INVESTIGATING USER ACCEPTABILITY AND EFFECTIVENESS OF THE SIMPILL DEVICE AS A STRATEGY TO IMPROVE TREATMENT ADHERENCE AMONG TB PATIENTS ENROLLED IN THE SIMPILL PROJECT: A PILOT STUDY IN THE FRANCES BAARD DISTRICT, NORTHERN CAPE PROVINCE

By

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RESEARCH DISSERTATION

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Supervisor: Ms Sphiwe Madiba

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DECLARATION

I declare that the hereby submitted to the University of Limpopo for the degree of Master in Public & investigating user acceptability and effectiveness of the SIMpill device as a strategy to improve treatment adherence among TB patients enrolled in the SIMpill project: a pilot study in the Frances Baard district, Northern Cape Province and has not been previously submitted by me for a degree at this or any other University: That it is my work in design and in execution, and that all material contained herein has been duly acknowledged.

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Abstract

INTRODUCTION: Sub-optimal adherence to prescribed medications is documented as a major cause of drug resistance in tuberculosis (TB). Directly observed treatment – short course (DOTS) remains the WHO gold standard for improving adherence. Concerns with DOT as the single solution have been raised and a range of adherence strategies are increasingly being recommended.

RESEARCH QUESTION: Can the SIMpill electronic reminder system increase medication adherence amongst TB patients?

METHODOLOGY: A cohort of TB patients in the Frances Baard District (Northern Cape) was recruited to the project. Each patient was given their TB medication in a special SIMpill container that uses cellular phone technology to remind those patients who forget to take their medication on time. Each time the container is opened an SMS is sent to a computer server. If the container is not opened at the prescribed time the SIMpill computer sends a reminder SMS to the patient. The data collected on the computer server was analysed to show which patients opened the medication container within the agreed tolerance time, which required to be reminded by SMS, and which failed to take their medication. After the treatment programme, patients were taken through a structured questionnaire to find out their views on the functioning and user acceptability of the SIMpill system.

RESULTS: 65 patients completed the SIMpill project and were subsequently interviewed. 97% of patients felt the SMS reminders helped them take their medication. The aggregated data from the SIMpill computer server showed adherence levels averaged 83% with no SMS reminders, rising to 92% if SMS reminders needed to be sent.

CONCLUSION: Poor adherence is a problem in long-term therapy programmes such as those required for TB treatment. Using the SIMpill system with a cohort of 65 patients, adherence increased from 83% to 92% if SMS reminders needed to be sent by the SIMpill system

Acronyms

AIDS	Acquired Immune-Deficiency Syndrome
ART	Anti-Retroviral Therapy
ARV	Anti-retroviral
BNF	British National Formulary
CST	Community Service Telephones
DOTS	Directly Observed Treatment – Short course
GPRS	General Packet Radio Service
HIV	Human Immune-deficiency Virus
ICT	Information & Communication Technology
IT	Information Technology
MDR-TB	Multi-Drug Resistant Tuberculosis
MEMS	Medication Event Monitoring System
MRC	Medical Research Council
SASSA	South African Social Security Agency
SMS	Short Message Service
Stats SA	Statistic South Africa
TB	Tuberculosis
UK	United Kingdom of Great Britain & Northern Ireland
USA	United States of America
WHO	World Health Organisation
XDR-TB	Extensive (or Extreme) Drug Resistant Tuberculosis

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CHAPTER 1: BACKGROUND AND INTRODUCTION

1.1 Background

The Northern Cape Province consists of five Districts, each made up of three to eight local municipalities. Geographically the Northern Cape is South Africa's largest province, and distances between towns are enormous. With a total area of 362,591 square km, this vast and arid province takes up some 30% of South Africa's land area. The province has the country's smallest population level with fewer than one million people. This equates to about 2% of the national population. The population density is extremely sparse with less than three people per square km.

The Provincial capital is Kimberley, located to the east of the province, just 15 km from the border with the Free State. Other important towns include Upington, centre of the province's wool, dried fruit and wine industries; Springbok, in the heart of the Namaqualand spring flower country; Kuruman, founded by the Scottish missionary Robert Moffat; and De Aar, the historical hub of the South African railway network. (Government Communication and Information System)

The Frances Baard District is the smallest district in the Northern Cape. Although it accounts for just 3.4% of the total surface area of the province, it accommodates the largest proportion of the population, giving it the largest population density (26.2 persons per square km compared to less than 3 for the province as a whole). The Frances Baard District includes four local municipalities: Dikgatlong, Magareng, Phokwane and Sol Plaatje. The city of Kimberley, which is the seat of the District Municipality and of the Northern Cape Legislature, is located in Sol Plaatje Municipality, the largest of the four. (Frances Baard District Municipality)

The Frances Baard District has a total population of 325,501 people or 40% of the provincial population. About 62% of the population of Frances Baard District lives in Sol Plaatje municipality, which is highly urbanized. The gender split mirrors that in the province, with slightly more females (52%) than males (48) in the Frances Baard District – a difference of 4%. Unlike other districts in the province the population is dominated by Black Africans (mainly Tswana, Sotho, and Xhosa) rather than being dominated by coloureds, as is the case in other regions in the province. There are

83,653 households in the district, 72% of which are formal brick structures on a separate stand. An insignificant percentage of dwellings are of very poor quality - 12% informal dwellings/shacks and 6% backyard shacks/flats. (Frances Baard District Municipality)

The population is largely a young population with 30% being under 15 years, 43% being 15 to 39 years, and 27% being 40 years and older. In all age groups there are fewer males than females. An analysis of the economically active population (15 and 65 years) shows a significantly high rate of unemployment at 24%, with 34% in formal employment. During the Official Census (2003), the majority of people still recorded their principal mode of transport as being on foot (59%). In terms of education, 25% of the adult population has undertaken study to Standard 12 (18%) or higher education (7%). At all levels of education, more females than males completed their learning.

1.2 Burden of disease

The Northern Cape Department of Health issued its annual performance plan in February 2007, which included the following information.

In the HIV & Syphilis antenatal Sero-Prevalence Survey the Province showed a slight increase in the prevalence of HIV/AIDS from 17.6% in 2004 to 18.5% in 2005. The prevalence of syphilis remains of concern with an increase from 7.0% in 2004 to 8.5% in 2005.

Tuberculosis (TB) still poses a major public health challenge in Province. Important factors aggravating TB and hampering its control include increased migration of seasonal workers, an increase in HIV prevalence, high poverty levels, poor nutrition, inadequate housing, high defaulter rates and inadequate case finding.

In addition to TB and HIV/AIDS, the main causes of morbidity and mortality are diarrheal diseases, acute respiratory infections, Varicella, and other communicable diseases such as Meningococcal meningitis and haemorrhagic fevers.

Based on self-reported conditions, major non-infectious chronic conditions in the Northern Cape include high blood pressure, ischaemic heart disease and Type 2 diabetes. Asthma and chronic bronchitis also appear to be particular problems for

men, whereas in women high blood pressure and emphysema are predominant. Men receiving treatment for hypertension in the Northern Cape are double that of the national average (21,5% compared to 10,7%), whilst the figure for women is 35% compared to 27,7% nationally.

The maternal mortality ratio for 2006 was 308 per 100,000. An increase in maternal mortality is being felt throughout the country and is likely to be due to the increased risk of complications in pregnant women with AIDS.

People living in towns of the Northern Cape are all within 5 km of a health facility. It is in the rural areas where this is not the case and 47 mobile clinics service these areas. Access to health services has an important role to play in supporting health promotion activities, taking a lead in caring and support to people living with HIV, and in supporting appropriate home-based care. Access to health facilities by the youth in the Province (based on time taken to reach a medical facility) is improving. 35% of the youth have access to a facility closer than 15 minutes walk and 36% have access between 15 – 30 minutes. The Youth, especially those living in rural settlements, tend to use clinics more than private general practitioners.

Pre-hospital care has rapidly evolved to be an integral and exciting component of the health care system. Advances in medicine and health technology allow specialized emergency care to be brought closer to patients in the community (Northern Cape Department of Health, 2007).

1.3 Adherence to medication

In the health arena, adherence (also known as compliance) refers to the degree with which a patient's behavior in taking medication complies with, an agreed programme of treatment as recommended by a health care provider. Depending on the context this could be, for example, regular attendance at clinic, self-fitting of a surgical appliance, performing self-directed physiotherapy exercises, or regular taking of prescribed medication.

There is little data on medication adherence in South Africa. In developed countries, it has been estimated that only 50% of patients suffering from chronic disease adhere to their treatment programme (Sabaté, 2003). The British National Formulary

(BNF, 2004) lists many reasons or causes of poor adherence to taking prescribed medications, including forgetfulness. In the case of tuberculosis (TB), a significant reason why treatment adherence is poor is that patients “simply forget” to take their medication (Green, 2003).

Methods to improve treatment adherence traditionally include the use of patient information leaflets, patient counseling, enrolment in a patient support group, and the administration of medications by the health care worker (e.g. doctor, nurse or pharmacist). Recently other tools for improving compliance have been tested and these range from patient information and recall systems, to prescription loyalty programmes, patient diaries, measuring medication adherence retrospectively (by examining prescription refill rates, performing pill counts, interviewing patients, or by the use of the Medication Event Monitoring System (MEMS). However,these methods are costly and only expose non-compliance after the occurrence.

Green (2003) argues that whilst forgetfulness is often the primary reason given by patients for non-adherence, this reason has not been adequately acknowledged or explored, and it seems likely that some patients do just “simply forget.” This led to the development of new tools that fulfil the requirements of simplicity and ease of application, such as reminding systems. An innovative reminding method developed a few years ago makes use of SMS text messages which are sent to a patient a few minutes before each scheduled medication administration (Green, 2003). Studies among patients with Type 2 diabetes showed that this method has immediate positive results, however, these SMS-messages are not demand-induced and over time become a routine and their effect diminishes.

The SIMpill-system was developed to improve on the SMS-alert system by only sending SMS-messages in cases where the patient indeed forgets to take their medication. Patients who take their medication at the scheduled time are not reminded and thus habituation is minimised.

1.4 Problem statement

Despite current interventions in many parts of Southern Africa, including the Northern Cape Province, TB cure rates are poor. It is generally accepted that poor treatment adherence (including defaulters) leads to poor cure rates and the

emergence of drug resistant forms of TB. The cure rate for 2003 was 38.3% and for 2005 was 50.1% and about 11.3% of patients defaulted.

Although Directly Observed Therapy System (DOTS) remains the gold-standard for supporting treatment adherence in most TB programmes, the resource requirements for DOTs in developing countries can create challenges and obstacles. DOTS programmes require large numbers of trained DOTS support workers, who are not always available. Volmink & Garner, (2000), and Roberts & Buikstra, (2003) argue that DOTs is labour-intensive and intrusive.

For many patients, factors like bad weather, distance, time and travel costs can be significant disincentives to the DOTs approach. A recent Cochrane systematic review found no evidence that DOTs showed better cure rates than people having self administered treatment (Volmink & Garner, 2007)

Implementing DOT support is particularly a problem in the Northern Cape Province where patients are spread over very large areas, the average person density ranges from 1.3 people per square km in the most rural district to only 30 people in the most urban district (Census, 2006). It is therefore challenging for DOTs supporters to see every patient assigned to them. Depending on the number of patients they support, it usually takes up to five days to visit all of their patients. This was the rationale for the Northern Cape Province to seek to adopt the SIMpill system, which addresses some of the treatment adherence issues by prompting patients to take their medication, and alerts the DOTS support workers as to which patients require additional support. The added advantage of the system is that it offers a means of determining which patients are most in need of support, and offers a means of improving communication with the patient throughout the time they are on treatment.

1.5 The Northern Cape SIMpill Pilot Project

In 2005, a 100 tuberculosis patients undergoing TB treatment were asked to volunteer to participate in the SIMpill pilot project. The patients all resided in communities in the Frances Baard district of the Northern Cape Province and received healthcare from the public health services in their communities. The pilot study aimed to determine the feasibility of using an electronic monitoring and reminder system (SIMpill) to improve TB medication adherence in a patients.

