is possible if researchers could show that the study was guided by concepts, models and the use of multiple data collection methods (de Vos *et al.*, 2013:420).

The research setting was in the clinics of the Matzikama sub-district. The clinics deliver a preventive, curative and rehabilitation service and promote health. The clinics serve people from different ethnic groups and countries. The researcher enhanced transferability by applying the inclusion criteria when recruiting the sample to be included in the study. The collected data were described as accurately and detailed as possible by using the participants' own words in support of the researcher's interpretation of the data. The findings were compared with other studies in similar contexts, for example, the conceptual framework that was used by Getahun *et al.* (2010:S61). The authors used this framework to present the key health system-related barriers and enhancers. The researcher used the conceptual framework as a guide when conducting interviews and analysing the data. Purposive sampling used to select participants maximised the range of information collected.

3.9.3 Dependability

Dependability corresponds with reliability of data over time and conditions (Polit & Beck, 2014:323). It is the stability of data over time and the inquiry audit (Brink *et al.*, 2007:119).

However, qualitative researchers recognize that individual experiences may vary and therefore a similar study may not yield the same results as another study in a similar context (Shenton, 2004:69).

Stability of data was ensured by using an interview schedule (Appendix 4) to ensure that all the interviews were done in the same manner. The audio-recorded data were transcribed by a transcriber and analysed by the researcher. An audit trail of communication between the researcher and study supervisor was kept as proof, for example, electronic mail.

3.9.4 Confirmability

Confirmability relates to objectivity and refers to the extent to which the reader can confirm that the findings reflect the perceptions of the participants, rather than the researcher's own preferences (Brink *et al.*, 2007:119). The researcher ensured as far as possible that the findings were the result of the experiences and perceptions of the participants. After transcribing the participants' data, it was verified with each participant to ensure that the data was accurately transcribed and that researcher bias was excluded. Working in the Matzikama sub-district for a long time and understanding the barriers to the implementation of IPT faced by the PNs, assisted the researcher in interpreting the data.

Transcripts are available upon request from the researcher to ensure that conclusions, interpretations and recommendations are correct and can be traced to confirm that such findings are supported by their sources. Table 3.1 Quality-enhancement strategies present a structural outline of the quality-enhancement strategies used to ensure trustworthiness (Polit & Beck, 2014:324-331).

Table 3.1: Quality-enhancement strategies

Criteria	Strategy applied
Credibility	Prolonged engagement Comprehensive recording of information Member checks Peer review/ debriefing Reflexivity
Transferability	Comprehensive field notes Data saturation Detailed description of methods Thick descriptions
Dependability	Careful documentation Audit trail Member checking Stepwise replication
Confirmability	Peer review / debriefing Careful documentation Inter-coder checks Stepwise replication

Source: Polit & Beck, 2014:324-331

3.10 DATA COLLECTION

Data collection is an orderly and systematic process of obtaining information, which is relevant to the aim, and objectives of the research study (Grove *et al.*, 2013:45). Data collection took place in the form of individual interviews using a semi-structured interview guide (Appendix 4). The ethical principles was discussed in detail in chapter one.

Data collection is determined by the research question and objectives of the proposed study (Grove *et al.*, 2013:507). The methodology selected for this research was that of one-on-one individual interviews. The researcher was fluent in the local language, Afrikaans and conducted the interviews herself. For the purpose of this study, the researcher conducted ten one-on-one individual interviews. The data was transcribed in English. The data that the researcher gathered needed to answer the research question and the study objectives.

3.10.1 Interviews

The individual interviews were conducted with adult participants who had agreed and were willing to be interviewed. All the participants heard the same questions in a specific order and in the same manner (Brink *et al.*, 2007:151). In individual interviews the researcher converses with one person, face to face. It allows the researcher to probe their attitudes,

beliefs and experiences to get a deeper understanding of the research problem (Alvesson, 2011:9). The researcher had time to discuss the topic in detail.

The researcher felt a face-to-face interview provided a stronger basis for the establishment of a good rapport between the researcher and the participant, helping to create an environment where the participant can respond unconditionally (Ritchie *et al.*, 2014:182).

Interviews can be flexible and interactive with clear, non-leading questions (Ritchie *et al.*, 2014:209). A skill that is required by the researcher is the ability to listen and to hear by giving full attention to what is being said (Ritchie *et al.*, 2014:209).

The participants were interviewed at the clinic where they worked during working hours. Interviewing took place in a private consulting room. The researcher and the operational managers of the different clinics agreed on the days of the week and the times for the interviews, so that the interview times did not interfere with clinic services. The researcher introduced herself to the participants and explained the aim of the project and the importance of their confidentiality and the safety of the information collected. Once the consent had been signed, the interview started by collecting demographic data first to create an easy atmosphere and to reduce anxiety that the participant may have felt (Grove *et al.*, 2013:272). All participants answered the questions in their own words and during the interviews; reflective summaries were made by the researcher.

The interviews were conducted in Afrikaans, as the participants were more comfortable in expressing themselves in their home language. The interviews were audio-recorded and permission was obtained from the participants for the audio recording. The advantage of recording is that the researcher can keep a full record of the interview (Terre Blanche *et al.*, 2007:298). In each interview, the participant was allowed to express their thoughts and experiences in their own words.

The data was collected in the clinics over three weeks and field notes were taken during the interview. These notes helped the researcher to reflect and were useful during the analysis of the data (de Vos *et al.*, 2013:359). The researcher summarized and reflected on the participants' words during the interview and the participants had an opportunity to verify the contents of the interview to fulfil the requirements of member-checking, thus enhancing the credibility of the data. The duration of the interviews were between 20 and 30 minutes and were transcribed by a professional bilingual transcriber (Appendix 5). The researcher conducted follow up visits with the participants to obtain feedback on the research findings. This adds validity to the researcher's interpretations by ensuring that the

participants perspectives are represented and not curtailed by the researchers own agenda and knowledge (Tong, Sainsbury & Graig, 2007:356).

3.11 DATA ANALYSIS

Data analysis is the process of categorizing, ordering, manipulating, summarizing and describing of the data (Brink *et al.*, 2007:184). Creswell (2014:195) describes analysing of data as the intent to make sense of text data. It involves segmenting and taking apart the data, while aggregating it into a small number of themes (Creswell, 2014:195). The accuracy of the transcripts was checked by the researcher. After the transcriber transcribed the data, the participants and study supervisor also checked it. The interviews were captured onto a Microsoft Word document. The researcher followed the steps described by Creswell (2014:196-200) to analyse the data.

3.11.1 Creswell's approach

Although Creswell (2014:196-200) presents his approach as a linear, hierarchical process, he states categorically that the six steps are interrelated and do not necessarily follow in the order they are given. These steps are:

- Organize and prepare the data for analysis.
- Read all the data to gain a general sense of the information and reflect on the overall meaning.
- Conduct analysis based on the specific theoretical approach and method. This involves coding or organizing related segments of data into categories.
- Generate a description of the setting or people and categories or themes for analysis.
- Represent the data within the research report.
- Interpret the larger meaning of the data.

3.11.1.1 Organize and prepare the data for analysis

This refers to the transcription of the interviews and the sorting and arranging of the data if different sources of information are used (Creswell, 2014:197). The researcher was immersed in the data by personally conducting the interviews. In this study, she replayed the audio-recording after the interview, but did not personally transcribe the interviews.

3.11.1.2 Read through all the data

To uncover the meaning and in order to become familiar with the data of the barriers and enhancers of IPT, the researcher read the transcripts several times. By doing this, the researcher obtained a general sense of the information and its overall meaning. The researcher wrote down general ideas about the data and underlined key phrases. Eventually

recurring patterns and emerging themes of parts within the whole started to surface (Grove *et al.*, 2013:281).

3.11.1.3 Coding of the data

Coding means labelling or naming (Grove, *et al.*, 2013:281). It is the process of organising the data into chunks of information and writing a word that represents a category in the margin. In Table 3.2 Tesch's eight steps for coding is provided (Creswell, 2014:198).

Table 3.2: Tesch's Eight Steps for coding

-
1. Read all of the data and jot down ideas as they come to mind.
 2. Pick one document and ask: What is this about? Write thoughts in the margin.
 3. Repeat it with other documents, make a list of all topics, cluster similar topics and form them into columns.
 4. Take the list and go back to the data, abbreviating the topics as codes, writing the codes next to the corresponding segments in the data, trying out the preliminary organizing scheme to check for emerging categories and codes.
 5. Find the most descriptive wording and turn the topics into categories. Group topics together that relate to each other.
 6. Make a final decision on the abbreviation for each category and alphabetize these codes.
 7. Assemble the data material belonging to each category in one place and perform a preliminary analysis.
 8. Recode the existing data if necessary.
-

Source: Creswell, 2014:198

The code names originated from the words used by the participants. From the codes, the researcher composed what seemed best to describe the information (Creswell, 2014:198), as well, what was expected to find, based on literature. As data analysis and insight in the data progressed, a framework emerged. The framework with themes and sub-themes developed. The researcher and the supervisor regularly discussed the content, co-checked the coding, data analysis process, findings and conclusions.

3.11.1.4 Description of the setting or people and categories or themes for analysis

During the coding process, the researcher gave detailed descriptions of the events in the setting and the people involved, as well as descriptions of the categories or themes for analysis (Creswell 2014:199). The material within the categories was compared to identify variations and nuances in the meanings. It was used to store and retrieve information. Reflexive thought may influence the study and therefore the researcher requires a self-awareness and thinking about the data and the decisions made about the coding (Burns & Grove, 2011:95). Out of the findings, five themes were identified by the researcher. These

themes were displayed as perspectives of the participants and were supported by quotations.

3.11.1.5 Present the results of the analysis

This is often done in a narrative passage to convey the findings of the analysis. It may include a chronology of events, a detailed discussion of several themes or a discussion of interconnecting themes. The discussion is presented as themes with interconnected sub-themes. The researcher included quotations from different participants to add transparency and trustworthiness. The findings are presented in chapter 4 (Tong, Sainsbury & Craig, 2007:349).

3.11.1.6 Interpretation of the results of the analysis

The aim when interpreting the results is to answer the following question: 'what were the lessons learned?' (Creswell 2014:200). The data analysis was checked for weaknesses, for example, over- or under-interpretation by the researcher and supervisor. The outcome of the findings was described and compared with literature on the topic and was presented in chapter 5.

3.12 SUMMARY

Each qualitative approach is unique. The philosophical orientation of qualitative research is within a holistic framework and the purpose of this research was to examine the whole rather than the parts (Grove *et al.*, 2013:57). The research approach was used to describe the life experiences from the perspective of the PNs about the barriers and enhances to the implementation of IPT in the HIV positive adult.

This chapter described the research design, the processes used during sampling, data collection and the steps taken to ensure the trustworthiness of the data collection process. The research findings will be discussed in the next chapter.

CHAPTER 4: FINDINGS

4.1 INTRODUCTION

The findings of the research are presented and discussed in this chapter. The discussion is structured according to the themes and sub-themes that were identified through the analysis of the data that were collected to explore the experience of professional nurses about the barriers and enhancers to the implementation of IPT amongst HIV positive adults. Participant quotes appear in italics followed by the participant's identification number from which the excerpt was taken.

