AN ASSESSMENT OF CURRENT PRACTICE PATTERNS OF TB/HIV AT PRIMARY HEALTHCARE CLINICS IN THE WESTERN CAPE AND A NEEDS ASSESSMENT FOR CLINIC-BASED TRAINING AMONG FINAL YEAR PHARMACY STUDENTS

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A thesis submitted in fulfillment of the requirements for the degree of Master of Pharmacy in the Department of Pharmacology at the University of the Western Cape.

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About the researcher

My names are Abiola Oluwatoyin Iyabode Tokosi and I am a Nigerian by nationality. I completed my B.Pharm degree at the University of the Western Cape (UWC) in 2007 and immediately proceeded to further my studies by enrolling for an M.Pharm degree in 2008. I am fluent in English only but can understand some basic words in Xhosa such as Ewe (Yes) and Hayi (No). Having completed my undergraduate degree, I realized that the TB and HIV theoretical knowledge which I had acquired in class was not actually being applied in practice. My desire to understand the practical application of this theoretical knowledge in a clinic-based setting underpinned the start of my research journey.

DECLARATION

"I declare that an assessment of current practice patterns of TB/HIV at primary healthcare clinics in the Western Cape and a needs assessment for clinic-based training among final year pharmacy students is my own work, that it has not been submitted before for any degree or assessment in any other university, and that all the sources I have used or quoted have been indicated and acknowledged by means of complete references".

Signature ……..

Abiola Oluwatoyin Iyabode Tokosi

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June 2010

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TABLE OF CONTENTS

Acknowledgements…….iv-v

List of Tables……..xiii

List of Figures…….xiv

List of Appendices…..……..xv

List of Abbreviations……...xvi

Summary……..xvii-xix

CHAPTER 1: INTRODUCTION……..1

1.1. Overview of Tuberculosis (TB) and HIV…….....1

Tuberculosis…….....1

HIV…….....1

1.2. Rationale for the study…….....2

1.3. Hypothesis of the study……...2

1.4. Aims…….2

1.5. Objectives of the study……3

1.6. Brief description of research methods…….....3

1.7. Study Phases……4

1.8.Chapter description…….5-6

CHAPTER 2: LITERATURE REVIEW……7

Section A

2. Epidemiology of TB and HIV……7-8

2.1. Prevalence and incidence of TB…….....9

2.2. Burden of co-infection with TB and HIV…….10

2.3. Children and TB: challenges……..11

2.4. The South African healthcare system…….....12

2.4.1. Primary healthcare in the Western Cape…….12

2.4.2. Health services barrier to TB/HIV management…….13

2.5. Clinical management of TB/HIV…….....14

2.6. Approaches to TB drug treatment…….....14
2.6.1. Cotrimoxazole prophylaxis therapy (CPT)…….15
2.6.2. TB Treatment regimens ……..15
2.6.3. Pharmacological properties of individual anti-TB drugs……15
2.6.4. Pharmacological properties of individual ARV drugs……16
2.6.5. TB treatment phases……17
Revised treatment drug regimens for TB patient (2007)……...18
2.7. Adherence treatment strategies……...19
2.7.1. DOT versus DOTS…….....19
2.7.2. Effectiveness and non-effectiveness of DOT……...20
2.8. Clinical criteria for initiating anti-retroviral therapy (ART) in TB patients ……..20
2.9. Role of pharmacist in TB/HIV management……..21

Section B

2.10. Current teaching practice of TB/HIV at UWC School of Pharmacy…….....22
2.11. Evaluation of the Service-learning in pharmacy (SLIP) module at UWC……..23-24

CHAPTER 3: RESEARCH DESIGN AND METHODOLOGY……25

Phase I study

3. Description of research sites……26
3.1. Ravensmead Community …….26
3.1.1. Ravensmead Community Health Centre (CHC)…….....26
3.2. Delft South community…….27
3.2.1. Delft South clinic……..27
3.3. Elsies River community……28
3.3.1. Elsies River clinic……..28
Figure 3.1: Layout of Elsies River TB room…….....29
3.4. Study population……..29

Phase II study

3.4.1. Recruitment of final year pharmacy students at UWC……..30
3.4.1.1. Inclusion criteria…….....30

3.4.1.2. Exclusion criteria……..31
3.5. Mixed methods…….....31
3.6. Triangulation as a combination of qualitative and quantitative approaches…….....31
3.7. Programme evaluation……32
3.8. Summative evaluation…….32
3.9. Quantitative research design……...33
3.9.1. Randomization……..34
3.9.2. Solomon four-group design……..34
Table 3.1: Solomon four-group design……..35
3.10. Quantitative data collection methods……35
3.11. Sampling……...36
3.12. Qualitative data collection methods……..37
3.12.1. Interview……37
3.12.1.1. Structured one-to-one interviews…….....38
3.12.2. Participant observation……...38
3.13. Validity and reliability……..39
3.14. Data input and analysis…….....39
3.15. Ethics…….....39
Table 3.2: Outline of research design and methods used for this study……...41-42

CHAPTER 4: BASELINE STUDY…….....43
4. PALSA Plus training…….43
4.1. Role of district TB coordinator……..43
4.2. TB treatment wheel……44
4.3. Baseline study……45
4.3.1. Description of baseline site……..45
4.3.2. Selection of baseline site to conduct baseline study……46
4.3.3. Entry into TB clinic……..47
4.3.3.1. Attire…….....47
4.3.3.2. Interaction with nursing staff members……...47
4.3.3.3. Initial meeting with nursing staff members……47

4.3.3.4. DOTS supporter……..48
4.3.3.5. Access to patient folders…….49
4.4. Design of questionnaires……49
4.4.1. Patient questionnaire……49
4.4.2. HCP questionnaire…….....50
4.4.3. Layout of questionnaire…….50
4.5. TB consultation room……51
4.6. Patient interview process and data collection……52
4.7. Sample size……53
4.8. Recruitment process…….....53
4.9. Results……54
4.9.1. Patients qualitative results…….....55
4.9.1.1. Observation from DOTS procedure…….....54
4.9.2. Quantitative results……55-58
4.10. Graphical representation of baseline results……...59-61
4.11. HCP results……61-62
4.12. Summary of baseline study……63-64
4.13. Modification of questionnaires for study at Delft South and Elsies River clinics…64
4.14. Conclusion…….....65

CHAPTER 5: DESIGN, IMPLEMENTATION OF INTERVENTION TOOL AND ASSESSMENT OF FINAL YEAR PHARMACY STUDENTS…….....66

5.1. Implementation of the clinic based intervention…….....67
5.2. Delft South Staff members…….67
5.2.1. ARV nurse/clinic nurse…….....67
5.2.2. Adherence counsellor……...67
5.2.3. Patient advocate (PA)……...68
5.3. Elsies River staff members…….68
Table 5.1: Summary of staff roles and responsibilities at Elsies River clinic……..……68
5.4. Design of intervention tool: Tuberculosis clinic record card……69-70

5.5. Rationale for the clinic record card……...70
Section A: Demographic profile……70
Section B: TB patient category……..70
Section C: ICD-10 code…….....71
Table 5.2: ICD-10 code for different types of TB…….....71
Section D: Sputum results…….....71
Section E: Treatment supervisor……71
Section F: TB drug treatment……....72
Intensive phase of TB treatment……....72
Continuation phase of TB treatment……..73
Assessing patient adherence to treatment at Delft South clinic…….....73
Section G: patient adherence status…….....74
Section H: TB side effects……74
Section I: Anti-TB-ARV drug interactions……...74
5.6. Applicability of tool for potential use by trained pharmacists …….....75
Part 1: rationale for assessment questions……76
Part 2: Questionnaire to assess student's views and perceptions…….....77
5.7 Introduction of a clinic-based training for UWC final year pharmacy students……..77
5.8. Outline of training conducted by researcher for final year pharmacy students at UWC……77-78

CHAPTER 6: RESULTS

Phase I study……78
Pre-intervention results……78
Aim and method……78
6.1. Section one: Pre-intervention results…….78-79
Enquiry into patient knowledge of contracting TB……80
Table 6.1.2: Patient knowledge of TB infectivity……..80
Table 6.1.3: Enquiry into patient knowledge of TB/HIV tablets……...80
Table 6.1.4: Enquiry into patient's preference for a HCP(s)…….81

Table 6.1.5: Enquiry into patient lifestyle…….82
Table 6.1.6: Enquiry into the role of the pharmacist in patient treatment provision…….83
Section two: HCP results…….83-84
6.2. Intervention phase results (n=98) ……..85
Aim and method……85
Table 6.2.1: Age distribution of patients……...86
Table 6.2.2: Correlation between patient weight and CD4 count…….86
Table 6.2.3: Demographic profile…….88
Table 6.2.4: Patient diagnosis by their HCP…….88
Table 6.2.5: Type of TB treatment case……89
Table 6.2.6: Patient adherence status……89
Table 6.2.7: Patient treatment outcomes and side effects…….91
Table 6.2.8: Patient drug interactions…….....92
Table 6.2.9: Number of other drugs taken by patients……..92
6.3. Post-intervention phase results ……92
Aim and method……...91-93
Table 6.3.1: Patients initial perception(s) of clinic pharmacists…….....93
Table 6.3.2: Key interventions by researcher on patient's treatment…….....95
Table 6.3.3: Patients views on pharmacist working together with other HCP's……...96
Table 6.3.4: Patients responses after exposure to the intervention……97
Summary of results according to research design…….....97-99

Phase II……...100
6.4. Aim and Method……...100
Section three: UWC final year pharmacy student's results…….100
Table 6.4: Comparative responses between control (n=37) and experimental (n=7) students…….100-102
6.4.1. Results……....103-106
6.4.2. Students feedback session on PALSA Plus training received……107-109

CHAPTER 7: DISCUSSION……110
7.1. Current TB/HIV clinic-based practice patterns: Does it allow for pharmacist involvement?.....110
7.2. A patient-centered approach to TB and HIV management……..111
7.3. Impact of the clinic-based TB/HIV intervention……..111
7.4. Inter-professional teaching and learning opportunities…….112
7.5. Integrating services for co-infected TB/HIV patients……...112
7.6. Influence of socioeconomic and educational status on treatment adherence…112-113
7.7. Need for TB/HIV clinic-based exposure for pharmacy students……..114
7.7.1. Students performance in clinical scenarios……114
7.8. Effectiveness of mixed methods in this study…….....115
7.9. Conclusions and recommendations……...116

REFERENCES……...117-129
APPENDICES……130-172

List of Tables

Table 1.1: Commonly used abbreviations for TB drug treatment

Table 1.2: Comparison of defined roles for pharmacist in HIV management

Table 4.1: Demographic profile (Gender, Ethnic group, Age, Education, and Language)

Table 4.2: Results from Baseline study

Table 4.3: Comparative survey responses between DOTS supporter and clinic nurse

Table 5.1: Summary of staff roles and responsibilities

Table 5.2: ICD-10 code for different types of TB

Table 6.1.1: Demographic profile (n=19) at Delft South ARV clinic

Table 6.1.2: Knowledge of TB infectivity

Table 6.1.3: Enquiry into patient knowledge of TB/HIV tablets

Table 6.1.4: Enquiry into patient's preference for a HCP(s)

Table 6.1.5: Enquiry into patient lifestyle

Table 6.1.6: Enquiry into the role of the pharmacist in patient treatment provision

Table 6.1.7: Comparative responses from ARV nurse, adherence counselor and TB/ARV doctor at Delft South ARV clinic

Table 6.2.1: Age distribution of patients

Table 6.2.2: Correlation between patient weight and CD4 count

Table 6.2.3: Demographic profile of intervention patients

Table 6.2.4: Patient diagnosis by their HCP

Table 6.2.5: Type of TB treatment case

Table 6.2.6: Patient adherence status

Table 6.2.7: Patient treatment outcomes and common side effects

Table 6.2.8: Patient drug interactions

Table 6.2.9: Number of other drugs taken by patients

Table 6.3.1: Patients initial perception(s) of ARV pharmacist

Table 6.3.2: Key interventions by researcher on patient's treatment

Table 6.3.3: Patients views on pharmacist working together with other HCP's.

Table 6.3.4: Patient responses after the exposure to the intervention

Table 6.3.5: Comparison between experimental and control groups to assess the receptivity of the intervention among patients

List of Figures

Figure 3.1: Layout of Elsies River TB room.

Figure 4.1: Layout of Ravensmead CHC TB room.

Figure 4.2: Gender distribution of baseline patients.

Figure 4.3: Type of patient TB treatment case.

Figure 4.4: Number of patients taking Rifafour® with other drugs.

Figure 4.5: Common TB side effects experienced by patients.

Figure 6.1: Patients preferred HCP for their TB/HIV treatment.

Figure 6.2: Assessment of patient adherence status.

Figure 6.3 Students knowledge of first line ARV regimen.

Figure 6.4 Students knowledge of potential drug interactions.

Figure 6.5 Students knowledge of Bactrim® and Vitamin B complex importance.

List of Appendices

Appendix A: Patient pre-intervention questionnaire (English)

Appendix B: HCP questionnaire (English)

Appendix C: PALSA Plus Training Notes (2007 Edition)

Appendix D: The TB treatment Wheel

Appendix E: TB Screening Tool

Appendix F: Pre-ARV Counselling

Appendix G: Tuberculosis Clinic Record Card for Pharmacists (intervention tool)

Appendix H: National Tuberculosis Control Programme patient clinic/ hospital card

Appendix I: Patient Medication Diary (English)

Appendix J: Disclosure and positive living

Appendix K: Basics of HIV, CD4 and Viral load

Appendix L: Opportunistic infection's, ARV Treatment Plan, Adherence

Appendix M: Patient post-intervention questionnaire (English)

Appendix N: Patient post-intervention questionnaire (Xhosa)

Appendix O: Final year Pharmacy student's assessment questions

List of Abbreviations

AIDS- Acquired Immune Deficiency Syndrome

ART- Antiretroviral Therapy

CHC- Community Health Centre

CHW- Community Health Worker

CPT- Cotrimoxazole Prophylaxis Therapy

DOH- Department of Health

DOTS- Direct Observed Treatment Short-course

HCP – Healthcare Provider

HIV- Human Immunodeficiency Virus

NNRTI- Non-Nucleoside Reverse Transcriptase Inhibitor

NRTI- Nucleoside Reverse Transcriptase Inhibitor

PA- Patient Advocate

PALSA Plus – Practical Approach to Lung Health and HIV/AIDS in South Africa

PHC- Primary Healthcare

SA- South Africa

SAMF- South African Medicines Formulary

SAPC- South African Pharmacy Council

SLIP- Service Learning in Pharmacy

TB- Tuberculosis

UK- United Kingdom

UNAIDS- Joint United Nations Programme on HIV/AIDS

USA- United Sates of America

UWC – University of the Western Cape

WHO – World Health Organization

SUMMARY

Rationale/ Background

Tuberculosis and HIV

Tuberculosis (TB) is a major contributor to the disease burden in developing countries resulting in deaths of approximately 2 million people a year. South Africa (SA) has one of the highest annual TB incidences with an estimate of 558 per 100 000 population (2003) and the situation shows no sign of abating. TB remains the most common opportunistic infection and cause of death amongst HIV- infected patients. Both TB and HIV treatment depend exclusively on multi-drug regimens that require close monitoring among health care professionals.

With increasing workload due to staff shortage and high patient load, the quality of care in nurse-led primary care clinics maybe compromised. Existing clinic staff may overlook drug-drug interactions, side effects and may not be aware of the consequences when a formulation is modified during multi-drug therapy administration.

As the custodian of medicines, pharmacists are ideally placed to monitor therapy. Clinic-based training programmes which are offered to nurses provide an opportunity to work alongside clinic staff and engage in patient-centered care where the pharmacotherapeutic outcome of TB and HIV drug regimens could be closely monitored.

Aims

The primary and secondary aims of the study were to:

- Assess current practice patterns of TB/HIV at primary healthcare clinics in the Western Cape,
- Assess the need for a clinic-based TB/HIV training among final year pharmacy students in UWC.

Objectives

To achieve the primary aim the researcher;

1. Conducted a baseline study at Ravensmead Community Health Centre(CHC) to assess current TB/HIV practice among HCP's and co-infected patients,
2. Assessed current practice patterns at Delft South ARV clinic and Elsies River TB clinic (pre-intervention),
3. Designed and implemented a clinic-based TB/HIV intervention tool for potential use by pharmacists at Delft South and Elsies River clinics (intervention phase),
4. Evaluated patient receptivity of the intervention tool amongst patients at Delft South and Elsies River clinics (post-intervention phase).

To achieve the secondary aim the researcher;

5. Introduced a clinic-based training for seven final year pharmacy students,
6. Designed and administered an assessment to both control and experimental students,
7. Assessed scores between students who received the training (experimental) with those who did not receive the training (control).

Results and discussion

Findings from the baseline study indicate the need for involvement of a trained pharmacist in TB and HIV management. Even though three-quarters (77.8%; 14) of the patients preferred receiving their TB information from the clinic nurse, almost two-thirds (63.2%; 12) of the patients believed that pharmacists assisted with their treatment provision.

Patient data obtained from the clinic record card showed that almost two-thirds of the patients reported that they had experienced side effects (64.4%); the therapy of more than one-quarter (26.4%) showed drug-drug interactions and onset of adverse effects (1.1%).
Post-intervention, the data showed that patients' viewed the pharmacist's role more positively. Almost all responses (97.5%; 39) favoured the services of a pharmacist in the

clinic. In conclusion, findings from the post-intervention patient study clearly underpin that a clinic-based role for the pharmacist is imminent.

All seven (100%) of the experimental students passed the assessment and had marks in the range between 26 and 45 and more than three-quarters (78.4 %; 29) of the control students passed with marks within this range.

Conclusion

A trained pharmacist would be competent to work alongside nursing staff in optimizing care provision in the clinical management of TB and HIV in patients. The existing clinic-based TB/HIV programme could be supplemented with theoretical concepts in the final year of undergraduate pharmacy training.

Keywords: *Assessment, Current practice patterns, Tuberculosis, Human Immunodeficiency Syndrome, Primary Healthcare, Clinic-based training, Pharmacy students*.

CHAPTER 1: INTRODUCTION

1.1. Overview of Tuberculosis (TB) and HIV

Tuberculosis

Tuberculosis (TB) is caused by the organism known as M.*tuberculosis* and also to a lesser extent M.*bovis* and M.*africanum*. Tuberculosis (TB) is a major contributor to the disease burden in developing countries and remains a global challenge to the health services, resulting in deaths of approximately 2 million people a year. It is estimated that 95% of all cases and 98% of all deaths occur in SA (Waisbord S, 2005). SA has one of the highest annual TB incidences with an estimate of 558 per 100 000 population (Internet Department of Health, 2006), and the situation shows no sign of abating even with the relatively good health care infrastructure and TB control activities. This is a disease whose morbidity and mortality rates continues to rise and has even been declared as a global emergency by the World Health Assembly, but still is poorly managed in SA (Department of Health, 1996).

HIV

The Joint United Nations programme on HIV/AIDS (UNAIDS) estimated that 40 million people were infected with HIV worldwide (2004). More than 95% of these people live in low and middle income countries and approximately 70% of them live in sub-Saharan Africa (Mansoor L.E, and Dowse R., 2006). Currently, it is estimated that 4.8 million South Africans are infected with HIV/AIDS every month, and an alarming 600 people die every single day (UNAIDS, 2004).

Co- morbidities that exist between TB and HIV/ AIDS cannot be overlooked, because the incidence of TB has increased in parallel to the human immunodeficiency virus (HIV) epidemic(Bleed D *et al*, 2000; WHO, 2001). Tuberculosis remains the most common opportunistic infection and cause of death amongst HIV- infected patients (UNAIDS 2000).

1.2. Rationale for this study

Generally nurses manage only TB clinics. HIV clinics are commonly conducted by doctors. Some satellite HIV clinics are managed by nurses. These clinics involves stable patients.TB/HIV care is primarily managed by nurses. Their extensive administrative duties along with clinical responsibilities, attending to emergency care, monitoring treatment adherence and evaluating therapeutic outcomes could impact on the quality of care provision (Pillay R, 2009). In contrast, other healthcare professionals such as pharmacists are underutilized in the clinical management of TB and HIV. While they have a thorough knowledge of pharmacotherapy, they lack exposure to clinic-based management of TB/HIV. If a clinic-based training could be designed for potential use by pharmacists, it would strengthen the primary healthcare team approach to TB/HIV management. It is envisaged that such an intervention would improve the quality of care provision among HIV-positive patients.

1.3. Hypothesis of this study

The first hypothesis for this study is that co-infected patients who received an intervention (a trained researcher using a specially designed clinic-record card) will change their initial perceptions towards the pharmacists. The second hypothesis was that final year pharmacy students who received a clinic-based introductory session (experimental) will be able to apply theoretical concepts than those that did not receive the training (control). However, it was not possible to compare scores between the control and experimental students due to the difference in sample size attained during this phase of the study.

1.4. Aims

The primary aim of the study was to:

- Assess current practice patterns of TB/HIV at primary healthcare clinics in the Western Cape and test the effectiveness of a clinic-based TB/HIV intervention,

The secondary aim of the study was to:

- Assess the need for a clinic-based TB/HIV training among final year pharmacy students in UWC.

1.5. Objectives

To achieve the primary aim the researcher;

1. Conducted a baseline study at Ravensmead Community Health Centre (CHC) to assess current TB/HIV practice among HCP's and co-infected patients,
2. Assessed current practice patterns at Delft South ARV and Elsies River TB clinic (pre-intervention),
3. Designed and implemented a clinic-based TB/HIV intervention tool for potential use by pharmacists at Delft South and Elsies River clinics (intervention phase),
4. Evaluated patient receptivity of the intervention tool amongst patients at Delft South and Elsies River clinics (post-intervention phase).

To achieve the secondary aim the researcher;

5. Introduced an introductory clinic-based session for seven final year pharmacy students,
6. Designed and administered assessment to both control and experimental students,
7. Assessed scores between students who received the training with those who did not receive the training.

1.6. Brief description of research methods

Quantitative and qualitative research methods were used throughout the different phases of this study. Qualitative research methods such as participant observation and interviews was used to generate rich, detailed data that is imbedded in context while quantitative methods such as the use of semi-structured questionnaires was used to convert the data into numbers which were then analyzed using the Epi Info 1993 package. Two sets of questionnaires were designed namely pre-intervention and post-intervention questionnaires. The intervention consisted of a trained researcher who used a clinic record specially adapted for potential use by pharmacists. The card was modified from the nurses TB clinic record card that is used routinely in TB/HIV clinics.

Patients were randomly selected from each clinic namely Delft South ARV and Elsies River TB clinics. The Solomon four-group design was used in this study and patients enrolled were assigned to either a control group or an experimental group. Patients assigned to the experimental group received the pre-intervention questionnaire, intervention and post-intervention questionnaire whilst the control group patients received only the pre-and post intervention questionnaires but they were not exposed to the intervention.

1.7. Study Phases

This study consisted of 2 phases namely: Phase I which entailed the baseline study, pre-intervention, intervention and post-intervention studies with TB/HIV patients attending primary care clinics and Phase II consisted of final year pharmacy student's assessment and an introductory clinic-based session.

Phase 1

The aim of the baseline study was to assess the current practice patterns of TB management provided to TB patients by nursing staff. The baseline study was conducted at Ravensmead Community Healthcare Centre (CHC). A face-to-face questionnaire directed to the patients, and HCP's was designed and was used to collect data on routine TB care provision from the clinic.

Following findings from the baseline study, the patient and HCP questionnaires were subsequently modified for their implementation at the intervention clinics. The intervention consisted of a trained researcher using a specially adapted clinic record card for the pharmacotherapeutic management of TB/HIV positive patients. The intervention took place over a period of 3 months at Delft South ARV clinic and 1 month at Elsies River TB clinic from July 2008-October 2008.

The aim of the pre-intervention study was to assess patient perceptions towards the pharmacist and knowledge of their TB/HIV treatment. Data was collected from questionnaires used during semi-structured interviews that lasted for approximately 10

minutes per patient. A total of 19 co-infected patients received the pre-intervention questionnaires.

The aim of the intervention study was to assess the effect of the pharmacotherapeutic intervention used on patients receiving TB/HIV treatment. The trained researcher used the intervention tool for 4 months (July to October, 2008) to collect clinical data. A total of 98 co-infected patients from Delft South ARV clinic and Elsies River TB clinic received the intervention.

The aim of the post-intervention study was to assess patient receptivity and effect of intervention on the quality of care provision. Data was collected from 48 patients that had previously received the intervention (trained researcher using specially designed clinic record card) by using questionnaires.

Phase 2

The aim was to assess final year pharmacy students' on their current TB/HIV knowledge and assessment scores of students who received an introductory clinic-based TB/HIV session and those who did not. The researcher designed an assessment and this was used as the sole method of data collection from both the control and experimental students.

1.8. Chapter description

Chapter 2- provides a comprehensive literature review of TB and HIV as co-morbid conditions. This chapter is subdivided into two sections namely section A and B. Section A reviews both quantitative and qualitative literature whilst section B provides the rationale for TB/HIV training for final year UWC pharmacy students.

Chapter 3- provides an overview of the research methods applied during the different phases of this study. It concludes with a schematic representation of the qualitative and quantitative methods used in different phases of this study.

Chapter 4- describes the clinic-based PALSA Plus training that the researcher received. This training equipped the researcher with the clinic insight and procedures required in the management of TB and HIV. This chapter discusses the results obtained during the baseline study conducted at Ravensmead Community Health Centre.