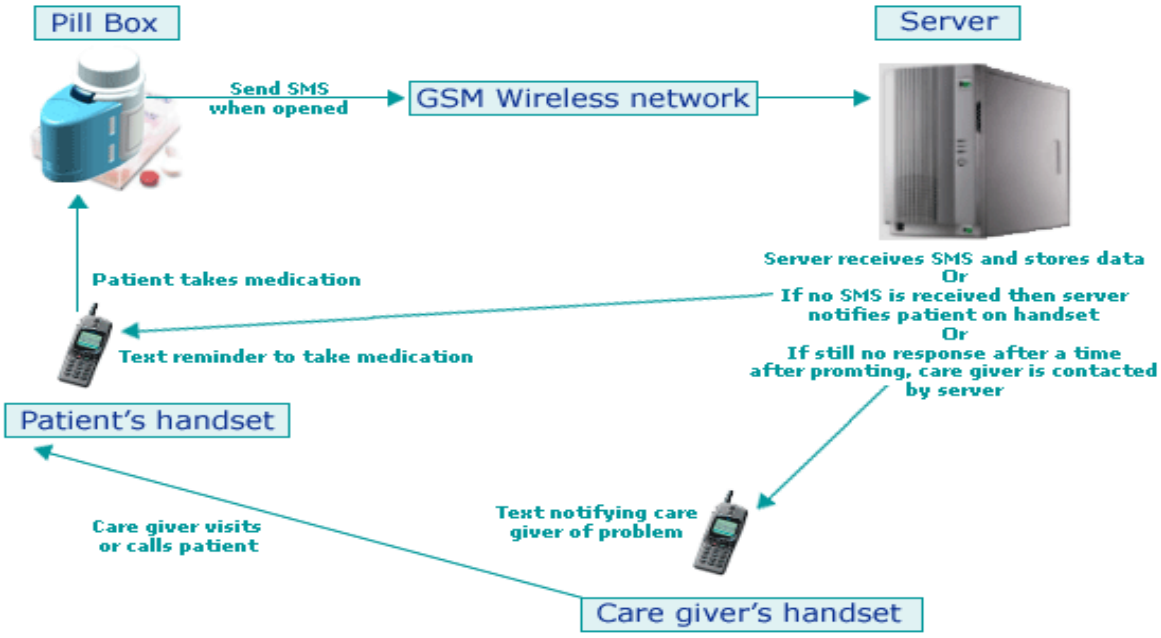
The SIMpill system is an interactive pill container that uses cellular phone technology to help patients remember to take their medication on time. The SIMpill container is an ordinary medicine pill container with an attached device that includes a SIM card and transmitter. The SIMpill computer is initially loaded with demographic and prescription information of each patient. Every time the container is opened, it sends an SMS text message to a SIMpill computer server which collects the date and time the patient 'opens the pill bottle' to take their medication. If the container is not opened at the prescribed time (or within a set tolerance period), the SIMpill computer sends a reminder SMS text message to the patient's Cell phone. Additional messages can by agreement, also be sent to a family member or caregiver's cell phone. If the patient still does not take their medication after being reminded, the clinic or DOTS health worker is alerted so that he/she can telephone the patient or visit them at home.

Before patients enrolled in the pilot project, it was explained to each patient how the SIMpill system works. For those patients accepting to participate in the pilot study, it was explained that in addition to their current treatment programme, they would receive a reminder SMS text message any time they did not open and close their pill container at the prescribed time. It was explained that if this SMS text message did not result in them opening and closing their pill container within an agreed time span, a further SMS text message would be sent to their DOTS worker who would then contact them.

As part of the current TB treatment programme, clinic staff from Betty Gaetsewe clinic where the pilot study was located had previously matched each TB patient with a DOTS support worker from a local Non-Governmental Organisation (NGO). The same DOTS caregivers were recruited to participate as the supporters for the SIMpill pilot. By aligning with existing structures, this ensured that the pilot did not create any confusion. The professional nurse responsible for the daily administration of the DOTS system was the designated person to receive the third level escalation text message. The project was an initiative of the DoH of the Northern Cape Province and there was no additional cost to the patients enrolled in the project.

The health clinic was equipped with the necessary computer hardware and software to administer the SIMpill system, and health professionals were provided with training to administer the system. Technical support was provided by the SIMpill Company based in the Western Cape.

Figure 1.1: How the SIMpill system works *(Diagram courtesy of www.simpill.com)*



1.6 Study aim

The aim of the study is to assess the effect of the SIMpill device on treatment adherence and describe the level of acceptability of the device to TB patients enrolled in the pilot project.

1.7 The study answered the following research questions

1. What are the socio-demographic profiles of TB patients enrolled in the SIMpill project in the Frances Baard district of the Northern Cape Province?

2. Does the use of the SIMpill system improve treatment adherence of TB patients undergoing anti-TB therapy?

3. What is the level of acceptability of the SIMpill device to TB patients who were enrolled in the project?

1.8 Study objectives

1. To determine the socio-demographic profiles of patients enrolled in the SIMpill project.

2. To determine the level of acceptability of the SIMpill device to TB patients who were enrolled in the project.

3. To determine the level of TB treatment adherence among patients using the SIMpill device.

1.9 Study justification

South Africa is among 10 hotspots of MDR-TB identified by the World Health Organisation. MDR-TB is mostly found in people who have defaulted on TB treatment. Findings from the study may result in expansion of the SIMpill project in the Province and the proven benefits can be expected to impact on greater numbers of TB sufferers (and potentially other conditions where SIMpill supported treatment adherence may be of benefit).

The data collected from this study will contribute to new knowledge in field and to research in general. The results will influence policy on the management of tuberculosis in the province and the country at large. By using the SIMpill system, it is estimated that one health worker can manage 100 TB patients who are self medicating, only having to contact those patients who default (SIMpill).

CHAPTER 2: LITERATURE REVIEW

2.1. Introduction

This chapter reviews the literature on tuberculosis (TB) and drug resistance, problems of medication adherence and potential solutions, how cellular phone technologies are being developed to support issues of adherence, and in particular, how the SIMpill system is being developed. The chapter is structured in a way that first literature on tuberculosis is reviewed with a particular emphasis on the problems of drug resistance, including multi-drug and extreme drug resistant TB. This is followed by review of literature in relation to medication adherence and a review of cellular phone technology will conclude the chapter.

2.2. Tuberculosis and drug resistance

2.2.1 Tuberculosis

TB is a very serious health problem with two million people dying each year, mostly in developing countries. It is caused by a bacterium, Mycobacterium tuberculosis. Effective drugs for tuberculosis have been available since the 1940s, but the problem still abounds. People with tuberculosis need to take the drugs for at least six months, but many do not complete their course of treatment. For this reason, services for people with TB often use different approaches to encourage people to complete their course of treatment. Noting the fact that TB is curable with compliance to appropriate treatment.

The South African Department of Health estimates that 5.54 million South Africans were living with HIV in 2005 (WHO, 2005), an estimated prevalence of 10.8% (Shisana, et al., 2005). Partly as a result of HIV, South Africa is one of 22 countries with high burden of TB and has the fifth highest number of notified TB cases in the world (WHO, 2005). The number of TB cases reported annually has quadrupled from 61 486 in 1988 to 279 260 in 2004.

TB is the most common opportunistic infection and is the most significant cause of mortality in people living with HIV in developing countries where access to anti-retroviral therapy (ART) is limited. Obtaining good TB treatment outcomes is critical

to decreasing HIV-related morbidity and mortality. Likewise, access to appropriate treatment and care for HIV is essential to containing TB (Health Systems Trust, 2006).

2.2.2 Drug resistance

The South African MRC survey in 2001-02 found that multi-drug resistant TB (MDR – TB - resistance to rifampicin and isoniazid) was low in new patients at 1.6% but much higher at 6.6% in patients who had prior TB treatment. WHO defines an MDR-TB 'hot spot' as an area where the prevalence of MDR-TB in new patients exceeds 3% (Weyer, Lancaster, Brand, van der Walt, & Levin, 2004).

Extensive drug resistant TB or XDR-TB (also referred to as extreme drug resistance) is MDR-TB that is also resistant to three or more of the six classes of second line drugs (MMWR, 2006). The 2005 outbreak of XDR-TB in KwaZulu-Natal showed alarmingly high mortality rates and attracted international attention. The study showed that XDR-TB is an important cause of death in TB/HIV co-infected patients even where ART is available. It has also highlighted the need for improved drug resistance surveillance, contact tracing and infection control in health care facilities (Gandhi, Moll, Pawinski, Lalloo, Sturm, & Zeller, 2006).

Treatment success is the combination of cure and completion rates. The 2003 WHO/South African Health Department study found that the treatment success rate in parts of South Africa was low (62.9%). The high death rate of 7.4% is most likely due to HIV-related illnesses. A high proportion of patients defaulted on their treatment (11.5%) and 9.8% were not evaluated (WHO & South African Department of Health, 2005). High default and loss-to-follow up rates could be improved through strengthened Directly Observed Treatment (DOTS) and other community adherence programmes. Community workers could assist by confirming addresses, educating patients about the importance of good adherence, encouraging patients to go to health facilities for sputum smear examinations at the end of the intensive and continuation phases and tracing defaulters (Health Systems Trust, 2006).

People living with HIV are more vulnerable to developing TB irrespective of whether they are receiving ARVs or not. TB also hastens the progression of HIV. Integrated care addressing the interconnection between these infections is critical to controlling

both HIV and TB. The WHO makes several important recommendations for collaborative TB/HIV activities (WHO Stop TB Department and Department of HIV/AIDS, 2004):

1. Establish the mechanisms for collaboration (joint TB/HIV planning, monitoring and evaluation).

2. Decrease the burden of tuberculosis in people living with HIV/AIDS (intensified TB case finding and isoniazid preventive therapy).

3. Decrease the burden of HIV in tuberculosis patients (HIV counselling and testing, cotrimoxazole preventive therapy and ARV therapy for TB patients).

2.3 Medication adherence

2.3.1 Overview

“Keep watch also on the faults of the patients, which often make them lie about the taking of things prescribed." The problem of poor adherence was recognised by Hippocrates more than 2000 years ago (Carrick, 2001).

There is little data on medication adherence in South Africa, although in developed countries it is estimated that only 50% of patients suffering from chronic disease adhere to their treatment programme (Sabaté, 2003).Double the literature suggests that multi factors are responsible for poor adherence to prescribed medications. The British National Formulary (BNF, 2008) lists these as; forgetfulness, prescription not collected or not dispensed, purpose of treatment not clear, perceived lack of effect, real or perceived side-effects, instructions for administration not clear, physical difficulty in complying (e.g. opening medicine containers, handling small tablets, swallowing difficulties, travel to place of treatment), unattractive formulation, such as unpleasant taste, complicated regimen, and the cost of medication.

Methods to improve treatment adherence traditionally include the development and distribution of patient information leaflets, the institution of patient counselling, attendance at patient support groups, and the physical administration of medications by the health worker (e.g. doctor, nurse, pharmacist, etc.)

Retrospective methods of measuring adherence such as asking the patient if they took their medication as prescribed (both quantity and time of taking) are prone to errors. The patient may not accurately report back because of fear of possible embarrassment or being chastised.

A study in the USA revealed a number of barriers and facilitators to adherence to HIV medications (Konkle-Parker, Erlen, & Dubbert, 2008) similar findings are likely in TB. Barriers included the perceived burden of extra planning, denial, life stress, difficult characteristics of the medicines, social stigma and shame. Facilitators included acceptance of the diagnosis, thinking about the consequences of not taking the medicines, prayer and spirituality (the study was undertaken in the highly religious 'Deep South" of the USA), improvements in the medicines, and support from family and friends.

2.3.2 'Remembering to remember'

The issue of remembering to take medication for HIV and medication for TB are not dissimilar – both involve regular taking of medication over prolonged periods.