4.2 SECTION A: DEMOGRAPHICAL DATA

The demographic profile of the participants was considered as it provides a background of the characteristics of the participants. All the participants were female. Most of the participants were white and six participants had more than 10 years of experience in a primary health care facility. The profile of the participants included is similar to that of the district. The demographical data that was collected is summarised in the Table 4.1

Table 4.1: Demographical data

CHARACTERISTICS AND NUMBER OF PARTICIPANTS			
Gender: 10 Female			
Years of experience			
1-10	11-20	21-30	31-35
4	3	2	1

4.3 SECTION B: THEMES AND SUB-THEMES EMERGING FROM THE DATA

In this section, the findings are presented in themes and sub-themes. This made up the thematic structure of the perceptions of professional nurses about the barriers and enhancers to the implementation of IPT amongst HIV positive adults. Table 4.2 summarises the interview outcomes and forms the basis of the subsequent discussion of the research findings. The findings will be discussed under the main headings: enhancers to the implementation of IPT, barriers to the implementation of IPT and recommendations to improve IPT implementation, which form the themes induced from the objectives of the study.

Table 4.2: Themes and sub-themes

4.2.1 Enhancers to the implementation of IPT	
Themes	Sub-themes
Leadership and governance	Clear standardized protocol
Health system	Adequate supplies TB screening on all patients Monitoring and evaluation system - correct reporting and recording of statistics Utilizing counsellors
Provider or health workforce	Regular staff training Prescription by nurses and dispensing practices
Patient-related	Simplicity of regimen
4.2.2 Barriers to the implementation of IPT	
Themes	Sub-themes
Leadership and governance	Policy and protocol changes and differences Inadequate communication
Health system	Inadequate stock and supplies Mantoux challenges Patient flow in the clinic Clinic hours Tracing of defaulters Mobile clinic rotation Information management challenges
Provider-related and health workforce	Perceptions about IPT implementation Inadequate knowledge of IPT implementation Responsibility to recognise eligible patients High workload Inadequate counselling of patients
Patient-related	Poor adherence Knowledge and attitudes towards IPT Socio-economic factors Pill burden
Context specific factors	Rural farm communities Transport problems and distance
4.2.3 Recommendations for improving implementation of IPT	
Themes	Sub-themes
Leadership and governance	One standard protocol
Health system	Medication dispensing Introducing new screening practices Services integration Monitoring and evaluation system – correct reporting and recording of statistics

Themes	Sub-themes
Provider-related and health workforce	Involving all staff categories Training for all health care workers on new protocols, administering TST and counselling
Patient-related	Improve patient support Engaging the community and patient employers

4.4 ENHANCERS TO THE IMPLEMENTATION OF IPT

The participants identified several enhancers to the implementation of IPT. All the participants generally had a positive attitude towards implementing IPT. The enhancers are grouped into four themes: leadership and governance; health system; provider or health workforce; and patient related.

4.4.1 Theme 1: Leadership and governance

The participants discussed enhancers that related to leadership and governance. One sub-theme was identified. This sub-theme concerned the IPT protocols.

4.4.1.1 Clear standardised protocols

IPT protocols are written and distributed by the Department of Health on a national, provincial and district level. These protocols are important to guide healthcare workers. Some participants mentioned that changes in protocols are communicated and that training is available on the changes.

Three participants felt that the protocols were clear. These three participants were in management positions, namely the HAST coordinator and operational managers from different clinics with high and middle IPT implementation rates.

“From the side of Province and the Department of Health, all protocols and policies are in place. So I think all guidelines are there to make the implementation successful...” (Participant 07).

All the clinics received the protocols via email or at PHC meetings. It is the duty of the operational managers of each clinic to communicate the protocols to the staff and arrange in-service training.

“The protocols are clearly set out; the training we get is very good.” (Participant 08).

One participant felt that if she memorises the protocol, it would help her not to refer to the written protocol when treating a patient.

“[A]nd can memorise it so that I don’t have to keep on looking for what I have to do again.” (Participant 05).

Clear standardised protocols were therefore perceived as an enhancer to the implementation of IPT.

4.4.2 Theme 2: Health system

Three sub-themes were identified that enhance the implementation of IPT in the health system. The three sub-themes are adequate supplies of INH, TB screening that relies on the absence of all four clinical symptoms and a monitoring and evaluation system.

4.4.2.1 Adequate supplies

One participant felt that INH is readily available in the clinics, but that the supply of Mantoux tests was a problem. Two other participants felt that there was no problem with stock.

“[W]e do not really have problems with stock...” (Participant 09).

The availability of stock, especially INH, therefore enhanced IPT implementation in certain clinics.

4.4.2.2 TB screening on all patients

One participant who was in a management position and involved in clinical care felt that all patients are screened for TB and that stock such as INH is available.

“TB screening now gets done on all patients and the stock is available.” (Participant 10).

This participant also felt that when management raises awareness, TB screening practices improve.

“[S]creening the people for IPT was somewhat lost, but we were again made aware of it and we are now trying to screen the HIV patient for IPT.” (Participant 10).

Patient stationery that prompts screening for IPT eligibility also improves IPT uptake. For example, the health care worker has to screen for IPT when completing the ART stationery.

“The first time you get a patient testing positive, then you have to complete the paperwork where they ask specifically whether you screened the patient for IPT...” (Participant 10).

TB screening of all patients was therefore seen to facilitate IPT implementation.

4.4.2.3 Monitoring and evaluation system: correct reporting and recording of statistics

The HAST coordinator visits the clinics on a regular basis for quality assurance checks on the registers and folders. If the implementation of IPT is low, the registers are not complete or patients default, the HAST coordinator follow it up with the operational manager of the clinic.

“Then to really check the IPT registers, to see that it is kept, and if IPT has not been given, to really follow-up with the personnel.” (Participant 05).

The participants further felt that regular monitoring of registers and folders will improve recording and reporting of IPT statistics.

4.4.3 Theme 3: Provider-related and health workforce

The participants mentioned several provider and health workforce related enhancers to IPT implementation. Three sub-themes were identified: utilizing counsellors to help improve the uptake of IPT; training of all staff and nurses that prescribed IPT; and the use of assistant pharmacists to dispense IPT.

4.4.3.1 Utilising counsellors

Utilising and training counsellors to screen HIV positive patients for TB helped to improve the uptake of IPT. One participant felt that if she can allocate the task of identifying eligible patients to a lower cadre of staff it would help. The role of counsellors can be expanded to include TB screening of patients.

“The counsellors that we have at this clinic are really very nice. They make it much easier for the professional nurse. They identify the patients that have to start or that can possibly start, bring them to us, and from there we can do the tests, like the Mantoux and stuff.” (Participant 04).

“[T]he counsellors definitely play a big role. They mostly see the HIV patients and screen them for TB...” (Participants 04).

When screening for and initiating IPT, the patient must be provided with the correct information and good counselling is important. Counsellors can also be allocated tasks such as keeping the IPT register up to date.

“Sister, this man got his pills, we just have to put it in the register.” (Participant 06).

“We have now appointed one of our counsellors to complete the register and to fill it in so we can just give the file to her to do it...” (Participant 10).

Counsellors that screen HIV positive patients for TB and identify eligible patients can be an enhancer to the implementation of IPT.

4.4.3.2 Regular staff training

Three participants said that all staff need the necessary training. One participant reported that they started IPT implementation since all the staff was informed. In-service training is done together with meetings at some clinics on a regular basis.

“[T]raining, it is essential that all must know and be aware of how the IPT should be implemented.” (Participant 06).

Regular and adequate training therefore enhances IPT implementation.

4.4.3.3 Prescription by nurses and dispensing practices

The fact that nurses can be trained and authorised to prescribe IPT was seen as an enhancer to IPT implementation. Some clinics included IPT as part of the ARV prescription. This allowed for better record keeping. Some of the clinics used the assistant pharmacist or pharmacist to dispense INH.

“We try to do it together with the ARVs on the same prescription, all the admin around it.” (Participant 02).

“[T]he prescription card that you use is like for any other chronic medication. Any CNP or trained PN that has NIMART or CMART can prescribe the medication.”
(Participant 07).

One participant stated that with prescription simplicity, the pharmacist can dispense the INH. The patient does not need to see the PN every month; the pharmacist can dispense the follow-up treatment if the patient does not have any complaints.

“[W]hen the prescription has been written up, even the pharmacist can issue it.”
(Participant 04).

The prescription of IPT by trained PN's and the dispensing of follow-up medication by pharmacists enhances IPT implementation.

4.4.4 Theme 4: Patient-related

A patient-related enhancer of IPT implementation was the simplicity of the regimen.

4.4.4.1 Simplicity of regimen

When the patient is already on ART and the IPT is part of it, the patient is more adherent to treatment.

“[B]ut it will definitely make it easier if the INH can be part of his HIV medication.”
(Participant 01).

Two participants felt that INH is available in one pill form of 300mg and that makes it easier for the patient.

“I just think that the INH 300mg, which is available these days, also makes it easier for the patient because they only have to drink the one pill, where they used to drink three times 100mg” (Participant 04).

Simplified regimens were therefore seen to improve patient adherence to IPT.

4.5 BARRIERS TO THE IMPLEMENTATION OF IPT

The barriers to the implementation of IPT were diverse. The participants identified several barriers to the implementation of IPT in the clinics that is grouped into five themes: leadership and governance; health system; provider and health workforce related; patient-related; and context specific factors.

4.5.1 Theme 1: Leadership and governance

Although some mentioned that clear protocols enhanced implementation as discussed previously, most participants mentioned that protocol changes were a barrier. Policy and protocol changes as well as the gap between the existence of a policy and the actual implementation thereof due to inadequate communication are barriers to the implementation of IPT.

4.5.1.1 Policy and protocol changes and differences

IPT policies differ across the nine provinces. The Western Cape does not accept protocols from national immediately and there are often differences in the protocols. This can be very confusing for health care workers working in the Western Cape. In the West Coast, there are non-governmental organizations (NGO) that support clinics in the HIV and TB programs. They use national guidelines and protocols and this may confuse health care workers. Many patients are from the Eastern Cape and Lesotho and move between the different provinces during harvesting times. Policy differences may therefore also confuse patients.

“[T]he Western Cape is different from other Provinces. When new policies are implemented by National the Western Cape accepted it later or not at all.”
(Participant 06).

Health care workers in management positions felt that although the policy is in place, it is an add-on, meaning that there are many protocols for every programme such as HIV, chronic

diseases and woman's health; and they saw it as another one. Two participants said that the protocols are definitely in place and they are not difficult to understand, but that it can be confusing when health care workers do not work with them every day. In some clinics, there are certain nurses that are allocated for TB care and if these nurses are not there other nurses need to do the work and they are not familiar with the policies.

Participants felt that protocols change often and that they sometimes cannot keep track of these changes and the reasons for the change. The reasons for protocol changes are also not communicated clearly.