Chapter 5- describes the design and implementation of the intervention tool (clinic record card) at Delft South ARV and Elsies River TB clinics. It concludes with an outline of the clinic-based TB/HIV training conducted by the researcher to the final year pharmacy students.

Chapter 6- provides the results of the pre-intervention, intervention and post-intervention phases. The quantitative results are expressed as numbers and where applicable tabulated whilst the qualitative data were complied from observations, interviews and semi-structured questionnaires.

Chapter 7- this chapter discusses the implication of findings from the preintervention, intervention and post-intervention phases to the patients, HCPs and final year pharmacy students.

Note: In this thesis, as a participant observer I mimicked the role of a trained pharmacist, where I engaged with clinic staff and patients to explore a clinic-based TB/HIV intervention.

Use of personal pronoun

In this thesis, the terms researcher and "I" will be used interchangeably.

Use of numbers

In this thesis, numbers less than ten are written in words and those greater than ten are written in numbers.

Referencing

The bibliography follows the Harvard style of referencing. Referencing is by first author (where available) and year of publication in parenthesis in the text.

CHAPTER 2: LITERATURE REVIEW

This chapter is divided into two sections namely section A and B. Section A reviews the epidemiology of TB and HIV, transmission of TB, prevalence and incidence rates for TB, the burden of co-infection, and the treatment challenges in children with TB. I review the South African health system including primary healthcare in the Western Cape, and discuss the barriers that are encountered in practice. I outline the clinical management of TB/HIV, drug strategies used to improve adherence and ART initiation in patients with TB. Finally, I discuss the views of other healthcare professionals in TB/HIV management. Section B assesses the current status of undergraduate (final year) pharmacotherapeutic training in TB/HIV management.

Section A

2. TB and HIV: Epidemiology

It is estimated that about one third (2 billion) of the world's total population has latent tuberculosis, caused by the pathogen belonging to the *M. tuberculosis* complex, primarily *M. tuberculosis* (Koch's bacillus), and rarely *Mycobacterium bovis* or *M. africanum* (Raviglione MC *et al*, 1995; Aaron L *et al*, 2004). From the world's population, 8-9 million cases of active TB emerge annually, resulting in 2-3 million deaths (Snider *et al*, 1994). The highest incidence rate is seen in sub-Saharan Africa, the Indonesian and Philippine archipelagos, Afghanistan, Bolivia, and Peru (Chan ED, and Iseman MD, 2002). Thus TB remains the single biggest killer in developing countries (UNAIDS 2002). Globally, the HIV and TB epidemics are stroking each other, creating a public health crisis of enormous proportions. It was estimated that at least 10.7 million persons were co-infected with HIV and TB (1997), and that HIV-1 patients represent 8% of the worldwide total of TB cases (Dye C *et al,* 1999). Because of the infectious nature of TB, it remains an ongoing public health concern.

The Joint United Nations Programme on HIV/AIDS (UNAIDS), estimated that out of the 42 million people living with HIV/AIDS globally, 70% (29.4 million) were in sub-Saharan Africa. Twenty-three sub-Saharan African countries had an adult HIV

seroprevelance rate (1999) greater than 5%, superceeded only by Haiti. Eight of these twenty-three countries (all in Southern Africa), showed that the adult HIV seroprevelance rate was above 15% and that sub-Saharan Africa bears most of the overwhelming burden of the HIV/AIDS epidemic (UNAIDS, 2002).

Transmission of TB

TB commonly affects the lungs but can cause disease in any part of the human body. It spreads by airborne route through inhalation of droplet nuclei and transmission can occur in several ways:

- When a patient who is already infected has a productive cough for 2 weeks or more,
- Living with someone infected with pulmonary TB in a place where there is no cross- ventilation, where windows are small or closed most of the time, or
- The longer one stays with an infected person who coughs, the more likely one is to become infected with TB (National Department of Health, April, 2007).

Clinical signs and symptoms of TB include; chronic cough (≥ 2 weeks), weight loss, coughing up blood, chest pains, drenched night sweats, tiredness and weakness of the body, and loss of appetite.

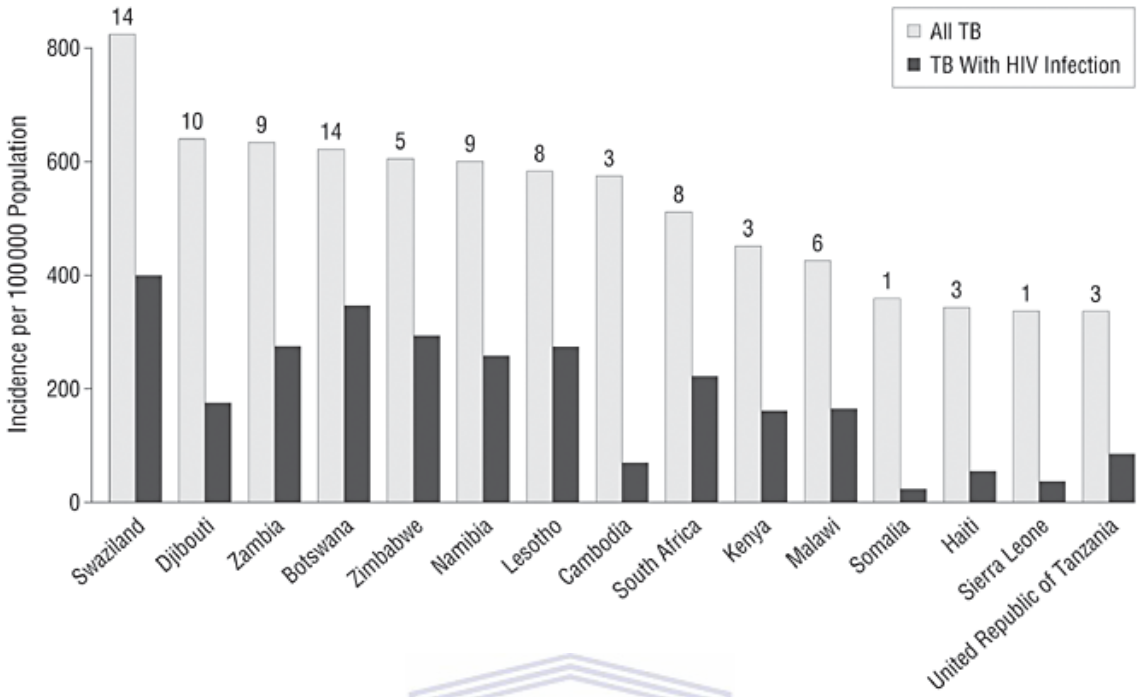
Transmission of HIV

The main routes of HIV transmission vary between regions. The main routes of transmission of HIV in sub-Saharan Africa are through sexual intercourse, blood and from mothers to their infants. Blood borne HIV transmission occurs through contaminated blood transfusion, injections with contaminated needles and syringes, and the use of non-sterile skin-piercing instruments (Harris A *et al*, 2004).

2.1. Prevalence and incidence of TB

In spite of increasing knowledge and control measures (e.g. **STOP TB** strategy), there has been a resurgence of TB in many parts of the world, a situation that led the World Health Assembly (1993) to take the extraordinary step of declaring TB a global emergency (Buso DL *et al*, 2000; Afari-KT *et al*, 2005). Although the incidence of TB has declined in developed countries (North America and Western Europe), detection rates in Southern Africa have increased mainly because of immigration, HIV/AIDS, and the neglect of tuberculosis control programmes (Cantwell MF *et al*, 1992; Burwen DR *et al*, 1995).

South Africa (SA) has one of the highest annual TB incidences in the world. SA reported 302 457 cases of TB which translates to an incidence rate of 645 per 100 000 population in 2005 increasing to 342 315 in 2006 (National Department of Health, 2007-2011). In 2006, 27,017 TB clients were registered with an incidence of 867 per 100,000 population (City Health: TB in Cape Town). As the HIV epidemic in SA progresses, the incidence of new cases of TB continues to increase because an individual's susceptibility to TB is increased from the time of HIV infection. SA is ranked among the top 5 of 15 countries with the highest estimated TB incidence rates per capita (all ages) and their corresponding incidence rates of HIV infected TB. Graph 1 below shows the percentages (numbers above the bars) of *Mycobacterium tuberculosis*–HIV co-infection (Corbett EL *et al*, 2003). Therefore, concerted efforts from healthcare professionals are needed to manage patients who are diagnosed with these diseases. Regular monitoring and evaluation of treatment outcomes is cornerstone to care provision.



Graph 1: Fifteen countries with the highest estimated TB incidence rates per capita (all ages) and their corresponding incidence rates of HIV infected TB (Corbett EL *et al*, 2003).

2.2. Burden of co-infection with TB and HIV

Nelson Mandela on July 15, 2005 in a media briefing on 'Confronting the joint HIV-TB Epidemics' stated that ' *The world has made defeating AIDS a top priority. This is a blessing. But TB remains ignored. Today we are calling on the world to recognize that we can't fight AIDS unless we do much more to fight TB as well*.'

TB is a major cause of morbidity and mortality worldwide and the situation is worsened by the HIV pandemic (Pedro C *et al*, 2003; 106). TB is by far the most common opportunistic infection diagnosed during the first three months on ART — particularly in Africa. Two hundred thousand people with HIV die of TB each year, again, most of them in Africa (Smart T, 2007).

Recent data from WHO/STOP TB Partnership shows that globally 14 million people are co-infected with TB and HIV but around 80% of those who are co-infected live in Sub-Saharan Africa. In Sub-Saharan Africa, the incidence rates of TB increased from 146 per 100 000 (1990) to 345 per 100 000 (2003) due to HIV (WHO report, 2005).

Five million of the 40 million people infected with HIV worldwide are in SA, amounting to approximately 10% of the population (Benatar SR, 2004). TB remains the most common opportunistic infection and cause of morbidity and mortality in HIV-infected South Africans (Rowe KA *et al*, 2005). The emergence of multi-drug resistant TB (Medical Research Council, 2000) imposes an additional burden to the health system in resource-limited countries. The World Health Organization (WHO, 2005) stated that as a result of HIV, SA was ranked seventh out of 22 high burden TB countries (defined as countries that contribute 80% of the total global TB burden) and had the fifth highest number of notified TB cases in the world. In this same year, the annual incidence of TB was 536 per 100 000 with 61% of patients diagnosed as having both TB and HIV (WHO report, 2005; National Department of Health, 2007-2011).

Changes in TB notification data from a Cape Town peri-urban township over the last 10 years reported that HIV adult seroprevelance has increased from 8% (1996) to 23% (2005) indicating the impact of HIV on a TB clinics (Lawn SD *et al*, 2006). During this period TB incidence rates increased 4.75-fold from 400 per 100 000 to 190 000 per 100 000 (1999-2005), with the highest increase occurring in 20-40 age groups (Wood R, 2007).

An annual TB/HIV co-infection showed an incidence of 2.7%, with an estimate of 1.5% in males and 3.6% in females. The prevalence of HIV was found to be 13.3% in females and 8.2% in males (HSRC, 2005). This statistic clearly shows that TB/HIV prevalence is higher in women than in men. Such an enormous disease burden underpins the need for collaborative efforts from healthcare professionals to explore management strategies to combat the growing epidemic.

2.3. Children and TB: Challenges

TB remains one of the major diseases afflicting children worldwide, with approximately 1 million new cases and 400 000 deaths per year (WHO *guidelines for national TB programs on the management of TB in children*, 2006). ART in children follows the same principles as in adults. The main differences are that dosing is more complex, and

requires careful titrations. Dosing is often based on surface area, and liquid formulations require exact measurements. Since there are no fixed dose combinations suited for children yet, frequent re-adjustment of dosing is necessary. Liquid formulations are problematic in that they often have an unpleasant taste, and in some cases involve administration of large volumes of liquids. Dosing also involves the use of syringes for liquid formulations and it requires special attention by the caregiver when drawing the correct volume and expelling excess air (Southern African Journal of HIV Medicine, Antiretroviral therapy in children, 2005: 18-19). Children were excluded from this study because of the complexity involved in dosing and the level of specialized care required by well-trained healthcare professionals.

2.4. The South African Healthcare system

The South African healthcare system comprises of both private and public health sectors (Geyer SN *et al*, 2002). Although the state contributes about 40% of all expenditure on health, only 11% of the government's budget is allocated for healthcare and the public health sector is therefore under pressure to deliver services to about 80% of the population. The healthcare delivery system of South Africa is based on a comprehensive primary healthcare approach with an expanded district-based system of care. Most health professionals work in private sector hospitals except for the majority of nurses who are employed in the public sector (Benatar SR, 2004; South Africa .info, 2007). An added strain on the South African healthcare system is the continual loss of its trained doctors and nurses who are highly sought after in other countries (DOH, 2007; South Africa .info, 2007). Therefore public sector healthcare facilities are severely understaffed.

2.4.1. Primary Healthcare in the Western Cape

Primary healthcare (PHC) is the backbone of the South African healthcare system and local authority clinics (City Health) renders primary healthcare services through the district health system. PHC services rendered include amongst others: HIV/AIDS treatment, care programmes and TB control programmes.

In SA, TB is managed by nurses employed by Local Authority/ Municipal health clinics. Cape Town is a city of extremes with 86% of the population uninsured and reliant on public health services. Even though the City of Cape Town's eight health sub-districts boast the best rate of curing TB in SA, there are 25, 000 people in the city metro area that have TB. About two-thirds of these people are also living with HIV and AIDS. The city's health directorate uses the World Health Organization's DOTS method in its 93 clinics and they work closely with the TB Care Association and other non-governmental organizations to recruit and train TB treatment supporters. These supporters visit patients at home or observe them taking their treatment in the clinics. (www.capetown.gov.za/health: TB in Cape Town).

2.4.2. Health services barrier to TB/HIV management

The proposed ARV plan of the Department of Health requires 28 doctors to treat every 10 000 patients. The public health system requires 1 400 additional doctors to handle the target of 500 000 patients on ARV, excluding other professionals such as pharmacists and nurses. Inadequate resources and the burden of the disease already challenge the healthcare system. Recruiting medical practioners is difficult; therefore it is vital that other healthcare professionals be collectively involved to make a substantive contribution to HIV/AIDS management (Department of Health, 2003; www.aidsmap.com, 2003). Integration of services may help overstrained health systems to cope with the unparalleled dual burdens of the TB and HIV epidemics.

HCP's and Patients: barriers

A major barrier to accessing free government-provided antiretroviral treatment (ART) in SA is the shortage of suitably skilled health professionals. Despite efforts to improve quality of care for these patients, many fail to complete their treatment as prescribed. Poor rapport between health care providers and patients with TB is a major reason for non-adherence to treatment (Dick J *et al*, 2004).

In SA, the shift in service delivery from inpatient services to outpatient services and from hospitals to clinics increases the workload in PHC services (Quinlan T, and Veenstra N, 2007). Public-sector nurses are extremely overloaded and the emergence of deadly diseases such TB and HIV/AIDS in the wake of the already burdened public health care system contributes further to their workload since patients with these illnesses generally require more specialized care and long-term treatment than other patients (Pillay R, 2009). An increased workload among nurses resulting from the severe staff shortage as well as increased demand for care has led to burnout (Cameron SJ *et al*, 1994).

2.5. Clinical management of TB/ HIV

In SA management of TB is mainly done at the primary healthcare (PHC) level and nurses at the primary level manage approximately 90% of TB patients at clinics (Department of Health, 2000; Dick J *et al*, 2004). These clinics also arrange for people suffering from TB to receive treatment at their place of work away from the community. Nurses provide clinical services such as screening new suspects for TB, treating and tracing TB contacts, giving preventive treatment (BCG vaccine) to children who have been exposed to TB and providing social assessments.

2.6. Approaches to TB drug treatment

WHO and the International Union against Tuberculosis and Lung Disease (IUATLD) recommend the use of fixed-dose combinations for the treatment of TB. Fixed-dose combination tablets include two or more drugs within the same tablet. The use of four drug combinations for the treatment of TB includes rifampicin, isoniazid, ethambutol and pyrazinamide known as Rifafour®. The advantages of fixed drug combinations are as follows:

- An increase in compliance as patients having fewer pills to swallow, thereby making treatment easier to take orally and it reduces the likelihood that people will split doses or only take some of the pills they have been given.
- Reduction in the emergence of drug resistant-TB by ensuring that more than one drug is used and reducing the occurrence of incorrect drug selection.

2.6.1. Cotrimoxazole Prophylaxis Therapy (CPT)

Co-trimoxazole is given routinely for the prevention of opportunistic infections in HIV-infected patients. Co-trimoxazole is a fixed dose combination of Sulfamethoxazole and Trimethoprim. This combination is also referred to as Bactrim® and is a broad spectrum antibiotic that kills a range of gram-positive and gram-negative organisms, fungi, and protozoa. Co-trimoxazole is given to TB patients for the entire duration of their treatment.

2.6.2. TB treatment regimens

The National Tuberculosis Control Programme decides upon TB regimens in South Africa. These regimens are based on the characteristics and proven efficacy of the medicines, although regimens may deviate from this for special circumstances e.g. known resistance, pregnancy, treatment of children.

Table 1.1: Commonly used abbreviations for TB drug treatment

Isoniazid	H	INH
Rifampicin	R	RIF
Pyrazinamide	Z	PZA
Ethambutol	E	EMB
Streptomycin	S	SM

2.6.3. Pharmacological properties of individual anti-TB drugs

Isoniazid (INH)

This drug is highly bactericidal and is given orally once a day. It is safe to use during pregnancy. It is more likely to cause hepatotoxicity than any other first-line anti-TB drug. Peripheral neuropathy can occur due to INH-induced Vitamin B6 (pyridoxine) deficiency especially in pregnant or undernourished patients, alcoholics, and the elderly. However, a daily dose of pyridoxine (25-50mg) can prevent this.

Rifampicin (RIF)

This drug is also bactericidal which is given orally and is well absorbed. It is used because it eliminates dormant organisms in macrophages that cause late relapse and is

given throughout therapy. It adds slightly to the hepatotoxicity of INH but is also safe during pregnancy. A common adverse effect is discoloration of urine and is a potent hepatic enzyme inducer.

Pyrazinamide (PZA)

It is bactericidal and is also given orally. It is given to prevent the development of resistance to RIF and shortens therapy to 6 months when used during the intensive initial 2 months of treatment. Main adverse effects associated with PZA are gastrointestinal upset and hepatitis. This drug is contraindicated in pregnancy.

Ethambutol (EMB)

This drug is the best tolerated of all four anti-TB first line drugs. It is bactericidal and is also taken orally. Its main adverse effect is optic neuritis at high doses.

Streptomycin (S)

It is the most commonly used aminioglycoside and is also bactericidal. It is contraindicated in pregnancy because of damage to the 8th cranial nerve in the fetus. Its main side effect is ototoxicity.

2.6.4. Pharmacological properties of individual ARV drugs (SAMF, 8th edition; 322-328)

Lamivudine- this drug is a NRTI used for the treatment of HIV infection, reduction of peri-natal transmission of HIV, post-exposure prophylaxis, in combination with other ARVs. Common adverse effects include peripheral neuropathy and pancreatitis.

Stavudine- this drug is also a NRTI used for the treatment of HIV infection, in combination with other ARVs. Adverse effects include lipo-atrophy of the face and limbs, peripheral neuropathy, pancreatitis and other CNS effects such as headache and haematological side effects.

Zidovudine-this drug has the same indications as Lamivudine and is also a NRTI. Adverse effects are dose-dependent and are more frequent and severe in advanced HIV disease. Common haematological effects include anaemia, leucopenia or neutropenia.

Efavirenz- this drug is a NNRTI used for the treatment of HIV infection, in combination with other ARVs. Adverse effects include hypersensitivity rashes and common CNS effects include abnormal dreams.

Nevirapine- this drug is also a NNRTI and has been commonly used for the reduction of peri-natal transmission of HIV. Common adverse effects are rash which appear in the first six weeks of therapy.

2.6.5. TB treatment phases

Standard adult treatment regimens for newly diagnosed pulmonary TB patients start with an initial (or intensive) phase. This phase consists of four first-line drugs, which are rifampicin, isoniazid, ethambutol and pyrazinamide. These drugs are taken orally for two months. This is followed by a continuation phase of 4 to 6 months normally consisting of oral treatment with rifampicin and isoniazid. For re-treatment pulmonary TB patients classified as relapses or defaulters, the two phases are of longer duration as follows:

The duration of the *Intensive phase* is 3 months with oral treatment consisting of R, H, E, and Z (see table 1.1) plus the intramuscular administration of streptomycin (S) during the first two months. *The continuation phase* consists of R, H and E given for 5 months. The aim of the continuation phase is to ensure that after reducing the bacterial burden of the infection, the TB patient is further sterilized against recurrence of the disease.

Revised Treatment Drug Regimens for TB patient

This is a policy developed by the National TB control programme to give TB treatment seven days a week in both the intensive and continuation phases. The following are guidelines used in the treatment of TB for the year 2007:

- Dosages needs to be adjusted based on weight gain,
- Cure of the new Pulmonary TB (PTB) patients depends on taking Regimen 1 for 6 months (Table 1),
- Cure of the re-treatment PTB patients depends on taking Regimen 2 for 8 months (Table 2),
- All TB patients should receive clinic DOT for the first 2 weeks of treatment,
- TB patients must be supervised for the full duration of their treatment either at the clinic or by a community treatment supporter or a workplace programme,
- All retreatment TB patients must receive treatment at the clinic Monday to Friday, for the first 2 months of the intensive phase.

Regimen 1: New Adult Patients (SAMF, 2008:302)

A new case is a patient who has never been treated for TB in the past or who has taken treatment for less than 4 weeks. Drug treatment must be taken for at least 6 months.

Pretreatment Body Weight	**Two Months Intensive Phase Given Seven Days A Week**	**Four Months Continuation Phase Given Seven Days A Week**	
	RHZE (150, 75, 400, 275)	RH (150, 75)	RH (300, 150)
30-37 kg	2 tabs	2 tabs	-------
38-54 kg	3 tabs	2 tabs	-------
55-70 kg	4 tabs	-----	2 tabs
≥71 kg	5 tabs	------	2 tabs

Regimen 2: Retreatment Adult Cases (SAMF, 2008:303)

These are patients previously treated for TB or returning for treatment after cure, completion, default or failure.

Pretreatment Body Weight	**Two Months Intensive Phase Given Seven Days A Week**		**3rd Month Initial Phase Seven Days A Week**	**Four Months Continuation Phase Given Seven Days A Week**			
	RHZE (150,75,400,275)	Streptomycin [g]	RHZE (150,75,400, 275)	RH (150,75)	E (400)	RH (300,150)	E (400)
30-37 kg	2 tabs	0.5	2 tabs	2 tabs	2tabs	-------	-----
38-54 kg	3 tabs	0.75	3 tabs	3 tabs	2tabs	------	-----
55-70 kg	4 tabs	1.0	4 tabs	-------	-----	2 tabs	3tabs
≥71 kg	5 tabs	1.0	5 tabs	-------	-----	2 tabs	3tabs

2.7. Treatment adherence strategies

From a public health sector point of view it is critical to stop both the spread of TB to others, and the development of drug resistance. A number of strategies aimed to improve adherence has been successfully implemented in hard-to-reach populations, especially in areas where TB is an endemic. These include the DOT and DOTS strategies.

2.7.1. *DOT versus DOTS*

Directly Observed Treatment (DOT) is currently the most recommended adherence method. DOTS on one hand stands for Directly Observed Treatment Short-course and refers to the WHO's comprehensive internationally recommended policy package for TB control. On the other hand, DOT is an element of DOTS and is a strategy having all of a TB patient's medicine doses observed by a designated person that could be a health care worker, or trained and supervised community member to help ensure adherence to

therapy (Practical Pharmacy for developing countries, 2008). The DOTS strategy has been implemented in SA since 1996 (Department of Health, 1996).

2.7.2. *Effectiveness and non-effectiveness of DOT*

DOT increases the likelihood that full treatment course will be completed from 61% to 86% (The Merck Manual Professional, November 2005). The rapid decline of TB incidence rates in the United States from a peak of 10.5 cases per 100,000(1992) to 5.8 cases per 100,000 (2000) has been attributed to DOT (Pedro C *et al*, 2003; 107). From 1995 to 2000, the incidence rate of TB in the United States fell by an average of 7.8% per year (Chan ED, and Iseman MD, 2002). Even though the principles of DOT has led to significant treatment success rates for both TB and HIV diseases (Chaulk CP, and Kazandjian VA, 1998; Weis SE *et al*, 1994), the role of DOT within the TB/HIV co-infection context still requires further evaluation (Pedro C *et al*, 2003;121).

2.8. Clinical criteria for initiating anti-retroviral therapy (ART) in TB patients

As at the time of this study, the guidelines for initiating TB treatment in HIV-positive patients are as follows; If the patients CD4 count is >200cells/$mm^{3,}$ ART is commenced after completing TB therapy provided that the patient fulfils the criteria above. In other words, the CD4 count must be < 350cells/ mm^3 i.e. between 200 and 350cells/ $mm^{3.}$ If the CD4 count is <200cells/ mm^3 then ART treatment should be delayed until the intensive phase of TB therapy (2 months) has been completed unless the patient has other serious HIV- related illness or has a very low CD4 count (< 50cells/mm^3). In such a case, ART should be introduced once the patient is stabilized on TB therapy at around 2 weeks *(SAMF*, 2008). However, the 2010 guidelines states that the CD4 count should now be at 250 cells/ mm^3 to start ARV treatment (SAMF, 2010). The South African HIV Clinicians Society guidelines states that TB should always be managed by public sector TB clinics (*The Southern African Journal of HIV Medicine*, 2005: 26). Its guidelines for starting ART when patients are already on anti-TB therapy depends on the patients ART regimen and CD4 count. Both anti-TB therapy and ART are complex regimens that require regular monitoring. Co-infected TB/HIV patients receiving dual therapies would therefore rely on the pharmacist to optimize care provision.