"Forgetting" and "being busy" are two of the most common reasons that HIV-infected individuals miss medications doses (Chesney, Ickovics, Chambers, Gifford, Neidig, & Zwickl, 2000). A person with limited awareness of their prospective memory deficit (remembering to remember to take their medication!) may not employ otherwise effective compensatory strategies (e.g., use of a pillbox) and thereby be at risk for mismanaging their medication regimen (Woods, et al., 2008). For such patients, it has been suggested that a programmable electronic device that prominently notifies the patient when it is time to take a medication with a detailed text message that includes the medication, dosage, and particular conditions under which it should be taken (e.g., with food) might be maximally effective (Andrade, McGruder, Wu, Celano, Skolasky, & Selnes, 2005). A voicemail message has also been proposed (Leirer, Morrow, Tanke, & Pariante, 1991).

A Cochrane systematic literature review of interventions for enhancing medication adherence (Haynes, Ackloo, Sahota, McDonald, & Yao, 2009) found that for short-term treatments (a few days or weeks), several interventions improve adherence, including simply informing patients that all of the prescribed medication is to be

consumed, but these findings were not consistent from study to study. For long-term treatments (as is the case with TB), simplifying the dosage regimen and several complex strategies showed some improvements in adherence, including combinations of more thorough patient instructions and counselling, reminders, close follow-up, supervised self-monitoring, rewards for success, family therapy, couple-focused therapy, psychological therapy, crisis intervention, and manual telephone follow-up can improve adherence and treatment outcomes.

If there is a common thread to these at all, it is more frequent interaction with patients with attention to adherence. However, these complex strategies for improving adherence with long-term medication prescriptions are not very effective despite the amount of effort and resources they can consume. There is no evidence that low adherence can be 'cured'. Thus, efforts to improve adherence must be maintained for as long as the treatment is needed.

Below are descriptions of some of the principle techniques used to improve adherence.

2.3.3 Pill counts & Blood tests

Objective retrospective methods to measure medication adherence include pill counts and blood tests. Each of these methods has its shortcomings. Pill counts, where the patient's pills get counted at each visit, have been shown to be valid, if slightly more prone to active patient deception than some other forms of measurement. Pill counts suffer from the shortcoming of only documenting non-adherence after the event, which is often too late. They also render no data on the patterns of non-adherence with respect to timing and other factors that may influence non-adherence, e.g. alternating under- and over- adherence or discarding of pills (Cramer, Mattson, Prevey, Scheyer, & Oulette, 1989).

Measuring the metabolites of medication ingredients or other markers placed in the medication for that purpose give an indication of adherence for only as long as these substances persist in measureable quantities in the blood - invariably a short-term measure of adherence. Conversely, traces of some medications may be found in the blood long after the medications have stopped (Dahl, 1988).

2.3.4 Directly Observed Treatment Short Course (DOTS)

"Drugs do work in patients who do take them." Although originally said about the effects of statin and aspirin in cardiovascular disease, this adage could equally apply to tuberculosis (Wei, Fahey, & MacDonald, 2008). Adherence to prescribed medications in clinical practice is crucial to the success of pharmacologic interventions.

Tuberculosis is curable and DOTS is considered by many to be the most successful and cost-effective treatment strategy. In its simplest form, DOTS means watching the patient take his/her medication to ensure they are taken at the right time, in the right combination and for the correct duration.

The objectives of the DOTS approach, as promoted by the World Health Organisation and the South African Department of Health, are to decrease the risk of infection, reduce morbidity and the transmission of infection, and prevent TB deaths. This means that a patient takes their daily medication supervised by a community-based DOTS worker, or visits a clinic to take their medication under the eye of a health-care worker.

Achieving these objectives through the DOTS approach is simple:

- Identify TB cases in communities.
- Treat TB cases by directly observing their medication intake for six to eight months. This is to ensure that medication is taken in the right combination and appropriate dosages in an effort to prevent the development of multidrug resistant TB.

The DOTS approach was first adopted in studies in India and Hong Kong as early as the 1960s (Bayer & Wilkinson, 1995). Today DOTS is widely recommended for the control of tuberculosis (Bass, Farer, Hopewell, O'Brien, Jacobs, & Ruben, 1994) (Chaulk & Kazandjian, 1998) (Enarson, Rieder, Arnadottir, & Trebucq, 2000) and to prevent relapse and the development of drug resistance (Frieden & Sbarbaro, 2007).

The main advantage of DOTS is that people can be closely monitored and that there is a social process with peer pressure that may improve adherence. On the other

hand, the disadvantages associated with DOTS are that it moves away from adherence models of communication with cooperation between patient and provider back to a traditional medical approach with the patient as the passive recipient of advice and treatment. Resource implications for such a policy are substantial, particularly in low-income and middle-income countries where the case load is high; and it may make adherence worse if it is rigidly applied in an authoritarian setting or where people are expected to travel considerable distances to have their treatment supervised.

Not only can DOTS be labour-intensive and intrusive (Roberts & Buikstra, 2003), but a Cochrane systematic review found no evidence that direct observation showed better cure rates than people having self- administered treatment (Volmink & Garner, Directly observed therapy for treating tuberculosis - Review, 2009).

2.3.5 The relationship between DOTS and Adherence

Direct observation of people taking their anti-tuberculosis drugs is widely advocated and forms part of the World Health Organization's adherence strategy.

According to Volmink and Garner (Volmink & Garner, Directly observed therapy for treating tuberculosis - Review, 2009), while this strategy includes a number of useful components, the available evidence does not provide strong support for the routine adoption of direct observation in favour of self- administration of treatment either for people with active tuberculosis or those with latent tuberculosis requiring prophylaxis.

This Cochrane systematic literature review also found no evidence that one form of direct observation is better than another: direct, randomized comparisons between clinic-based DOTS and community-based DOTS did not demonstrate a difference; and, within community-based DOTS, comparisons between DOTS provided by a family member versus a community health worker had similar outcomes (Volmink & Garner, Directly observed therapy for treating tuberculosis - Review, 2009).

Given the prevailing support for DOTS-based programmes, these findings are important. It is possible that the benefits associated with DOTS programmes in observational studies may be attributable to simultaneous interventions rather than

direct observation being the key adherence-promoting strategy (Volmink, Matchaba, & Garner, Directly observed therapy and treatment adherence, 2000). In this regard it is interesting to note that the implementation of DOTS in the field appears to be shifting from being a rigid model involving observation of drug swallowing to one that includes an array of incentives and enablers for supporting the patient (Macq, Theobald, Dick, & Dembele, 2003).

People with TB are often poor and encounter numerous barriers to treatment adherence. Strategies aimed at reducing social and health system barriers may therefore be preferable to coercive approaches that impact negatively on patient autonomy. A trial in a rural South Africa showed that motivation and support from a lay health worker (with or without direct observation of treatment - DOTS) was shown to be more effective in ensuring treatment than a conventional DOTS-based service (Clarke, Dick, Zwarenstein, Lombard, & Diwan, 2005).

In trials in South Africa where the disease burden is high, overcrowded clinics, and poorly motivated staff, the authors suggest an increasingly negative and demoralising effect of direct observation on participants with tuberculosis (Zwarenstein, Schoeman, Vundule, Lombard, & Tatley, 1998). This trial found that in participants with a first episode of tuberculosis, the outcomes were equivalent in DOTS and self administration of treatment arms, while 'retreatment' participants who were assigned to DOTS faired worse than those who self administered treatment. However, given the small numbers of participants in the retreatment group, further research is warranted.

Volmink and Garner come to the following conclusion in their systematic review of DOTS trials (Volmink & Garner, Directly observed therapy for treating tuberculosis - Review, 2009): "*Randomized controlled trials provide no assurance that the routine use of DOTS in low- and middle-income countries improves cure or treatment completion in people with tuberculosis. There is also no rigorous evidence to support the use of DOTS for prophylaxis in people with latent tuberculosis. There appears to be no sound reason to advocate the allocation of resources to the routine use of DOTS until we better understand the situations in which it may be beneficial. In the meantime, it could reasonably be argued that resources should be invested in*

interventions that have been shown to be effective for improving adherence, such as providing patient motivation and support, incentives, and defaulter action."

2.3.6 Medication Event Monitoring System

The introduction of electronic monitoring for assessing medication non-adherence has enabled clinicians to gather detailed data about medication-taking behaviour. Electronic monitoring systems such as MEMS® (Medication Event Monitoring System) use pill containers fitted with a small electronic processor that record the date and time of each cap opening, resulting in a more detailed non-adherence measurement. Compared to other methods (e.g., assay, self-report, collateral report, prescription refills), electronic monitoring captures more of the dynamics of medication-taking behaviour (Liu H, Maldonado, Duran, & Kaplan, 2001).

Electronic monitoring systems, such as MEMS®, have long been used as the gold-standard for assessing medication adherence (Cramer J. , 1995) (Chaisson, et al., 2001). It integrates a small microcircuit into the medication packaging, in such a way that the microcircuit records the time and date it detects the 'event' needed to remove a dose from the package. For tablets or capsules, the 'event' is the removal of the container cap, followed by replacement of the cap. Although the recording of the pill-taking event is real-time, the analysis is still retrospective - alerting care givers to non-adherence after the non-adherence has occurred. In addition, like pill counting, it requires patients to bring their pill containers in for consultations so that data can be downloaded for analysis.

The first-generation MEMS® product became available in 1988. Initially there were doubts and worries that patients might open and close the package without taking the medicine. By 2005, there was wide acceptance of MEMS® as the 'gold standard' in the field of monitoring medication adherence (Vrijens, 2005). Other researchers support this view, recommending that MEMS® continue to be used for future research, particularly studies of adherence-enhancing interventions to augment self-reported adherence measures (Arnsten, 2001).

MEMS® is said to be the most proximate and the most objective adherence measure - collecting data in real time as the pills are removed from the bottle and ingested (Liu, 2001).

2.3.7 SMS text message reminders and SIMpill

In 2002, Green, a medical practitioner and consultant in the Western Cape, South Africa, developed a system using the telecommunications Short Messaging Service (SMS) to alert tuberculosis patients to take their medication (Green, ICT-Enabled Development Case Studies Series: The Compliance Service uses SMS technology for TB treatment, 2003). The names of patients are entered onto a computer database, and at the appropriate time, the computer reads the database and sends personalised SMS text messages to the patient, reminding them to take their medication. This reminder is sent regardless of whether or not the patient remembered to take their medication.

Following the success of the SMS text messaging approach to alert TB patients to take their medication, Green collaborated with a the Tellumat telecommunications technology company (Tellumat Ltd, 2009), to develop the next generation of MEMS-based medication packaging – a semi-intelligent product known as SIMpill (SIMpill, 2008).

The SIMpill system is an interactive pill container that uses cellular phone technology to help patients remember to take their medication on time. The SIMpill container is an ordinary medicine pill container with an attached device that includes a SIM card and transmitter.

The SIMpill server computer is loaded with demographic and prescription information of each patient. Every time the container is opened, it sends an SMS text message to the computer which collects the date and time the patient opens the pill bottle to take their medication. If the container is not opened at the prescribed time (or within a set tolerance period), the SIMpill computer sends a reminder SMS text message to the patient's cell phone. Additional messages can, by agreement, also be sent to a family member or caregiver's cell phone. If the patient still does not take their medication after being reminded, the clinic or DOTS health worker is alerted so that he/she can telephone the patient or visit them at home.

There is an assumption that if a patient physically opens their pill container, that they will also take their medication and not discard it. The possibility for deception is no greater with the SIMpill system than it is with the MEMS® system, which, by 2005

was widely accepted as the ‘gold standard’ in the field of monitoring medication adherence (Vrijens, 2005).

2.3.8 Considerations when using electronic monitoring systems

There are two important assumptions when using electronic monitoring systems such as MEMS® and SIMpill:

1. That the electronic monitoring device functions correctly

   Quality tests of the widely used MEMS® device show that the system performs well under normal or extreme laboratory conditions (i.e., if exposed to heat, cold, shocks, or water) where a failure rate of below 0.5% is reported by product company, Aardex (Aardex, 2007).

   Reports of how MEMS® performs in the field show a similar pattern. A two-month assessment of eleven purposively sampled MEMS® bottles used in a one-year study of HIV patients showed that electronic monitoring failed to register only 2.5% of the generated events (Bova, Fennie, Knafl, Dieckhaus, Watrous, & Williams, 2005).