"They do not explain this to us. The protocols just get shoved in your face and you are told to do it like that." (Participant 08).

Changes in protocols makes it difficult for health care workers to familiarise themselves with the protocols. Therefore, they have to consult the printed guidelines every time they see a patient. They felt that protocols should not change so frequently.

"Protocols change so many times. You have just gotten into the system or figured out how to do the stuff, and then new protocols are being added. That makes it difficult for people or for yourself to adapt to the protocol because you are still on the old one then they say no it has changed..." (Participant06).

When policy and protocols changes, it is difficult for health care workers to be informed immediately and be trained if necessary, for example, in performing a TST. One participant found it easy to implement a protocol, but mentioned that there are too many protocols (for example, a protocol for IPT and one for ART) and it is difficult to adhere to all of them. Sometimes new updates or protocols are communicated to the sub-districts via email until new guidelines are printed.

"It is difficult if you don't really have one guideline that you can follow..." (Participant 10).

The duration of treatment indicated in the protocol may be confusing for some health care workers as two participants explained:

"[I]t can be confusing for some people who do not work with it every day, especially the different time periods of patients on the IPT program. I do not think all personnel are always certain about the time period for the patient." (Participant 06).

"[A]t the beginning of the 6 months to the 12 months, now it is three years. So it is very confusing, and you have to keep your head together..." (Participant 08).

The Western Cape policies differ from national policies and if the healthcare worker is not working in a specific program every day, protocols can be confusing. Health care workers felt they could not become familiar with the protocols, because of the frequent changes and sometimes there was a lack of communication.

4.5.1.2 Inadequate communication

Participants identified inadequate communication of new policies and protocols as a barrier to IPT implementation, especially in the clinic with low implementation. In the past, the IPT protocol changed about every six months. The protocols are emailed to the clinics or the hard copies are distributed at PHC meetings. Some of the operational managers give feedback to the staff shortly after the meetings. However, in some cases, it takes longer or it never happens, therefore the implementation of IPT takes longer.

“[C]ommunication should really be strengthened. Sometimes protocols and things are being said at meetings, but to get it through to you, how long does that take? Two weeks, a week? Then the other clinics have already started with their protocols, or people have already started, but many others are not aware of the changes and stuff. This for me is also a type of problem, the communication.”
(Participant 06).

Inadequate communication of new protocols is a barrier to the implementation of IPT.

4.5.2 Theme 2: Health system

Participants encountered various health system obstacles. These included: inadequate stock and supplies; patient flow in the clinic; clinic hours; tracing of defaulters; mobile clinic rotation and information management challenges.

4.5.2.1 Inadequate stock and supplies

Inadequate supplies or stock outs is a problem with many consequences for patients. All ten participants mentioned the stock out of the Mantoux tests for several months. The result of the Mantoux test determines how long a patient should be on IPT.

“Mantoux was out of stock for a long time.” (Participant 04).

With the stock out of Mantoux, implementing the protocol was not always practical.

“Something else from the Department’s side is the stock-outs of the Mantoux. Then according to protocol you can give it for six months without a Mantoux, and within six months a Mantoux must be done, but we lose those patients within the six months because we do not follow them up to come back for the Mantoux.”
(Participant 04).

Two participants mentioned the stock-out of pyridoxine. Pyridoxine should be prescribed with INH since it helps with the prevention of peripheral neuropathy. Peripheral neuropathy is a side effect of isoniazid and pyridoxine must therefore be provided together with IPT. When pyridoxine is out of stock, only INH is dispensed.

“The B6 or pyridoxine that gets handed out with it is also often out of stock.”

(Participant 02).

Three participants mentioned the stock out of isoniazid (INH). This was especially identified as a barrier in the clinic with a high implementation rate. Participants were unsure how to manage INH stock outs in patients already on IPT. They were not sure if these patients should be classified as defaulters.

“INH was out of stock now for some time and the problem then is when do you call him a defaulter? Because a defaulter is when the patient is not, adherent with his medication, but then you have a stock-out of the medication and you cannot put it as a defaulter. The personnel are not always so aware of the period of a defaulter because it is actually two months. But do you call him a defaulter because there was a stock-out? Or should you start him again with IPT or is he a defaulter?”

(Participant 05).

One participant felt that they order enough INH for the clinic, but that it was rejected on a higher level.

“The other thing is the INH was out, or not enough INH is being ordered. Or the clinic orders enough but the numbers are being rejected at a higher level and then we get reduced numbers of INH.” (Participant 08).

One participant saw the stock out of Mantoux tests in a positive light since the patient do not have to return to the clinic for the reading of the Mantoux. The patient could then be started immediately on INH. However, it is important that the patient have a Mantoux in the next six months of treatment to determine how long he/she must be on IPT.

“But then the Mantoux were out of stock, and we could carry on by doing the evaluations based on signs and symptoms. It then definitely became easier to start patients on IPT.” (Participant 01).

“What also happens when the Mantoux is out of stock, you start them say for the six months. When Mantoux all of a sudden comes back in stock then the time has to change.” (Participant 04).

Stock out of Mantoux, INH and pyridoxine can be an obstacle in the implementation of IPT.

4.5.2.2 Mantoux challenges

Doing the Mantoux test was expressed as a barrier to IPT implementation by several participants. When the health care worker commences IPT based only on the screening of the patient, the experience was that it is easier. There is no need for the patient to come back after three days for the reading of the Mantoux, as the PNs can evaluate the patient and start immediately if there are no TB symptoms.

All patients eligible for the Mantoux test are usually inoculated on a Friday and are required to return the following Monday for the reading. This is more cost effective as a Mantoux costs around R129.00 for a vial of ten doses.

“The Mantoux tests are being done on a Friday and it has to be read on a Monday. Because the Mantoux is so expensive...” (Participant 05).

When the patient attends the clinic in the middle of the week, the PN cannot give the Mantoux and the patient has to come back. Doctors refused to prescribe INH without a Mantoux although the protocol makes provision for six months of INH.

“Many doctors refuse to prescribe without a Mantoux even though the protocol makes provision for six months without a Mantoux. So there is also a stumbling block...” (Participant 05).

Implementing the Mantoux test is therefore a challenge in practice since it must be read after three days, which is not always possible.

4.5.2.3 Patient flow in the clinic

In this sub-theme two participants felt that the patients leave the clinic and do not return to the PN for the necessary treatment. After the patients see the PN, they are sometimes referred for counseling, observations or to the pharmacy. They often leave the clinic without going back to the PN with their folders for a follow-up date, for sputum sampling or for administrative purposes.

“The fact that after the patients see me, they have to go for vital tests, and I think that’s where one often gets lost because they do not come back to me again.” (Participant 03).

The flow of patients in the clinic as mentioned above, together with the flow of patient folders is a problem. IPT is not always recorded in the register and therefore are not reflected in the statistics.

“[B]ut it is mainly the counselors who keep the IPT registers. Perhaps there is also a gap. We all know the registers are there, but it is up and down from the pharmacy

and the Sisters. There is not a nice flow because he goes to the pharmacy where he gets his medication; the pharmacy throws out the files, so when does it get back again?" (Participant 06).

The flow of patients, as well as the patient folder is mentioned here as barriers.

4.5.2.4 Clinic hours

The clinics are open from half past eight until half past four and are open during lunch hours. There is currently no after-hour services provided in the clinics. All of the clinics are only open during the day and in the case of any emergencies, patients must go to the hospital. Two participants mentioned that patients who work late are not able to come to the clinic, for example, for the reading of a Mantoux or for collection of treatment. Currently, there is no system in place for these patients to collect treatment after hours.

"The clinic is from half past seven until half past four. All the people, the public is aware of the times, but it is possible that some people work until whatever time." (Participant 06).

Clinic hours can be a barrier for patients that work late.

4.5.2.5 Tracing of defaulters

Tracing of patients who default IPT in the health system is inadequate because more emphasis is placed on TB and ARV treatment defaulters. Tracing is done by the community health care workers in the informal settlement. However, it is more difficult on the farms, because the community health care workers do not have transport and the mobile clinic services to the farms are only provided every six weeks.

"[T]he tracing of the defaulters, which is also a problem. I do not think the IPT defaulters are being attended to. More emphasis is placed on, for example, TB defaulters or ARV defaulters, but IPT which is beneficial for the patient, a preventative measure, is not really managed successfully, and the tracing is not good." (Participant 07).

"We do not have tracers, so you have to physically go to the farms and look for the people." (Participant 06).

Defaulters are a big problem and it is not always possible to trace them, especially on the farms.

4.5.2.6 Mobile clinic rotation

The sub-district of Matzikama has a vast farm community. In order to provide the farm communities with essential healthcare services, mobile clinics are used. However, these mobile clinic services are only provided every six weeks. This makes it difficult to give a Mantoux and to follow up on the patient after three days.

“We have a mobile unit that goes out. They also see the patients in the middle of the week and cannot give the Mantoux.” (Participant 10).

4.5.2.7 Information management challenges

The under reporting of how many patients are started on IPT can reflect badly on statistics in the sub-district. When a HIV positive adult starts on IPT, it must be ticked off on daily tallies so that all data can be captured on Sinjani (DoH tool for statistics). Sometimes the health care worker forgets to record it. The INH is then recorded in the patient’s folder, but not in the IPT register.

“[O]ne other thing that also reflects badly on our sub-district is the keeping of statistics. I personally think there is under-reporting on IPT, because people simply do not mark it off on their daily tallies. So the patients receive it, but it is not being reflected on our statistics.” (Participant 09).

“Then there is the register that we also have to fill in. The problem is that you always have to go back to it to fill it in. So some information gets lost because you sometimes forget to do that.” (Participant 10).

Then there is the register that is filled in, which is not always up to date because the pharmacist hands out INH. Now the file has to come back to somebody who writes it in the register. So that’s where it often falls through.” (Participant 02).

Poor information management can reflect negatively on the reporting and recording of statistics.

4.5.3 Theme 3: Provider and health workforce related

The following provider and health workforce related barriers delayed the implementation of IPT in the research setting. The sub-themes identified were: perceptions about IPT implementation; inadequate knowledge of IPT implementation; responsibility to recognize eligible patients; high workload; and inadequate counselling of patients.

4.5.3.1 Perceptions about IPT implementation

Participants expressed several perceptions about IPT that could affect their prescription practices.

There is the perception that when a patient stops the IPT they are no longer protected against TB. The participants felt, that the benefit stops if the patient stops the IPT.

“[B]ut the moment they stop using the IPT over either 12 months or 36 months, depending on how he started, then he is actually no longer safe against TB.”

(Participant 01).

“I will say to you 50% of those people did get TB afterwards. It does not give you prolonged immunity afterwards.” (Participant 02).

One participant believed that IPT protects the patients, but was not sure what happens when the course of treatment is complete.

“It protects him. What happens after the 36 months?” (Participant 10)

Participants felt that although alcohol abuse is a concern in the community, patients could not be excluded from receiving IPT. They found it difficult to assess alcohol abuse since they could not request liver function tests.