2.9. Role of the Pharmacist in TB/HIV management

In view of the increasing TB/HIV co-infection pandemic, the pharmacist is ideally suited to work alongside other health practitioners especially the nurse. The World Health Organization has supported the notion that pharmacists should expand their role in the general healthcare system. This entails interacting with the healthcare team, interviewing and assessing patients, making specific therapeutic recommendations, monitoring patient responses to drug therapy and providing drug information (World Health report, 2006). Pharmacists can also work alongside nurses to interview and assess patients, a role outlined by the Doncaster model and other authors (Dayton C.S., 1978; Andalo D, 2002). They can be flexible in adapting to different situations, which includes working outside a pharmacy setting with a range of HCP's, and having direct TB patient involvement (Rennie, TW, and Bates, IP, 2009).

Zappa (1999) conceptualised a new model for pharmacists in HIV management that concentrated on drug-related activities, information provision and patient confidentiality. Findings from the Van der Walt (2006) study indicated that other healthcare professionals perceived an expanded role for pharmacists in HIV management beyond that of a drug supplier (Zappa AJ, 1999; Van der Walt E, and Summers RS, 2006). The South African Pharmacy Council's Position Paper clearly underpins the role and need of the pharmacist in TB management to help curb the epidemic (2003). However, documented evidence of a patient-centered role for pharmacists is not yet available. According to the Van der Walt's study, a comparison of defined roles for pharmacists in HIV management is outlined in table 1.2 (Van der Walt E, and Summers RS, 2006).

Table 1.2: Comparison of defined roles for pharmacist in HIV management

Zappa (1999)	**SA Pharmacy Council Criteria (2003)**	**Responses of Van der Walt survey (2006)**
Responsible for all drug-related activities	Supply ARV's, manage tuberculosis and treatment of opportunistic infections	Dispense medication Be aware of side effects and drug interactions Counsel patients on correct use of medication

Supply products, services and information in one place	Provide prevention, treatment, care and support services	Provide post-exposure prophylaxis
Focus on education, prevention and screening programmes	Provide voluntary testing and counselling	Do pre-test counselling
Include services of a nutritionist and nurse, and complement services provided by the medical doctor	Monitor complications and referrals for medical intervention	Pharmacies as HIV information centres Pharmacies as registered preferred HIV treatment providers
Ensure patient confidentiality	Ensure patient confidentiality and privacy	

While the literature underpins a role for the pharmacist, newly qualified graduates are also expected to be competent care providers in TB and HIV management. Therefore, a review of undergraduate pharmacy training would provide insight into current teaching on TB/HIV at an academic institution.

The dynamic nature of the pharmacy profession necessitates continual revision of undergraduate training to meet both changing and challenging health needs (Smith, Coons & Quinns, 1990). The University of the Western Cape's (UWC) School of Pharmacy's TB/HIV programme (2009) was reviewed for the purpose of this study.

Section B

2.10. Current teaching practice of TB/HIV at UWC School of Pharmacy

In the UWC undergraduate pharmacy curriculum, basic pharmacology is introduced in second year. Systemic pharmacology taught in third and fourth (final) years covers a range of common clinical conditions including TB and HIV. Classroom teaching which is largely didactic is supplemented with practical exposure at hospitals and Community Health Centres. These consist of the Clinical Block and the Service Learning in-pharmacy modules. However, education about TB and HIV should extend beyond traditional didactic methods (Chaulet P, 2007). The objectives of the Clinical Block are to develop skills in assessing treatment plans, counselling of patients and interacting with

healthcare professionals at district and tertiary hospitals. Service learning provides opportunities for students to both deepen their mastery of the technical skills and knowledge-base in pharmacotherapy, pharmacy practice and pharmaceutics while also developing social responsibility among students. Final year students at CHCs and hospital pharmacies fill prescriptions, dispense, manufacture compound, and pre-pack medicines (Pollack S, 2008).

2.11. Evaluation of the Service learning in- Pharmacy (SLIP) module at UWC

An independent evaluation of the SLIP modules indicated that despite the fact that each student spends 3 weeks a year in hospital pharmacies through the SLIP programme, there is still the lack of "socially responsible, patient –centered" practice and direct interaction with patients, doctors, nurses, and other healthcare professionals (Pollack S, 2008). A further deficiency in the current SLIP program is that rotation of students is limited to the provincial hospitals and CHCs. Primary healthcare clinic that provides integrated care for TB and HIV patient's i.e. ARV clinics are not included as learning sites.

By interacting directly with patients in the clinics or private counselling area, students can obtain a deeper understanding of the range of barriers such as cultural, socio-economic, gender, racial including those affecting HIV/AIDS and TB. From these patient-centered discussions, interventions can be developed to address the healthcare needs of diverse communities (Pollack S, 2008). Since learning generally occurs through experiencing the activities and cultural norms of the discipline, it is essential that students become exposed to real situations in TB and HIV clinics. Exposure of students to primary healthcare TB/HIV clinics will enable them to focus on the development of professional and social skills that are necessary in real life situations.

TB and HIV impose an increasing burden on the health system. Complex drug therapies require regular monitoring of patients to prevent resistance and relapse. Concerted efforts from pharmacists are required at primary healthcare clinics to screen, monitor and evaluate TB and HIV treatment outcomes. In preparing graduates for the work

environment, pharmacotherapy and service learning modules are cornerstone to developing knowledge and skills in clinic-based TB/HIV care.

CHAPTER 3: RESEARCH DESIGN AND METHODOLOGY

This chapter outlines the research methods used in this study. I discuss triangulation as an approach used to combine data obtained from both quantitative and qualitative methods. I describe the study sites and provide an overview of the study population. The effect of the intervention (described in chapter 5) was evaluated using evaluation methods namely programme and summative evaluations. This chapter concludes with an algorithmic and schematic representation of the research design used in the different phases of this study.

The primary aim of this study was to assess current practice patterns in the management of TB and HIV amongst co-infected patients (Phase I). The secondary aim of the study was to ascertain the need for an undergraduate TB/HIV clinic-based training for final year pharmacy students (Phase II). In order to meet these objectives it was necessary to engage with the management of the primary healthcare clinics at the City Health department of the Tygerberg Sub-district, Cape Town (2008). The researcher who is an academic intern at the School of Pharmacy, UWC required in-depth insight and knowledge into clinical procedures in TB/HIV primary healthcare clinics. A meeting was held to outline the purpose and objectives of the study, and to seek a participatory approach in implementing the intervention (chapter 4, section 4.1). A TB coordinator of the Tygerberg Sub-district was subsequently assigned to train the researcher using the same approach when training and updating clinical nurse practitioners at primary care clinics on TB and HIV care provision. The TB coordinator used the PALSA Plus training materials and training approach. The contents and training style of PALSA Plus is outlined in chapter 4.

The main qualitative method of data collection was through interviews and participant observations whilst the quantitative data was collected from survey responses and these noted as numbers and analyzed. The research design chosen allowed the use of mixed methods throughout the different phases of study namely the pre-intervention, intervention and post-intervention phases.

Phase I study

3. Description of research sites

The study sites namely Ravensmead CHC, Delft South ARV clinic, and Elsies River TB clinic were chosen because they are located in the Northern suburbs and are of close proximity (about 25km) to the University of the Western Cape. Further, they are typically representative of care offered by most primary healthcare clinics in the Western Cape. Ravensmead CHC mainly provides care for TB patients and this site was used for the baseline study to assess current practice patterns in TB management (see chapter 4). Delft South ARV clinic provides integrated care for both TB and HIV patients and was used for implementation and evaluation of the intervention. Elsies River is mainly a TB clinic and caters for a very small number of HIV-positive patients and was used as an add-on site. A brief description of the community profile is provided for each of the research sites.

3.1. Ravensmead Community

Ravensmead community consists of predominantly lower income coloured earners whose language preference is Afrikaans. Ravensmead was chosen as a study site because it has a very high TB load. The rate of registered new-smear positive TB cases increased from 228 per 100 000 in 1994 to 299 per 100 000 in 1998 and to 341 per 100 000 in 2002 (Statistics South Africa: Western Cape, 2001; Western Cape Tuberculosis Programme, 2002; Boon SD *et al*, 2007).

3.1.1. Ravensmead CHC

This CHC is targeted at TB patients however there is a small proportion of patients co-infected with TB and HIV. The CHC operates 5 days a week but weekend TB regimen is given as packages to TB patients.

Following the PALSA Plus training the researcher's first clinical observation took place at Ravensmead CHC to obtain baseline knowledge and views about current practice

patterns in order to prepare for the pre-intervention, implementation of the intervention, and post-intervention phases of the study (see chapter 4).

3.2. Delft South Community

The Delft community is predominantly coloured (75%), with a minor population of Black Africans (25%). This community is split into two sections: Delft and Delft South. There is a 44% unemployment rate from the economically active total population of 24,000. Over half (58%) of the residents have a yearly household income of R0 – R19,200 and over a third (38%) with R19, 201 – R76,800, an indication of the income disparity in this area. Many people in the community come from the Eastern and Western Cape provinces while others have immigrated from other African countries such as Nigeria and Somalia (www.capetown.gov.za/Censusinfo/Census2001/).

3.2.1. Delft South Clinic

The Delft South clinic was the main site used for this study because it is an integrated clinic that offers services for TB and HIV co-infected patients. The clinic has been active since June 2006 and provides care to about 150 clients per day. The clinic has a total of five nursing sisters working five days a week, and a dedicated TB doctor that visits once a month. It offers a nurse-based service with a promotive and preventative focus. About 140-150 people are tested for HIV per month, with about 30 patients testing positive many of which are expectant teenage mothers. The most common health problems handled by the clinic are HIV, TB, and sick babies especially in winter. The facility consists of 17 consultation rooms, three treatment rooms and ample waiting areas (www.capetown.gov.za/Censusinfo/Census2001/).

In this study, patients were recruited and interviewed in one of the consultation rooms. Since clinic nurses and DOTS supporters use a dedicated TB room for consultation of TB patients exclusively, recruitment of co-infected TB and HIV patients in this study was done in the consultation room occupied by the adherence counsellor who usually attends to TB patients and co-infected TB/HIV patients. Delft South ARV clinic consists of English and isiXhosa speaking patients, it was necessary to contract a translator who is

fluent in both languages to assist with post-intervention data collection at the clinic because the researcher was fluent in only English.

3.3. Elsies River Community

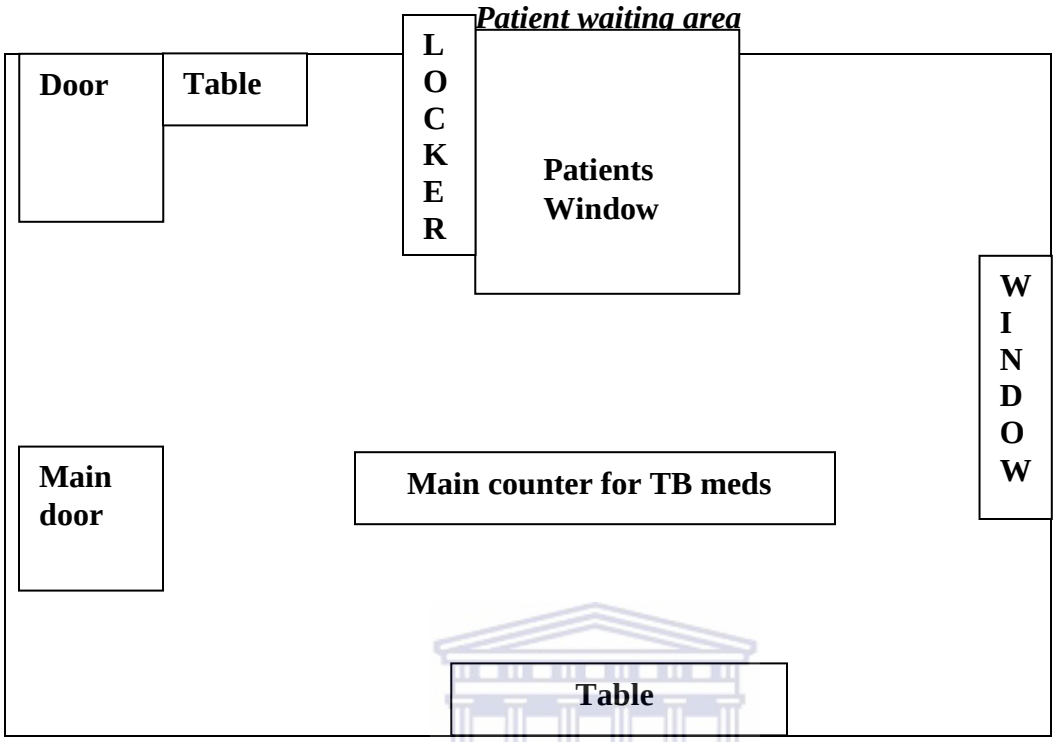
Elsies River is predominantly a coloured community (92%). The population has approximately 40,000 people, among which 34% are unemployed. Generally, wages are low with majority of the income ranging from R0–R1, 600 per month. Although the community has 14 primary schools and six high schools, problems with drug addiction, prostitution and alcohol abuse reduce the high school graduation rate (www.capetown.gov.za/Censusinfo/Census2001/).

3.3.1. Elsies River Clinic

A doctor visits the clinic once a week attending to only TB patients. Elsies River clinic offers family planning, HIV and TB testing and counselling, postnatal care, and basic health. About 85-90 patients are tested for HIV per month, with an average of 5 testing positive per month. Relatively few patients test positive for HIV in Elsies River, but TB, STIs and teenage pregnancy are very common in the area. The staff roles and responsibilities at Delft South ARV clinic and Ravensmead CHC deviate slightly but generally duties are similar across both clinics.

The duties performed by the various HCP's at Elsies River TB clinic were closely related to those performed by the HCPs at Ravensmead CHC. However, duties performed by the HCPs at Delft South ARV clinic were of no resemblance to those at Ravensmead and Elsies River clinics. The reason being that both Ravensmead and Elsies River clinics provided services to mostly TB patients whilst Delft South ARV clinic provided integrated care for TB patients (in the TB room) and those co-infected with TB and HIV (consultation rooms).

Figure 3.1: Layout of Elsies River TB room



The layout for Elsies River TB room is similar to that of Ravensmead TB room (see chapter 4, figure I) probably because both clinics are TB clinics and are staffed by mainly clinic nurses and DOTS supporters. The locker has four compartments numbered one to four. The first locker contains folders of patients attending the clinic daily. The second locker contains folders of daily patients and TB defaulters. The third locker contains folders of patients attending the clinic weekly, monthly and patients from other clinics. The fourth locker contains folders of patients receiving DOTS outside the clinic.

3.4. Study population

Patient recruitment from PHC clinics

For phase I of the study, the study sample for assessing current practice in TB/HIV management consisted of TB patients from Ravensmead CHC, and TB/HIV co-infected patients recruited from Delft South ARV and Elsies River TB clinics. In addition, HCP's namely the clinic nurse, adherence counsellor and TB doctor were approached to participate in this study. For phase II of the study final year pharmacy students were recruited from UWC.

Phase II study

3.4.1. Recruitment of final year pharmacy students from UWC

The final year pharmacy class of 2009 was made up of 72 students. Forty-four of these students were randomly assigned into 2 groups namely control and experimental groups. The control group had 37 students whilst the experimental group had seven students. The researcher approached a senior academic staff member and informed them about the purpose and objectives of the study. The academic staff member agreed to offer a teaching slot where half of the class was expected to undertake an assessment on TB/HIV management. The remaining half of the class had already been assessed in the first term and an assessment on TB/HIV was due for the remainder of the class. The purpose was to assess the current knowledge of TB/HIV and to determine the need for a clinic-based programme for undergraduate pharmacy students. The experimental group (n=7) students received an introductory clinic-based TB/HIV training during the July school vacation (2009) from the trained researcher. The control student group (n=37) students received the usual classroom based TB/HIV programme. It was not possible to obtain participation from the entire class because of the intensive academic programme.

3.4.1.1. Inclusion criteria for clinic-based study

Phase I study

- TB and HIV co-infected patients attending a City Health clinic diagnosed and receiving treatment for at least 1 month ,
- Other participants that provide health services at each of the primary healthcare clinics namely the clinic nurse, adherence counsellor and TB doctor.

Phase II study

- Final year pharmacy students from UWC (Class 2009).

3.4.1.2. Exclusion criteria for this study

Phase I study

- ARV pharmacist and children

Children were excluded from this study because of the complexity involved with their management and drug therapy (see chapter 2, section 2.3).

Phase II study

There was no exclusion criterion.

For Phase II of this study, final year pharmacy students from UWC's School of Pharmacy (2009) were invited to participate to ascertain the need for a clinic-based TB/HIV training. The aims of the student's assessment were to firstly ascertain their current knowledge on TB/HIV clinic-based management (see Appendix O, questions 1-19d) which served as the main quantitative data. The qualitative data was collected from questionnaires completed by the students (see Appendix O, questions 20-23). Their views on the potential role for pharmacists in a clinical setting were also explored.

3.5. Mixed Methods

For this study a combined research methods termed mixed methods was used. A combined method study can be described as one in which a researcher uses multiple methods of data collection and analysis. An element of combined method could be mixing between methods, drawing on both qualitative and quantitative data-collection procedures and one such example is triangulation.

3.6. Triangulation as a combination of qualitative and quantitative approaches

Triangulation was used as a way of combining the quantitative and qualitative methodologies. Padgett defined methodological triangulation as the use of mixed methods to study a single topic (1998:97) and further describes triangulation in qualitative research as the convergence of multiple perspectives that can provide greater confidence that what is being targeted is accurately captured (1998:32). Most authors agree that in real life, most human based research utilize both quantitative and qualitative

methodology (De Vos AS *et al*, 2005:361). Both quantitative and qualitative methodologies are used in programme evaluation.

3.7. Programme evaluation

Programme evaluation as defined by Patton (2002:10) is the systematic collection of information about the activities, characteristics and outcomes of programmes to make judgment thereof, improve its effectiveness and/or inform decisions about future programming. Programme evaluation assumes the prior existence of a programme or "intervention" designed and developed by someone else, long before the evaluator ever entered the field (De Vos AS *et al*, 2005:367). The programme is the "intervention" and the evaluation is based on an existing programme. The intervention is the independent variable that is being investigated whilst the dependent variable is the criterion with which the independent variable is being evaluated (Fox W, and Bayat M, 2007:79).

For the phase I study, the programme evaluation focused on a clinic-based intervention designed for potential use by trained pharmacists in TB/HIV management. The intervention consisted of a trained researcher who made use of a specially designed TB/HIV clinic record card. For the phase II study, the intervention programme consisted of exposure to an introductory clinic-based session on TB/HIV management.

The overall aim was to determine if a clinic-based TB/HIV programme would make a difference to the quality of care at primary healthcare clinics (phase I study) and if an introductory clinic-based session would demonstrate application of theoretical concepts among students (phase II study).

3.8. Summative evaluation

Summative programme evaluation measures the effectiveness of a programme and is more quantitative. Successful programmes may be replicated and implemented if the designer(s) of the programme can demonstrate scientifically that the programme had positive outcomes. Summative evaluation compares the "intervention group" with the

"no intervention group" to assess any positive change in the former (Kagee A *et al*, 2006: 61).

Since phase I of the study focused on assessing TB/HIV management among patients who received the intervention, quantitative data obtained from those who received the intervention were compared with those patients who did not. Therefore the summative evaluation was employed to assess care provision between the two groups. For phase II of the study scores of students who received the introductory clinic-based session and those who received the usual classroom based teaching on TB/HIV management were assessed.

3.9. Quantitative research design

A research design should be tailored to the exact needs of the problem. Research designs have two essential components. The first is observation and the second is analysis of the relationship between variables. Three categories of research design can be distinguished and are named in increasing order of scientific rigour. They are pre-experimental design, quasi-experimental design and lastly the experimental design. The pre-experimental design is least likely to establish a clear relationship between the independent and dependent variable. Though the experimental design was developed before the quasi-experimental design, the latter accommodates social reality constraints, thus quasi-experimental designs are amendments to stricter experimental designs (Kagee *et al* 2006: 75-76). An example of an experimental design is the Solomon Four-group design (details outlined in 3.9.2). It consists of the following variables denoted as follows:

R = random assignment of subjects to each group

O = observation or point where data is collected as a dependent variable and

X = exposure of a group to an independent variable (e.g. intervention)

The purpose of the observation is to measure the effects of the intervention.

3.9.1. Randomization

Most experimental designs make use of randomization to create two or more groups. The use of randomization ensures that the groups' characteristics are identical. Randomization requires that every subject involved in a study has an equal chance of being assigned to any of the groups of the study. This can be achieved by first identifying the entire group of subjects, then randomly dividing the group into two or more subgroups depending on the chosen design (Kagee A *et al*, 2006; 75-88). Random selection means that each member of the population has an equal chance of being selected into the sample. The advantage of randomly generated groups is that the researcher starts the experiment with two (or more) equivalent groups. If only one group is subjected to the treatment, the researcher can be reasonably sure that any difference between the groups thereafter is due to the effects of the treatment. The group that does not receive the intervention is called the control group, while the group that receives the intervention is called the experimental group.

For phase I of the study patients who attended the clinic for the day and met all the inclusion criteria were randomly selected. For phase II, a convenient sample of students was used since over half of the class was available to participate in the usual method of assessment (n=37) and a smaller group received the introductory clinic-based training (n=7).

3.9.2. Solomon Four-group design

This design is used when the effect of a pre-test on subjects is of concern. It is attractive to researchers because it accounts for each alternative of the pre- and post- testing. This design controls for most threats due to internal validity (Kagee A, Higson-Smith C, Bless C, 2006; 88). Campbell and Stanley rated this design as prestigious and felt it was the first to explicitly consider external validity factors (1963; 24). Its major drawback is that four separate groups are needed and thus will require more time, energy and resources to implement his design. Furthermore, statistical analysis of this type of design has been shown to be complicated (Saber L, 1985). There are two experimental groups (E) and two control groups (C), but the pretest is received by only one of each of these groups (Table

3.1). Group 1 and 3 are experimentals while Group 2 and 4 are controls. All the groups receive the post-test.

Table 3.1: Solomon four-group design

Group 1: E^1 (experimental)	R	O^1	X	O^2	**(*Pre* + Intervention + Post)**
Group 2: C^1 (control)	R	O^3		O^4	**(*Pre* + Post)**
Group 3: E^2	R		X	O^5	**(Intervention + Post)**
Group 4: C^2	R			O^6	**(Post only)**

In this study, data obtained from patients at Ravensmead CHC served to provide baseline information so that the researcher could firstly familiarize herself with clinical procedures thus the research design did not apply (see chapter 4). Therefore the Ravensmead CHC patients only received the pre-questionnaires. The patients at Delft South ARV clinic were grouped into either experimental or control groups. The experimental patients at Delft South clinic received the pre-questionnaires, intervention and post-intervention questionnaires whilst experimental patients at Elsies River clinic only received the intervention and post-questionnaires. An algorithmic framework of the research design is outlined in table 3.2.

3.10. Quantitative data collection methods

Quantitative data collection methods used for quantitative processes can be categorised into questionnaires, checklists, indexes, and scales. Questionnaires were used to collect data for this study.

A questionnaire is a set of questions on a form which is completed by the respondent in respect of a research project (*New social work dictionary*, 1995; 51). Questionnaires are distinguished from research interviews since the latter is a form of data gathering within the qualitative approach. There are five types of questionnaires namely mailed, telephonic, self-administered, questionnaires delivered by hand and group-administered questionnaires.

With regard to self-administered questionnaires, the researcher (or fieldworker) limits his/her own contribution to the completion of the questionnaire to an absolute minimum. The researcher remains in the background but can encourage the respondent with a few words to continue with their contribution, or lead them to the subject (De Vos AS *et al*, 2005:166-168). For phase I of the study, self-administered questionnaires were handed to the patients (see Appendix A) who completed them independent of the researchers' input. The researcher was only available to clarify terms or phrases from the questionnaire, and this was done in a neutral manner. For phase II of the study, quantitative scores were obtained from the assessment that students had undertaken.

3.11. Sampling

Before understanding the concept of sampling one must define certain terms such as population and sample. The population is the entire set of subjects or people to which the research is focused. A sample is part of a population to be included in a study i.e. the subset of a whole population which is investigated by the researcher and whose characteristics will be generalized to the entire population (Bless C, and Higson-smith, 2000:85). Sampling is the study of the relationship between a population and the samples drawn from it thus means leaving *certainty* for *probability.* The major reason for sampling is feasibility (i.e. probability) because it is impossible to cover a total population (i.e. certainty) (Yates SJ, 2004: 25).