2. That there is correspondence between opening of the electronic monitoring container and actual intake of the prescribed dose

   Validity of adherence as measured by electronic monitoring requires that there is little or no discrepancy in container opening and actual ingestion time. If patients correctly ingest the medication either from a source other than the electronic monitoring container or from a supply of pills previously removed from the electronic monitoring bottle (Fennie, Bova, & Williams, 2006), for example because the electronic monitoring bottle is impractical or embarrassing for privacy reasons (Deschamps, et al., 2004), non-adherence will be overestimated.

   Under- or overestimation may also occur when patients open the electronic monitoring container but do not remove any pills, as has been reported in 26% of patients on HIV medication (e.g., to demonstrates the electronic

monitoring system to friends) (Burke, 2001). Likewise, ingesting doses that are larger or smaller than those prescribed will result in underestimation of non-adherence.

The use of an electronic monitoring systems such as the SIMpill can in some patients have a negative effect of their adherence, whilst in others it can have a positive effect.

1. Negative (reduced adherence)

   Electronic monitoring may influence normal intake behaviour because patients cannot use medication aids like pill organisers as usual and, at the same time, be electronically monitored (Wendel, Mohler, Kroesen, Ampel, Gifford, & Coons, 2001).

2. Positive (increased adherence)

   The awareness of being monitored may change the patient's typical adherence habits. In most cases, patients reported an increased adherence, seldom a decreased one (Wagner & Ghosh-Dastidar, 2001) (Elixhauser, Eisen, Romeis, & Homan, 1990) (Deschamps, et al., 2004).

2.4 Cell phone technology in the South African context

2.4.1 Overview

"The quickest way to get out of poverty right now is to have one mobile telephone." This quote by Muhammad Yunus, the founder and director of the Grameen Bank in Bangladesh, makes a simple, yet powerful statement about the causal link between cell (mobile) phones and poverty alleviation (Sinha, 2005).

The SIMpill system is an example of how SMS (short messaging service) technology has been used for sending important reminders and to capture data for real-time measurement of medication taking, with the aim of improving adherence. The solution uses a combination of mobile/cell phone and web/internet technologies,

combined with traditional enterprise information system components such as a system database collecting data from various service processes.

For this reason it is worthwhile reviewing how cell phone technology has developed in South Africa and how people use this technology.

2.4.2 Objectives of the Telecommunications Act

The Telecommunications Act was passed as law in November 1996 (South African Government, 1996). The Act aimed at, among other things, transforming the South African Telecommunications industry to be globally competitive and eliminate previous infrastructure allocation imbalances. These objectives were based on the government's vision for telecommunications to balance the provision of basic universal service to disadvantaged rural and urban communities with the delivery of high-level services capable of meeting the needs of a growing South African economy.

The transformation period started after the 1994 elections until the first half of 1997. This was immediately followed by a period of implementation from 1997 until mid-2000. The post-2000 period, was a policy reformulation and an assessment period (Schofield & Sithole, 2006).

One of the objectives of the Telecommunications Act of 1966 was to make progress towards the universal provision of telecommunication services. In 1997, Telkom incurred license obligations that included the provision of basic services for priority customers and the provision of 1.67 million access lines to under-serviced areas. Telkom's priority customers included villages, schools, hospitals, libraries and local authorities.

In 2000, access to cell phones surpassed fixed line phone access in sub-Saharan Africa. These numbers imply that cell phone is the preferred means of telecommunications in these regions. Moreover, lower absolute rates of cell phone penetration can underestimate the real impact they are having through the innovative and entrepreneurial ways in which the technology has been extended beyond the model of individual ownership. The portable nature of cell telephony lends itself to being shared, both in terms of access and payment (Gough & Grezo, 2005).

By March 2004, Telkom reported only 4.821 million active fixed lines compared to 4.259 million active lines in 1997. The challenge of fixed-line penetration was a balance between economic benefit and cost, especially in the 'uneconomically' viable areas. In some areas fixed-line investment per line outweighed revenue per line, thus making sustainability questionable.

Universal service intervention by mobile/cell operators had a positive impact – Vodacom installed 30,000 community service phones, while MTN rolled-out 8,000. This supported the initiative to promote universal access to under-serviced areas.

The growth in cell phone penetration in the African continent is interesting. By the end of 2003 there were six cell phone subscribers for every 100 inhabitants in Africa, compared with three fixed line subscribers per 100. Cell phone penetration is high in other regions of the world such as Asia with 15 per 100 inhabitants, the USA with 49 and Europe with 55. Even so, Africa stood at 51.8 million subscribers by the end of 2003 indicating an increase of 1,000 percent in five years.

2.4.3 How cell phones are used

A number of researchers have emphasised that cell phone penetration is more extensive than subscriber figures suggest, as many users share handsets and subscription (Coyle, 2005) (Townsend, 2000). Indeed research published by Vodacom in South Africa (Gough & Grezo, 2005) shows that it is wrong to simply extrapolate our developed world models of needs and usage patterns to poorer nations. In the UK, the ratio of the number of outgoing voice calls made to the number of SMS messages sent is 0.6:1; in South Africa as a whole, the ratio is 3:1 for pre-paid phones; yet in some rural communities the average ratio was a remarkable 13:1. These researchers reported that in Ndebe, a rural community in South Africa, the ratio of outgoing calls to SMS was 17:1. When this is considered in the context of a community in which access to education is not universal, the data is more understandable. The combination of illiteracy and indigenous languages clearly has dramatic effects on the use of SMS messaging (the implications of this will extend to other types of data usage, including the internet).

Low literacy rates, diverse indigenous languages, limited electricity, strong oral traditions, and nomadic lifestyles or livelihoods are some of the contributing factors that make it difficult for communities in developing countries to adopt certain information & communication technology (ICT) tools. One of the major impacts cell phones have in less developed countries in the southern hemisphere is its capacity to include partly illiterate mass populations, who will never have the means to buy a computer and who hitherto were not even connected to the traditional networks of landline phones.

Vodacom's research shows that people in parts of Africa use cell phones very differently. While penetration rates are by the standards of the developed countries low, the way in which mobiles are informally shared between people, the formation of private resellers of mobile services and the provision of cell phones for public use, all increase accessibility, even in rural communities. The impact of cell phones extends well beyond what might be suggested by the number of subscriptions alone.

The informal arrangements that extend the reach of telecommunications are very powerful. Above that we described the differences between outbound calls and SMS, the former being much higher. There is also an interesting phenomenon with regards the ratio between inbound and outbound SMS. In a rural South African community, the ratio of inbound texts to outbound texts is approximately 8:1. Such an imbalanced ratio is explained by an entrepreneurial phenomenon that finds more literate individuals with cell phones relaying SMS text messages to those without cell phone, or those who cannot read or write, for a marginal fee. The advantages of text messaging is its lower cost, relative to voice calls, as well as the fact that the receiving party does not have to immediately acknowledge the message and/or respond to it.

2.4.4 Cell phone growth

In South Africa, cell phones pose a much greater opportunity for communication than internet or even fixed lines do. The cell phone industry operators appear to be the fastest growing communications industry - when Vodacom started operations in 1994, it connected 10,000 subscribers on its first day, by June 2006 had 20.4 million

subscribers. Cell-C started up in 2001 and 2 year later passed had three million subscribers, MTN in June 2006 reported having 11.2 million subscribers.

Cell phone service providers also seem to have developed relatively innovative ways of encouraging subscription, having more pre-paid than post-paid customers by far. In fact, the cell phone industry has come closest to universal service. Universal service innovations include: pre-paid subscriptions, various tariff rates, Community Service telephones (CSTs) and by contributing to the Universal Service Fund (Schofield & Sithole, 2006).

Table 2.1: South African Information & Communication Technology statistics *(Source: International Telecommunication Union, 2008)*

Population	49,667,628
Fixed telephone lines per 100 inhabitants	8.91
Mobile cellular subscriptions per 100 inhabitants.	90.60
% population covered by mobile signal (2007)	99.79
Computers per 100 inhabitants. (2005)	8.25
Internet users per 100 inhabitants.	8.43
Broadband Internet subscribers per 100 inhabitants. (2007)	0.77
Radio sets per 100 inhabitants. (2002)	24.24
TV sets per 100 inhabitants. (2003)	19.50

Figure 2.1: Telephone access in the Frances Baard District (Statistics SA, 2008)

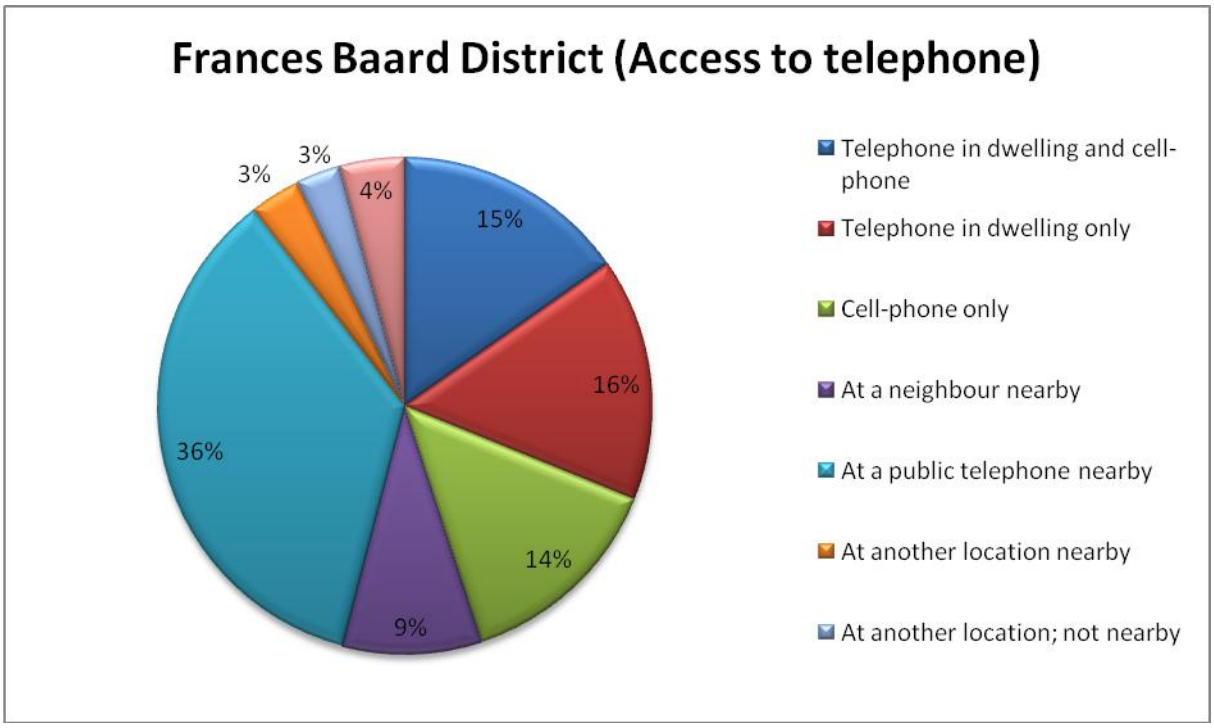


Figure 2.1 above shows the accessibility to land line and cell phones in the Frances Baard District.

2.4.5 Key considerations for cell-phone use in development practice

Shackleton (Shackleton, 2007) pays special attention to the social aspects when using cell phones in research and development practice, particularly for conditions such as HIV/AIDS. Many of the issues raised are pertinent when considering the use of SIMpill in the treatment of TB.

2.4.6 Uses of cell phone technology in Health Care

The majority of projects using cellular phone technology in the healthcare environment deals with health information – for the most part, general data. Data is collected using cellular phone technology and the data collectors are usually health care workers or home-based carers. Projects like the Dokoza corporate healthcare system launched in 2004 involves the use of cell phone to provide the healthcare practitioner with an interactive health administration capability anytime, anywhere and in real-time (Dokoza Corporate Healthcare Systems, 2009). Others, like SIMpill

(SIMpill, 2008), aim to increase drug adherence by providing reminders to patients, and information on the patient adherence to a health care provider.

Projects using cell phones for healthcare are the most experienced, some, like Cell-Life, have been testing their products in the field for over five years (Cell-Life, 2009). Their iDART software solution is designed to support the dispensing of ARV drugs in the public health care sector. It supports pharmacists in their important role of dispensing accurately to an increasing number of patients whilst still being able to engage and assist the patient. The intelligent software is used by the pharmacist to manage the supplies of ARV stocks, print reports and manage collection of drugs by patients.