“[B]ut the vast number of our patients is really alcohol abusers or misuses, and that disqualifies them.” (Participant 01).

The healthcare workers' perception was that giving IPT increased the pill burden of the patient and in some cases the patient refused IPT.

“They do feel they drink too many pills. As I have mentioned, especially when the purbac is added and the INH and the pyridoxine. So they feel they start on ARV's for example, then all of a sudden there are four, five other different pills that they need to use with it and then they sort of resist accepting more pills.” (Participant 04).

The fear of resistance and side effects from the INH were obstacles in prescribing IPT. IPT and HIV medication had similar side effects and therefore healthcare workers were reluctant to prescribe both. There was an underlying fear that with the high rate of MDR TB in the sub-district, patients will develop resistance to INH.

“[T]he perception that the use of INH will lead to resistance of TB medication. So they are not that willing to prescribe IPT. Side effects, particularly with the HIV patients, you have the same side effects for IPT and HIV medication. Personnel then prefer to rather not give the IPT, because then they know it is only the side effects from HIV medication.” (Participant 05).

“I think because we are in a sub-district where MDR TB is so unbelievably high, there may be an underlying, let’s call it fear, that we will make our people INH resistant as well.” (Participant 09).

A participant mentioned that personnel saw IPT as an add-on and it is difficult for them to see it as a *prevention therapy*.

“My experience is that the clinics do not see IPT as part of preventative therapy for the HIV positive patient. They experience it as an add-on...” (Participant 09).

One participant’s perception was that patients would benefit from IPT, if it were implemented correctly.

“IPT is a very good remedy used by the clinics. It will be of benefit if it is used correctly.” (Participant 05).

The perceptions of some health care workers were that some patients will acquire TB when they stop IPT. It is difficult to assess alcohol abuse and some do not see IPT as a preventive therapy. Fear of drug resistance and the concern of adverse side effects were also obstacles to the implementation of IPT.

4.5.3.2 Inadequate knowledge of IPT implementation

The lack of evidence and knowledge about the safety of IPT made staff hesitant to start pregnant women on IPT. One participant felt that studies done in America shows that IPT reduce TB by 60% and one should engage role players such as doctors and gynaecologists, that are resistant towards implementing IPT and provide them with the scientific evidence regarding the benefits of IPT.

“IPT for pregnant women, one should really start to emphasise the importance and to get the doctors and gynaecologists on your side about the fact that there is no proof that it is harmful for the baby, the foetus.” (Participant 05).

“[P]ersonnel are hesitant to start patients on IPT, particularly pregnant women because it has not yet been proven to be safe for the unborn baby.” (Participant 05).

The duration of treatment is a challenge and the knowledge of the health care workers regarding this is not up to date. First IPT was given only for six months. Then the protocol changed and the length of treatment depended on the outcome of the Mantoux test. Some participants found that not all staff knew the length of treatment.

“There is definitely a gap...knowledge of the personnel about IPT, and that there is still a great need for training about IPT...” (Participant 05).

Two participants experienced that only INH is dispensed, without the pyridoxine that prevents peripheral neuropathy.

“[O]ften only the INH is being handed out. The nursing professionals forget about the pyridoxine that has to go with it. This is then when peripheral neuropathy occurs.” (Participant 02).

Inadequate knowledge about the length of treatment that depends on the outcome of the Mantoux test, safety of IPT in pregnant women and preventing peripheral neuropathy are obstacles to the implementation of IPT.

4.5.3.3 Responsibility to recognise eligible patients

The PN's know that IPT is essential for the patient, but sometimes the patient missed the opportunity to start IPT. One participant felt that all health care workers must take responsibility and check that the patient had received a Mantoux, was started on IPT and that the register was completed.

“Who becomes responsible for the IPT?” (Participant 02).

“So I feel all in the clinic or health system should take responsibility and it should not just be the responsibility of one person.” (Participant 04).

“There is not somebody specifically in the clinic that is taking responsibility.” (Participant 09).

In some clinics, the health care workers do not take responsibility for the IPT programme.

4.5.3.4 High workload

The workload and pressure in the clinic can be high. Although there are enough personnel, when staff members are on leave or are needed to help in another clinic, the remaining staff struggle to cope with the workload. Sometimes only one sister has to attend to the patients and the implementation of IPT is then not a priority, due to the workload.

“[S]ometimes it also depends on the pressures in the clinics as well.” (Participant 06).

“[T]here are days when people are on holiday, helping out at other clinics, some are on sick leave and then there is for example only one sister on her own in the whole clinic. Then it gets a bit too rough to spend time on IPT as well.” (Participant 08).

There are specific programs, for example, medical male circumcision (MMC), TB, HIV, chronic and women's health that increases the workload of the personnel in addition to the implementation of IPT.

“IPT came at a stage when all kinds of other programs were rolled out at the same time. I think at that stage personnel just thought it was too much, just too many new things that they were burdened with.” (Participant 09).

One participant mentioned specifically that patients who need to initiate IPT fall through the cracks due to the high workload.

“I think sometimes it is just that all the things we need to do on a patient get too much. So it is a lot, and you have to see the patient and treat him and all those things. So, some of it can get lost.” (Participant 10).

In some cases the register is not up to date, because the pharmacist does the dispensing. The folder does not come back to the PN or counsellor and this is when the information gets lost. There are many registers e.g. Pre-ART, TB, IPT and Antenatal that must be kept. One participant felt that there are too many registers. The under-reporting of IPT had a negative influence on the statistics of the sub-district. The patients received INH, but it does not reflect in the statistics.

“Here at ground level all the add-ons get a bit much, too much for us. It is another register, more admin.” (Participant 02).

“[S]ometimes there is no uniformity. Everyone must know when the patient comes in, he has to fetch his pills, or that the file must come back to the counsellors to record. We all know the registers are there, but it is up and down from the pharmacy and the Sisters. There is not a nice flow because he goes to the pharmacy where he gets his medication; the pharmacy throws out the files...” (Participant 06).

“The problem is that you always have to go back to it fill it in.” (Participant 10).

The high workload plays a role, due to many programmes and sometimes only one PN in clinic. This factors influences recording and reporting and patients not commencing IPT.

4.5.3.5 Inadequate counselling of patients

Inadequate counselling was identified by participants as one of the reasons why patients do not adhere to their treatment.

“I think their knowledge is weak about IPT because they do not get adequate counselling about why it is important to take IPT. So the patient does not actually know why he swallows the pill, how important the pill is for him to prevent TB, and this causes adherence to be a problem. The important thing for me is counselling to

the patient who uses alcohol, and then to be aware of the side effects.” (Participant 05).

Lay counsellors usually provide counselling to the patient about IPT. These counsellors are often not equipped to educate the patient fully or there may be no counsellor in the clinic and sometimes the PN has to do the counselling. However, PN's have limited time to do the counselling due to their other responsibilities. Motivation and communication plays a role in the adherence of the patient and the person who does the counselling needs sufficient time.

“[W]e did not have an adherence counsellor. I think it depends a lot on them, how they communicate with the patients and encourage and motivate them. The sisters don't really have time to do that.” (Participant 10).

Inadequate patient counselling due to untrained or ill-equipped counsellors can be a barrier to the adherence of the patient.

4.5.4 Theme 4: Patient-related

The participants felt that retention of patients in care is a challenge, together with inadequate patient knowledge and patient attitudes towards IPT. Other issues that emerged were socio economic factors, transport and the distance from the clinic, especially in the rural area.

4.5.4.1 Poor adherence

Adherence was a challenge in the rural area. Participants felt that patients do not take responsibility or understand why they need to take their treatment. They perceived patients to default because of a low level of education or not caring about their own health. The farms, there are no treatment supporters or tracers to look for defaulters. Patients therefore have to take responsibility for their own treatment, which was problematic.

“In the mornings they are in a hurry to get to work. Do not eat. Now you have to take the pills to work. So then you just leave it at home and forget about it.” (Participant 02)

“[P]atients started off on IPT, but for some reason they do not come for their follow up medication.” (Participant 03).

“[T]o get that through to people, that you drink the pill so that you will not get TB, it is quite a problem. The responsibility that is also their responsibility to take care of it. We do not have tracers, so you have to physically go to the farms and look for the people. I think our personnel are informed, but the problem is from the patient's side to take the responsibility.” (Participant 06).

4.5.4.2 Knowledge and attitudes towards IPT

Two participants felt that the lack of understanding or the attitude of the patients could create a negative feeling towards their medication. Some participants reported that the patients did not have adequate knowledge about their treatment, resulting in non-adherence because they did not think the treatment will help them; or because they were confused if their medication was not provided due to stock-outs.

“Pyridoxine, which goes together with the IPT, was out of stock. I now give you just these pills this month, makes him feel that if he can go without the one then he can go without the other. It creates a negative feeling...” (Participant 01)

“Ignorance because they think, oh well, the pills are not going to help me.”
(Participant 03).

One participant felt that due to the patients lacking any signs and symptoms of disease, they might not be motivated to complete the full course of treatment.

“And remember, they do not have signs and symptoms of TB. Think about it, it is difficult to drink a pill if you do not have a headache...or if you do not really feel sick. And the time period is rather long.” (Participant 02).

Protocols that change also had a negative influence on the patients and they wanted to be informed why it changed.

“[P]atient is just nicely on track with the medication, and then stuff has to be changed. That also influences medication. The patients also want to know why things are changing. They say it sometimes also discourages them to continue with the treatment” (Participant 06).

Sometimes the counselor does not have the knowledge or skills to transfer the information correctly to the patient. Furthermore, the patient lacks understanding about the importance taking *the treatment as prescribed*.

“They do not see it as something important, even though you give all the necessary counseling that they need. I do not think they have a good understanding of what it is about.” (Participant 04).

It is important to provide the patient with the correct information. If the PN told the patient the medication is essential and thereafter stops the treatment, then the patient could perceive this as illogical. The participants felt that stopping IPT after 6 or 12 months gives a wrong impression to the patient about the importance of IPT.

In addition to informing patients, informing their employers was also highlighted as challenging due to the principle of confidentiality.

“[W]e as nursing professionals can also not explain to the employer what is wrong with the patient or the reason why he has to come to the clinic so many times. The trust between you and your patient will be gone, and confidentiality, because you are not allowed to give out medical information.” (Participant 08).

Patients’ lack of knowledge or understanding the reason for treatment can be a barrier to their adherence. This can be due to lack of symptoms, attitude, wrong information or changes in protocols.

4.5.4.3 Socio-economic factors

Participants mentioned several socio-economic factors that may affect the adherence of patients to IPT.

Patients must stay away from work for the reading of the Mantoux and may therefore not attend follow-up appointments since they do not want to lose wages.

“[A] relative healthy patient who is HIV positive but not sick, had to stay away from his work again in three days’ time so that I could read a Mantoux.” (Participant 01).

Farmers employ people from other provinces or countries, for example Zimbabwe, to work on the farms during the harvesting season. Language barriers between these patients and the healthcare worker may lead to patients not being adequately informed about IPT.