A large sample provides conclusions that are more reliable and valid than a small sample even though the former is more costly (Schaller, 1992:66; Bless C, and Higson-smith, 2000:93; Mitchell M, and Jolley J, 2001: 496). The researcher must be careful not to use a very large sample size and vice versa. The sample size can impact on the statistical test by making it insensitive (small sample size) or too sensitive (very large sample size). Factors that influence the size of a sample are: heterogeneity of the population, desired degree of accuracy, type of sample, available resources, and the number of variables in which data is grouped (Singleton R *et al*., 1988: 158; Neuman WL, 2003: 232).

The sample size for the primary study (Phase I) was calculated by using the Epi Info, Statcalc version 6 November 1993. A 95% confidence interval was used, and the ratio of exposed to unexposed patients was set as 1:1. The sample size was calculated to be 56 patients when the frequency of disease (in percentage) of the unexposed group was put at 30% and percentage of exposed group was put at 70%. However, 98 patients were recruited for this study to cater for external validity and reliability. The sample size for the secondary phase (Phase II) depended on student availability. The student sample undertaking the usual method of assessment was 37, and those who received the clinic-based training was seven.

3.12. Qualitative data collection methods

A combination of two procedures was used when collecting qualitative data namely interviewing and participant observation and these were advantageous because of the ease in cross-checking and validating findings. Each of these procedures has its strengths and weaknesses but by using triangulation the strengths of one procedure compensates for the weakness of the other (Patton MQ, 2002:306).

For Phase I of the study, prior to the interview process at Delft South ARV clinic, the questionnaires required translation form English to isiXhosa. A translator fluent in both English and isiXhosa language was contracted to assist with pre- and post intervention data collection at the clinic. The researcher ensured that the interview did not impact on service provision at the clinic.

3.12.1. Interviews

Qualitative studies use either unstructured or semi-structured interviews to collect information about the study sample. Confusion sometimes arises between unstructured and semi-structured interviews as some books use both terms interchangeably. Unstructured interviews are in-depth interviews whilst semi-structured interviews are those organised around areas of particular interest, while still allowing considerable flexibility in scope and depth (Morse JM, 1991: 189).

In the Phase I study, the interviews took place within the clinic setting of each site. Participants consisting of patients and HCP's were rarely distracted as the clinic environment provided adequate privacy which was non-threatening, and readily accessible.

Semi-structured one-to-one interviews

With semi-structured interviews, the researcher makes use of an interview schedule which contains predetermined questions to guide the interview. In Phase I of this study, semi-structured interviews were used to ascertain participant's (patients and HCP's) views and perceptions. It was used because it provided flexibility for both the participants and the researcher. In preparation for such interviews, questions are written to guide the enquiry process. It forced the researcher to think of difficulties that might be encountered, for example the type of vocabulary used. In this study, the technique known as *funneling* was used because certain questions were dichotomous (*Yes/No*) but still remained open-ended. For Phase II of this study, semi-structured interviews were not applicable.

3.12.2. Participant observation

This is a typical qualitative approach to collect data. In participant observation, data gathering is based on the actual observation of subjects and taking field notes. Participant observation at designated research sites provides an opportunity for rich contextual information to be collected and recorded in the form of field notes: Where appropriate, actual quotations are provided. The researcher is involved in the daily behaviour, actions, interactions, and events of subjects by taking notes in a semi-structured manner in order to gain additional insight (Muller JH, 1995; Shephard M, 1995; Creswell JW, 2003; Ritchie J, and Lewis J, 2003).

In this study (Phase I), I observed interactions and practice patterns that occurred routinely during patient-HCP consultations and between HCP's. The observations focused on the screening procedures for patients with TB and HIV, history-taking, counseling on medicine use, and provision of follow-up care. I noted these observations

in detail in a research journal especially during the interview process that took place in the clinic.

3.13. Data input and analysis

Data input, analysis and calculation of sample size was obtained by using the Epi Info 2002 package. For Phase I of this study, responses obtained from pre-intervention questionnaires, intervention (trained researcher using modified clinic record card) and post-intervention questionnaires were first coded, then data entered into the Epi Info spreadsheet and analyzed. Proportions for each parameter were obtained and cross comparisons of common parameters were obtained to determine the effect of the intervention on the quality of care provision among TB/HIV patients.

3.14. Validity and reliability

Validity means that a measurement represents what it is supposed to. There are six types of validity namely face, construct, predictive, concurrent, internal and lastly external validities. Internal validity tests instruments used to measure whether a phenomena is free from bias. External validity measures how far the research can apply outside the research setting. Reliability refers to consistency of a test, model or measurement having the same outcome at different times. Since this is an exploratory study (Phase I and II) attempts to adhere to valid approaches were made where possible in each phase of the enquiry process (Kagee A *et al*, 2006; Fox W, and Bayat M, 2007).

3.15. Ethics

Ethical clearance was obtained from the UWC Research Ethics Committee (May 2008). Approval to engage with clinic patients and staff was obtained from the management of City Health, Tygerberg Sub-district, Cape Town (April 2008). Written information about the aim and objectives of the study was provided to the participating patients in either English (pre-questionnaires) or isiXhosa (post-questionnaires) depending on language preferences. Written consent was subsequently obtained from both the patients and HCP's who agreed to participate. Both verbal and written communication to all participants before commencement of each phase of the study indicated that participation

was completely voluntary, confidential and anonymous. Participants were informed that they had the option to leave at any phase of the study.

Table 3.2: Outline of research design and methods used for this study

1. Phase I: Baseline study

Primary aims: **Assess current practice patterns at Ravensmead CHC(chapter 4)**

TB coordinator offers clinic-based training to the researcher. ⇒ **Trained Researcher**

⇓ Proceeded to

Ravensmead CHC

- Qualitative and Quantitative data obtained from this baseline study (one week) was used to design the intervention tool and modify the pre-intervention questionnaire for further investigation at Delft South ARV and Elsies River TB clinics.

⇓

1.1. Pre- intervention at Delft South ARV clinic

Aim: to assess patient perceptions towards pharmacist's involvement in TB/HIV management and knowledge of their drug treatment.

- Qualitative data was collected from participant by using observation technique and interviews.

- Quantitative- patient's face-to-face unstructured questionnaires (Appendix A) and HCP questionnaire was used to assess patient perceptions towards pharmacist's involvement in TB/HIV management and knowledge of their treatment (Appendix B).

⇓

1.2. Implementation of Intervention tool at Delft South and Elsies River clinics. (chapter 5)

- Intervention conducted over 4 months (July–October 2008).
- Intervention tool was adapted from patient TB clinic record card (GW 20/12, 2002) and modified by researcher to cater for co-infected patients.
- HCP questionnaire to assess their perceptions and attitudes towards pharmacist's involvement in TB/HIV management (Appendix B).

⇓

Post-intervention phase

- Conducted at Delft South ARV and Elsie's river clinics.
- Post-intervention questionnaires (Appendix C) were designed by researcher to assess receptivity of the intervention tool by co-infected patients.

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2. Phase II

Secondary aim: assess the need for a clinic-based TB/HIV among final year pharmacy students at UWC (chapter 5)

- Assess students' current knowledge of TB/HIV management (June 2009).
- Offer introductory clinic-based training to seven final year pharmacy students.
- Assessed results of both trained students (experimental) and students who received no training (control).

CHAPTER 4: BASELINE STUDY

In this chapter, I describe the clinic-based training in TB/HIV management called PALSA Plus which I received from a district TB co-coordinator. I discuss the baseline study which was conducted at Ravensmead community health centre (CHC). I provide a demographic profile of the Ravensmead community and a description of the Ravensmead CHC. I also discuss my introduction to the clinic and its staff members. I outline the design of the face-to-face questionnaires directed to the patients, and HCP's. I discuss the interview process, data collection process and conclude with findings from the baseline study which served as the preparatory framework for the subsequent study phases.

4. PALSA Plus Training

I describe the role of a district TB coordinator and the clinic-based PALSA Plus training approach which I received from her.

4.1. Role of a District TB coordinator

Depending on the size of the district and number of staff available, a district TB coordinator may be one person or a team of people. Therefore, the person or team responsible for TB control at the district level is called the district TB coordinator. The coordinator is usually a physician or a nurse and reports to the district medical officer (DMO) and is supervised by the provincial TB coordinator (WHO, 2005). A district TB coordinator typically conducts a clinic-based training on guideline implementation in TB/HIV management for primary care nurse practitioners. The district TB coordinator is responsible for updating nursing staff on latest protocols and guidelines as stipulated by the Department of Health, Provincial government of the Western Cape. Other duties include supplying anti-TB drugs, training health workers to prepare them to identify TB suspects, planning, organizing, implementing, and evaluating activities of a district TB control programme.

A telephonic conversation was arranged with the then district TB coordinator of the Tygerberg sub-district to discuss potential training dates. The training started on the 17th

of April 2008 and took place at the UWC's School of Pharmacy building. The three training sessions which lasted for approximately 30-45 minutes took place in a private consultation room situated in the first floor of the building. This venue was chosen to avoid potential disruption to the training sessions. The first session focused on TB symptoms and diagnosis. The second session emphasized the inter-relationship between TB and HIV. The last session was aimed at the treatment approaches and protocols for both conditions.

PALSA Plus is a training programme directed to nurse practitioners and aimed at the management of patients with TB, STI, HIV including other respiratory problems (see Appendix C). "PALSA" is the acronym for Practical Approach to Lung Health in South Africa and "Plus" refers to the inclusion of HIV/AIDS management. The PALSA Plus approach condenses the national guidelines and the standard treatment guidelines into a desktop manual format which enables trained clinical nurse practitioners to screen, diagnose and treat a patient who presents with respiratory symptoms at the clinic (Stein J *et al*, 2008). The PALSA Plus manual follows an algorithmic system for the diagnosis and treatment of TB that can be followed in a step-wise approach. This training is offered in primary health care clinics and its major goal is to standardize care across the entire Western Cape. Notable pages from the 2007 PALSA Plus manual that are pertinent to this study include 6, 7, 8, 9, 15, 16, 17, 19, 20, and 21 (see Appendix C, pages 145-154). In addition a TB treatment wheel which forms part of the PALSA Plus material is used as a tool to encourage follow-up care.

4.2. The TB Treatment Wheel

The TB treatment wheel (Appendix D, Department of Health, 2008; http://www.coregroup.org/storage/documents/Workingpapers/Union_Meeting_Rpt_TB_2007.pdf) was developed to assist healthcare workers identify return dates for TB patients. The wheel serves as a guide for patients on Regimen 1 and 2. Healthcare workers can note the dates on which new and retreatment TB patients on regimen 1 and 2 should be recalled for sputum collection and indicate the termination date of their treatment. The information is then entered in the patients' clinic record cards.

The length of TB treatment can be prolonged in certain types of TB if the patient does not respond to treatment, or defaults during the course of treatment. This wheel also serves as a reminder to offer HIV testing to all TB clients. The combination of drugs to be administered during each phase of treatment is also noted on the wheel.

The TB treatment wheel is designed around a circular base. Around the rim is a calendar showing the days and months of the year. A central rotating wheel is marked with arrows, which point from the centre outwards to the calendar. The TB treatment wheel is double sided. On one side of the wheel are dates for enrollment of new TB patients while on the other side are the dates for re-treatment patients. On each side the inner wheel has arrows for the date treatment started, 2 and 3-month sputum tests, 5 and 7-months sputum tests and 6 and 8-months treatment termination dates. These arrows are a fixed, and at a calculated distance.

Form my theoretical knowledge of TB and HIV as an academic intern the PALSA Plus training served as a preparatory platform for my entry into a City Health clinic. It provided me with the practical perspective needed for clinic-based management of respiratory diseases such as TB. It also provided me with the skills and awareness needed to embark on my clinic visits.

4.3. BASELINE STUDY

4.3.1. Description of baseline study site

Ravensmead as a community consists of predominantly lower income coloured earners whose language preference is mainly Afrikaans. The demographic profile of the Ravensmead community is outlined in Table 4.1.

TABLE 4.1

Demographic Profile (Gender, Ethnic Group, and Language)

RAVENSMEAD	**Male**	**Female**	**Total**
ETHNIC GROUP			
African/Black	93	102	195
Coloured	11,526	12,682	24,208
Indian/Asian	41	37	78
White	35	30	65
Unspecified	266	309	575
Total	**11,961**	**13,160**	**25,121**
LANGUAGE			
English	793	916	1,709
Afrikaans	11,044	12,106	23,150
Xhosa	3	6	9
Other	14	14	28
Unspecified	107	118	225
Total	**11,961**	**13,160**	**25,121**

Compiled by Urban Policy Unit from the 1996 Census data supplied by Statistics South Africa.

The baseline study took place over 5 days at the TB room situated within the Ravensmead Community Healthcare Centre (CHC). The study began on the 28th of April and ended on the 2nd of May 2008.

4.3.2. Selection of site to conduct baseline study

Ravensmead Community Healthcare Centre (CHC) lies in close proximity to the University of the Western Cape (UWC), serving as an appropriate site to conduct the baseline study. Three key staff members that provide healthcare are; a nursing sister (TB nurse), a DOTS supporter (administrative support staff) who attends to TB patients on a regular basis and a doctor (TB medical officer) who attends to patients only on a Monday. TB services carried out at the Ravensmead TB room include screening, provision of TB treatment by both the nurse and DOTS supporter, and diagnosis of TB which is exclusively performed by the TB nurse.

I familiarized myself with the screening tool used by the clinic nurse to diagnose new TB suspects. This tool is used for routine clinical procedures and its design is adapted from PALSA Plus (see Appendix E). The history section of the tool can be completed by an administrative support staff such as the DOTS supporter whilst the diagnosis and action section can only be completed by the TB nurse. The doctor's assessment is required when diagnosis is uncertain or the patient is smear negative and still symptomatic. The TB nurse is also expected to complete a short questionnaire on socioeconomic status, substance abuse, other underlying conditions, use of contraceptive methods and chronic medication.

4.3.3. Entry into TB clinic

I provide a brief description of my attire, the TB consultation room, meeting with the nursing staff and access to patient folders.

4.3.3.1. *Attire*

During my visits to the clinic, I opted to wear my white, short sleeved clinical coat mainly to differentiate myself professionally from the other staff members. I wore my nametag with the UWC logo at all times to enable people identify me. I adhered to a professional code of conduct. A protective clinical mask was worn properly at all times to avoid risk of infection when interfacing with patients diagnosed with TB.

4.3.3.2. *Contact with clinic*

I telephoned the sister-in-charge to arrange an introductory meeting. A day was confirmed a week later. In our meeting, I outlined the objectives and focus of my study. She gave me verbal consent to conduct my baseline study at the CHC. I felt assured that all was on track up until my first interaction with the nursing sister.

4.3.3.3. *Initial meeting with nursing staff members*

My first visit to the clinic seemed unexpected to the clinic staff. The staff members were surprised by my presence and as result I could not engage with patients or have access to patient folders, thereby negating the purpose of my visit. Having confirmed my visit with

the sister-in-charge four days beforehand, it seemed evident that the clinic staff were not informed of my proposed visit. However, on the second day, I re-introduced myself to the staff and outlined the objectives of my study where an improved rapport was imminent.

4.3.3.4. *DOTS supporter*

I worked closely with the DOTS supporter during the duration of this baseline study, and below is a brief overview of how DOTS supporters are chosen in SA, the training they receive and duties they perform. These duties may deviate slightly across different sites depending on staff competence and patient load.

Overview

TB DOTS supporters are required to be accessible to patients. They are recruited from specific areas where there is a high density (caseload) of TB. They assist clinic nurses with their caseload of TB and this has been proven to be effective in making contact with potential patients. Candidates need to be reasonably mature, as some older patients do not like being supervised by younger people. Potential DOTS supporters should be functionally literate to keep records of dealings with patients (Dick J *et al.* 2005).

DOTS supporter training

The introductory training for DOTS supporters varies from site to site and ranges from five days to five weeks. The training covers aspects about being a DOTS supporter, details about TB as an illness, HIV/AIDS, and general health issues such as hygiene and nutrition. Many DOTS supporters have little formal education, with only a few completing secondary school (Dick J *et al*., 2005).

Duties of DOTS supporter

1. Collect medication each month from the clinic nurse.
2. Check that patients take their medications.
3. Record dose on TB clinic record card.
4. Encourage non-adherent patients to adhere to treatment program.
5. Remind patients to attend the doctors' appointment.

6. Ensure that patients go to clinic and,
7. Provide two-and five months follow-up sputum regimen.

4.3.3.5. *Access to patient folders*

Access to patient folders not only validated patients responses to the questionnaire, (Appendix A), but provided some degree of reliability about their medical and treatment histories. For example, some patients would not mention other chronic conditions that they have been diagnosed with other than TB. Only after checking their folders, such information could be retrieved so access to patient folders helped to eliminate biased reporting amongst patients, and authenticate their medical history.

From my professional working relationship with the DOTS supporter I realized that their scope of practice is crucial to understanding barriers to treatment adherence. It provided me with the opportunity to engage directly with TB/HIV patients where I was able to access patient folders for information, conduct my one-to-one interviews, and observe the DOTS procedure personally amongst others.

4.4. DESIGN OF QUESTIONNAIRES

A questionnaire was designed for patients (Appendix A) and healthcare providers (Appendix B). Both questionnaires, were adapted from a previous pilot study (Bhawan D *et al*, 2007) and outlined information such as a title, official UWC logo, contact details, sub- headings, a brief description of the study, patient's and healthcare provider's (HCP) consent and lastly the date.

4.4.1. *Patient questionnaire*

The patient questionnaire comprised of 31 questions which were grouped into 5 categories lettered A-F. Category A aimed at ascertaining the patient's background information such as the folder number, demographics which included the gender, age, race, home language, highest education, residential status, employment status, living conditions, and socioeconomic status. Category B focused on the medical history of the patient with regards to TB. Questions were designed to assess the knowledge and

perceptions of patients towards TB e.g. *In your view, is TB contagious?* Category C assessed the symptoms the patients experienced and what they would do if and when the discomfort became unbearable. Category D focused on drug treatment, namely the drug–readiness training programme, duration of treatment, attitude and views towards treatment. Category E focused on the patient's lifestyle such as their social habits and behaviour. Category F was reserved for counseling and the patient's opinions on the perceived role of the pharmacist with regard to their TB/HIV side effects.

4.4.2. *HCP questionnaire*

The aim of this questionnaire was to explore current practice patterns of HCP's namely nurses and doctors who provide TB/HIV care to patients and to elucidate a role for the pharmacist. The HCP's questionnaire consisted of 14 questions with neither categories nor groupings. Enquiry was made into their qualification, TB care experience, materials used to screen and treat for TB, protocol used, and how they coped with the workload. Pharmacists were not included as a target group for this study because the Van Der Walt study (2003) conducted amongst Western Cape pharmacists clearly indicated that they were willing to explore an expanded role in HIV management.

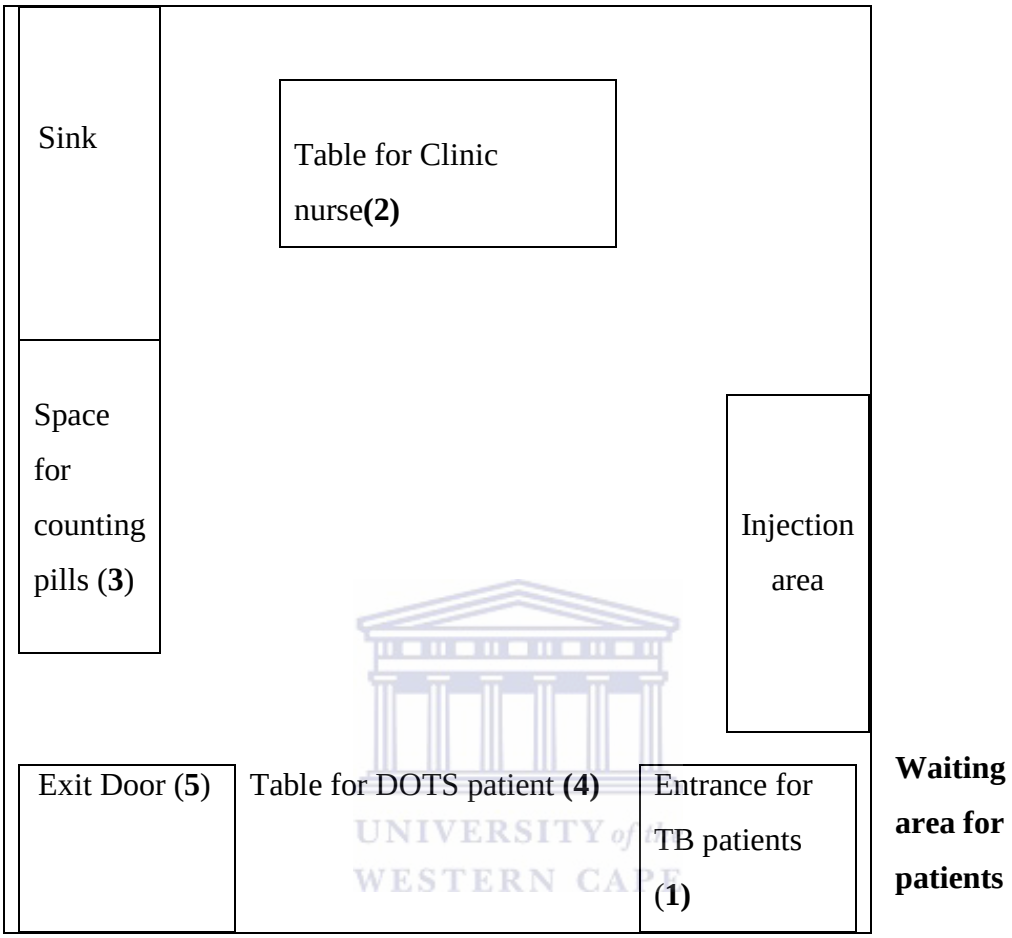
4.4.3. *Layout of the questionnaire (Appendix A and B)*

Questionnaires were printed in English, and were printed back to back on white paper. The active voice was used at all times. Uniformity was maintained throughout both questionnaires with regard to formatting. Arial (bold) font size 14 was used for the main heading which was in capital letters and was also justified, centered, and bolded. In order to demarcate the consent form from the questions, a bold line was ruled above them. Sub-headings had font Times new roman (bold) with font size 12. Keywords were italized with font Times new roman and size 12. The boxes had 0.5 point line width, single solid line and an Arial border. The text was typed using font Times new roman size 12 and contained 718 and 403 words for the patient and HCP questionnaires respectively. The paragraphs had mixed line spacing. The consent form was single spaced whilst the rest of the questionnaire was exact. There were no borders included because it was a scientific research. All pages were numbered at the bottom with a centered alignment.

4.5. *The TB consultation room*

The TB room was a small, well-ventilated room located at the airy part of the CHC. The TB room had two doors that allow fresh air in to prevent the spread of TB. A small private area, secluded with an opaque curtain was used to administer streptomycin injections. Because the TB room itself is limited in space, the patients waiting area is situated just outside the room which is justified as overcrowding is a risk factor for the spread of TB. On entering the TB room, eye catching posters were mounted on walls aimed at low-literacy patients. They contained information on TB management that was written in simple language for the English and Afrikaans speaking patients. Within the TB room was a small area reserved for DOTS patients to drink their medication. A sink located at the corner of the room is used by staff to wash hands after the administration of medications. A bathroom scale for weighing the patients is usually kept under the nurse's table.

Figure 4.1: Layout of Ravensmead CHC TB room



Note: *Numbers 1-5 indicates but is not limited to patient route within the TB room.*

4.6. Patient interview process and data collection

Patient's interviews were largely dependent on the availability of the DOTS supporter. Patients reported to the clinic between 7am-8am because the DOTS supporter was only available from 9am to 11am (for two hours only) therefore her presence was crucial to recruit patients and obtain a reasonable sample size of 12. Since I am English speaking, and the DOTS supporter is fluent in both Afrikaans and English and very familiar with the clinic procedures, she served to streamline the recruitment and interview process.

4.7. Sample size

The sample size was calculated from the present population of patients with active TB at Ravensmead CHC (2008).

Population of TB patients (sample) = 52 (active TB)

10% of sample population = sample size

Therefore: 10/100 X 52 = 5.2

n= 5.2

Some methodologists suggested that 10% sample of a known population has become a convention which serves as a handy rule of thumb for random sampling (De Vos AS *et al*, 2007:197), therefore 10% of the sample was enough to control for sampling errors (Seaberg, 1988:254; Grinnell, Williams, 1990:127). For this baseline study, sample size was estimated at 6 patients; however 12 patients were recruited to arrive at more conclusive findings.

4.8. Recruitment process

At recruitment, TB patients were assured that all information would remain strictly confidential and that their participation was completely voluntary. After verbal agreement, patients signed a consent form. In keeping with routine clinical procedures, a standard approach was used for all interviews. After the TB patients took their daily medications under the supervision of the DOTS supporter, they were escorted to the private consultation room where I was also located. The researcher greeted the TB patients, provided an overview of the study and received verbal and written consent for their voluntary participation. The baseline questionnaires were completed with assistance from the DOTS supporter when the need arose. All the patients were thanked for their time.

I ensured that consistency was maintained when interpreting each question to the patients by cross-checking patient responses to randomly chosen open-ended questions from their TB record card. All the questions under category A were closed-ended questions and did not require any interpretation. They were asked to tick the options that applied to their

individual situation. There was a box available for "Other" which meant if their answers was not part of the options listed, then they could provide their personal ones. I made sure to avoid using ambiguous words that would have different meanings to different patients. Questions such as number 3, 8a, 8b, 12, 16, 18b, 26, 27, 30 and 31 (Appendix A) were targeted at getting opinions from the TB patients. The patients were provided with a pen to complete the questionnaire and each interview lasted for about 5-7 minutes depending on their level of understanding. At the end of each interview, the patients were thanked and wished well with their treatment.