Many healthcare projects using telecommunications technology fail to move beyond pilot phase because once the product has been tested, government policy requires it to go to a tender process before it can be rolled out in the public sector (Shackleton, 2007). This can sometimes mean a significant amount of time, money and investment in a pilot is lost because roll out is not timeous.

All projects in the health information management field must be able to 'plug-in' to the national health management system. At this point, the health information systems differ from province to province, and sometimes from health institution to health institution. However, the strategies for adherence in the Government's Operational Plan for Comprehensive HIV and AIDS Care specifically "Encourage use of alarms, pagers or other available mechanical aids for adherence" (Department of Health, 2003) . Furthermore, the National Health Act (2003) states that "the national department [of health] must facilitate and coordinate the establishment, implementation and maintenance by provincial [health] departments, district health councils, municipalities and the private health sector of health information systems at national, provincial and local levels in order to create a comprehensive national health information system." (South African Government, 2004) So, while projects using information and communications technology have a base in policy, and the need is certainly there, the infrastructure, money and staffing is not consistently present to promote its holistic development.

CHAPTER 3: METHODOLOGY

3.1 Introduction

This purpose of the study was to assess the effect of the SIMpill device on treatment adherence and describe the level of acceptability of the device to TB patients enrolled in the pilot study.

This chapter describes the methods, materials and human resources used in the study, followed by consideration of any bias, validity, assumptions and ethical issues that impacted on the study implementation and project results.

3.2 Study design

Descriptive retrospective quantitative design was employed for this study which was conducted in two parts. First, semi-structured interviews were conducted with patients who were enrolled in the SIMpill study on the acceptability of the SIMpill device. This was be followed by a retrospective review of data within the SIMpill system to extract data from the SIMpill computer on treatment adherence, the SIMpill computer has a built in reporting function for data extraction.

3.3 Study setting

This project was undertaken in the Betty Gaetsewe Clinic in the Frances Baard District of the Northern Cape Province. The health clinic was equipped with the necessary computer hardware and software to administer the SIMpill system, and health professionals were provided with training to administer the system.

The study population were patients who participated in the 2005 SIMpill pilot project, a total of 100 patients undergoing treatment for TB were enrolled in the pilot project. There was no sampling as the study population was the same as the number of patients enrolled in the SIMpill project

3.4 Data collection

3.4.1 Data collection tools

A researcher-administered structured questionnaire was designed for data collection. The questionnaire was designed in English and translated to Afrikaans and Xhosa. Patients could choose which language they preferred to use. (See appendix).

3.4.2 Patient recruitment

As part of the TB treatment programme, clinic staff from the Betty Gaetsewe Clinic in the Frances Baard District had previously matched each TB patient with a DOTS support worker from a local NGO. The same DOTS caregivers participated as the supporters for the SIMpill study. With permission from the clinic to contact the patients, DOTS supporter workers were trained to administer the questionnaire and conduct the interview at the patient's home. Data collection took about two weeks with three DOTS supporter workers and the researcher collecting the data.

To ensure that all patients were reached, the DOTS supporter workers contacted the patients and set up a date for the interview, this also catered for patients who were employed and who could only be interviewed on weekends. Data collected from patients covered their demographics, their perceptions on the use of the SIMpill device, acceptability of the SIMpill device, treatment taking pattern over time (e.g. missed, reminded, wrong-time, right-time),and completion of both treatment and study.

3.4.3 Data collected by SIMpill software

Before patients enrolled in the project it was explained to each patient how the SIMpill system works. For those patients who participated in the study in addition to their current treatment programme, they received a reminder SMS text message every time they did not open and close their medication container at the prescribed time. If this SMS text message did not result in them opening and closing their medication container within an agreed time span, a further SMS text message was sent to their DOTS worker who then contacted them. In addition SIMpill software collected information on the treatment taking pattern of each patient over time, recording medication episodes as missed, reminded, wrong-time, and right-time.

3.4.4 Inclusion and exclusion criteria

100 patients undergoing treatment for TB were invited to participate in the study and all patients who gave consent were included. Patients who did not consent to participate in the study and patients who could not be traced were excluded from the study

3.5 Bias

There is a risk that the answers of the participants could be different to reality due to the fact that the interviews were conducted after the treatment programme was completed (Recall Bias).

The Potential selection bias was eliminated by including all patients who enrolled in the SIMpill project. However, it should be noted that some degree of patient bias is likely since those patients who did not like the SIMpill system may also be some of those who dropped out of the trial or were untraceable.

It is also possible that the simple fact of participating in a research study, with the expectation that they are being 'watched and monitored' more than other patients increased the level of medication adherence. This is due to the fact that some were afraid that they might lose their grant if they are seen not to be taking their medication on time.

3.6 Validity and reliability

A structured standardized data collection tool was used for data collection, the tool was piloted on five TB patients who were enrolled in the study and their data did not form part of the analysis.

The following assumptions are deemed to be valid in this project:

- A patient who physically opened their pill container then removed their medication from the container.
- A patient who removed their medication from the container will then ingest it and not discard it.

- Technical failure of the device is not a significant factor.

3.7 Ethical Considerations

Ethical clearance was sought from the Research Ethics Committee of the School of Public Health and the Medunsa Research and Ethics Committee.

Permission to conduct the project was sought from the Northern Cape Department of Health Research and Ethics Committee and the Francis Baard Health District manager.

Permission will was sought from the manager of Betty Gaetsewe clinic where the project was conducted.

Informed written consent was obtained from the patients and only patients who consent were included in the project.

The following ethical principles were observed by the researcher:

- Explained to the patients that participation was voluntary and that they can withdraw from the project at any time.
- Confidentiality was ensured during data collection and patients were not required to indicate their names on the questionnaires.
- Patients were treated with respect and their views and opinions respected and maintained during the interview.
- This project posed no potential or additional risk or discomfort to respondents.
- Informed the School and the District about the outcome of the project

CHAPTER 4: DATA ANALYSIS

4.1 Introduction

This chapter analyses two sets of data. Firstly it analyses the results of the patient questionnaire in terms of general demographic data, their experience of using the SIMpill systems, and in terms of their TB treatment programme. Secondly it analysis the data output from the SIMpill computer server in terms of what actually happened with the SIMpill medication container and the SMS reminders it generated.

4.2 Demographics

A total of 65 patients completed the project and their information is given below.

Figure 4.1: Age and gender distribution

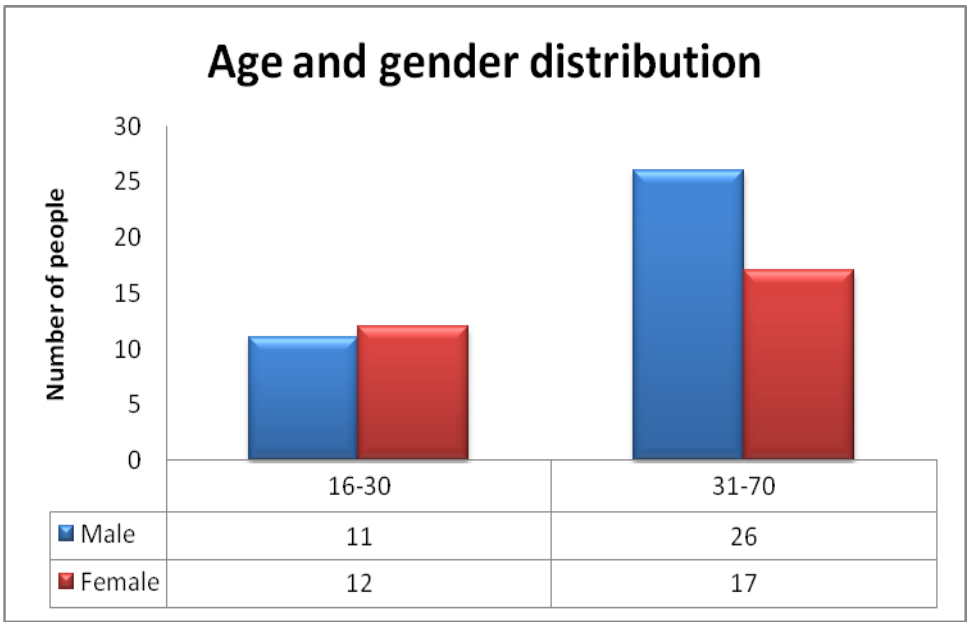


Figure 4.1 above shows the distribution by age and gender of the sample population, with an age ranging from 16 to 67 years. Of these 37 (56%) were male and 28 (44%) female. 35% of the sample population were 30 years and younger, whereas 65% were 31 years and above. This suggests that TB is a disease that predominantly affects the middle and older age groups.

Figure 4.2: Marital status by gender

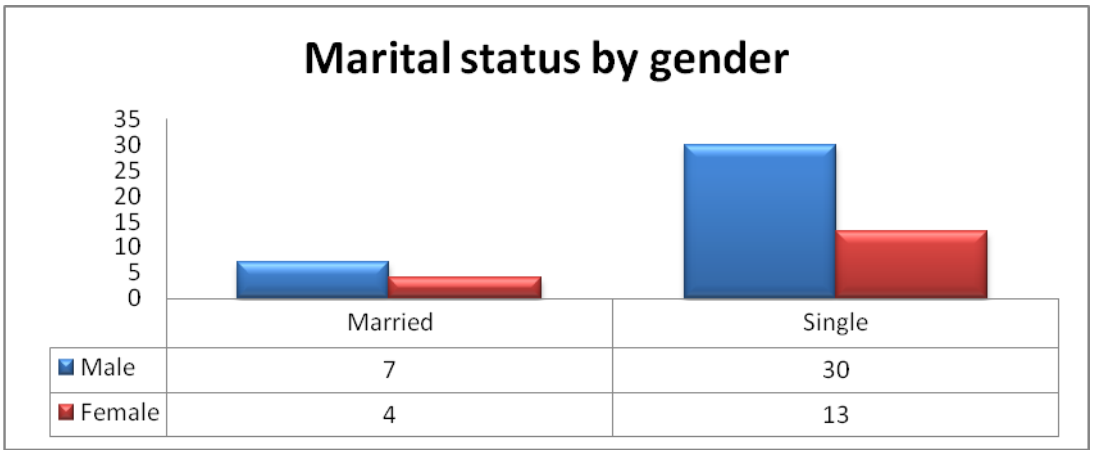


Figure 4.2 above shows the marital status, by gender, of the sample population. An analysis of marital status showed that 46% were male and single, 20% were female and single, 11% were male and married, and 6% were female and married. Interestingly, 66% of the sample population were single.

Figure 4.3: Level of education by gender (Grades 6 to 12)

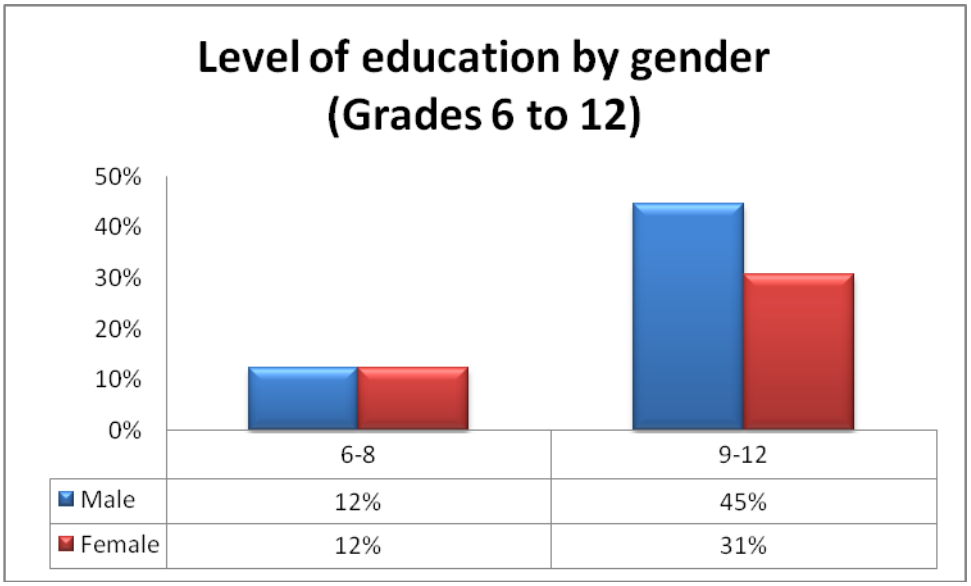


Figure 4.3 above shows the level of education by gender attained by the sample population. Of the 65 patients, 16 said they had only received primary education and/or first year of secondary education, and 49 said they had received Grade 9 to 12 secondary education. 45% of males received grade 9-12 secondary education compared to females.