“They do not come back then you do not get the right Mantoux results that you need to determine whether they need to start and how long they have to be on it. I think the language barrier is also a big problem...” (Participant 04).

Patients in the rural areas experience difficulties, since they work on the farms and cannot attend the clinic during clinic hours. There are also financial implications for farm workers if they stay away from work.

“Many live on farms, much work on farms, so they have to take two days off from work to come to the clinic for doing the Mantoux. Many go out to farms on the lorry at six o’clock in the mornings when the clinic is still closed and get back home at five or half past five. So they don’t always come back.”(Participant 04).

“[H]e has to stay off work; he loses a day’s pay...” (Participant 08).

Patients who abuse alcohol are more likely to get side effects from INH or be non-adherent.

“[A]lcohol usage of clients in the Western Cape is quite high.” (Participant 05).

“There are other problems as well, such as taking responsibility for your illness. Even though you say to them every time, you have to drink this to prevent you from getting TB, they still do not realize it. Alcohol is also a problem...forgets to drink his pills.” (Participant 06).

One participant mentioned that stigma against people living with TB were still present in the communities. Since IPT is associated with TB, patients may want to hide their treatment or refuse to take the treatment.

“Yes, look, IPT is a TB thing, and people have still got that stigma of TB, so if one can fix that.” (Participant 06).

Being away from work, loss of wages, language barriers, alcohol abuse and stigma influence the implementation of IPT.

4.5.4.4 Pill burden

Participants mentioned that many patients were already on ART and cotrimoxazole or other chronic medication. Adding IPT would therefore increase their pill burden and decrease their motivation to take treatment. Three participants found that the pill burden is challenging for the patients, especially if the patient is also on chronic medication, for example diabetes or hypertension.

“They just simply say to you that they are not up to drinking another pill; there is already enough other stuff that they have to drink. Especially if the purbac is added...” (Participant 04).

4.5.5 Theme 5: Context specific factors

Matzikama is a rural area with many farms. Some of the farms are quite far from the nearest clinics. A mobile clinic only visits the farms on a six weekly basis. The participants mentioned transport and financial problems as a barrier to IPT implementation.

4.5.5.1 Rural and farm communities

When a patient stays on a farm, regular follow-up, especially the follow-up for the reading of the Mantoux can be a problem. Employers do not understand why their workers must go to the clinic so many times.

“Our farm folk had to come in from the farm which made it almost impossible to put them on.” (Participant 01).

“[S]ometimes it is pruning time or whatever time of year, and they cannot take time off work.” (Participant 06).

4.5.5.2 Transport problems and distance

Another challenge for the patients is the long distances to attend the clinic. It is a rural area and there is a lack of transport services.

“As I say, for the farm folk distance is an issue. They really do not have opportunities and have to travel long distances.” (Participant 01).

“[B]ut transport costs, we live on the farm, there is no money for transport...” (Participant 06).

The mobile clinic visits the farms every six weeks. However, due to weather conditions or staff shortage, they sometimes have to postpone and reschedule. Even if the mobile clinic provides six-weekly services, it remains insufficient and distance is still a problem since some patients have to travel far to reach the clinic.

“We have a mobile unit that goes out. They also see the patients in the middle of the week and cannot give the Mantoux. The patient has to come back to the clinic for a Mantoux and he has to come again for a reading. Some of our farms are more than 30km out of town...” (Participant 10).

4.6 RECOMMENDATIONS FOR IMPROVING IMPLEMENTATION OF IPT

The participants made some recommendations for effective implementation of IPT. These were also grouped into four main themes: leadership and governance; health system; provider-related; and patient-related.

4.6.1 Theme 1: Leadership and governance

Recommendations related to leadership and governance is to have one standard protocol.

4.6.1.1 One standard protocol

One participant mentioned that it would be helpful if the frequent changes in protocols could be curtailed. A standard protocol for IPT would be more efficient.

“I feel that they should not keep on changing it. Just get one standard protocol that I can make my own...” (Participant 01).

One participant felt that IPT is essential and if it can be part of a chronic medication, it will help with adherence.

“It is not a life dependent pill, or it is only a pill that helps prevents you from contracting something. So if it becomes part of a life dependent pill, they will feel that they have to get it, like for heart or blood pressure or diabetes.” (Participant 01).

4.6.2 Theme 2: Health system

The participants made several recommendations for improving IPT implementation within the health system. The availability of INH in the consulting rooms, introducing new screening practices, integration of TB and ART services and correct recording and reporting of statistics were sub-themes identified.

4.6.2.1 Medication dispensing

The availability of INH in the consulting rooms will make it easier for the health care workers to remember IPT, because not all the clinics have a pharmacist or assistant. The pharmacist or pharmacy assistant can dispense the refills once the prescription is made.

“[T]he medication is available in everyone’s consulting rooms...” (Participant 04).

4.6.2.2 Introducing new screening practices

One participant suggested that new screening practices that are similar to TB screening should be implemented, especially for patients who regularly attend the clinic for ART.

“I think we will have to make a standing rule or screening, like for TB screening, and act quicker for the implementation and treatment. There are people who have been HIV positive for years but have never been screened for IPT. I think the screening will have to happen quicker because there is quite a backlog with the administering and implementation of IPT.” (Participant 07).

4.6.2.3 Services integration

In the district, ART and TB services are not yet integrated and ART is not provided at all clinics. In some clinics the ART service is provided by a professional nurse who only visits the clinic monthly. These patients may therefore not be screened and initiated on IPT due to a lack of communication between healthcare workers, since they are unsure who is responsible for initiating and monitoring IPT. The decentralization of services where the patient can receive comprehensive health care under one roof will help to upscale IPT.

“There is also the fact that our ARV services are not yet fully decentralized, which makes it somewhat of a challenge because at this stage, at some of the clinics, the HIV positive patients become somebody else’s responsibility.” (Participant 09).

IPT is essential and if it can be part of other chronic medication, it can become part of a patient’s life and they may feel that it is essential, for example, hypertension and diabetes.

“I think if they make the IPT part of the program such as purbac...part of chronic treatment...perhaps it will improve.” (Participant 10).

4.6.2.4 Monitoring and evaluation system – correct reporting and recording of statistics

One participant thought that proper information management and quality improvement on the reporting of IPT would ensure that accurate IPT statistics are captured.

“I think information management will gain a lot of ground, if you can do a quality improvement on the reporting of the IPT being given.” (Participant 09).

4.6.3 Theme 3: Provider-related

Involving all staff members with proper training on protocols, administering TST and counseling were provider-related sub-themes identified.

4.6.3.1 Involving all staff categories

The involving of all staff categories will make it easier on the workload and more staff can do better screening and identify eligible patients. If all staff become involved, all eligible patients will start on IPT.

“I think we should try and get all personnel on board. At our clinic they tend to only send it to one nursing professional who has to take care of all these things. On a day when she is absent it gets passed by. The patient is asked to come back on a following date... In this way many of the patients get lost. They just don't come back. So I feel all in the clinic or health system should take responsibility and it should not just be the responsibility of one person.” (Participant 04).

In some clinics, there is a dedicated person who is responsible for administering IPT, but it is important to get everyone involved in screening, since if the dedicated person is absent, the implementation of IPT is low.

“You will notice at the clinics where there is a dedicated person for TB, it goes much better with IPT. In order to improve it, I think it is fine tuning and to just get everyone's buy-in.” (Participant 09).

4.6.3.2 Training for all health care workers on new protocols, administering TST and counselling

Health care workers need the necessary training, especially on counselling. If the patient is counselled well, it will help with adherence. First, the knowledge of the staff must be assessed and the gaps identified so that the training can be tailored to the needs of the staff. Training is essential and all sectors of nursing should be well informed.

“You have to orientate your patients better, and give your personnel at ground floor level full training.” (Participant 01).

“[S]tudies done in America about IPT that prevents 60% of TB that you can give such proof to personnel to let them believe more in IPT. If the personnel believe in IPT, they will prescribe it.” (Participant 05).

“We have to look at training, what the level of knowledge is now, and then look at where the gap is and give the necessary training.” (Participant 07).

4.6.4 Theme 4: Patient-related

On-going support, better counselling to the patients and engaging the employers (especially farmers) will help with adherence.

4.6.4.1 Improve patient support

Two participants felt that the patients must get on-going support through counselling and support sessions.

“Giving them follow-up appointments, and to reinforce it every time they come back for their follow-up appointments.” (Participant 03).

“The counsellors must keep on giving talks, inform people, and make it more public, like a TB talk on radio, IPT and retro-positiveness.” (Participant 08).

4.6.4.2 Engaging the community and patient employees

Two participants felt that the stigma around TB and HIV must be addressed. Good communication and relationships between the employer, employee and the clinic, will help the employer achieve a better understanding of the clinic services.

“The counsellor can, for example, also go to the employer where there are many people, like our farms or big corporations, so that the employers can get better insight into retro-positiveness and also IPT. To remove the stigma and give good information so that all will understand.” (Participant 08).

4.7 CONCLUSION

In this chapter, the findings of the study have been presented. Several themes and sub-themes in connection with the research objectives were identified from the data and discussed in the context of the study setting. In the next chapter the discussion of the findings in relation to the literature, conclusion and suggested recommendations are presented.

CHAPTER 5:

DISCUSSION, CONCLUSIONS AND RECOMMENDATIONS

5.1 INTRODUCTION

Prior to this chapter, the objectives for this study were stipulated, an in-depth literature review was presented, and the appropriate research methodology and data analysis for the purpose of this study was described. In the previous chapter, the research findings were presented. This chapter includes the discussion of the findings according to the study objectives, conclusions and recommendations based on the findings of the study, including the study limitations.

5.2 DISCUSSION

The aim of the study was to explore the barriers and enhancers to the implementation of IPT amongst HIV positive adults, from the perspective of professional nurses. The findings are based on the interviews with participants at the clinics in the sub-district of Matzikama in the West Coast of the Western Cape Province. A discussion of the findings in relation to each study objective follows.

5.2.1 Perceptions of professional nurses about the enhancers to the implementation of IPT

Participants mentioned several enhancers to IPT implementation. These enhancers were grouped according to leadership and governance, health system, provider or health workforce and patient-related.

5.2.1.1 Leadership and governance

Although the clinics used the same protocols, there were differences in opinion. Participants in management positions generally felt that protocols were clear and that they were communicated clearly. Other participants felt they were confusing and that communication from management was inadequate. These differences may be related to how closely the participants work with the protocols. Those participants in management positions may not always be aware of the day-to-day challenges in the clinic and protocols might not have been communicated well in all clinics. Charles *et al.* (2016:9) found that constant communication is important. A study done in Brazil by Wysocki *et al.* (2016:6) also found that communication and accountability are necessary between health workers. Modi and Dave (2012:173) found that clear direction and bold leadership from a political level nationally are crucial for strengthening IPT. National guidelines that is clear and consistent with WHO are likely to promote IPT and improve health outcomes for HIV positive adults.