Self-administered questionnaires were completed by the DOTS supporter and clinic nurse to obtain their views and perceptions towards the pharmacist involvement in TB/HIV care. As opposed to the patient data collection process that required a standardized interview process, the HCPs simply completed the questionnaires and handed it back to the researcher. Responses obtained from the questionnaire collectively were noted as the HCP results (details in section 4.11).

4.9. Results

The results obtained in the baseline study were from mainly TB (and some HIV-positive) patients and HCP's. Quantitative data was obtained from face-to-face interviews with patients, while my observations of the DOTS procedure with patients provided the qualitative data. The HCP results presented in table 4.3 below are only qualitative.

4.9.1. Patients' qualitative results

I provide an overview of the observations from the DOTS procedure in the clinic and highlight the specific skills learnt during my involvement with the clinic staff.

4.9.1.1. Observations from DOTS procedure

When the patients take their medication, the DOTS supporter sat directly opposite the patient to ensure that TB medications were taken by them e.g. making sure they have swallowed properly by talking to them. For those patients unable to attend the clinic

because of employment duties their TB medication was given to the employer provided that a patient consent was established.

It was observed that elderly patients crush their tablets because they were unable to swallow them whole. This act was however **not** done under the direct *personal supervision* of the *nurse or DOTS supporter* and the pharmaceutical implication was that this could lead to poor bioavailability of the drug. In addition, the crushing of tablets should only be done by an authorized HCP such as a clinic nurse. Furthermore, the bioavailability of enteric coated tablets such as Rifafour® is reduced when crushed because the active ingredients are degraded by gastric acid (Decloedt E., and Maartens G, 2009).

The 7-day TB regimen which includes Saturday and Sunday weekend supply was given to TB patients and this meant that patients were entrusted with taking their medications on their own. The main pharmacotherapeutic concerns relating to this are firstly possible non-adherence and secondly personal social habits such as alcohol consumption over the weekend which could negatively affect the therapeutic outcome of their treatment.

4.9.2. Quantitative results

Quantitative data obtained from the patient questionnaires are tabulated in Table 4.2 below.

TABLE 4.2: RESULTS FROM BASELINE STUDY

A. Patient background information	**Frequency (n= 12)**	**Percentage %**
Gender		
Male	4	33,3
Female	8	66.7
Age range in years		
<20	1	8.33
20- 29	7	58.3
30- 39	1	8.33
40-59	2	16.7
>60	1	8.33
Race		
Black	0	0
White	0	0

Coloured	12	100
Indian	0	0
Other	0	0
Home language		
English	0	0
Afrikaans	12	100
Xhosa	0	0
Other	0	0
Highest education		
None	0	0
Primary level (<8)	3	25
Secondary level (grade 8- 12)	9	75
Tertiary level	0	0
Employment status		
Employed	1	8.3
Unemployed	11	91.7
Other	0	0
Residential status		
Urban	11	91.7
Rural	1	8.3
Living conditions		
House	10	83.3
Informal settlement	0	0
Flat	2	16.7
Other	0	0
Socioeconomic status		
Salary/wages	1	8.3
Casual handouts	0	0
UIF(unemployment insurance fund)	0	0
Social services grant	3	25
None	8	66.67
B. Medical History		
Family member with TB	3	25
Knowledge about TB infection		
Contagious	10	83.3
Non-contagious	2	16.7
Duration with TB*		
<1 month	4	33.3
2–3months	4	33.3
3-4 months	2	16.7
4-5 months	3	25
>5 months	2	16.7
Patients with TB only	9	16.7
With HIV	2	75
With diabetes	1	8.3
C. Symptom History*		
Vomiting	2	16.7
Nausea	3	25
Increased appetite	4	33.3
Headache	3	25
Abdominal pain	2	16.7
Diarrhea	1	8.3

Drowsiness	3	25
Muscle weakness	4	33.3
Decreased appetite	2	16.7
Other (back pain)	1	8.3
None	1	8.3
Patient preference for an HCP regarding discomfort resulting from TB medication		
Doctor	3	25
Nurse	2	16.7
Pharmacist	0	0
Other	0	0
Facility most consulted for TB care		
Clinic	12	100
Hospital	0	0
Pharmacy	0	0
Other	0	0
D. Drug Treatment		
TB drug readiness programme attendance		
Yes	0	0
No	12	100
Opinions about duration of TB treatment		
Too long	1	8.3
Fine	11	91.7
Too short	0	0
Other	0	0
Knowledge about main function of TB tablet		
Yes	12	100
No	0	0
Opinions about the amount of TB tablets administered		
Too big	5	41.7
Fine	6	50
Too much	1	8.3
Other	0	0
Other medications taken by TB patients		
ARV's	2	40
Traditional medicine	1	20
Other (antidiabetics)	2	40
Number of patients collecting TB medication monthly		
Yes	0	0
No	12	100
Patients whose TB treatment supervised		
Yes	12	100
No	0	0
Duration of treatment		
6 months	9	75
8 months	2	16.7
9 months	1	8.3

E. Lifestyle*		
Smokes cigarettes	6	50
Consumes alcohol	3	25
3 or more course meal	11	91.7
Barriers to follow up appointment		
No transport	1	8.3
No money	0	0
Work	1	8.3
Forgetfulness	1	8.3
Other	3	25
None	6	50
F. Counselling*		
HCP seen as information source		
Nurse	9	75
Doctor	3	25
Pharmacist	0	0
Support group	1	8.3
Other	1	8.3
Patients preference for HCP to		
Nurse	8	72.7
Doctor	3	27.3
Pharmacist	0	0
Other	0	0
Type of information preferred by patients		
Verbal		
Reading material	5	41.7
Both	0	0
	7	58.3
Perceived involvement of pharmacist in TB		
Positive (means any opinion other than that of a drug supplier)	4	36.4
Drug related information		
Negative(means opinions that is drug-related)		
Psycho-social information	7	63.6

***** Patients could indicate more than one answer and therefore total percentages may exceed 100%.

4.10. Graphical representation of baseline results

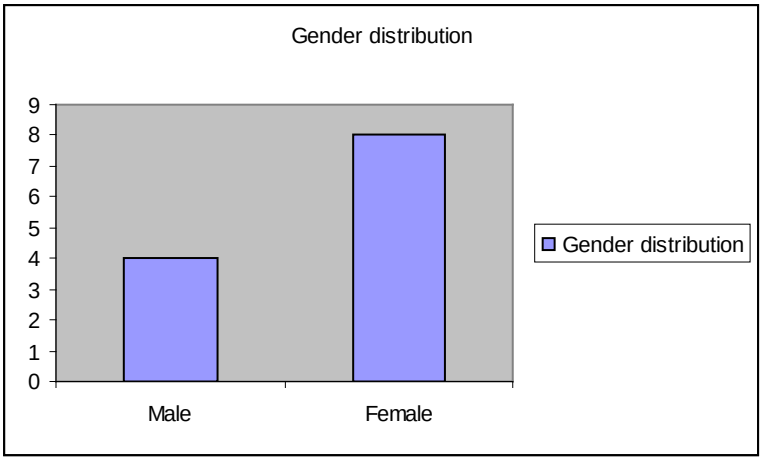


Figure 4.2: Gender distribution of patients

A total of 12 patients were approached to participate in the baseline study; none were lost to follow-up. Therefore, all 12 patients were recruited and interviewed, and their gender distribution is shown in the figure 4.2 above. Clearly there are more females (66.7%) than males (33.3%). This finding could imply that the burden of TB is more likely among females (HSRC report, 2005, see chapter 1, section 2.2).

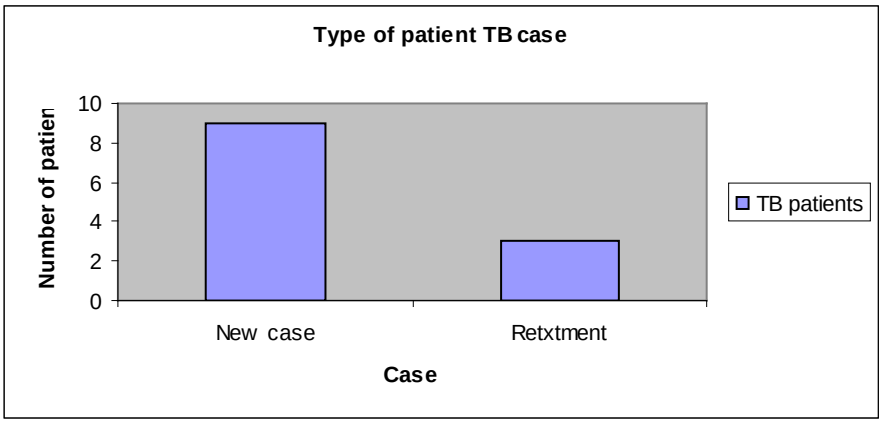


Figure 4.3: Type of patient TB treatment case

Figure 4.3 shows that nine of the 12 (75%) patients interviewed in this baseline study were newly diagnosed TB treatment cases and the remaining three (25%) were retreatment cases. Newly diagnosed TB patients receive treatment for a duration of 6 months while for retreatment patients, the treatment is usually 8-9 months (PALSA Plus

manual, 2007). Findings from above indicate that the incidence rate of TB in this community seems to be on the increase as three-quarters of the patients have been newly infected. With the rising number of newly infected patients, pharmacists, other HCPs and students will need to keep abreast of screening, monitoring, treatment protocols and referral systems of HIV and its opportunistic infections (Syed IA *et al*, 2009).

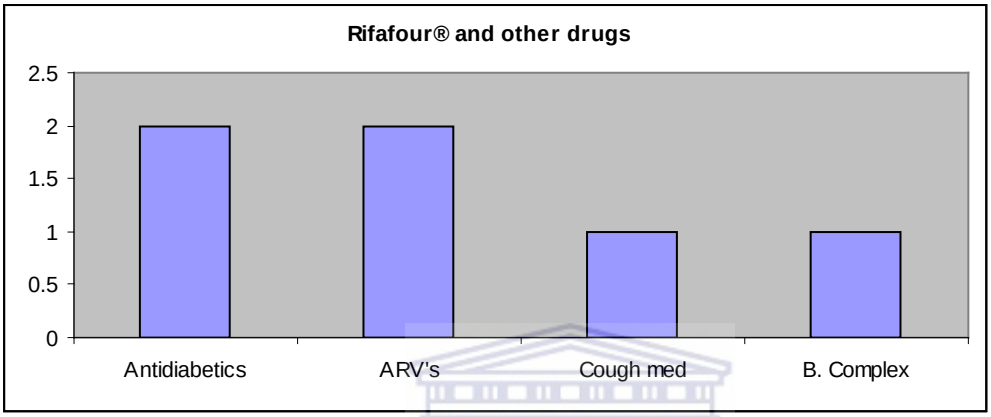


Figure 4.4: Number of patients taking Rifafour® with other drugs

Four of the 12 TB patients were taking Rifafour® with their antidiabetics (n=2) and ARV's (n=2). One patient each took cough medication and Vitamin B.Complex. As mentioned in the previous chapter, Ravensmead CHC is predominantly a TB clinic with very few HIV-positive patients and may have been the reason why only one-quarter of the patients took other medications (ARV, antidiabetics and cough medication) with their anti-TB drugs. The pharmacist's responsibility to check for potential drug-drug interactions is crucial to ensure optimal therapeutic outcomes.

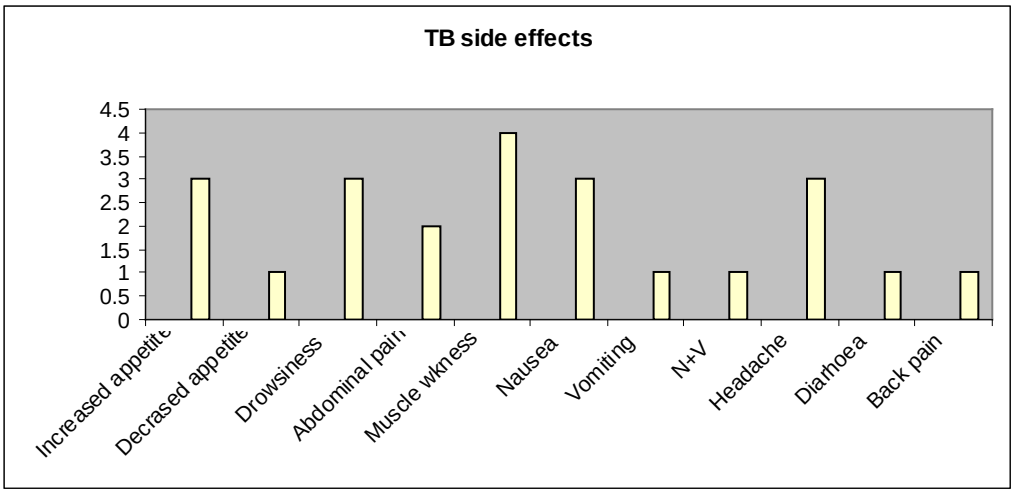


Figure 4.5: Common TB side effects experienced by patients

Four patients experienced nausea, three patients experienced increased appetite, drowsiness, and headache, two patients experienced abdominal pain, and five patients each experienced decreased appetite, vomiting, nausea and vomiting, diarrhea and back pain. The onset of side-effects resulting from complex drug therapy is likely to deter patients from adhering to their prescribed regimen (Chesney MA *et al*, 2000) which impacts negatively on health outcomes. Healthcare professionals including pharmacists are required to closely monitor side-effects and take appropriate actions where necessary.

4.11. HCP results

Since the clinic nurse and the DOTS supporter were the only staff alongside which I worked with, it was essential to ascertain their views and opinions about the pharmacist's involvement in TB and HIV management. This was achieved when they completed the survey (Appendix B).

TABLE 4.3: Comparative survey responses between DOTS supporter and clinic nurse

	DOTS supporter(n=1)	**Clinic nurse(n=1)**
1. Gender	Female	Female
2. Age	40-59	< 60
3. Qualification	DOTS training	Basic nursing Diploma
4. TB experience (years)	3-5	1-2

5. Use of clinic card to monitor TB care	Yes, only TB symptoms but not adherence to treatment.	Yes, both TB symptoms and adherence to treatment.
6. Provision of drug information to TB patients	None	Yes, provides information on side effects and frequency of drug administration.
7. Frequency in promoting HIV testing	Always	Always
9. Onset of TB counselling	TB suspects	TB suspects, new and re-treatment patients.
10. Response to side effects and drug interactions	Refer to doctor.	Refer to doctor.
11. View on which HCP is most equipped to deal with drug interactions and side effects and a possible reason	Doctor, extensive clinical experience.	Doctor, extensive clinical experience.
12. View on a trained pharmacist offering TB clinical services other than of a drug supplier	Yes	No, pharmacists should place more emphasis on drug interactions.
13. Ability to manage TB patients who suffer from co-morbid conditions and receive treatment that illicit potential drug interactions	Not well managed.	Not well managed.
14. Would you support a complementary role for pharmacists in a clinic- based TB programme?	Yes	Yes
HCP comments		Stressed that time maybe limited in such a setting to interact with pharmacists due to her workload.

It seems evident that both the DOTS supporter and the clinic nurse perceived the pharmacist as a peripheral member of the primary healthcare team. Even though they believed that the pharmacists' role was related to addressing dug-related risks, both the DOTS supporter and the clinic nurse supported a complementary role for pharmacists engaging in a clinic-based TB programme.

4.12. Summary of findings from baseline study

There was an unequal proportion of male (33.33%) to female (66.67%) patients. Even though three-quarters (75%) of the patients had secondary level education almost all (92%) were unemployed. Three quarters (75%) of the patients were newly treated for the first time and were prescribed Regimen 1 which is specifically for adult patients. A quarter (25%) of the patients were being re-treated for TB. If pharmacists could screen patients and trace contacts for TB symptoms, this could help prevent the spread of the infection and subsequently lower the incidence rates.

None of the patients had attended a TB/HIV drug readiness-training programme and they were not familiar with its importance. Even though almost all (92%) of the patients indicated that the duration of TB treatment was fine, a few (8.3%) believed that it was too long. All the patients (100%) claimed to understand the TB information given to them by the clinic nurse and felt that they were aware of the functions of the tablets however, 16% of these patients did not know the names of their anti-TB drugs. Most patients (83%) seemed to identify TB treatment from at least one of two coloured tablets comprising the TB regimen namely Rifafour® and Vitamin B_6. Half of the patients (50%) felt that the purple tablet (Rifafour®) was too big to swallow. Even though all patients (100%) received supervised TB therapy, most of them (83%) claimed that they were actually comfortable being observed. Half of the patients (50%) smoked at least 1 cigarette stick per day and a quarter of them (25%) stated that they consumed alcohol while on TB treatment. With increasing TB caseload possibly due to HIV co-infection and increasing clinical workload in PHC, nurse-led TB care can easily be supported by trained pharmacists.

A trained pharmacist who has extensive knowledge in pharmacotherapy and drug formulation could work alongside a clinic nurse and promote treatment adherence. By alerting patients to the actions of drug therapy, highlight the factors that lead to drug resistance, and offer tailored advice to pharmaceutical formulation needs, it would lessen the load expected of clinical nurse practitioners. In view of the extensive pharmacotherapeutic training, pharmacists are under-utilized in TB management. Their

peripheral role contributes minimally to addressing the social and economic barriers affecting treatment adherence. Therefore an expanded role towards a clinic-based TB care programme could optimize care provision.

Survey responses from the DOTS supporter and clinic nurse underpin the need for pharmacotherapeutic and pharmacokinetic expertise from a clinic-based pharmacist, who can complement the role of a TB clinic nursing staff. Findings from the baseline study demonstrate the need for the involvement of a pharmacist in TB and HIV management. Of particular interest was the answer to question 5, where both the clinic nurse and DOTS supporter answered "Yes" to using the TB clinic record card to monitor patients. Based on this positive response, the researcher subsequently adapted and modified the existing clinic record card (Appendix H) into a clinic-based intervention tool for potential use by trained pharmacists. The effectiveness of the clinic-based intervention tool was subsequently tested at Delft South ARV clinic and Elsies River TB clinic (chapter 5). In preparation for this, I modified the existing baseline questionnaires for implementation at Delft South ARV and Elsies River clinics.

Modifications to baseline questionnaires (Appendix A and B) for study at Delft South and Elsies River clinics.

A few modifications were made to the original baseline questionnaires (Appendix A and B) for the study at Delft South ARV and Elsies River clinics. From Appendix A, question 1b was made a closed ended question i.e. Yes or No response to obtain definitive answers. Question 3 became number 2 and in addition was also made a closed-ended question. Question 4 became question 3 and vice versa. Question 15 was specified to include open-ended questions. Questions' having "Other" as an option was also specified. From Appendix B (HCP questionnaires), question 6 was made a closed ended question by providing options.

4.14. Conclusion

It is clear that TB management offered by nurses is suboptimal with regard to addressing the pharmacotherapeutic needs of patients. The presence of a trained pharmacist in a clinic setting could promote better understanding of TB treatment, address key aspects of pharmaceutical formulation and devise adherence strategies. A trained pharmacist could work alongside nursing staff to provide both drug and non-drug related treatment strategies, access patient readiness to start ARV's and be part of the decision making team in the clinical management of TB and HIV.

CHAPTER 5: DESIGN, IMPLEMENTATION OF INTERVENTION TOOL AND ASSESSMENT OF FINAL YEAR PHARMACY STUDENTS.

In order to meet the primary objective of this study and following findings from the baseline study, this chapter discusses the design of a clinic-based intervention tool and its implementation at two clinics, namely the Delft South ARV clinic and Elsies River TB clinic. The intervention tool was designed with the intention that it could be used by trained pharmacists. However, along with severe staff shortage, high patient overload and an array of administrative commitments the recruitment of practicing pharmacists in this exploratory study was not possible. The researcher's training in PALSA Plus served as a common platform to engage with the staff on clinical activities with minimum disruption. Both qualitative data and quantitative data were collected to obtain insight that would be both holistic and authentic during implementation of the intervention tool at the two clinics.

Qualitative data was collected from the researcher's observations to obtain an in-depth account from interactions and experiences with clinic staff. The researcher diarized each day's experiences which included amongst others patient-HCP interaction and staff interactions. These notes were subsequently transcribed in detail, categorized and common themes were identified. Quantitative data was obtained from the researcher's use of the clinic-based patient data.

In order to meet the secondary objective of this study, this chapter describes the assessment administered to final year pharmacy students (2009), at UWC School of Pharmacy. The objective was to ascertain if a clinic-based TB/HIV management programme was needed in undergraduate pharmacy training. It provides the rationale for the assessment of students' knowledge, perceptions of TB/HIV management and concludes with a description of the clinic-based training that the researcher conducted with a group consisting of seven final year pharmacy students.

5.1. Implementation of the clinic-based intervention phase

Following findings from the baseline study (chapter 4), the patient and HCP questionnaires were subsequently modified for their implementation at the intervention clinics. The intervention was implemented over a period of 3 months at Delft South and 1 month at Elsies River clinics from July 2008 to October 2008.

5.2. Delft South Staff members

I describe the duties of the staff namely the ARV nurse, adherence counsellor, and patient advocate whom I worked with at Delft South ARV clinic. The description of their duties is largely based on my personal observations during my interactions as a participant observer.

5.2.1. ARV nurse/clinic nurse

The ARV nurse also known as the clinic nurse at this clinic was responsible for a number of HIV related duties such as dispensing ARV's to patients, screening HIV-positive patients to determine whether they were eligible for ARV treatment, monitoring patient adherence, drawing blood for CD4 count, and providing patients having HIV/AIDS with health education. Other duties include seeing HIV-positive patients on a weekly basis in the first month of their treatment and once a month after successful initiation of ART.

5.2.2. Adherence counsellor

The adherence counsellor at this clinic was a female in her middle forties. She was responsible for the drug-readiness training programme otherwise described as the clinical assessment of patients for ART initiation. The programme runs for 3 weeks at Delft South ARV clinic as opposed to the 4 weeks recommended by the Free State Department of Health and is divided into three sessions. Session one covers general HIV education and healthy living. Session two covers ARV's, and the third session deals with adherence planning. The counsellor uses a clinic form as a guide (see Appendix F, number 6) to ascertain patient adherence information. The adherence counsellor works closely with the patient advocate (PA) to monitor adherence. In some instances patients were "fast-tracked "which meant they were started on ART within 2 weeks as opposed to 3 weeks

because their CD4 count was considered to be very low (i.e. below 50 and already on anti-TB medications). The counsellor ensures that continual HIV education is provided even after initiation of ART.

5.2.3. Patient advocate (PA)

A total of ten PA's offer their services at the clinic, with each assigned to at least one patient as a treatment supporter. Patients who had successfully completed counselling with the adherence counsellor were deemed clinically ready to start ARVs. The PA's usually visit patients at their homes to assess adherence to treatment and factors that prevent them from taking their medication such as lack of food, lack of a grant e.t.c. In addition, PA's assist the clinic nurse when undertaking pill counts to verify patient adherence to prescribed treatment and they also supervise support group meetings which is held every Friday at the clinic.

5.3. Elsies River staff members

Table 5.1 (below) outlines a brief description of the roles and responsibilities of the various staff members who render services mostly to TB patients and some HIV positive patients at Elsies River clinic**.**

Table 5.1: Summary of staff roles and responsibilities at Elsies River clinic.

Staff	Roles and responsibilities
1. Clinic nurse (located within the TB-room)	Completes prescriptions, checks VCTs and family planning done on all new patients, and writes out medication packets for monthly DOTS supporter treatments.
2. VCT counsellor	Test all TB suspects, gives patient appointment for care clinic if Retroviral Disease (RVD) positive.
3. HOPE(HIV outreach program and education) CHW	Assists with DOTS, TB defaulters, advices health promotion daily in TB waiting rooms for 10 minutes, and checks folder of TB patients to see if VCT has been done.

4. Clinic DOTS supporter	Assists and observes patients taking medications in clinic, weighs all TB patients' monthly, advices on health promotion, interacts with patients, and checks folders for sputum reminders.

The various roles and responsibilities of each staff member at the clinic clearly underpins the ARV roll out at primary healthcare facilities. In their engagement with each other, it is envisaged that care provision should be integrated. However, the pharmacist seems peripheral and disconnected with the rest of the clinic staff. In a TB/HIV clinic a trained pharmacist would be pivotal to engage directly with the clinic staff and patients to monitor treatment outcomes.

Findings from the baseline study prompted the design of a tuberculosis clinic record card for potential use by trained pharmacists.

5.4. Design of intervention tool: Tuberculosis clinic record card

The intervention tool (see Appendix G) entitled "Tuberculosis clinic record card" was intended for use by trained pharmacists. Its design and layout was adapted from the TB patient record card routinely used by clinic nurses (see Appendix H: GW 20/12, 2002). The tool was blue as this was one of the universally acceptable colours for respiratory disease. The tool was divided into sections A-J but also had some uncategorized information such as TB record card number, clinic file number, clinic name, registration date with pharmacist, the date TB treatment started and expected date of treatment completion. Section A focused on the patient facility status and helped to collect data on patient details, Section B focused on patient TB treatment, Section C categorized TB according to the international code for disease (ICD-10), Section D was for noting patient sputum results because it aided the clinic nurse with diagnosis and screening, Section E was intended to record the patients TB treatment supervisor(s) and their details, Section F focused on adult regimen and dosages, Section G was used to assess patient adherence status, Section H was used to collect data on specific TB side effects, Section I focused on drug interactions and lastly Section J was reserved for patient treatment outcomes. A

graphic designer used Corel Draw to enhance the layout of the card. The main headings for each section were bold type, Times New Roman font was used with font size 14. The remaining text had the same font, but the font size was reduced to 12.