Figure 4.4: Number of occupants per house

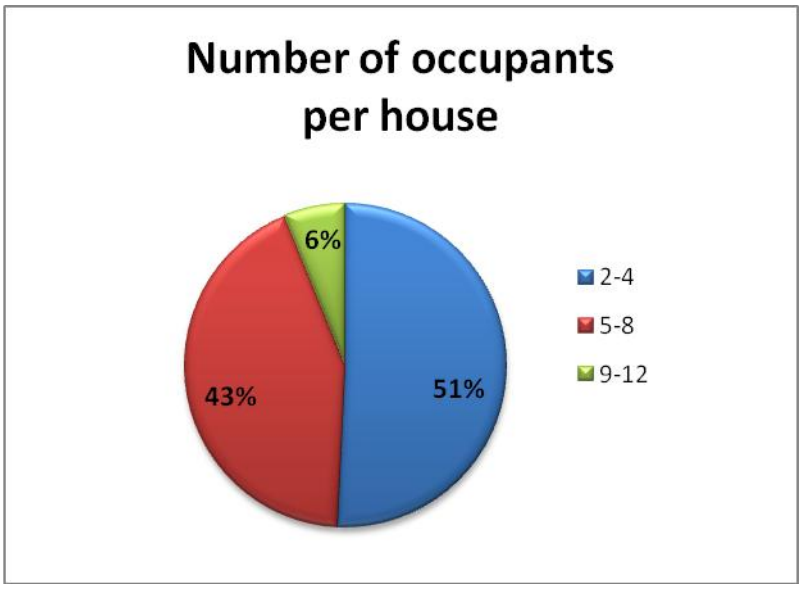


Figure 4.4 above shows the number of occupants living in each house of the sample population. The number of occupants per household ranged from 2 to 12, with the majority 33 (51%) of houses being in the range of 2-4 people per household, followed closely by 28 (43%) houses having 5-8 people per household. A few (4) houses had between 9 and 12 people living in them. About 49% of houses in the sample population had households of between 5 and 12 people, potentially increasing the chance of contracting TB through close contact.

35 people said that they lived in their own privately owned house, 30 of these were of brick construction and five where wood/tin shacks. The remaining 30 patients said that they were tenants or lodgers in property owned by someone else, 23 of these were of brick construction and seven were wood/tin shacks. The total number of people living in wood/tin shacks was 12 (18%).

Figure 4.5: Employment status by gender

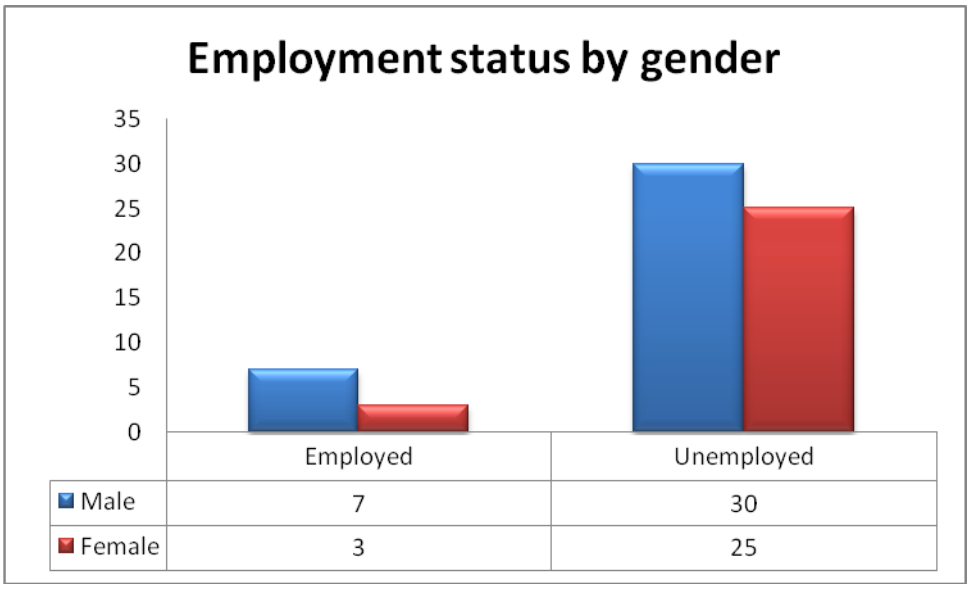


Figure 4.5 above shows the employment status, by gender, of the sample population.

Just ten (15%) of the patients were in employment at the time of the project, with 55 (85%) saying they were unemployed. 81% of males were unemployed and 89% of females were unemployed.

Figure 4.6: Monthly income of the ten employed people

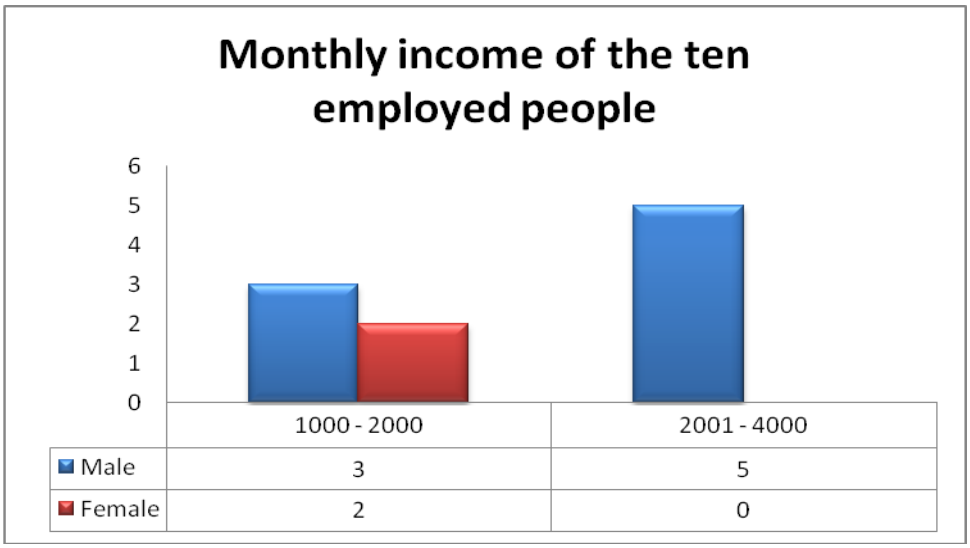


Figure 4.6 above shows the income level, by gender, of the ten people in the sample population who were in employment. The monthly income of the ten people in paid employment ranged from R1, 000 to R3, 800. Of the remaining 55 people, 35 said

they were in receipt of social grants, two were receiving a pension and two were receiving child maintenance.

4.3 Participant experience with SIMpill

All participants said they had experience of using a cell phone prior to enrollment in the project, and all said that they used their own cell phone throughout the project.

Figure 4.7: Ease of use of cell phones for SMS reminders

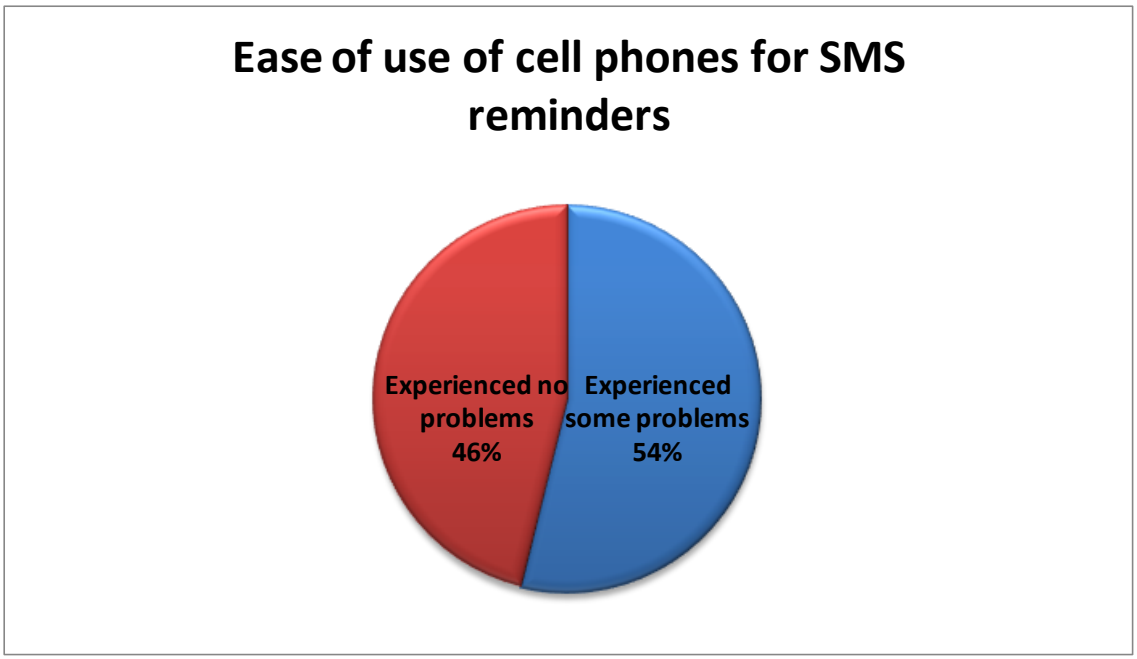


Figure 4.7 above shows that 54% of sample experienced some problems when using their cell phones to receive SMS reminders.

When asked if they found it easy to use the cell phone during the SIMpill project, 35 (54%) participants said that they had experienced some difficulty, although the only negative comment in relation to cell phone use was one comment that they "*Did not always hear the SMS*."

Very few 2(3%) of participants said that clinic staff did not explain how the SIMpill device worked, although they did not record any problems using the device. While 10 (15%) of participants reported having some difficulty in opening the SIMpill medication container.

Figure 4.8: Did SMS reminders help patients remember to take medication?