5.2.1.2 Health system

Screening of all patients for TB and identifying eligible patients that can commence IPT was seen as an enhancer for IPT uptake. To strengthen the implementation of IPT, integration, intensified case finding and development of operational guidelines is necessary (Assebe *et al.*, 2015:346). In some clinics IPT was part of the ART programme and participants felt this increased uptake, as supported by Getahun *et al.* (2010:S58).

5.2.1.3 Provider or health workforce

In some clinics counsellors were trained and willing to identify eligible patients for IPT and participants saw that as an enhancer to IPT implementation.

Participants reported that in certain clinics, the pharmacist or assistant pharmacist helped with the dispensing of INH. This finding was supported by Adams *et al.* (2014:281) who found that simplification of dosing and the involvement of pharmacists enhance IPT adherence.

Participants mentioned that when IPT is part of ART, record keeping is enhanced, since the ART stationery provides prompts for IPT screening. Denegetu and Dolamo (2014:5) reported that TB screening for newly enrolled persons with HIV increased after the introduction of TB screening questions in the clinical record.

In clinics where decentralization of TB and HIV services occurs, IPT implementation was higher according to some of the participants. The implementation of IPT in an ART clinic will probably be easier than in a pre-ART clinic, since the pre-ART phase involves retaining HIV positive patients into care until they are initiated on ART. Furthermore, patients on ART visit the clinic more frequently (Rangaka *et al.*, 2014:688). A study done by Gupta, Granich, Date, Lepere, Hersch, Gouws and Samb (2014:1155) found that integrating and linking services could lower barriers and ensure that HIV positive adults are offered ART and IPT.

5.2.1.4 Patient-related

Participants reported that patients on ART and those who received adequate counselling were more adherent. Patients require educating and counselling in order to promote adherence to IPT (Adams *et al.*, 2014:281). Counselling should include the duration of treatment, the drug and the patient's needs and motivation to complete their treatment. Comprehensive counselling of patients that are diagnosed with HIV, prior to ART and IPT initiation, might lead to better acceptance of their condition as well as good adherence (Oni *et al.*, 2012:e52489).

5.2.2 Perceptions of professional nurses about the barriers to the implementation of IPT

According to the participants, frequent changes of protocols, stock-outs of Mantoux tests, a lack of knowledge of healthcare workers and the fear of poor patient adherence, were the main barriers to IPT implementation.

5.2.2.1 Leadership and governance

An important barrier was that protocols changed frequently and healthcare workers were unfamiliar with the current protocols. When healthcare workers are not working in a specific program every day, protocols can be confusing. Protocols are not difficult to implement, but there are too many and it can be seen as an add-on by the healthcare workers. Healthcare workers in Upper Northern Thailand reported that the main barrier to IPT implementation was unclear direction of national policy (Moolphate *et al.*, 2013:64).

The Western Cape policies differ from national policies. The IPT policy was implemented on a national level before the Western Cape approved it for implementation. Initially there were also slight differences in the national and Western Cape guidelines concerning the use of the Mantoux test and the duration of IPT. However, since 2015, the policies are now aligned. Bristow *et al.* (2012:2021) also found that in South Africa there were varying degrees of guideline implementation across the country. The difference in IPT uptake among the provinces suggested the need to align the provincial policy with the national policy.

5.2.2.2 Health system

All participants mentioned that inadequate stock and supplies for example INH, pyridoxine and Mantoux tests were a barrier to the implementation of IPT. One participant stated that they did not receive the quantities of stock they requested. Isoniazid stock-outs prevented 44% of IPT-eligible individuals from enrolling in Uganda (Namuwenge *et al.*, 2011:5). This was also found by Teklay, Teklu, Legesse, Tedla and Klinkenberg (2016:9) in Northern Ethiopia, where participants complained of not receiving the isoniazid supplies that they requested.

Another challenge was the reading of the Mantoux test within the stipulated three days after administration. Kapoor *et al.* (2016:90) also identified the challenge with administering and reading the Mantoux test and that providing IPT irrespective of the Mantoux is more cost-effective when compared to Mantoux-driven strategies.

A problem that was identified by a participant in a management position was that low IPT statistics reflected badly on the sub-district. Patients received INH, but it was not recorded

on the clinical record. According to Briggs *et al.* (2015:S303) there are no systematic methods for monitoring and evaluating individual outcomes of IPT implementation. A study done in the primary healthcare services in Brazil (Wysocki *et al.*, 2016:10) identified errors such as no evaluation, the lack of recording in the IPT register and incomplete assessment in medical records and forms.

The flow of patients and patient folders in the clinic influenced the recording and reporting of IPT. After patients were referred for counselling, or to the pharmacist to collect medication, the patient or folder frequently did not return to the consultation room. Moreover, the folder was often filed without the necessary recording of statistics. This barrier was not reported in previous studies that the researcher reviewed.

5.2.2.3 Provider or health workforce

Several healthcare worker perceptions that may influence the implementation of IPT were identified. Some participants saw IPT as an add-on to services and that it increased the pill burden for the patients. This finding was mirrored in a study by Yirdaw *et al.* (2014:e104557) who reported that the uptake of IPT was also limited, due to the added pill burden for patients, medication side effects, poor adherence and concerns of drug resistance.

In South Africa, with its high annual risk of TB, a study done among gold miners, found that the protection of IPT was lost within six to twelve months after cessation of treatment (Hermans, Grant, Chita, Lewis, Chichota, Lewis, Vynnycky, Churchyard & Firelding, 2016:9). In this study it was also found, that the perception of some of the professional nurses was that when the patient stopped IPT, the benefit ceased and the patient was no longer protected against TB.

Another perception was that participants did not see IPT as prevention. MDR cases are high in the Matzikama sub-district and the fear of INH resistance was expressed. As identified by Lester *et al.* (2010:47), the prescription of INH without other TB drugs could induce drug resistance, particularly in South Africa with its high rate of MDR and XDR TB. Alcohol abuse, the fear of resistance and side effects, especially peripheral neuropathy, was a great concern for healthcare workers. This was mirrored in a study done in Northern Ethiopia, where the fear of resistance and the side effects were identified. Some side effects are preventable. However the unavailability of pyridoxine, as in this study in the Matzikama sub-district, had contributed to neuropathy (Teklay *et al.*, 2016:9).

Participants were concerned about the safety of IPT in pregnancy and were therefore reluctant to prescribe it. Pregnant women with HIV are a target population for IPT due to

their increased risk of developing TB during pregnancy and in the postpartum period. Even when there may be concerns about potentially severe INH-induced hepatotoxicity in pregnancy, the benefits of providing IPT outweighs the potential risks (Kapoor *et al.*, 2016:91).

Inadequate knowledge and not understanding the benefits of IPT was mentioned by the participants as a barrier to IPT implementation. This is confirmed by a previous study done in South Africa where the lack of knowledge and experience about TB screening as well as ignorance regarding the benefits of IPT contributed to low IPT use (Yirdaw *et al.*, 2014:e104557).

Participants felt that knowing and remembering the duration of treatment were problematic due to frequent changes in protocols. In Northern Ethiopia it was found that training should first be provided before the introduction of a program and it should continue thereafter for new staff (Teklay *et al.*, 2016:9).

Inadequate counselling due to untrained or ill-equipped counsellors have an influence on patient's adherence and understanding of IPT. Southern Africa has a high rate of TB among HIV positive pregnant women, with a completion rate of 59% for six months of IPT in both Lesotho and South Africa (Tiam *et al.*, 2014:E9). There are few studies that investigated IPT completion rates in adults in general. Makanjuola *et al.* (2014:e781660) found in other studies that a patient's personal beliefs are core factors contributing to the adherence of IPT. For example, the lack of knowledge contributes to the fear of the safety of INH including the side effects and the importance of the treatment for health.

In some clinics, few participants wanted to take responsibility for IPT due to the high workload. This had a negative effect on IPT uptake and the recording and reporting of statistics. Some healthcare workers felt that there are too many registers. Previous studies mentioned that the Mantoux test can be a challenge in a busy clinic (Ait-Khaled *et al.*, 2009:932), however, this study identified recording and reporting as an additional challenge.

Participants mentioned that they had to implement various programmes together with IPT and that it caused an increased workload. In some clinics, the daily number of staff available in clinics decreased due to sick leave, leave or training. Frequently only one professional nurse was available to deliver the service. This is confirmed by the findings of Wood and Bekker (2014:175) that the implementation of IPT may over burden the healthcare system.

5.2.2.4 Patient-related

Poor adherence was the main patient-related barrier to the implementation of IPT.

According to the participants, many of the patients did not take responsibility or had a negative attitude towards their treatment. Some of the reasons they were not adherent included: they did not understand why they must take the pills; a lack of symptoms; wrong information; rapid changes in protocol and pill burden. In Botswana, Gust *et al.* (2011:e118435) found that patients are less adherent to treatment when they feel well. Moreover, a low level of education was also evinced as a barrier.

Socio-economic factors that play a role are alcohol abuse. A study in Cape Town found that alcohol use and smoking significantly increased the risk of non-adherence (Oni *et al.*, 2012:e52489). A lack of education and non-disclosure of HIV status also contributes to reduced adherence. Kwara *et al.* (2008:868) found that poor health knowledge and lower socio-economic status were predictors for poor adherence.

Another factor mentioned by one participant was the stigma associated with the illness. Howard, Gasana, Getahun, Harries, Lawn and Miller's research in Kenya (2012:s142), found that stigma was a major challenge to TB/HIV integration among patients as well as healthcare workers.

Participants reported that inadequate knowledge of the patient together with a low education level can hinder completion of treatment. Alcohol abuse, language barriers between healthcare workers and patients from other provinces, and missed follow-up dates were further barriers.

Sometimes patients misunderstood or forgot about the information that they received. A barrier to effective treatment or adherence is that advice given by the healthcare workers is misunderstood, carried out incorrectly or forgotten by patients (Berhe, 2015:2).

5.2.2.5 Context-specific

Matzikama is a rural sub-district and for patients living and working on farms it is sometimes impossible to attend the clinic during clinic hours. The mobile clinic only renders services every six weeks. Although the mobile clinic improves the quality of medical services and provides patients with access to basic medical care, the mobile service has inherent weaknesses (Abbasi, Mohajer & Samouei, 2016:1). These include the lack of sufficient evidence about the feasibility of providing a range of services, referral of patients can be difficult, absence of health care services for example medical tests, and the large population

that requires simultaneous access to the mobile clinic. Patients may also be unwilling to use the mobile services.

Patients employed on farms who default are difficult to trace. This has not been reported in the context of IPT, but the lack of healthcare services in rural areas has been identified in other studies (Abbasi, Mohajer & Samouei, 2016:2). This is also confirmed in a systematic review done by Makanjuola, Taddese and Booth (2014:e87166) that patients found it difficult to remain adherent to INH when they were required to participate in harvesting. Instead of seeking permission from their employers to attend the clinic, they default.

Distance to the nearest clinic and transport are problematic for patients. When patients stayed away from work, there are financial implications for them. A study in rural South Africa (Mindachew *et al.*, 2014:23) found the same barriers to adherence, namely, the lack of money and transport problems. This was confirmed in the systematic review by Makanjuola *et al.* (2014:e87166) who highlighted that patients experienced problems in accessing IPT because of distance, location of the clinic and including the non-availability of healthcare workers.