5.5. Rationale for the clinic record card

I discuss the rationale for the questions pertaining to each section (sections A-G) of the clinic-based record card. I also draw on the main aims for each and its applicability for use by a trained pharmacist.

Section A

This section was aimed at collecting patient data such as their demographic profile namely age, weight, race, and sex respectively. Non-demographic data collected from this section included the diagnosis of the patient, other concurrent conditions the patient had, duration of the other condition(s) and finally the type of TB case they were being treated for. The questions pertaining to the patient facility status were used to ascertain whether the patient was newly listed to the facility or if s/he had been newly transferred to the clinic for the first time. All of these patient details were required for tracking purposes i.e. name and surnames helped to track patients for follow-up care and to check the patient's progress during the post-intervention phase.

Section B

This section was themed "TB patient category" and aimed to categorize the type of TB treatment case each patient received from the clinic. This was necessary as there are different types of retreatment cases encountered clinically for example some patients had previously received TB treatment and defaulted whilst some where new case patients. The retreatment patients were sub-categorized into retreatment after failure (RF), retreatment after previous cure (RC), retreatment after interruption (RI), and retreatment after previous completion (RAC).

Section C

Questions from this section were based on the ICD-10 code mentioned above (see 5.4). The selected codes and their clinical definitions namely A16.2, A16.5, A16.7 and A18.8 (outlined in table 5.2) represented cases of TB that were frequently encountered in practice.

Table 5.2: ICD-10 code for different types of TB

ICD-10 code	Definition
A16.2	According to the ICD-10 code, this is defined as TB of the lung without bacteriological or histological confirmation. It includes TB of the lungs, bronchiectasis, pneumonia, fibrosis of the lung, and pneumothorax.
A16.5	This is TB of the pleura, TB emphyema and unspecified respiratory TB.
A16.7	This is primary respiratory TB without mention of bacteriological or histological confirmation that combines hilar/mediastinal lymphadenopathy. It is also a combination of a small opacity in the lung, 3-10mm in diameter.
A18.8	This is TB of other organs such as peripheral lymphadenopathy, skin, eye, ear etc.

Section D was required to record the results obtained from diagnostic and screening tests that were conducted with sputum results from TB patients. This was tabulated and had three sub-headings namely; pre-treatment, end of intensive phase and culture results respectively. Under the pre-treatment and end of intensive phases the smear dates and smear result(s) were noted. The culturing of sputum is done because TB cultures are more sensitive than smear microscopy in detecting TB among patients with TB symptoms and signs. These patients are considered as nonconverters and must receive the retreatment regimen. The DOTS supporter usually collects the sputum for culturing in the laboratory (Ndjeka N *et al*, 2008).

From the baseline results, I found that all the patients surveyed were supervised by a treatment supervisor (see chapter 4, table 4.2) and this prompted the theme for *section E*. Six possible treatment supervisors that were identified were the patient's relative, a clinic

nurse, teacher, DOTS supporter, pharmacist and other healthcare provider(s). Information pertaining to the treatment supervisor(s) name, address, and telephone number was needed to monitor the patient treatment progress.

Section F investigated the appropriateness of the prescribed pharmaceutical regimen and its dosages. Enquiry was made into the type of adult TB regimen the patient was receiving and its initiation date. This section was subdivided into the intensive phase and the continuation phase because TB treatment is received over a 6-month period divided into two phases namely, the intensive and continuous phases.

Intensive phase of TB treatment

Information on the number of drugs, their dose, strength and frequency of drug administration to patients are required to check adherence and treatment outcomes. A fixed combination drug known as Rifafour® is given in clinics because it reduces pill burden. Rifafour® comprises four of the first-line anti-TB drugs used for the treatment of TB as a single pill (see chapter 2, section 2. 6). Other drugs taken concurrently during this phase include Pyridoxine (Vitamin B6), Vitamin B complex and Cotrimoxazole (Bactrim®) and for the purpose of this study, other drugs would include Antiretrovirals (ARV's). The DOTS supporter who monitors the patient's daily intake of TB medications records this activity in the tabular template (see Appendix G, section I, number 1).

The DOTS supporter is guided by certain symbols when supervising the patient's drug treatment. The DOTS supporter usually notes the name of the drug administered on the particular day and uses either one of the following symbols "√", "X", "O", and " -''as deemed appropriate. The symbol ''√'' means that medication has been taken under the supervision at the clinic, the symbol ''X'' means that the patient did not collect his/her medication, the symbol ''O'' means that the patient did not have to collect the medication because they were given a weekend package. The symbol ''-'' means that medication was collected for self-administration or supervision elsewhere (National Tuberculosis Control programme patient clinic/hospital card (GW 20/12, 2002).

In this study symbols ("X", "O", and "-") were used in noting the supervision of the patient's treatment. In addition, other symbols were added namely "N" and "P" where "N" denoted nurses and "P" denoted pharmacists. If the patient took the medication under the strict supervision of a nurse, the symbol ''N'' was noted in the card and if the medication was taken under the strict supervision of a pharmacist, "P" was noted in the card. A calendar depicting each day of the month was included under this section for tracking follow-up visits.

Continuation phase of TB treatment

The drugs used for the continuation phase were different from those used in the intensive phase. Therefore the drug RHZE in the first column was replaced with HR, the combination RHZ replaced with H, and S replaced with E (see Appendix G). The layout for capturing drug information (dose, number of tablets given, strength and frequency of dosing) for the TB continuation phase was similar to the intensive phase. A table resembling a calendar depicting each day of a month was also included under this section.

Assessing patient adherence to treatment at the intervention clinics

The terms adherence and compliance are defined because they have different meanings. The term adherence focuses on the degree to which a patient follows a treatment regimen while compliance has psychologically fewer benefits and can be perceived as an instruction where the patient is a passive recipient of the treatment (HIV/AIDS clinical management for pharmacist students, 2006).

At Delft South ARV clinic, adherence is measured at the end of the month from pill counts and compliance diaries. The patient advocate determines adherence by counting the number of tablets that are left over in the pill container. Compliance is measured from a patient's medication diary (see Appendix I). The patient is required to record each dose taken for the day in the medication diary. The accurate completion of the diary rests solely with the patient's level of motivation and honesty. The medication diary is written in several languages (isiXhosa, Afrikaans or English) to accommodate the patient's

preference for example an isiXhosa medication diary will not be given to an Afrikaans speaking patient and vice versa.

Section G assessed the patient's adherence status according to the remaining number of pills leftover after a month's treatment and this figure is expressed as a percentage of the total number of tablets that was dispensed at the beginning of the month. For example, if there are no tablets left over, then the patient is regarded as 100% adherent. The adherence status was categorized as either "bad", "good" or "excellent" depending on the level of adherence that the patient could achieve. The patient's adherence was considered "bad" when more than 2 pills were leftover, if 1-2 pills were leftover then their adherence was considered "good", and "excellent" indicated that all pills were taken as prescribed. Questions in this section also ascertained how patients took their medications with regard to timing and any discomfort(s) they might have experienced that prevented them from taking their medications.

Section H aided in collecting data on specific side effects such as peripheral neuropathy due to TB therapy, that the patient might have experienced. In addition their response in dealing with the side effect was noted. Four options were provided namely; stopping of their current treatment, continuing with treatment despite the discomfort, delaying taking their treatment or other potential responses. Patients were also expected to note their preferred HCP that they had consulted with when such side effects were experienced. HCP's that were listed included a nurse, pharmacist, doctor, traditional healer or any other person.

Section I explored the common drug interactions between anti-TB drugs and ARV's. Drug interactions of note occur between Rifampicin and ARV's such as Kaletra® and the NNRTI's namely Efavirenz and Nevirepine. Some side effects arising from individual anti-TB drugs in co-infected patients were also outlined here. An example of such side effect was peripheral neuropathy caused by isoniazid.

Patients' treatment outcomes such as drug interactions, contraindications, side effects, adverse effects were also recorded. For example, if patients suffered from rare conditions such as Immune reconstitution inflammatory syndrome (IRIS) then their treatment outcome will be recorded as adverse effects/reaction under this section.

5.6. Applicability of tool for potential use by trained pharmacists

The tool was designed with the intention to guide trained pharmacists in the clinic-based management of patients co-infected with TB and HIV. It was envisaged that this tool would enable pharmacists work directly with a clinic nurse, TB doctor, adherence counsellor and patient advocate in optimizing TB/HIV management. The tool would enable the ARV pharmacist monitor patients during their intensive and continuation phases of TB treatment. Of even greater importance is that during these TB treatment phases, patients may also be taking ARV's concurrently. It is therefore envisaged that such trained pharmacists will be in the ideal position to make timeous clinic-based interventions to prevent potential harmful drug interactions.

Following the clinic-based knowledge which I had attained from the PALSA Plus training (chapter 4, section 4.1), and my skills development in the TB and HIV clinics (4 months) enabled me to design the intervention tool. Furthermore, I was able to form a solid foundation and in-depth insight into routine clinic procedures and protocols which served to achieve the primary aim of my study. Both the knowledge and first-hand exposure had equipped me adequately to engage in TB/HIV clinic-based duties and care provision which prepared me to undertake the secondary objective of this study (Phase II).

The secondary objective of this study, aimed to explore if a clinic-based TB/HIV training was needed in undergraduate pharmacy training. Final year UWC pharmacy students were the target group as they were familiar with the theoretical concepts on most infectious diseases (Pharmacology module 417, 2009) and were exposed to clinical rotations at public-sector healthcare facilities. Since the class lectures on the

pathophysiological and pharmacological concepts of TB and HIV were already conducted. It was envisaged that familiarity with these topics would enable them to determine if a clinic-based TB/HIV training was needed to supplement their training. Student assessments were pre-arranged with the Pharmacotherapy course co-coordinator, a senior academic staff member from the Discipline of Pharmacology, School of Pharmacy at UWC.

Part 1: rationale for assessment questions

Following the PALSA Plus training I had received from the district TB coordinator (chapter 4, section 4.1). I was conversant with the TB and HIV management protocol followed in the clinic. I therefore assessed the current final year pharmacy students at UWC on their TB and HIV knowledge. Their perceptions about the potential role for pharmacists in TB and HIV management were also explored. In addition, my first hand clinic exposure at the two intervention clinics gave me the insight, practical knowledge and skills required for routine procedures at the clinic. The assessment was divided into two parts. The first part was used to collect quantitative data whilst the second part was not allocated any marks but was used to assess student's knowledge and perceptions on the clinical management of TB and HIV. Overall, my experiences acquired equipped me with the skills to assess and train final year pharmacy students. Consequently, student's assessment was based on the experiences I had acquired during my clinic visits. The student's assessment had 23 questions in total with part one having 19 questions and part two having 4 questions.

The layout of the assessment were as follows: student's basic knowledge of TB (questions 1 to 7), their drug treatment knowledge (questions 8 to 11), and their HIV drug knowledge (questions 15 to 19). A typical clinical scenario that I personally encountered on numerous occasions at Delft South ARV clinic (see Appendix O, questions 19a to 19d) was included to test the student's knowledge in the management of co-morbid conditions such as TB and HIV, assess their application of theoretical knowledge acquired from class lectures.

Part 2: questionnaire to ascertain student views and perceptions

This part of the student's assessment was in the form of a questionnaire (questions 21 to 23) that explored the views and perceptions of each student for a clinic-based training and the potential role of final year student in TB and HIV management. An enquiry was also made into their views of a proposed undergraduate clinic-based TB/HIV management programme to supplement their class lectures.

5.7. Introduction of a clinic-based training for UWC final year pharmacy students

The researcher conducted the training with seven final year students (chapter 3, section 3.4.1) on the 9th of June, 2009. The researcher designed an outline of the training session and handed a copy to each student. The training session was formal, yet interactive thus allowing students the opportunity to ask questions at any point during the session. The students engaged in meaningful discussions that related to the case scenarios. This training session was interactive as my personal experiences were shared with the students. The training lasted for approximately 2 hours after which they were assessed. All seven students were asked to give their feedback on the training session. The contents of the training and training notes which were extracted from the PALSA Plus 2007 edition are outlined below (see Appendix C).

5.8. OUTLINE OF TRAINING CONDUCTED BY RESEARCHER FOR FINAL YEAR PHARMACY STUDENTS AT UWC

Date: 9 JUNE 2009

Contents:

Importance of PALSA Plus approach to TB/HIV management
- Acronym
- Relationship with TB and HIV
- Target group

Suspecting TB
- Distinctive Symptoms
- HIV and TB

Diagnosing TB
- Criteria for new case suspect
- Criteria for retreatment case
- Treatment of TB (Sputum bacteriology)

Treatment of HIV TB client

CD4 count

1.1.1 < 50

1.1.2 50- 200

1.1.3 200 and above

Importance of Bactrim and Pyridoxine (Vitamin B6)

TB treatment Wheel: its use in follow-up care

Regimens for TB treatment

Smear-positive client

TB treatment table

Anti-TB drugs

Contra-Indications

TB treatment phases

Duration of TB Treatment phases

End of treatment

TB cured

TB completed

TB failure

ART first-line regimens for adult patients

Regimen 1a

Regimen 1b

Contra-indications

Second line ART regimen for adult patients

Regimens

Contra-indications

Counselling of TB/HIV patients (Drug Readiness Training)

Session 1: Disclosure and positive living (Appendix J)

Session 2: Basics of HIV, CD4 and Viral load (Appendix K)

Session 3: Opportunistic infection's, ARV Treatment Plan, Adherence (Appendix L)

Healthcare professionals are required to optimize care for HIV/AIDS patients and minimize the rate of infection. This has compelled HCPs to scrutinize their practice for ways to keep up-to-date with current knowledge, treatment modifications of HIV and its infectious opportunistic infections such as TB (UNAIDS, 2006). It is therefore essential that pharmacy students are also up-to-date with the current clinical practice patterns in the management of TB and HIV provided at primary care clinics such as Delft South ARV clinic.

CHAPTER 6: RESULTS

This chapter provides a narrative of results collected during the pre-intervention, intervention and post-intervention phases. The data was collected from the patients, HCP's and UWC final year pharmacy students. The results are divided into two phases which are subdivided into three sections namely section one, section two and section three. Section one presents the results obtained from patients who attended Delft South ARV clinic. Section two presents the results from HCP's at Delft South ARV and Elsies River clinics while section three presents the assessment results obtained from the UWC final year pharmacy students.

Phase I study
6.1. Section one: Pre-intervention results

The aim of the pre-intervention study was to assess patient's perception(s) towards the pharmacist and knowledge of their TB/HIV treatment. The main method of data collection was from questionnaires used during semi-structured interviews that lasted for approximately 10 minutes per patient. A total of 19 co-infected patients received the pre-intervention questionnaires. Knowledge of their clinical conditions and initial perception(s) towards the pharmacist was explored. A correlation between patient education and knowledge of their conditions seemed to be evident.

I highlight the pertinent parameters relating to patient-centered care that were used to assess current practice patterns of TB/HIV management. These include enquiry into patient knowledge of their TB/HIV medication use, patient preference for a HCP, and their perceptions of the pharmacists' role in treatment provision.

Table 6.1.1: Demographic profile of patients (n=19) at Delft South ARV clinic

Gender	Frequency	Percentage (%)
Female	10	52.6
Male	9	47.4
Age	Frequency	Percentage (%)
20-29	5	26.3
30-39	10	52.6
40-49	4	21.1
Education	Frequency	Percentage (%)
Primary	5	26.3
Secondary	13	68.4
Tertiary	1	5.3
Home language	Frequency	Percentage (%)
Afrikaans	5	26.3
English	1	5.3
isiXhosa	12	63.2
Others	1	5.3
Race	Frequency	Percentage (%)
Black	13	68.4
Coloured	4	21.1
White	2	10.5

Results

Just above half (52.6%) of the patients were females and the rest (47.4%) were males. Their age ranged from 20-49, with more than half (52.6%) of the population falling within the 30-39 age groups. Two-thirds (68.4%; 13) of them attained secondary (grade 8) education. In this study, most of the patients recruited were black South Africans (63.2%), mainly isiXhosa-speaking followed closely by the Afrikaans speaking patients (26.3 %; 5). Even though literature on Delft South community suggested that the dominant race were coloureds (75%) (Chapter 3, section 3.1.2.), in this study, the dominant race for the pre-intervention phase were primarily black South Africans (68.4%), with only one-fifth (21.1%) comprising Coloured patients.

Enquiry into patient knowledge of contracting TB

Table 6.1.2: Patient knowledge of TB infectivity

Is TB contagious?	Frequency	Percentage (%)
No	3	15.8
Yes	16	64.2
Are you aware of how you contracted TB?	Frequency	Percentage (%)
No	7	41.2
Yes	10	58.8

Almost two-thirds (64.2%) of the patients knew that TB was contagious. Although more than half (58.8%; 10) claimed they knew how they contracted TB, only one-quarter **(**30%; 3) attributed it to physical contact with infected sputum which may indicate poor understanding of information given to them by mainly nurses. Other mentioned reasons ranged from cold environment, cold beer, needles, and open wounds (70%; 7). Clearly many studies have indicated that patients with adequate knowledge of TB and its treatment are more likely to comply with their treatment than one with limited knowledge (Liam CK *et al*, 1999; Wandwalo ER, and Morkve O, 2000).

Table 6.1.3: Enquiry into patient knowledge of TB/HIV tablets

Knowledge of tablets	Frequency	Percentage
No	1	5.9
Yes	16	94.1
Colours of tablets	10	71.4
Names of tablets	4	28.6
Do you know what the tablets do?	Frequency	Percentage
No	1	6.7
Yes	14	93.3

For infectious diseases such as TB and HIV, it is crucial that co-infected TB/HIV patients understand how these infections are spread, so that adherence to their complex treatment regimens becomes meaningful. The correlation between patient education and knowledge of their condition was evident in the percentage of positive responses obtained. As mentioned earlier, more than two-thirds (68.4 %) of patients had received secondary education and 58.8% had knowledge of how TB was contracted (table 6.1.2). Furthermore, almost all (93.3%; 14) of

these patients knew what their tablets were meant to do, and knowledge of this requires some form of education that is beyond the primary level.

Table 6.1.4: Enquiry into patient's preference for a HCP(s)

Preference with regards to patients TB/HIV discomfort	Frequency	Percentage (%)
Doctor	4	66.7
Nurse	2	33.3
Who gives TB information?	Frequency	Percentage (%)
Doctor	2	11.1
Nurse	14	77.8
Other	2	11.1
Preferred HCP with regards to patients TB/HIV treatment	Frequency	Percentage (%)
Doctor	12	66.7
Nurse	2	11.1
Other	4	22.2

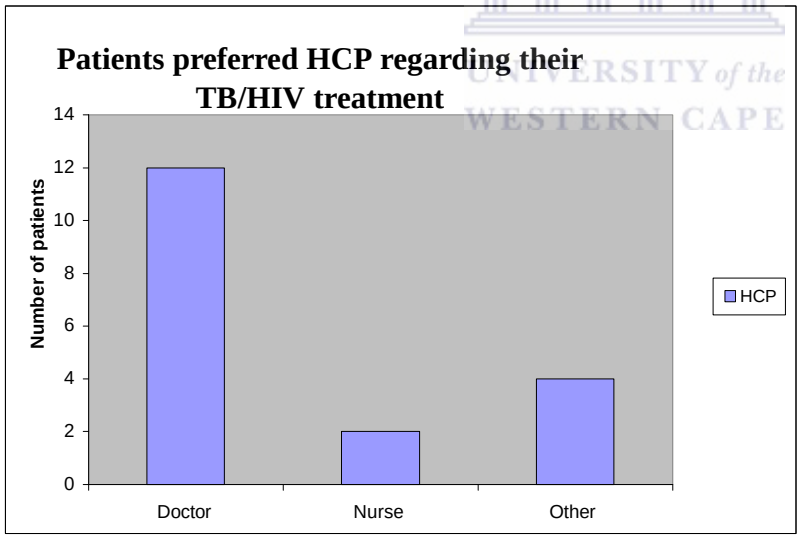


Figure 6.1: Patients preferred HCP regarding their TB/HIV treatment

In this study, over three-quarters (77.8%) of the patients preferred to receive TB information from the clinic nurse, while two-thirds (66.7%) of these patients preferred the doctor to the clinic nurse when it came to their TB/HIV treatment in general. The doctor seemed the most favoured HCP, since patients preferred consulting them for any discomfort arising from TB/HIV treatment. Even though nurses are designated front-line care providers at ARV clinics, patient

preference for care from doctors seem a primary source. One possible reason could be that due to the large number of patients receiving care from nurse-driven clinics and increasing administrative load, the quality of care may be compromised.

Supportive clinic-based services can also be offered by trained pharmacist who can address the pharmacotherapeutic needs of patients. The pharmacist's role in addressing medicine related risks are cornerstone to primary healthcare service provision.

Table 6.1.5: Enquiry into patient lifestyle

Smoking	Frequency	Percentage (%)
No	13	72.2
Yes	5	27.8
Alcohol consumption	Frequency	Percentage (%)
No	7	36.8
Yes	12	63.2
Access to 3-meals daily	Frequency	Percentage (%)
No	3	15.8
Yes	16	84.2

Smoking prevalence among Black South Africans is lower than their Coloured and Indian counterparts. The prevalence of smoking among people with primary and secondary education was shown to be higher than those with tertiary education (Walbeek C, 2001). Almost two-thirds (63.2%) of the patients claimed that they consumed alcohol. This percentage is disturbing considering that alcohol increases the risk of hepatotoxicity and peripheral neuropathy in patients concurrently on TB treatment. Furthermore, the risk of developing active TB disease is higher when tobacco smoking is combined with alcohol (Ramakant B, 2009). It has been shown that good nutrition is essential for the patient on ARVs because it helps to boost the immune system which contributes to an increase of their CD4 count (Prasad R, 2007)**.** It was relieving to know that more than three-quarters (84.2%; 16) of the patients ate at least three square meals a day, lack of food is a major barrier to adherence (http://All About Antiretroviral treatment art.mht). Therefore, Healthcare professionals who treat patients with TB and HIV should encourage a healthy lifestyle which includes amongst others refrain from the use of tobacco, and the consumption of alcohol when taking their chronic medications (Goodman A, 2009).

Table 6.1.6: Enquiry into the potential role of the pharmacist in patient treatment provision

Can the pharmacist help with treatment?	Frequency	Percentage
No	7	36.8
Yes	12	63.2

Almost two-thirds (63.2%; 12) of the patients believed that pharmacists assisted with their treatment provision without direct patient engagement. This implies that pharmacists currently offer a product-centered care rather than a patient-centered one, a finding that is fully endorsed by Williams (2006). Along with their technical skills, pharmacists are expected to develop a "covenantal relationship" which is one based on moral values with their patients. This role is however non-existent among pharmacists in primary healthcare facilities. If pharmacists need to be recognized as competent healthcare providers in the primary healthcare team, a clinic-based role might offer a feasible option.

Section two: HCP's results

The Delft South ARV clinic staff completed self-administered questionnaires and their responses are tabulated below.

Table 6.1.7: Comparative responses from ARV nurse, adherence counsellor and TB doctor at Delft South ARV clinic

	ARV nurse	**Adherence counsellor**	**TB/ARV doctor**
Gender	Male	Female	Female
Age range	40-59	40-59	30-39
Qualification	Basic nursing degree	No answer	Medicine degree
TB experience (years)	6-10 years	3-5 years	1-2 years
Use of clinic card to monitor TB care	Yes	Yes	Yes
Provision of drug information to TB patients	Adverse effects	No answer	Advice on drug interaction.
Frequency in promoting HIV testing	Sometimes	Always	Always

Onset of TB counselling	All patients	All patients	New patients
Response to side effects and drug interactions	Doctor	Doctor	TB Doctor
View on which HCP is most equipped to deal with drug interactions and side effects and a possible reason	Nurse	Doctor	Doctor
View on a trained pharmacist offering TB clinical services other than of a drug supplier	No answer	No answer	Pharmacists should consult on side effects and contra-indication.
Ability to manage TB patients who suffer from co-morbid conditions and receive treatment that elicits potential drug interactions	No answer	No answer	Frequent monitoring, explaining to patients when to come back, give them clinic phone number.
Would you support a complementary role for pharmacists in a clinic- based TB programme?	Yes	No answer	Yes
HCP comments	Pharmacists must have a complementary role.	No answer	None

The experience of the ARV nurse in TB care was approximately twice (6-10 years) the individual experience of both the adherence counsellor and TB doctor (3-5 years each). Interestingly, all HCP's answered "Yes" to using the routine clinic card (GW 20/12, 2002) to monitor TB care but none of the HCP's felt pharmacists were well equipped to deal with drug interactions and side effects. Although all three HCP's use the PALSA Plus approach, the ARV nurse only promoted HIV testing to some TB patients, an act which is contrary to the PALSA

plus approach of care which clearly states that HIV testing should be promoted to all TB patients (see PALSA Plus notes, 2007 edition, page 6).