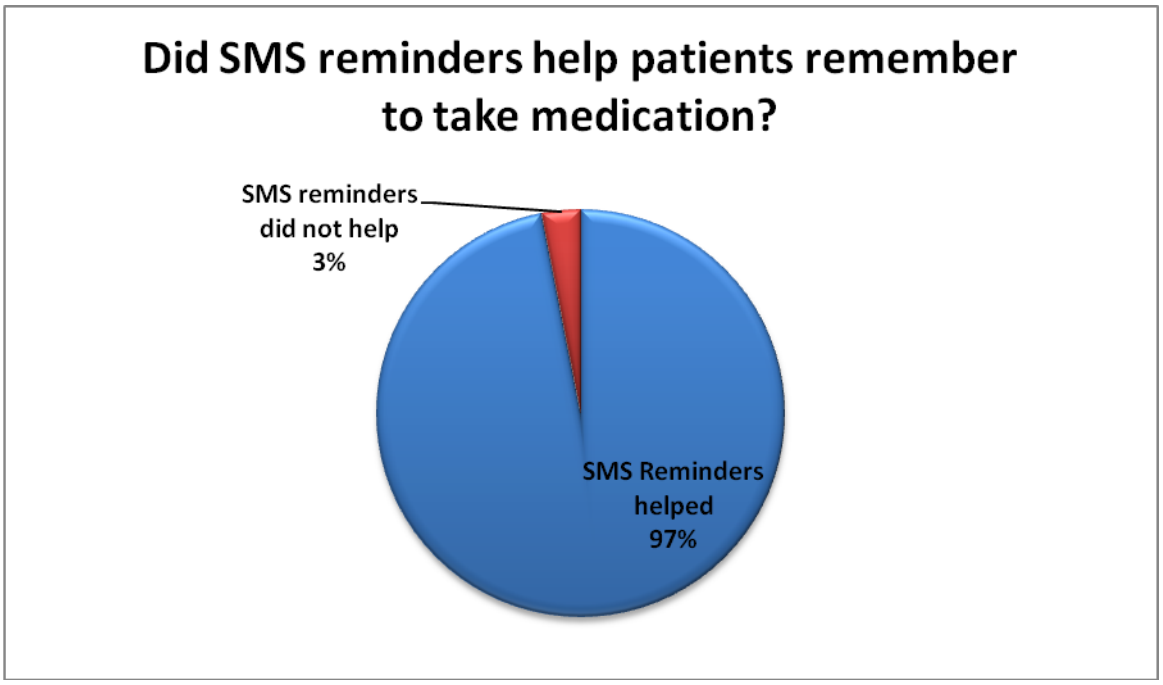


Figure 4.8 above shows that the majority (97%) of participants felt that the SMS reminders helped them remember to take their medication

Figure 4.9: Participant comments about the SIMpill system

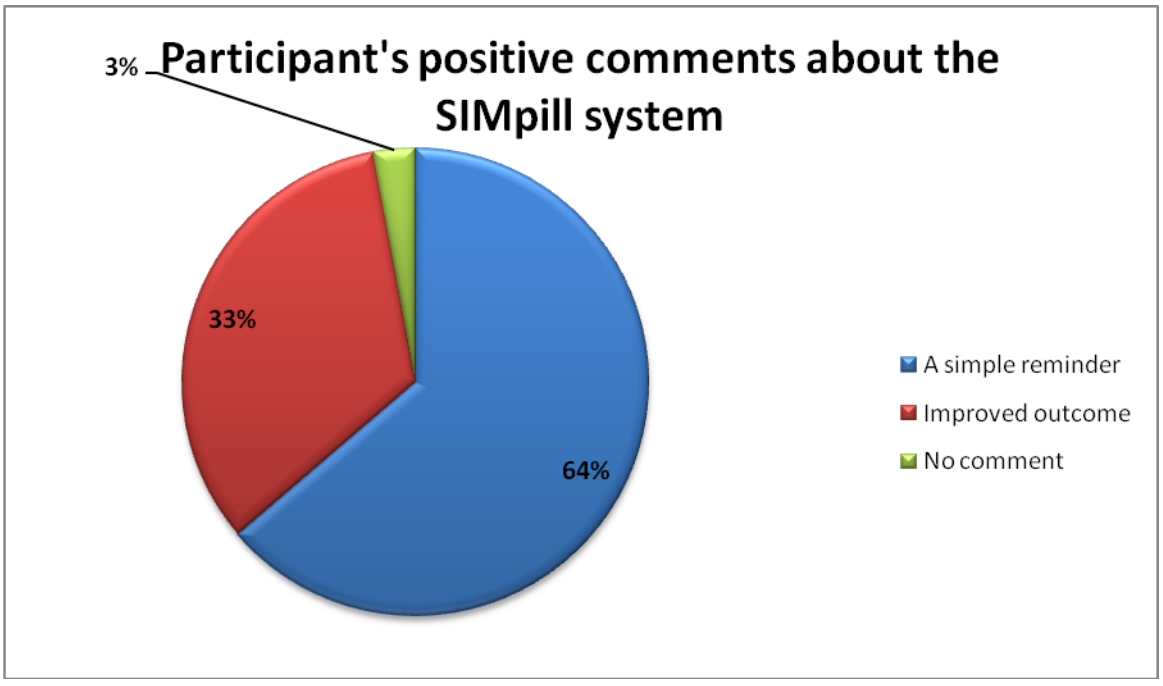


Figure 4.9 above shows that 41 (64%) people commented positively about the SIMpill system as a simple reminder to take medication, 22(34%) people appeared

to recognise the bigger picture in terms of assisting with a positive treatment outcome, and only 2(3%) two people made no comment.

All patients reported receiving at least one SMS reminder during the project. The majority 63 (97%) of participants felt that the SMS reminders assisted in their treatment programme. When asked, “What was good about using the SIMpill device?” Only two patients gave a negative response. These same two patients said that they did not use the SIMpill device all the time that they were taking their TB treatment. It is not clear whether these patients meant that they would remember regardless of the SMS reminder, or if after receiving an SMS reminder they still failed to take their medication.

Some of the more interesting positive comments were:

“Helped me to complete treatment”
“Helped to improve my health condition”
“In time to take medication. It's a motivator and reliable.”
“It helped me to fight TB, improved compliance”
“It improved my condition taking medication on time”
“It was a good motivation to me”
“It was good system”
“Reminder was good. Research was a motivator”
“It Was good participating in project, It helped to complete treatment”
“You will never forget to drink your pills”
“Helps taking medication on right time”

Six patients described issues that they felt were not good about the SIMpill device. These were:

“It's like you are being watched to take medication. The department is policing my complience. A negative feeling”
“You can take medication later then reported”
“You can cheat”
“Not always hearing the SMS”
“Loosing the social grant”
“Food not immediately available”

When asked, “What would you change about the project and the SIMpill device?” there were no suggestions put forward. All participants (including the one who felt that they were being ‘policed’) said that they would recommend the SIMpill device to family and friends.

Figure 4.10: Participant responses to questions about their TB treatment

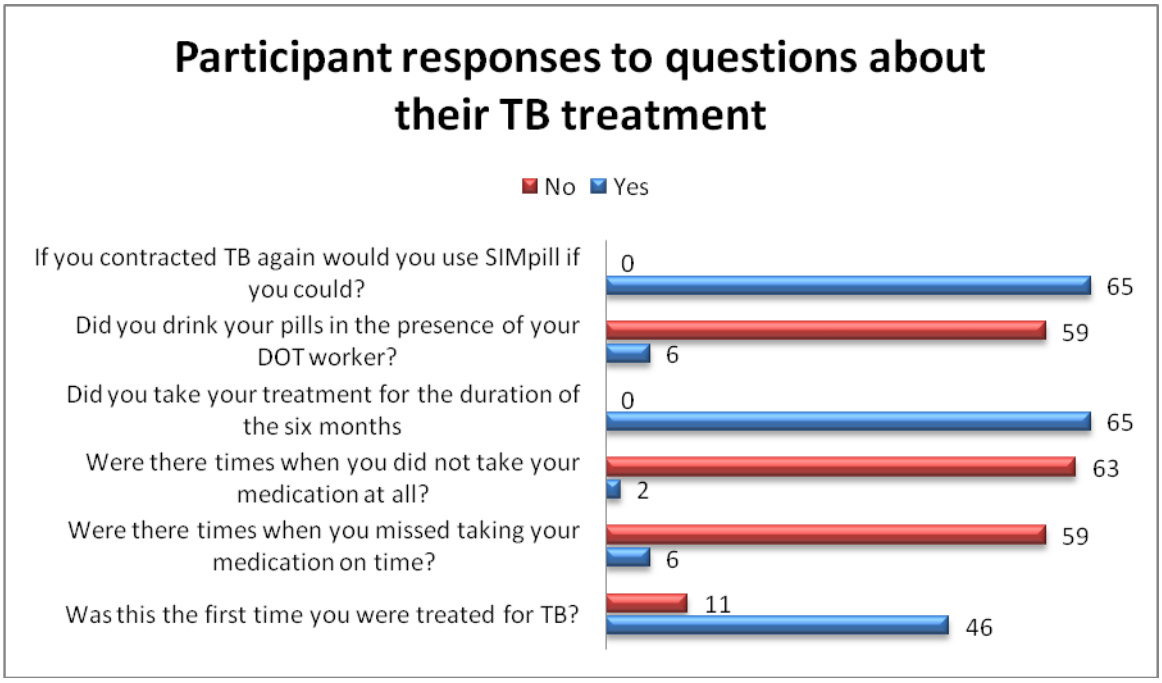


Figure 4.10 above shows the response of patients to questions specifically about how they viewed their TB treatment and the SIMpill system. The majority 11(17%) of patients said that this was not their first treatment programme for TB, 6(9%) of the patients who said that there were still times when they missed taking their medication on time, 2 (3%) of patients said that there were times when they did not take their medication at all. The reasons given were because they did not have their medication with them due to travelling or being away from home. All patients (100%) said that they took their full six month course of treatment.

When asked if they took their medication in the presence of their DOT worker, 91% (59 out of 65 people) said ‘No’.

All patients (100%) said that they would use the SIMpill devise in future if given the choice.

4.4 Data output from SIMpill computer server

Information was extracted from the SIMpill computer server to show how many times:

- The SIMpill medication container was opened at the right time as agreed during mediation dispensing (no SMS reminder message sent),
- The SIMpill medication container was opened at the wrong time but within and agreed tolerance level – usually within one hours either side of the agreed time (no SMS reminder message sent),
- The SIMpill medication container was opened only after a reminder SMS was sent,
- The SIMpill medication container was not opened even after an SMS reminder message was sent.

Table 4.1: Data output from SIMpill Computer Server (individual patients, sorted by gender and age)

Patient	Age	Gender	Took medication:			Medication	Medication Adherence (%)		
Identifier	(Years)		Right time	Wrong time	Reminded	Not taken	Taken at right time	Taken within clinical tolerance	Not taken
17	17	M	66	20	3	11	66.0%	89.0%	11.0%
49	17	M	91	2	3	4	91.0%	96.0%	4.0%
33	22	M	78	5	10	3	81.3%	96.9%	3.1%
25	24	M	81	4	5	10	81.0%	90.0%	10.0%
32	25	M	79	4	10	3	82.3%	96.9%	3.1%
51	25	M	81	7	9	3	81.0%	97.0%	3.0%
62	26	M	86	10	3	1	86.0%	99.0%	1.0%
54	27	M	82	11	5	2	82.0%	98.0%	2.0%
20	28	M	80	13	4	3	80.0%	97.0%	3.0%
50	29	M	76	10	3	11	76.0%	89.0%	11.0%
45	29	M	80	8	7	5	80.0%	95.0%	5.0%
30	33	M	77	6	9	4	80.2%	95.8%	4.2%
27	33	M	81	3	6	10	81.0%	90.0%	10.0%
63	35	M	83	10	6	2	82.2%	98.0%	2.0%
46	36	M	80	5	5	10	80.0%	90.0%	10.0%
15	38	M	70	14	5	11	70.0%	89.0%	11.0%

16	38	M	41	34	9	16	41.0%	84.0%	16.0%
4	38	M	81	11	4	4	81.0%	96.0%	4.0%
36	38	M	85	8	6	1	85.0%	99.0%	1.0%
61	39	M	84	8	6	2	84.0%	98.0%	2.0%
64	40	M	75	9	7	9	75.0%	91.0%	9.0%
9	41	M	57	38	4	1	57.0%	99.0%	1.0%
60	42	M	84	9	3	4	84.0%	96.0%	4.0%
48	42	M	92	2	3	3	92.0%	97.0%	3.0%
12	45	M	45	17	25	13	45.0%	87.0%	13.0%
19	45	M	77	8	4	11	77.0%	89.0%	11.0%
52	46	M	78	6	6	10	78.0%	90.0%	10.0%
66	48	M	79	6	5	10	79.0%	90.0%	10.0%
37	48	M	77	5	9	9	77.0%	91.0%	9.0%
23	49	M	75	10	6	9	75.0%	91.0%	9.0%
40	49	M	84	9	3	4	84.0%	96.0%	4.0%
44	51	M	86	5	7	1	86.9%	99.0%	1.0%
10	66	M	57	16	11	16	57.0%	84.0%	16.0%
34	16	F	77	10	3	10	77.0%	90.0%	10.0%
65	16	F	74	10	6	10	74.0%	90.0%	10.0%
7	18	F	21	46	18	15	21.0%	85.0%	15.0%
14	22	F	75	8	8	5	78.1%	94.8%	5.2%
8	22	F	62	20	6	12	62.0%	88.0%	12.0%
59	24	F	80	3	11	2	83.3%	97.9%	2.1%
57	25	F	78	10	7	5	78.0%	95.0%	5.0%
13	26	F	6	8	67	19	6.0%	81.0%	19.0%
31	26	F	80	3	14	3	80.0%	97.0%	3.0%
3	27	F	71	17	7	5	71.0%	95.0%	5.0%
2	28	F	62	22	4	12	62.0%	88.0%	12.0%
6	30	F	53	18	19	10	53.0%	90.0%	10.0%
63	33	F	21	46	18	15	21.0%	85.0%	15.0%
29	33	F	81	6	9	4	81.0%	96.0%	4.0%
42	34	F	90	2	5	3	90.0%	97.0%	3.0%
38	35	F	76	7	10	3	79.2%	96.9%	3.1%
22	36	F	85	8	5	2	85.0%	98.0%	2.0%
5	52	M	63	13	16	8	63.0%	92.0%	8.0%
56	52	M	79	8	3	10	79.0%	90.0%	10.0%
11	53	M	6	18	66	10	6.0%	90.0%	10.0%
35	36	F	82	11	3	4	82.0%	96.0%	4.0%
47	39	F	69	17	8	6	69.0%	94.0%	6.0%
28	40	F	82	2	4	16	78.8%	84.6%	15.4%
58	42	F	90	4	3	3	90.0%	97.0%	3.0%

1	42	F	8	38	13	41	8.0%	59.0%	41.0%
39	46	F	82	10	7	1	82.0%	99.0%	1.0%
24	46	F	79	6	2	13	79.0%	87.0%	13.0%
43	50	F	78	5	10	3	81.3%	96.9%	3.1%
26	53	F	75	9	6	10	75.0%	90.0%	10.0%
18	62	F	77	8	4	11	77.0%	89.0%	11.0%
21	67	F	84	8	5	3	84.0%	97.0%	3.0%
41	51	M	90	4	3	3	90.0%	97.0%	3.0%

When the output data is aggregated for the patient cohort as a whole (65 patients), it shows that there were a total of 6,476 medication taking events expected during the course of the project.