5.2.3 Recommendations of participants to enhance the implementation of IPT

Participant recommendations were not part of the study objectives, but they are discussed here since it was an identified theme.

5.2.3.1 Leadership and governance

A participant recommended the development of one standard protocol which does not change frequently. To strengthen the implementation of IPT, Modi and Dave (2012:173) recommend a clearly articulated policy.

5.2.3.2 Health system

Screening for TB and recognizing eligible patients for IPT is part of the ART stationery and it can help the healthcare worker to remember to implement IPT. Getahun *et al.* (2010:S58) recommended a screening algorithm that relies on the absence of all four clinical symptoms namely: cough, weight loss, fever and night sweats.

Another recommendation was that if pharmacists or assistant pharmacists could assist with the dispensing of medication, especially INH, it would lower the workload.

Two professional nurses in management positions mentioned that regular quality assurance checks on registers and folders, together with awareness, will improve IPT uptake. Enhanced monitoring of IPT uptake, quality improvement plans for tracking IPT use,

providing supervision and mentoring, may help to improve IPT implementation in clinics (Bristow *et al.*, 2012:2021).

In the district, ART and TB services are not yet integrated and ART is not provided at all the clinics. Decentralization of facilities, where TB and ARV services are available, is more successful in IPT implementation compared to the ones in which patients must be referred to another facility. The findings by Howard *et al.* (2012:S134) support this.

5.2.3.3 Provider or health workforce

Training on new protocols and evaluation of the current knowledge of healthcare workers, with focused updated training, was recommended by most of the participants. Denegetu and Dolamo (2014:52) found that on-going support, training and experience sharing for healthcare workers can be used as a tool for improving IPT implementation.

5.2.3.4 Patient-related

Some participants felt that all HIV positive adults will benefit if they start IPT without a Mantoux. In the past, a patient had to take three pills. Simplifying the regimen to one pill, together with improving the patient's knowledge would contribute to patient adherence. Berhe *et al.* (2015:5) asserted that counselling should focus on patients who are in their first and second month of treatment. Cellular phone alarms as reminders and diary cards can help patients to remember their follow up dates (Berhe *et al.*, 2014:5).

By identifying context-specific barriers to adherence, steps can be put into place. Participants mentioned that open communication between healthcare workers and patients regarding medication, as well as support, education and information about the benefits of IPT and attending follow up appointments at the clinic, will improve adherence.

One participant recommended involving employees and the community to support the patient to complete treatment. The importance of meaningful engagement of communities was also addressed by Getahun *et al.* (2010:S63).

5.4 CONCLUSIONS

The conclusions derived from the study are based on the findings yielded from the interviews with the participants at the clinics in Matzikama sub-district. The purpose of the study was to explore the barriers and enhancers for implementation of IPT amongst HIV positive adults, from the perspective of professional nurses.

Enhancers included clear protocols and availability of stock, especially isoniazid. TB screening on all patients, regular training of healthcare workers, monitoring of registers and

folders to improve IPT statistics, and counsellors that identified eligible patients for IPT, were health system and provider-related enhancers.

Barriers that related to leadership and governance were the frequent changes made to protocols and lack of communication. Stock outs of Mantoux tests and pyridoxine and problems with reading the Mantoux test within 72 hours were health system barriers. Healthcare providers' fear of INH resistance and side effects, uncertainty about the duration of treatment and inadequate knowledge of IPT were identified. Patient adherence was a major problem that could be attributed to a lack of knowledge or difficulty of attending clinic appointments. The rural context made it difficult to provide a regular service to farm communities including monitoring adherence and tracing defaulters.

Participant recommendations included one standard protocol, service integration and regular training. On-going patient support and engaging communities and employees may improve implementation of IPT. The conceptual framework of Getahun *et al.* (2010:S57) supports the findings of the study.

The study may increase awareness of how the rural setting and context can influence programme implementation. Medical access is a necessity for on-going health care. However, with the six-weekly rotations of the mobile clinic and distances from the clinic, care can be delayed, missed or lead to patients not accessing medication. These consequences may lead to poor adherence and health outcomes. Distance from the clinic and transportation is a barrier to health care for the patient in rural settings.

5.5 RECOMMENDATIONS

The following recommendations are based on the findings of the study.

5.5.1 Recommendation 1: Strengthening the IPT policy

Healthcare workers on all levels must take responsibility for the IPT program. IPT scale-up is an integral part of the HIV/TB collaboration activities and clear direction and leadership from the national and provincial political level is required. Communication must improve between leaders and managers, especially when new policies are implemented. Reasons must be given why policies change and training on the new policies is necessary. Karim *et al.* (2009:921) found that strong leadership, political commitment, adequate human and financial resources are needed for successful implementation of IPT.

5.5.2 Recommendation 2: Enhancing health services

The decentralization of HIV and TB services in primary health care is important to scale-up implementation of IPT. Not all clinics in the Matzikama sub-district have decentralized HIV

care. WHO encourages the integration of HIV and TB services, as studies show that it improves outcomes in lower income countries (Charles *et al.*, 2016:e0153243).

It is recommended that adequate supplies of isoniazid are available for HIV care programs. The ordering of enough medication is important and making the medication available to patients. The adult dosage of 300mg should be available for adults, including pregnant women and patients receiving ART. Getahun *et al.* (2010:S62) found that the National TB and AIDS Control Programs should ensure adequate supplies of INH and that INH are available for HIV care programs.

Integrative reporting formats, such as combined folders and pre-ART or ART registers to cross check the accuracy of data must be implemented to identify reporting gaps. If medical records are computerized and data from patient folders are captured by data capturers, it might improve recording. Training and support will assist in the recording of accurate data. Monitoring and evaluation should be integrated into the pre-ART register. ART clinics should incorporate in the record columns to indicate TB screening, diagnosis and treatment of active TB. The use of IPT on a monthly basis was recommended by Ait-Khaled *et al.* (2009:932).

5.5.3 Recommendation 3: Provider or health workforce involvement and training

Healthcare workers require on-going training, orientation and continuous support for improving implementation of IPT. All staff must take responsibility and be on board with the program, perform TB screening on HIV positive patients and initiate IPT as soon as possible. Counselors can play a role in identifying HIV positive adults for IPT. This is supported by the study done in Brazil by Durovni *et al.* (2011:S54) who showed that training of healthcare workers increased TB screening, provision of Mantoux tests and increased IPT implementation.

As recommended by Adams *et al.* (2014:281), the involvement of pharmacists will help to improve the implementation of IPT. Thus, in this research setting, participation of pharmacists in the dispensing of isoniazid may help to improve IPT implementation and adherence.

5.5.4 Recommendation 4: Patient education and monitoring

Adherence is an important issue and it is necessary to emphasise the completion of treatment to the patient. Patients must be educated and counselled on the side effects and the possibility of resistance and that any abnormalities must be reported to the clinic. This approach was endorsed by Makanjoula *et al.* (2014:e87166) who reported that patients who

received explanations about IPT were eight times more adherent. Support at home from family or community healthcare workers, especially in informal settlements will be helpful. Furthermore, healthcare workers could identify treatment supporters that reside on the farms to assist with education and monitoring.

Patients can be trained to interpret their own Mantoux test results. If the result is negative, they would not need to return. A positive result can be confirmed by the healthcare worker and IPT could be initiated immediately. Reducing the complexity of Mantoux testing may improve programmatic implementation of IPT (Cox *et al.*, 2015:1303). Cox *et al.*, (2015:1302) found that patients appeared to understand the training on Mantoux test self-reading. When comparing nurse and patient readings, nurses recorded 7% as TST-positive while patients recorded it as TST-negative, and 21% as TST-negative while patients recorded it as positive. This study shows that patients can be trained to interpret their own TST results. Patients interpreting their TST as negative would not need to return to clinic before their next follow-up date.

A strategy to reduce stigma, will encourage the HIV positive adults to talk about their status and treatment. Makanjuola *et al.* (2014:e87166) reported that patients completed their treatment when the family approved their decision to take IPT. Support groups in the community, as part of chronic care with follow up dates, will reinforce the value of IPT.

5.6 FUTURE RESEARCH

The uptake of IPT increased dramatically in South Africa in 2011-2012, making the IPT programme one of the largest in the world. Despite this, uptake of IPT among HIV positive adults remains poor (Churchyard *et al.*, 2014:246). This study is the first to explore the barriers and enhancers to the implementation of IPT amongst HIV positive adults from the perspective of professional nurses. Further research that focuses on the risk of isoniazid resistance, frequent interruption of IPT would be valuable. Furthermore, an exploration of the patient's perspective of IPT adherence, especially in rural and farm communities in the South African setting, is recommended.

5.7 LIMITATIONS OF THE STUDY

Limitations are described in Grove *et al.* (3023;598) as “theoretical or methodological restrictions in a study that may decrease the generalizability of the findings.” The health clinics included in this study are located in the rural area of Matzikama, West Coast, Western Cape. The study included 10 participants within one sub-district. It could have been more effective if the researcher had another sub-district to compare it with.

This study findings cannot be generalised to other areas as other sub-districts and districts were not included in the sample. However the researcher provided a rich description of the study context and used verbatim participant quotes to verify themes which may enhance transferability.

5.8 CONCLUSION

In this chapter, the findings of the study were discussed in relation to the study objectives and the available literature. The study revealed several leadership, health system, provider-related and patient-related enhancers and barriers, some of which are specific to the rural context. Addressing barriers and promoting enhancing strategies could improve the implementation of IPT. Early initiation of ART, the strengthening of TB screening and targeted case finding in healthcare facilities and communities is recommended. Moreover, the introduction and scaling up of IPT may have a substantial impact on TB control. In the rural setting patients are sometimes particularly disadvantaged regarding access to healthcare facilities. Access barriers include distance, transport, time and cost and lead to poor adherence and health outcomes. South Africa has made notable progress in IPT and improving TB control, but the burden of TB remains vast. Vaccines, new drugs and early diagnostics are required to accelerate progress towards TB elimination (Churchyard *et al.*, 2014:247).

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APPENDICES

APPENDIX 1: ETHICAL APPROVAL FROM STELLENBOSCH UNIVERSITY

Approval Notice Response to Modifications- (New Application)

14-Oct-2014

Agenbag, Sonet Elizabeth SE

Ethics Reference #: S14/04/094

Title:

Perception of professional nurses about the barriers and enhancers to the implementation of isoniazid preventive therapy amongst HIV positive adults.

Dear Mrs Sonet Elizabeth Agenbag,

The **Response to Modifications - (New Application)** received on **28-Jul-2014**, was reviewed by members of **Health Research Ethics Committee 2** via Expedited review procedures on **29-Aug-2014** and was approved.

Please note the following information about your approved research protocol:

Protocol Approval Period: **02-Sep-2014 -02-Sep-2015**

Please remember to use your **protocol number (S14/04/094)** on any documents or correspondence with the HREC concerning your research protocol.