Findings from above, coincides well with the Van der Walt's study (2006) where general practitioners did not support an expanded role for pharmacists because they felt pharmacists had limited knowledge (Van der Walt E, and Summers S, 2006).

In comparison to the baseline study (chapter 4), HCP's views on the most equipped to deal with drug interactions and side effects did not change as they all felt that the doctor was the HCP most equipped to offer these services. The doctor supported the notion that properly trained pharmacists can offer TB/HIV clinical services but on condition that they consult for treatment outcomes such as side effects, and contraindications.

I observed during the duration of my stay at this clinic that the ARV pharmacist was mostly always situated in the clinic pharmacy and did not interact directly with the other HCP's. It is envisaged that lack of constant presence by the ARV pharmacist contributed negatively to the views of other HCP's on the role of the pharmacist in TB/HIV management and the poor initial perceptions from the patients. The Health Systems Trust (HST) reported that there was still a need for more healthcare professionals, particularly pharmacists, to make the intended nurse-driven, clinic-based approach work properly (SOUTH AFRICA: Nurses to fill gaps, 2005).

6.2. Intervention phase results (n=98)

The aim of the study was to assess the effectiveness of the intervention (a trained researcher using specially designed clinic record card) on patients TB/HIV treatment. The researcher used the clinic record card for 4 months (July 2008 to October, 2008). A total of 98 co-infected patients attending the Delft South ARV (n=72) and Elsies River TB clinics (n=26) received the intervention. I discuss the clinical data which are relevant to testing the effectiveness of the intervention in relation to TB/HIV care provision and patient health outcomes.

Table 6.2.1: Age distribution of patients

Age range	Frequency	Percentage (%)
0-29	22	23
30-39	49	53
40-49	17	18
50-59	4	4
60-69	1	1.1
Total	92	100

More than half (53%) of the co-infected patients were between the age groups 30 and 39 with almost a quarter of them (23%) in the 0-29 age group. This indicates that the burden of co-infection with TB and HIV at both clinics were predominantly among the economically productive age group (i.e. the workforce). Even though the antenatal HIV prevalence report (2006) which serves as a reliable indicator of the progression of HIV/AIDS in SA showed a decrease in prevalence rates among the younger age group (30-39), the finding above is contrary to that report since majority of the co-infected patients during this phase belonged to the younger age group (30-39).

Table 6.2.2: Correlation between patient weight and CD4 count

Weight(in kg)	Frequency	Percentage (%)
40-49	20	23
50-59	32	37
60-69	28	32
70-79	4	4.6
80-89	3	3.4
Total	86	100
CD4 count	Frequency	Percentage (%)
0-49	17	19.3
50-99	15	17.0
100-149	28	31.8
150-199	17	19.3
200-249	6	6.8
250-299	4	4.5
300-349	1	1.1
350-399	1	1.1
Total	88	100

The weight of patients with immunocompromised conditions such as HIV is a determining factor in the initiation of their ARV treatment. The findings from this phase of the study showed that more than one-third (37%) of the patients who received the intervention had their recorded weights between 50-59kg, followed closely (32%) by patients having weights between 60-69kg and a few (3.4%) with a recorded weight between 80-89kg. A study showed a link between people with HIV and the negative effect of obesity on immunity. It was found that obese patients with HIV treated with ARVs gained fewer CD4 counts compared with their non-obese counterparts. Interestingly, this link was consistent with lower weights. In the absence of ARVs patients HIV disease progression was faster and fatal (Prasad R, 2007; Goodman A, 2009).

Lower weights have been associated with poor patient response to their treatment and possibly a correlation could be established between a low weight and a low CD4 count (Goodman A, 2009). The CD4 count is an indication of how patients with HIV are coping with their condition. Literature states that TB treatment can only be initiated in an HIV-positive patient when the CD4 count is less than 200 (chapter 2, section 2.8) but in this study, almost one-third (31.8%) of the patients had their CD4 count between 100 and 149. If the CD4 count is an indication of how patients are coping with HIV, then it can be safely speculated that when their weight is low they are not coping well with the disease.

A low CD4 count in co-infected patients with TB and HIV may be as a result of patients not starting ARVs on time thus these patients come to the clinic when they are very ill and are then fast-tracked. Most of the patients were unemployed and had their CD4 count below 200, which qualified them for a disability grant. However, this may adversely affect patient adherence to treatment because they may be tempted to keep their CD4 count low so as to continue collecting the grant (Rowe *et al*, 2005; Bond V *et al*, 2009).

Table 6.2.3: Demographic profile of intervention patients

Race	Frequency	Percentage (%)
Black	71	78
Coloured	20	22
Total	91	100
Gender	Frequency	Percentage (%)
Female	50	53.8
Male	43	46.2
Total	93	100

According to the data above, patients are predominantly female black South Africans (78%) which is contrary to the Delft and Elsies River community demographic profile provided in section 3.1.2 and 3.1.3 (chapter 3), the reason for this could be that Delft as a community is divided into Delft and Delft South. More than half (53.8%; 50) of the patients surveyed in this study were females, again showing that generally the burden of these conditions are seen more in females than males (HSRC, 2005).

Table 6.2.4: Patient diagnosis by their HCP

Diagnosis	Frequency	Percentage
Doctor	4	4.4
Nurse	86	95.6
Total	90	100

Diagnosis of patient is nurse-based at a primary healthcare level, as most patients received treatment from nurses with medically trained doctors having less direct contact (Kagee A, 2004). Since nurses are predominantly responsible for the diagnosis and treatment at the primary care level, the involvement of doctors is minimal.

Almost all (95.6%; 86) of the patients were diagnosed by nurses with either having TB, HIV or both conditions . In contrast, only 4 patients were diagnosed by doctors as having both conditions. A possible explanation based on my observations could be the fact that the doctor only saw patients twice a week (Tuesdays and Thursdays) whilst the clinic nurse who was present everyday, was the primary service provider involved in detecting, screening and diagnosing high risk patients. In this study, the workload on the clinic nurse is evident following the diagnosis of 86 co-infected patients. A trained pharmacist would be needed in such a setting

to alleviate the workload on lack of the clinic nurse, where the medicine-related risks, including to TB/HIV adherence to treatment could be addressed.

Table 6.2.5: Type of TB treatment case

Case type	Frequency	Percentage (%)
New	67	75.3
Retreatment	22	24.7
Total	89	100
Type of pulmonary TB	Frequency	Percentage (%)
N	67	75.3
RAC	1	1.1
RC	6	6.7
RI	1	1.1
RO	14	15.7
Total	89	100

More than 85% of people with TB in South-Africa have TB of the lungs known widely as pulmonary TB (Department of Health, 2006). In this study, majority (75.3%) of the co-infected patients were diagnosed as having new TB cases with a quarter (24.7%) receiving care for retreatment TB. Furthermore, 15.7% of patients were retreated after their previous completion (RO). These high retreatment cases clearly indicate that TB resurgence amidst the HIV pandemic is placing an enormous economic burden on the South African healthcare system. Pharmacists specializing in TB/HIV management are needed to undertake a clinical and patient-centered role alongside TB nurse practitioners. In providing such care pharmacists need to understand the patient's medical and social barriers that influence treatment outcomes.

Table 6.2.6: Patient adherence status

Adherence	Frequency	Percentage (%)
Bad	11	13.8
Excellent	23	28.8
Good	46	57.5
Total	80	100

Patient treatment adherence status was assessed from pill counts during the clinic visits. Adherence was assessed by using three keys which are outlined as follows; *excellent* adherence indicating that all pills were taken, *good* adherence indicating that 1-2 pills were leftover, and

bad adherence indicating that more than 2 pills leftover. The data presented here was largely supported by patient advocates who count pills and monitor patient adherence as part of their daily duties. Even though, more than half (57.5%) of the patients had achieved good adherence, just over a quarter of them (28.8%) adhered to their regimen excellently, while the rest (13.8%) of the patients seemed to adhere poorly to their treatment. The varying adherence status may be attributed to the poor rapport that exists between healthcare providers and patients with TB (Dick J *et al*, 2004).

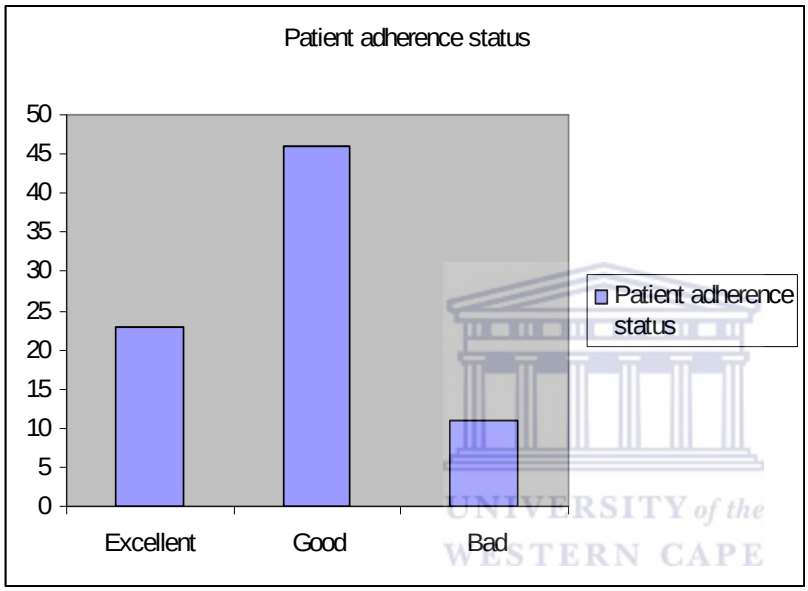


Figure 6.2: Assessment of patient adherence status

Even though the adherence status of patients in this study was mostly between good (45 patients) and excellent (24 patients), adherence is influenced by different factors. While there are numerous factors that contribute to poor adherence aside from the one stated above, in this study the most recognized factors are due to the patient's socioeconomic status such as poor living conditions (overcrowding), lack of food due to unemployment, and lack of good sanitation. South Africans who are unemployed attend primary healthcare clinics that are often overcrowded, under-resourced and staffed by over-worked HCP's (Kagee A, 2004). If basic needs such as good sanitation are not met, high risk patients become susceptible to infectious diseases. Consequently, they cannot maintain a sustainable income resulting in dependency on a disability grant. As social injustice prevails, infectious diseases that can be cured (TB) or controlled (HIV) will remain a challenge to the primary healthcare sector. Pharmacists who are

trained towards social responsiveness can engage with community partnerships to identify and address the injustice that impinge on healthcare.

Table 6.2.7: Patient treatment outcomes and common side effects

Treatment outcomes	Frequency	Percentage (%)
Adverse effect	1	1.1
Drug interaction	23	26.4
Side effects	56	64.4
Other	7	8.5
Total	87	100
Side effects	Frequency	Percentage (%)
Decreased appetite	2	16.7
Diarrhoea	1	8.3
Increased appetite	6	50
Muscle weakness	1	8.3
Nausea and vomiting	2	16.7
Total	12	100

Almost two-thirds (64.4%) of the patients reported that they had experienced side-effects, more than one-quarter (26.4%) claimed to have experienced drug interactions, and few (9.5%) of the patients identified adverse effects (1.1%) resulting from drug therapies. A trained pharmacist could offer suggestions or devise approaches to manage drug interactions and side effects.

Half of the patients indicated that they had experienced an increase in appetite (50%) as a side-effect. This is a common side effect when patients take their medications regularly and can be taken as a positive sign of patient adherence. However, increased appetite may be a negative factor to patients who are unemployed or without disability grant because they may lack food. Other side effects recorded were decreased appetite (16.7%), nausea and vomiting (16.7%), diarrheoa (8.3%) and muscle weakness (8.3%).

Table 6.2.8: Patient drug interaction

Drug Interaction	Frequency	Percentage (%)
Rifampicin + Efavirenz	19	82.6
Rifampicin + Nevirepine	4	17.4
Total	23	100

Rifampicin is a potent enzyme inducer of the liver enzyme P450 cytochrome. Rifabutin is a weaker enzyme inducer than rifampicin but unfortunately this drug is not available to the South African state sector e.g. clinics (Dawood H, 2006). The ART regimen has been modified to make it compatible with the standard, rifampicin-based TB treatment. The South African guidelines does not recommend increasing the dose of efavirenz when given together with rifampicin because of the risk of toxicity. Nevirapine is however well tolerated when co-administered with rifampicin. In this study, more than three-quarters (82.6%) of the patients received both rifampicin and efavirenz thus they were at risk for toxicity especially in women since efavirenz has been shown to be teratogenic (WHO ART guidelines meeting review, 2009).

Table 6.2.9: Number of other drugs taken by patients

Number of other tablets	Frequency	Percentage
Three	35	41.7
Four	45	53.6
Five	4	4.8
Total	84	100

More than half (53.6%) of the patients were taking four other tablets concurrently with their anti-TB drugs. This finding may adversely affect patient adherence due to pill burden. However, patients taking Rifafour® may be an exception because this drug is a fixed-dose combination. More than one-third of the patients (41.7%) were taking three other drugs and a small percentage (4.8%) was taking five other drugs.

6.3. Post intervention phase results (n=48)

The aim of this study was to assess receptivity and effect of intervention on patient therapy.
Data was collected using questionnaires (Appendix M and N) from 48 patients that had previously received the intervention during the pre-and intervention phases. The post-

intervention questionnaires were originally designed in English language (Appendix M) and they were translated into isiXhosa (Appendix N) for those patients recruited from Delft South ARV clinic. A patient advocate (PA) working at this clinic assisted with data collection. The questionnaires administered to patients attending Elsies River were provided in the English language.

In view of time and language constraints that were encountered during the pre-intervention phase, most of the questions in this phase were dichotomous (Yes or No). According to the research design (chapter 3, section 3.7.2), patients were distributed into four groups. However, it must be noted that the distribution of patients was uneven across the group. The reason for this was due to the fact that the researcher conducted the patient interviews within the personal workspace of the adherence counsellor and only gathered data after counselling was complete. *Most of the patients were grouped as experimental 2 patients* (see table 6.3.5) and received both the intervention and post-intervention. Data obtained was input into Epi Info (2003), analyzed and the results are outlined below.

It must be noted that only 48 of the 98 patients recruited during the intervention phase was available for the post-intervention phase. The rest of the patients were lost to follow-up care.

Table 6.3.1: Patients initial perception(s) of clinic pharmacist

Only give medications to patients	Frequency	Percentage (%)
No	11	26.2
Yes	31	73.8
No interaction with patient	Frequency	Percentage (%)
No	18	41.9
Yes	25	58.1
All of the above	Frequency	Percentage (%)
No	12	28.6
Yes	30	71.4
None of the above	Frequency	Percentage (%)
No	24	55.8
Yes	19	44.2
Other perceptions	Frequency	Percentage (%)
No	23	53.5
Yes	20	46.5

In this study, almost three-quarters of the patients (73.8%) believed that pharmacist's role focused primarily on dispensing of TB medications. This high response rate was further retained in a clarifying question that pharmacists are primarily involved in mechanical dispensing when more than half (58.1%) of the patients claimed to have had no interaction with the pharmacist. The patients' initial perception is due to their minimal contact and interactions with the clinic pharmacist who is located in the clinic pharmacy. Even though undergraduate training programmes underpin the importance of patient-centered care, this role seems non-existent among public sector healthcare facilities in the Western Cape.

As seen, the patients single most favoured perceived role for pharmacists was that they only gave medications (73.8%), and more than half (58.1%) of them perceived a poor level of patient-pharmacist interaction.

A study in Tanzania (2000) highlighted the role of the pharmacist in TB/HIV management. Their roles were primarily drug-related and included amongst others counselling of patients on adherence and their side effects, dispensing, ordering both isoniazid and pyridoxine supply. This meant that pharmacists were primarily used as an information resource about procurement and stock of medicines thus, leaving a large proportion of the pharmacist's pharmaceutical knowledge and skill untapped for use in patient-centered care. The perceptions of patients towards pharmacists at these clinics are primarily drug-related where there is no direct interaction. The movement towards the patient care approach has occurred to varying degrees in countries such as the UK and the USA where the role of the pharmacist has evolved from that of a compounder and supplier of pharmaceutical products towards that of a provider of services and information and ultimately to that of a provider of patient centered care (Williams K, 2006).

One of the primary assessments of the intervention was to determine the potential clinic-based role of the pharmacist. I outline key findings that were obtained from this phase of the study.

Table 6.3.2: Key interventions by researcher on patient's treatment

Identified new symptoms	Frequency	Percentage (%)
No	1	2.3
Yes	42	97.7
Identified side-effects	Frequency	Percentage (%)
No	4	9.3
Yes	39	90.7
Referred patient to ARV doctor	Frequency	Percentage (%)
No	1	2.3
Yes	42	97.7
Suggested additional medication for side-effects	Frequency	Percentage (%)
No	16	37.2
Yes	27	62.8
Informed patient about grant	Frequency	Percentage (%)
No	0	0
Yes	43	100
Advised on treatment	Frequency	Percentage (%)
No	1	2.3
Yes	42	97.7
Encouraged positive thinking and attitude	Frequency	Percentage (%)
No	2	4.7
Yes	41	95.3
Other	Frequency	Percentage
No	0	0
Yes	42	100

The researcher's key interventions included identifying new symptoms, identifying side-effects, referring patients to ARV doctor, suggesting additional medication(s) for side effects, informing patients about grant, advising on treatment and encouraging positive thinking and attitude. Overall the patients' responses were largely positive. Almost all (97.7%) of the patients surveyed responded positively as a result of the researcher identifying new symptoms, referring them to the ARV doctor (97.7%) and advising on their treatment (97.7%). Other key interventions included encouraging patients on positive thinking and attitude (95.3%), identifying their side-effects (90.7%) and suggesting additional medication to relieve unbearable side-effects (63.8%) accordingly. All the patients (100%) indicated that they were informed about the disability grant and the criteria for qualification.

Since primary healthcare focuses on a collaborative multi-disciplinary team approach, patient views on this crucial aspect in service delivery were also explored.

Table 6.3.3: Patients views on pharmacist working together with other HCP's

Doctor and pharmacist	Frequency	Percentage (%)
No	0	0
Yes	43	100
Clinic nurse and pharmacist	Frequency	Percentage (%)
No	0	0
Yes	43	100
Adherence counselor and pharmacist	Frequency	Percentage (%)
No	0	0
Yes	43	100
Patient advocate and pharmacist	Frequency	Percentage (%)
No	0	0
Yes	43	100
Other HCP and pharmacist	Frequency	Percentage (%)
No	1	2.3
Yes	42	97.7

All the patients surveyed (100%) responded positively for the integration of services. They all supported a multi-disciplinary team care approach to their treatment and it was interesting to note that these patients felt that potentially pharmacists could work alongside clinic nurses. As mentioned earlier, diagnosis of patients at both clinics was highly nurse-based but a nurse-led

clinic could imply a strong degree of independence. However if other healthcare professionals oppose it, then it is doomed for failure (Hatchett R, 2008). In addition, the sharing of knowledge and experience is a part of all nurses' professional development thus a multi-disciplinary care team involving pharmacists would be vital in optimizing care provision.

Table 6.3.4: Patients responses after exposure to the intervention

Like to be attended to by the pharmacist	Frequency	Percentage
No	1	2.5
Yes	39	97.5
Has patient perception changed?	Frequency	Percentage
No	1	2.3
Yes	42	97.7

The post-intervention data clearly shows that patient's initial perceptions towards pharmacists had tremendously changed. Almost all (97.5 %;39) of the 48 patients surveyed at this phase wanted to be attended to by the pharmacist, giving a positive indication that pharmacist at these clinics were now being viewed positively as result of the intervention (trained researcher using a specially designed clinic record card).

Furthermore, almost all (97.7%) of the patients surveyed, had changed their initial perception(s) towards the pharmacist. In conclusion, findings from the post-intervention patient study clearly underpin that a potential clinic-based role for the pharmacist is imminent.

Summary of results according to research design

According to the research design used in this study (Solomon-four group research design), the effect of the intervention was assessed by comparing experimental group 1 with control group 1 and experimental group 2 with control group 2 (chapter 3, section 3.7.2). It must be noted that a patient could only be grouped once i.e. a patient can be categorized only under one group. The total number of positive ("Yes") responses obtained from the researcher's key interventions was equal to total outlined on table 6.3.2.

Table 6.3.5: Comparison between experimental and control groups to assess the receptivity of the intervention among patients.

Type of key interventions	Experimental 1	Control 1	Experimental 2	Control 2
Identified new symptoms(n=42)	7	3	31	1
Identified side effects(n=39)	6	3	29	1
Referred patient to ARV doctor(n=42)	6	3	32	1
Suggested additional medications for side-effects(n=27)	6	3	15	3
Informed patient about grant(n=43)	7	3	28	5
Advised on treatment(n=42)	7	3	32	0
Encouraged positive thinking and attitude(n=41)	7	3	31	0
Other interventions(n=42)	7	3	32	0
Has patient perception(s) changed?(n=42)	7	3	32	0

Findings from above clearly indicates that experimental group 2 patients who received the intervention and post-intervention formed two-thirds (66.7%) of the study. The effect of the intervention was found to be significant when a comparison was made between experimental group 1 (received pre-intervention, intervention and post-intervention) and control group 1 (received only the pre- and post-interventions). Seven out of the nineteen patients who received the pre-intervention gave positive responses to the following; researcher identified new symptoms, informed patient about grant, advised on treatment, encouraged positive thinking and attitude, other interventions and changed their initial perception towards the pharmacist. In contrast, only three out of nineteen control patients gave positive responses to all the researcher's key interventions which resulted in a change from their initial perception. The difference in percentage could be attributed to the effect of the intervention since patients from control group 1 did not receive it.

Due to the uneven distribution of patients a comparison could not be made between experimental groups 2 (received intervention and post-intervention) and control group 2 (received only the post-intervention). However, experimental group 1 can be compared with control group 2 because the latter only received the post-intervention. When these two groups are compared, it is clear that the positive responses are due to the effect of the intervention. This conclusion is drawn because the ratio of experimental group 1 patients who changed their initial perceptions to control group two patients is an enormous 7:0.

Furthermore, control group 1 (received pre- and post-intervention) can be compared with control group 2 (received only post-intervention). When these two groups are compared, it is clear that the pre-intervention succeeded in sensitizing patients, thus the number of positive responses recorded. In conclusion, the research design used in this study was appropriate in ascertaining the perceived effect of the intervention across three groups.

Statistically, the Solomon four-group design demands a large number of patients thus its major drawback is that each of the four groups requires at least 30 patients. It's evident from table 6.3.5 that statistical analysis of the data cannot be applied (Yount R, 2006).

Phase II

6.4. The aim of the study was to assess final year pharmacy students' current TB/HIV knowledge and assessed scores between students who had received an introductory clinic-based session (experimental group) with those who received the usual classroom based teaching (control group). The researcher designed an assessment (Appendix O) which served as the sole method of data collection for student groups. The assessment was divided into two parts with the first containing 19 questions and used to collect mainly quantitative data whilst the second part was in the form of a questionnaire and was used to collect mainly qualitative data. The maximum score for the assessment was 42.5 (100%) and the pass mark was set at 50% (21.25). The control students had one hour to complete the assessment whilst the experimental students completed the assessment after receiving the introductory clinic-based training from the researcher (chapter 5). The findings from the student's assessment are provided below.

Section three: UWC final year pharmacy student's results
Table 6.4: Responses between control (n=37) and experimental (n=7) students

	Control	**Experimental**
Quantitative results		
Total number of students that wrote	n = 37	n = 7
Number of student that passed	15	7
Number of students that failed	22	0
Highest score	37.5	34.5
Lowest score	17	29.5
% passed	40.5	100
% failed	59.5	0
Range of marks	Frequency	Frequency
< 10	0	0
10-25	8	0
26-45	29	7
Students knowledge of 1st line ARV regimen and dosages(numbers refer to marks)	Frequency and Percentage (%)	Frequency and Percentage (%)
0-0.9	7 (18.9)	0
1-1.9	21(56.8)	0
2-2.9	8 (21.6)	3(42.9)
3-4	1(2.7)	4(57.1)
<u>Case-study (C) and (D)</u>		
C. Students knowledge of potential drug intervention between anti-TB and ARV's(numbers refer to marks)		
0-0.9	28(75.7)	5(71.4)
1-1.9	9(24.3)	2(28.6)
2-3	0	0
D. Students knowledge of the importance of Bactrim® and Vitamin B complex (numbers refer to marks)		
<0.5	1(2.70)	0
0.5-0.9	8(21.6)	0
1-1.5	28(75.7)	7(100)
Students views on expanded role for pharmacists?		
No	0	0
Yes	36(100)	7(100)

Students' previous TB/HIV clinic training?		
No	29(80.6)	7(100)
Yes	7(19.4)	0
Support for 4th year clinic- based TB/HIV exposure?		
No	1(2.86)	0
Yes	34(97.14)	7(100)
Qualitative results		
Students opinions on expanded role for pharmacists	…..**roles that are drug-related** *(n=3)*	(*n=3)*
	…to guide patients through their medication and condition.	*…pharmacists need more information on drug interactions and side effects.*
	….to minimize drug interactions and side effects.	*…pharmacists are drug agents thus they know drugs more than any other HCP's.*
	… Patients value pharmacist's opinions since they are custodians of medicines.	*…pharmacists can also help patients with potential side effects*
	…roles relating to counselling and adherence *(n=13)*	*(n=2)*
	…pharmacists should be involved in patient counselling and education.	*…pharmacists should explain side effects and counsel patients.*
	…pharmacists should be involved in patient care to aid in compliance and adherence of patients.	*…pharmacists can directly interact with the patients and help them understand their drug therapy.*
	…roles that are clinical *(n=6)*	*(n=1)*
	…pharmacists should be *well informed to undertake*	*…pharmacists should supply information on*

	patient centered care and lifestyle modification. *…pharmacists should be allowed to test TB/HIV patients since they have more knowledge.* **…roles that are clinical and relates to counselling** *(n=2)* *…Pharmacy has become more clinical and pharmacists can give advice to other HCP's on treatment of patients.*	*health, lifestyle modifications and all information pertaining to drugs.*
Summary of students feedback on clinic training to supplement 4th year class lectures on TB/HIV management	*TB/HIV counselling sessions* *VCT training* *TB/HIV testing techniques* *Dealing with actual case-studies* *Role-playing* *Attending HIV pre- and post-counselling sessions* *Exposure to clinic TB/HIV management,* *TB/HIV course* *Adherence counselling, Support groups/clubs* *Mandatory involvement at HIV clinics*	*Practical counselling sessions (OSCE's)* *Recognition of side effects due to drugs* *Practical hands-on approach* *Visits to TB/HIV clinic to experience* *PALSA Plus training* *Protocols used in TB/HIV clinics* *Treatment criteria used in clinic* *TB/HIV counselling processes*

6.4.1. Results

It must be noted that assessment scores obtained from the control and experimental students groups could not be compared due to the difference in sample size. However, the scores were assessed to find common themes between the two groups and these were recorded in table 6.4. Out of the 37 control students, 15 students passed whilst 22 students failed. The highest score recorded was 37.5 (88%) and the lowest score was 17 (40%). Less than half (40.5%) of the control students passed the assessment while in contrast, an overwhelming 59.5% of them failed.

All seven (100%) of the experimental students group passed the assessment and the scores ranged between 26 and 45. More than three-quarters (78.4 %; 29) of the control students passed with marks between 26 and 45, and less than a quarter (21.6%; 8) of these students had marks between 10 and 25.

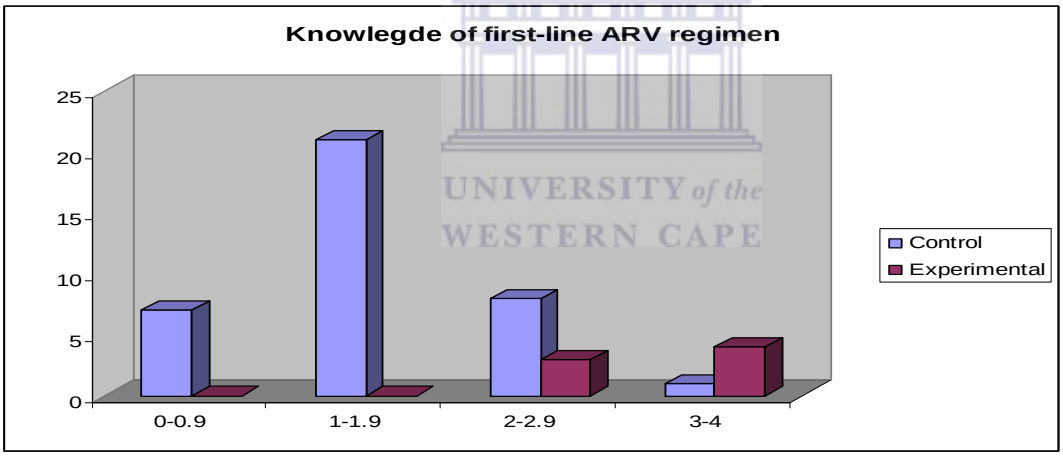


Figure 6.3: Students knowledge of first line ARV regimen

More than half (56.8%; 21) of the control students scored between 1 and 1.9, eight (21.6%) scored between 2 and 2.9, seven (18.9%) between 0 and 0.9 and only one (2.7%) student scored between 3 and 4. Almost half (42.9%) of the experimental students scored between 2 and 2.9, and four (57.1%) scored between 3 and 4. This means that the experimental groups were able to apply theoretical concepts to practice-based scenarios. This result is also evident from their knowledge of potential drug-drug interactions and the importance of Bactrim® and vitamin B. Complex among patients in TB/HIV management.

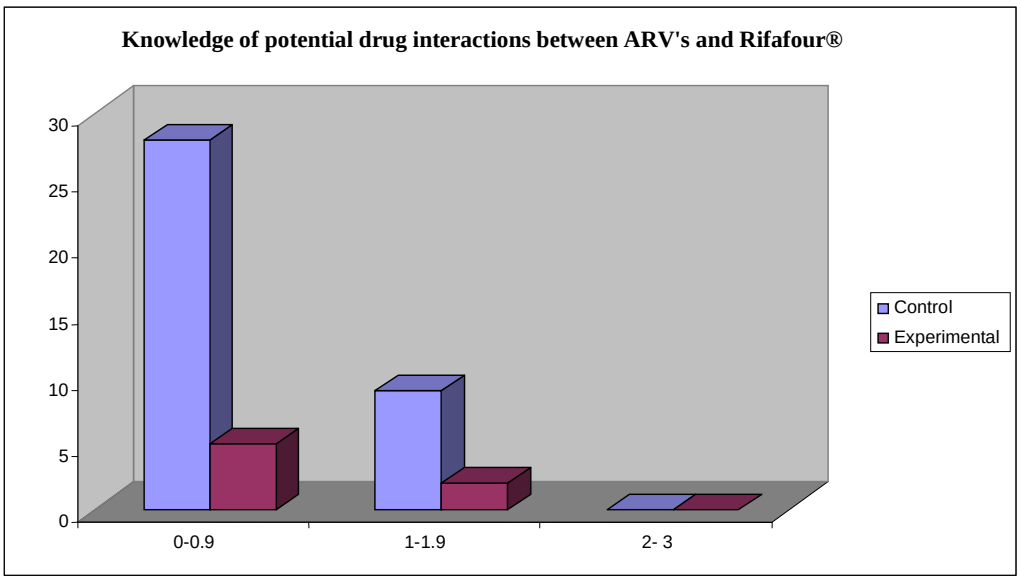


Figure 6.4: Student's knowledge of potential drug interactions

Students' knowledge of potential drug interaction between anti-TB drugs and ARV's showed 28 (75.7%) control students scoring between 0 and 0.9 and nine students scoring between 1 and 1.9. Five experimental students scored between 0 and 0.9 and two students between 1 and 1.9.

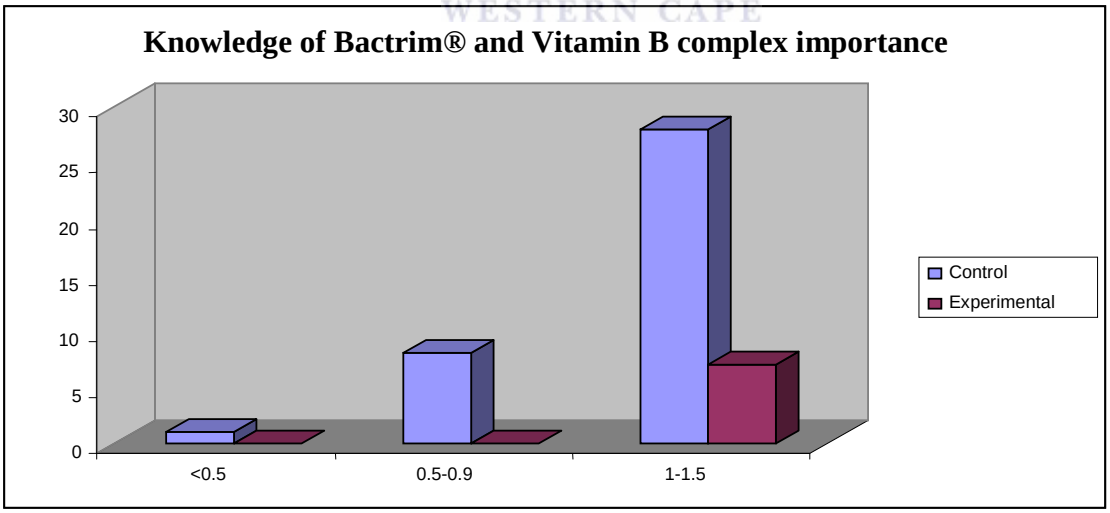


Figure 6.5: Students knowledge of Bactrim® and Vitamin B complex importance

All (100%) seven of the experimental students scored between 1 and 1.5 and while three-quarters (75.7%; 28) of the control students scored between 1 and 1.5. One control student and eight control students scored less than 0.5 and between 0.5 and 0.9 respectively.

Common themes amongst control and experimental students

It was interesting to note that all (100%) students from both the control and experimental groups supported an expanded role for the pharmacist. Three out of the 37 control students had opinions that were drug-related (three for experimental), 13 had opinions that related to counselling and adherence (two for experimental), six had clinical opinions (one for experimental), and two control students had opinions that related to counselling and clinical involvement. Five control students and one experimental student did not state their opinions. Seven control students gave opinions that were not pharmacy related. This question provided positive responses that were both quantitatively and qualitatively relevant to this study.

For example, 32 out of the 37 control students (86.5%) and six out of the seven experimental students (85.7%) stated their opinions. These two percentages are virtually the same quantitatively (less than 1.0% difference) and qualitatively, the student's opinions across the groups were also very similar even though only seven of them received the training. Furthermore, student's opinions were qualitatively relevant to this study because the responses obtained showed that both trained and untrained students supported an expanded role for pharmacists that was not only drug-related but was also clinical, and involved direct patient interaction (counselling).

All (100%) the experimental students and more than three-quarters (80.6%) of the control students had no previous TB/HIV training. Less than a quarter (19.4 %; 7) of the control students answered "Yes" to that question and according to these seven students TB/HIV training included exposure to an ARV pharmacist during SLIP rotation, how to live with HIV-positive people, assisting the ARV pharmacist with dispensing and counselling, and knowledge of ARV generics such as Aluvia®. Out of these seven students only two actually underwent a proper training, one

at Dr. Nkanyetsi Hospital for two months and the other with the HIV South African clinician's society (2007) conducted by Dr. Lin Webb.

All seven (100%) of the experimental students and almost all (97.14%) of the control students supported a clinic-based TB/HIV exposure and only a few (2.86%) of them answered "No" to that question. Students had varying, and overlapping views on clinic training to supplement their 4th year class lectures on TB and HIV management. This question was open-ended question to allow students express and suggest their views freely.

As stated above, students from both control and experimental groups felt that TB and HIV counselling sessions were important which corresponds with the SAPC's role for pharmacists. The students also shared overlapping views such as dealing with actual case studies (control) which corresponds with a practical hands-on approach (experimental), role-playing (control) corresponds with practical counselling sessions (experimental). It is obvious that the students were of the general opinion that the clinical management of TB and HIV requires clinical exposure and direct involvement from the pharmacist.

6.4.2. Students feedback session on PALSA Plus training received

As mentioned earlier in the research methodology (chapter 3, section 3.2.1), seven students were recruited as experimental students. The PALSA Plus training feedback session was conducted on the same day after the training (June 9, 2009). The students gave their feedback immediately after writing the assessment and each feedback was anonymous.

Key for feedback
S: represents the students
S1: represents student one
S2: represents student two and this consecutive order will be followed for all the subsequent students with whom I trained.

Practical approach to learning

Some students felt that the PALSA Plus training was a very practical approach to dealing with the clinical management of TB and HIV. They felt that it was the closest resemblance to what really happens in a clinic that provides integrated TB/HIV care to co-infected patients**:**

S1: "*the training provided better practical view on drug use. I felt good case study examples were used and the researcher stayed much on track with issues to discuss on outline and cleared all small issues like why Bactrim® and Vitamins B6 and B complex were used. Practical issues like patients refusing medicines were also dealt with".*

S3: *"I learnt new interesting facts from the training..... It showed me the practical and technical side of TB/HIV treatment. I think it is very important for students to know the practical side and to learn how to apply the theory in real life.*
…..It (PALSA Plus training) offered me the opportunity to ask questions on TB/HIV treatment in more detail. It showed me how to use my knowledge or theory in the practical field".

S7: *"I found the training session very helpful in the sense that I was able to put the theory learnt into perspective. It helped me assess how much I already knew and refreshed the aspects of TB/HIV treatment which I had forgotten or didn't understand previously.*

Educational approach to primary healthcare

Some students felt that the PALSA Plus training was very educational and hands-on. They felt that it was a way to get better attuned to the realities of primary care level treatment and care:

S2: *"The training was very useful as it helps us get out of the classroom scenario and visualize what goes on in the primary healthcare level. I now have a better understanding of TB/HIV management.*
…..It (PALSA Plus training) was also educative as I got to see the tools used for TB diagnosis and management in primary health care e.g. TB treatment wheel and TB screening tool. It was an eye- opening experience".

S4: *"It (PALSA Plus training) was educational as some of the issues dealt with I did not know in detail ….or did not really think about…... It made me think about a lot of things that would be of concern to patients that I was unaware of".*

S5: *"I felt it was a very informative session as I applied my theory to practice.*
…..It will be extremely useful in a TB/HIV management setting".

S7: *"I learnt about the TB treatment wheel as it was my first time of hearing and seeing it".*

Support for integration into 4th year curriculum

One student felt that the training was so important it had to be implemented into the current 4th year pharmacy curriculum:

S5: *"I suggest its (training) usefulness if all 4th year pharmacy students were to receive this training. The session was clear, concise and highlighted the important points of TB and HIV*
….. It brought a better or enhanced understanding of TB/HIV and protocols implemented in primary health care".

Training was well presented

One student felt the training was well presented in a manner they could relate to, and was not similar to what they were used to in class lectures:

S6: *"I think the training was well planned and it was more informative as it focused mostly on the practical approaches of the intervention.*
…..It was not over- loaded with information as the content was well presented and information presented was well managed. Most of the content was kept straight and simple to the point".

Following the student's feedback provided above, it can be safely concluded that the introductory clinic-based session was successful. As evident from student's performance and feedback, rigorous studies are needed to plan, implement and evaluate a clinic-based training programme for pharmacy students at primary care clinics.

CHAPTER 7: DISUSSION

The aims of this study were to assess the current practice patterns at TB/HIV primary healthcare clinics in the Western Cape and the need for a clinic-based TB/HIV training among final year pharmacy students at UWC.

This discussion focuses on the implications of the findings obtained from patients and HCP's (Phase I study) and final year pharmacy students (Phase II study). The key themes emanating from the Phase I study are the potential involvement of trained pharmacists in a clinic-based TB/HIV programme, the provision of patient-centered care, impact of the clinic-based intervention and inter-professional teaching and learning opportunities. For the Phase II study, the potential for clinic-based TB/HIV training for pharmacy students is highlighted. Finally, the use of mixed methods in this exploratory study is outlined.

In countries such as the USA and UK, the pharmacy profession has evolved beyond mechanical dispensing (Wiedenmayer VK, 2007). However, pharmacy in South Africa's public healthcare sector is confronted by an increasing demand on the primary healthcare services which is compounded by chronic diseases and exacerbated by the HIV/AIDS epidemic (Assal, 1999; Gilbert, 2004a; Yach & Hawkes, 2004). Primary healthcare has the potential to improve the quality of care given to patients with chronic illnesses provided that HCP's are trained for their roles (Becker MH *et al*, 1974; Wasson JH *et al*, 1984; Starfield B, 1992; Hjortdahl P, and Laerum E, 1992; Pearson P, and Jones K, 1994).

7.1. Current TB/HIV clinic-based practice patterns: Does it allow for pharmacist involvement?

It is inevitable that the patients viewed pharmacists as peripheral healthcare service providers as they lacked direct involvement with care provision (Rennie TW, 2009). Even though pharmacists may have the knowledge on medicine use, the current organizational structures in public sector primary healthcare facilities preclude them from engaging in clinic-based interactions. However, findings from this study indicate that integrating a trained pharmacist in a patient-centered approach to TB and HIV management remains a possibility.

7.2. A patient-centered approach to TB and HIV management

The Doncaster model suggests that pharmacists should work outside the dispensary where the patients' medical notes, doctors and nurses are present (Andalo D, 2002). In this study, the researcher worked directly with co-infected patients thereby establishing a patient-researcher relationship, which was positively received as a part of service delivery. Following from this patient-centered approach, it is evident that medicine related needs or risks could be identified. In addition, complex social, behavioural and cultural issues that impact on treatment adherence can be recognized and addressed collectively within the existing health system. A 'covenantal' relationship based on morals and values between the patient and a trained pharmacist is therefore imminent (Williams KE, 2007). A patient-provider relationship which builds on patient understanding and one that promotes self-responsibility for healthcare should not be under-estimated (Report on the integration of TB an HIV services in Site B Khayelitsha, 2005). Adherence is associated with a strong doctor and patient relationship (Ciechanowski PS *et al*, 2001; Catz SL *et al*, 2001; Roberts KJ, 2002). Therefore, pharmacist's active involvement results in establishing strong relationships with patients that will influence their adherence outcomes.

7.3. Impact of the clinic-based TB/HIV intervention

While this study revealed the positive impact and influence that HCPs especially the adherence counsellor and clinic nurse have on patient treatment, several gaps were identified in drug therapy in current practice patterns. These included the identification of side effects, pharmaceutical implication(s) of crushing TB/HIV tablets and referral of patients to the TB/ARV doctor.

The key interventions which ranged from identifying new symptoms, identifying side-effects, suggesting additional medication for side-effects, informing patients about grants, encouraging positive thinking and attitude (see table 6.3.2) may be attributed to the researchers' clinic-based PALSA Plus training, a thorough understanding of routine clinic procedures and designing and using the clinic record card. This clearly illustrates that pharmacotherapeutic concepts were being applied in 'real practice'. Prior to implementation of the intervention, patients did not view

pharmacists as important providers of care. However, data from the post-intervention showed that patient's perceptions changed following their direct engagement with the researcher.

7.4. Inter-professional teaching and learning opportunities

Even though HIV is a chronic illness that can be well managed by the patient and attending HCPs, its management is complicated with TB-co-infection. Successful chronic disease management usually involves a coordinated multidisciplinary care team that relies on effective interventions. Successful teams often include nurses and pharmacists with clinical and behavourial skills that ensure the critical elements of care are competently performed (Austin BH *et al*, 1996; Davis C *et al*, 1997; Calkins E *et al*, 1998; Wagner EH *et al*, 1998). When pharmacists work within such a team, they will be viewed as important care providers to patients and HCPs. This point was proven when patients fully supported (100%) pharmacists working with other HCP's such as doctor, clinic nurse, adherence counsellor and patient advocate.

7.5. Integrating services for co-infected TB/HIV patients

The treatment of dually infected patients facilitates the early screening and diagnosis of TB and HIV. Separating services in co-infected patient's results in care that is often fragmented (Tsiouris SJ *et al*, 2007). It is therefore essential, in areas of high HIV prevalence and TB burden (such as Delft South ARV clinic and Elsies River TB clinic) that national TB and HIV programs at the primary care level provide integrated care for TB/HIV to improve cure rates (Treatment Action Campaign, 2001). In addition, patients attend one consultation rather than two, which reduces travelling costs and waiting times (Report on the integration of TB and HIV services in Site B Khayelitsha, 2005).

7.6. Influence of socioeconomic and educational status on treatment adherence

Patient adherence is essential to achieving treatment success rates in TB and HIV management (Kagee A, 2004). Various factors affect patient adherence in the South African primary healthcare system, some of which were encountered in this study. They include amongst others socioeconomic factors and the educational status of the community. Social and economic factors

often combine to yield poor adherence outcomes which are worsened by poor treatment outcomes such as side-effects, drug interactions and adverse effects. Simoni and colleagues (1995) found low levels of adherence to the correct number of pills, dosing schedules and special instructions in a sample of HIV-positive patients. In this study, even though more than half (57.5%) of the patients attained good adherence (see chapter 5) almost two-thirds (64.4%) claimed to have experienced side-effects. As reported earlier, lack of food adversely influences treatment outcomes (Rowe KA *et al*, 2005). In this study, increased appetite was the most common reported side-effect (Table 6.2.7), thereby posing a problem for communities who cannot afford additional meals. In contrast, studies carried out in developed countries revealed that the most frequently cited reason by patients stopping their medications was side-effects (Chesney MA *et al*, 2000; Ammassari A *et al*, 2001). In underserved communities, lack of food coupled with an increase in appetite would adversely affect treatment adherence levels. In studies identifying the variables associated with non-adherence, a higher level of adherence was associated with higher education, and higher knowledge of their treatment (Williams KE, and Bond MJ, 2002). A correlation was also established between patients employment status, education, alcohol consumption with adherence outcomes (Kagee A, 2004). Similarly, in this study a correlation was reported between the level of patient education and knowledge of their conditions (see section 6.1).

In order to equip the graduates with the skills in the management of diseases that impose a health burden, it is crucial that clinic-based training forms part of the core curricula. In this exploratory study we attempted to assess the need for a clinic-based exposure for pharmacy students. There is a paucity of South African literature that explores the need for clinic-based TB/HIV training for pharmacy students. However, studies done in countries like the United States made notable references to the importance of involving pharmacy students in clinic-based activities such as immunization, whereby such training formed part of the core curricula (Bain TB, and Cullison MA, 2009). Medical students at the University of Colombo, Sri Lanka favoured clinical exposure as a better form of learning medicine than the traditional teacher oriented system as it provides a better understanding of their theoretical knowledge (Health Action International, 2005; 7-8).

7.7. Need for TB/HIV clinic-based exposure for pharmacy students

For the Phase II study, I discuss the students' performance in the clinical scenarios and the potential for supplementing clinic-based TB/HIV training with classroom teaching at UWC.

7.7.1. Student's performance in clinical scenarios

The assessment used in this study explored the final year students' application of their theoretical knowledge in clinic-based routinely encountered practice type case scenarios. Even though students performed fairly in the case scenario (see Appendix O, b and c), they were unable to identify common drug interactions between ARVs and anti-TB drugs and the initiation of ART in patients co-infected with TB having a CD4 count below 50. This may be attributed to lack of supplementary clinic-based exposure where the learning process is translated into practice and becomes more meaningful and consolidated. A Malaysian study which aimed to assess basic knowledge of HIV/AIDS and ART amongst pharmacy students clearly indicated the need for comprehensive training to improve their knowledge (Syed AI *et al*, 2009). Overall, the shortcomings clearly underpin the need for supplementary clinic-based TB/HIV training for pharmacy students.

At UWC, the service learning programme conducted at primary healthcare facilities is pivotal in engaging students in clinic-based learning. The SLIP rotations for final year pharmacy students should include exposure to TB/HIV clinics where inter-professional learning and teaching opportunities could be consolidated. Students could work alongside the clinic nurse, patient advocate and adherence counsellor where factors that affect treatment adherence and health outcomes can be fully contextualized. Through meaningful engagement with patients and clinic staff, this "hands-on" learning would enable students understand the local and contextual factors that affect adherence. This "social contract" would provide the platform for pharmacy students to accept responsibility for the outcomes of care (Berger BA, 2009).

Student feedback on the introductory clinic-based TB/HIV session indicated that such training is largely lacking in undergraduate pharmacy programmes (Eybers I *et al*, 2009). Barriers such as lack of contact between pharmacy students and patients may be responsible for the student's

poor clinical knowledge (Bheekie A *et al*, 2007). Clinic-based TB/HIV training for undergraduate pharmacy students should become institutionalized so that graduates are able to understand the local context in which primary healthcare is delivered and received.

7.8. Effectiveness of mixed methods in this study

The use of mixed methods in this exploratory study was successful in obtaining both quantitative and qualitative data. This approach allowed the researcher to obtain a comprehensive understanding of TB/HIV management in primary healthcare clinics. The study design provided additional perspectives and insights that were beyond the scope of using a single technique, as at some stage of the research the data was either relayed, integrated, or mixed (Cresswell JW *et al*, 2004). For example, using a single technique such as using a questionnaire (quantitative) to collect data throughout the study would have limited the depth of the enquiry process in the clinic. The qualitative participatory approach allowed the researcher to obtain key practical insights on disease management and inter-professional learning opportunities to design and implement the intervention. The results from both phases of the study are not generalisable due to the small sample size. More rigorous studies are needed to explore the potential role of pharmacists in TB/HIV management.

This study clearly demonstrated the establishment of a “covenantal relationship” between the trained researcher and the patients and healthcare providers where medicine-related risks were identified. Several fundamental barriers impede the public health system provision of patient-centered care from pharmacists. Pharmacist interaction with patients, other healthcare practioners and knowledge integration are necessary for both clinical exposure and application of theoretical concepts.

Conclusions and recommendations

This study clearly underpins the need for trained pharmacists in primary healthcare clinics that provide integrated care for patients co-infected with TB and HIV. A trained pharmacist can work alongside other healthcare professionals to optimize the provision of care and welfare of co-infected patients. A clinic-based role would enable trained pharmacists to screen patients for TB symptoms, identify side-effects and refer patients to the ARV doctor for further management. A specially adapted TB clinic record card serves as a useful tool to engage pharmacists in clinic-based pharmaceutical care.

One issue that confronts pharmacy education is the lack of experiential learning at primary care facilities. Therefore, student's assessment on TB and HIV should become more practical and focus on real-life case scenarios. The current SLIP programme should include exposure to TB and HIV clinics where students could engage directly with patients to establish a value-based relationship on medicine-related risks and accept responsibility for patient health outcomes.

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