Please note that the HREC has the prerogative and authority to ask further questions, seek additional information, require further modifications, or monitor the conduct of your research and the consent process.

After Ethical Review:

Please note a template of the progress report is obtainable on www.sun.ac.za/rds and should be submitted to the Committee before the year has expired.

The Committee will then consider the continuation of the project for a further year (if necessary). Annually a number of projects may be selected randomly for an external audit.

Translation of the consent document to the language applicable to the study participants should be submitted.

Federal Wide Assurance Number: 00001372

Institutional Review Board (IRB) Number: IRB0005239

The Health Research Ethics Committee complies with the SA National Health Act No.61 2003 as it pertains to health research and the United States

Code of Federal Regulations Title 45 Part 46. This committee abides by the ethical norms and principles for research, established by the Declaration of Helsinki, the South African Medical Research Council Guidelines as well as the Guidelines for Ethical Research: Principles Structures and Processes 2004 (Department of Health).

Provincial and City of Cape Town Approval

Please note that for research at a primary or secondary healthcare facility permission must still be obtained from the relevant authorities (Western Cape Department of Health and/or City Health) to conduct the research as stated in the protocol. Contact persons are Ms Claudette Abrahams at Western

Cape Department of Health (healthres@pgwc.gov.za Tel: +27 21 483 9907) and Dr Helene Visser at City Health (Helene.Visser@capetown.gov.za Tel: +27 21 400 3981). Research that will be conducted at any tertiary academic institution requires approval from the relevant hospital manager. Ethics approval is required BEFORE approval can be obtained from these health authorities.

We wish you the best as you conduct your research.

For standard HREC forms and documents please visit: www.sun.ac.za/rds

If you have any questions or need further assistance, please contact the HREC office at 0219389207.

Included Documents:

Investigator declaration Agenbag
Information leaflet and consent form
Application form
Synopsis
MOD_Cover letter response to Modification
Investigator declaration Woolgar
CV Agenbag
Department of Health permission letter
Investigator declaration Crowley
CV Woolgar
MOD_Protocol
Protocol
MOD_Protocol Synopsis
Application signature and declarations
Consent forms
CV Crowley
MOD_Checklist
HREC Checklist
Sincerely,
Mertrude Davids
HREC Coordinator
Health Research Ethics Committee 2

APPENDIX 2: PERMISSION OBTAINED FROM INSTITUTIONS/DEPARTMENT OF HEALTH



STRATEGY & HEALTH SUPPORT
Health.Research@westerncape.gov.za
tel: +27 21 483 6857; fax: +27 21 483 9895
5th Floor, Norton Rose House., 8 Riebeeck Street, Cape Town, 8001
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REFERENCE: WC_2014RP7_388
ENQUIRIES: Ms Charlene Roderick

Stellenbosch University
Francie van Zijl Drive
Tygerberg Hospital
Parow
7535

For attention: **Mrs Sonet Agenbag**

Re: PERCEPTION OF PROFESSIONAL NURSES ABOUT THE BARRIERS AND ENHANCERS TO THE IMPLEMENTATION OF IPT AMONGST HIV+ ADULTS

Thank you for submitting your proposal to undertake the above-mentioned study. We are pleased to inform you that the department has granted you approval for your research.

Please contact **D Schoeman** on **022 487 9207** the following people to assist you with any further enquiries in accessing the following sites:

Clanwilliam Clinic
Klawer Clinic
Van Rhynsdorp Clinic
Vredendal Central Satellite Clinic
Vredendal North Clinic

Kindly ensure that the following are adhered to:

1. Arrangements can be made with managers, providing that normal activities at requested facilities are not interrupted.
2. Researchers, in accessing provincial health facilities, are expressing consent to provide the department with an electronic copy of the final report within six months of completion of research. This can be submitted to the provincial Research Co-ordinator (Health.Research@westerncape.gov.za).
3. The reference number above should be quoted in all future correspondence.

Yours sincerely

A handwritten signature in black ink, appearing to be 'J Evans', written over a circular stamp or seal.

DR J EVANS
ACTING DIRECTOR: HEALTH IMPACT ASSESSMENT

DATE: 19/12/2014
CC

C BESTER

DIRECTOR: WEST COAST

APPENDIX 3: PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT: Perceptions of professional nurses about the barriers and enhancers to the implementation of isoniazid preventative therapy amongst HIV positive adults.

REFERENCE NUMBER: S14/04/094

PRINCIPAL INVESTIGATOR: S.E. Agenbag

ADDRESS: KaniKlani
KOEKENAAP
8146

CONTACT NUMBER: 083 6611 315

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff or doctor any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Health Research Ethics Committee at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

The Matzikama sub-district in the West Coast rural district will be the focus of this study.

The researcher will choose two professional nurses, one clinical manager and the HAST coordinator of these clinics to participate in the study. The researcher anticipates doing ten in-depth interviews.

The aim of the study is to explore the barriers and enhancers to the implementation of isoniazid preventative therapy (IPT) from the perspective of professional nurses.

The researcher will personally approach each participant and individual interviews will be conducted.

Why have you been invited to participate?

You have been selected since you currently prescribe IPT or are a facility manager or the HAST coordinator of the district. You therefore have a unique understanding of the barriers and enhancers of the implementation of IPT.

What will your responsibilities be?

You will be required to partake in an interview that will take approximately one hour. You are expected to give honest answers to the questions about what you experience as the barriers and enhancers to the implementation of IPT.

Will you benefit from taking part in this research?

There are no personal benefits, but the information gathered from this study will help to identify factors impacting on the implementation of IPT, which could lead to interventions that may improve the current situation.

Are there in risks involved in your taking part in this research?

There are no anticipated risks.

If you do not agree to take part, what alternatives do you have?

Participation is voluntary and you will in no way be compromised should you not agree to be part of this study.

Who will have access to the information you provide?

The information collected will be treated as confidential and protected. Your identity will remain anonymous in any published work. Only the researcher and supervisors will have access to the information.

Will you be paid to take part in this study and are there any costs involved?

You will not be paid to take part in the study. There will be no costs involved for you, if you do take part.

Is there anything else that you should know or do?

- You can contact the Health Research Ethics Committee at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by your study doctor.
- You will receive a copy of this information and consent form for your own records.

Declaration by participant

By signing below, I agree to take part in a research study entitled: Perceptions of professional nurses about the barriers and enhancers to the implementation of isoniazid preventative therapy amongst HIV positive adults.

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study doctor or researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) on (*date*)
2014.

.....
Signature of participant

.....
Signature of witness

Declaration by investigator

I *Sonet Elizabeth Agenbag* declare that:

- I explained the information in this document to
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above
- I did/did not use an interpreter. (*If an interpreter is used then the interpreter must sign the declaration below.*)

Signed at (*place*) on (*date*)
2014.

.....
Signature of investigator

.....
Signature of witness

APPENDIX 4: INTERVIEW GUIDE

Section A

Participant demographical information:

- Gender
- Age
- Race
- Professional qualification
- Current position (PN, Facility Manager or HAST coordinator)
- Years of clinical experience in primary health care

Section B

- Tell me about your experiences of implementing IPT in your clinic.
- What makes it easy for you to implement IPT? / What enhances this practice?
- What makes it difficult? / What are the barriers?
- Probing questions:
 - Are there leadership or governmental barriers/enhancers that play a role?
 - Are there barriers/enhancers in the health system? (stock supplies, facilities for excluding active TB)
 - Are there provider-related barriers/enhancers? (training, skills, knowledge, drug resistance)
 - Are there patient-related barriers/enhancers? (knowledge, transport, preferences)

APPENDIX 5: CONFIDENTIALITY AGREEMENT WITH DATA TRANSCRIBER

I, the undersigned Leigh Story

1. herewith undertake that all information disclosed or submitted, either orally, in writing or in other tangible or intangible form by Sonet Agenbag to me, or made available to me, or details of Sonet Agenbag's business or interest of which I may become aware of in respect of transcriptions being done by myself for Sonet Agenbag, to keep confidential and not to divulge to anyone for which Sonet Agenbag did not give written consent;
2. guarantee that I will apply the information, detail or knowledge in **clause 1** only for the purpose of the intended research;
3. indemnify Sonet Agenbag against any claims that may be instituted against Sonet Agenbag, amounts that may be claimed or losses that Sonet Agenbag may suffer in consequence of a violation by me of any provision included in this agreement.



SIGNED at Cape Town on _____

APPENDIX 6: EXTRACT OF TRANSCRIBED INTERVIEW

DVT A003 15.03.31 08.31

Speaker Key: IV Interviewer FS Female speaker

Interview

IV Good morning. Thank you very much for being willing to participate in the research. We are going to look at the perception of nursing professionals around the implementation of IPT. What the problems, stumbling blocks are, and what can strengthen it. So can you tell me about your experience with IPT?

FS Are we going to start with the negatives?

IV You can decide where you want to start. We are going to look at negative and positive effects. So you can start.

FS Let us start with the positives. There are certain guidelines and policies in place, and protocols in place. Some months we have a really big supply of IPT to hand out. Other months, this is a negative aspect, it is out of stock and we struggle a bit because it is difficult for the patient to come back later again to collect it.

IV Is it only the INH which is out of stock or other equipment?

FS The B6 or Pyridoxine that gets handed out with it is also often out of stock. A big side effect is very often only the INH is being handed out. The nursing professionals forget about the Pyridoxine that has to go with it. This is then when peripheral neuropathy occurs.

IV So you think the guidelines, policies and protocols are all in place, sometimes there is a shortage of INH and sometimes oversupplied?

FS You understand it correctly.

IV Then the Pyridoxine also gets out of stock and then only the INH are given, which causes the side effect, peripheral neuropathy, to occur.

FS Then one of the contra-indications for INH is of course alcohol abusers, persons with liver problems and then people who had TB in the past year and who had been treated for it. They are not allowed to get INH.

IV This is also a problem. So the alcohol is quite a problem.

IV Yes, but here there is much denial of the alcohol abuse, so we often give the person INH because there is active TB present in his environment or in his home.

IV So alcohol abuse is quite a problem and contra-indication.

FS And we cannot exclude somebody based on liver, you know, he does not have jaundice, his liver is seemingly not affected. So it is difficult. If you don't do LFTs you will not really know what is the state of his liver. So you cannot say this is really a contra-indication before you have done in-depth investigations.

IV So you give the INH based on no visible liver problems?

FS Yes. Then a big side effect is when a person is on INH and he has to come back again to the clinic just to collect it. That is why we try to hand it out together with the ARVs. So that when he comes for his anti retrovirals he will get the INH as well. This is

two birds with one stone, and we also try to prescribe it like that, on the same



To whom it may concern

This letter serves as confirmation that I, Lize Vorster, performed the technical formatting of Sonet Agenbag's thesis. This entails complying with the Stellenbosch University's technical requirements for theses and dissertations, as presented in the Calendar Part 1 – General.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Lize Vorster', is written over a large, stylized, hand-drawn 'X' or checkmark.

Lize Vorster
Language Practitioner