Table 4.2: Aggregated data output from the SIMpill computer server

SIMpill medication container was opened at the right time (no SMS reminder message sent)	4 664
Opened at the wrong time but within and agreed tolerance level (no SMS reminder message sent)	738
Opened only after a reminder SMS was sent	581
Container not opened even after an SMS reminder message was sent	493

Figure 4.11: Aggregated data output from the SIMpill computer server

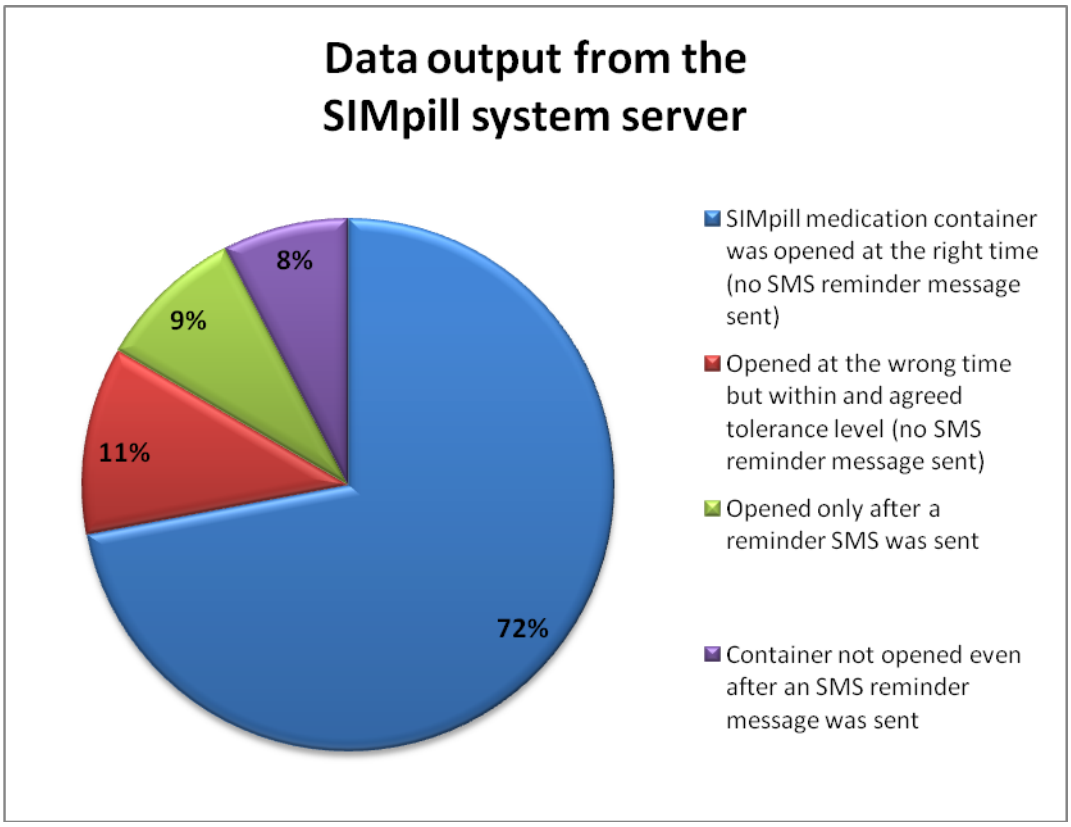


Figure 4.11 above shows how many patients did not require and SMS reminder in order to take their medication (72% + 11%), how many took their medication once reminded (9%) and how many failed to take their medication even after a reminder (8%).

The aggregated data suggests that adherence levels averaged 83% with no SMS reminders being sent (72% + 11%). This adherence was increase by a further 9%, taking it to 92% when SMS reminders were sent. There continued to be an 8% adherence failure rate even when SMS reminders were sent.

The level of adherence without being reminded (83%) may have been influenced by the enthusiasm generated by participating in a research study, or by the fact that they knew they were being monitored by the system. One or two participants appeared to say that they were complying due to fear that they might lose their grant if they did not adhere fully (presumably based on a fear that the social services department may have access to the adherence data).

CHAPTER 5: DISCUSSION

5.1 Introduction

Despite current interventions in many parts of Southern Africa, including the Northern Cape Province of South Africa, TB cure rates are poor. It is generally accepted that poor treatment adherence (including defaulters) leads to poor cure rates and the emergence of drug resistant forms of TB. In the Northern Cape the cure rate for 2004 and 2005 was 38.3% and 50.1% respectively, with about 12% of patients defaulting.

In this chapter the demographics of the general population and the sample population are discussed. The participant experience with the SIMpill device is explored, and the data output from SIMpill computer server is disucssed.

Conclusions with regards to the effect of the SIMpill device on treatment adherence and the acceptability of the device in the treatment of TB patients are drawn, with recommendations for future use of this device.

5.2 Demographics profiles of study participants

This study was undertaken in the urbanised Sol Plaatje Municipality, where 62% of the Frances Baard District population lives. Although the Frances Baard District is geographically the smallest in the Northern Cape, the population of 325,501 people gives it the largest population density (26.2 persons per square km) in the province.

There are more females than males in the District, with 52% of the population being female and 48% male. This contrasts with the gender make-up of the sample population of TB patients, where 44% were female and 56% male. This suggests that TB affects males more than females in this part of South Africa.

The Northern Cape, particularly in the Frances Baard District, has a long history of mineral mining – an industry almost exclusively male. Health and safety conditions within mines promote the risk of silicosis (known to be a Tb risk factor) and transmission of TB in close quarters. Furthermore, reports from South Africa suggest that miners pose transmission risks to other household or community members as they travel home undetected or inadequately treated, particularly with drug-resistant

forms of TB. This is reflected in research that suggests miners in southern Africa experience incident rates of TB up to ten times greater than the general population (Basu, Stuckler, Gonsalves, & Lurie, 2009).

The District population is largely a young population, with 30% being under 15 years, 43% being 15 to 39 years, and 27% being 40 years and older. In the sample population of TB patients, 35% were aged 30 and younger, with 65% aged over 30 years. This suggests that TB is a disease that predominantly affects the middle and older age groups. In Africa, research shows that TB primarily affects adolescents and young adults, although this may have more to do with the direct link with HIV/AIDS which predominately affects the sexually active. This contrast with countries where TB has gone from high to low incidence, such as the USA, where TB is mainly a disease of older people (Average Age of TB Cases). Although 65% of the sample population was over 30 years, 66% were single. This may indicate that people living alone may live a less healthy lifestyle in terms of contracting TB. This is consistent with evidence from the UK which shows that men may be twice as likely as women to be living on their own between the ages of 35 and 44 but are less well suited to the single life. Research showed they had fewer friends and were more likely to have poor diets, suffer from depression and live in less comfortable homes (Revill, 2005). There is no similar research for southern Africa.

About 49% of houses in the sample population had households of between 5 and 12 people. This is likely to increase the chance of contracting TB through close contact. TB is also much more common in poor communities where overcrowding is more common and people are more likely to live in dark, unventilated rooms, and thus an increased likelihood of being infected by TB and to receive large doses of the bacilli. The patients' resistance to TB is reduced, particularly by malnutrition and other diseases such as HIV (TB and Poverty).

There did not appear to be any correlation between private ownership of houses and TB prevalence in the sample pollution, nor between construction material of type of house and TB prevalence, although it may be significant did 18% of the sample population live in wood/tin shacks.

Just 15% of the patients were in employment at the time of the study and for patients who were employed their salaries ranged from R1000 to R3800. 85% were unemployed and 81% of males were unemployed as compared 89% of females. The gender disparity reflects employment patterns of the general population. An analysis of the economically active population in the Frances Baard District (age 15 - 65 years) shows a significantly high rate of unemployment at 24%, with just 34% in formal employment. Of those in formal employment, 60% are male. 60% of patients said they were in receipt of social grants, pension or child maintenance. These income levels suggest that TB impacts more on low/no income individuals and as such is a disease of poverty. This was encapsulates by Archbishop Desmond Tutu when he famously said, "TB is the child of poverty - and also its parent and provider."

5.3 Participant experience with SIMpill

Of the patients who were enrolled in the SIMpill project only 65 of the original 100 completed the study and were included in the study sample.

All 65 participants said they had experience of using a cell phone prior to enrollment in the study, and all said that they used their own cell phone throughout the study. This is consistent with other data showing the high use if cell phones in South Africa.

54% of the sample population said that they had experienced some difficulty using the SIMpill system, although most were not specific. 15% of participants reported having some difficulty in opening the SIMpill medication container. 3% of participants said that clinic staff did not explain how the SIMpill device worked, although they did not record any problems using the device. The only negative comment in relation to cell phone use was one patient saying that they "*Did not always hear the SMS*." This suggests that the SIMpill device itself may require further enhancements to make it more user-friendly. As far as its linkage with the patient's cell phone is concerned, this appears to be an acceptable technical solution from the user's perspective.

All patients reported receiving at least one SMS reminder during the study which is consistent with the data from the computer server. When asked, "What was good about using the SIMpill device?" 97% of patients felt that the SMS reminders helped them take their medication regularly. Some of the more interesting comments were: "In time to take medication - it's a motivator and reliable," "It helped me to fight TB,

improved compliance," "Reminder was good. Research was a motivator," "Was good participating in project, helped to complete treatment," and "You will never forget to drink your pills."

About 3% of patients said that the reminders did not help, although it is not clear whether these patients meant that they would remember regardless of the SMS reminder, or even after receiving an SMS reminder they still failed to take their medication. This was a shortcoming of the questionnaire. These same patients said that they did not use the SIMpill device all the time that they were taking their TB treatment. This may be because, when out with friends or family, they did not want them to see they had a different type of pill container, or even that they were taking medication at all.

9% of patients described issues that they felt were not so good about the SIMpill device, including, "It's like you are being watched to take medication. The department is policing. A negative feeling", "You can take medication later then reported", "You can cheat", "Loosing the social grant" and "Food not immediately available"

100% of patients, including the one who felt that they were being 'policed', said that they would recommend the SIMpill device to family and friends.

As previously reported 35 of the original 100 patients recruited to the project dropped of the study out or were untraceable. This suggests that if the SIMpill device is used to support routine TB treatment, 35% of patients would require significant additional support either than the SIMpill (e.g. through their DOTS worker) in order to complete their treatment. However, the study also suggests that 100% of those patients that remain loyal to the SIMpill system during their treatment will actually complete the full course with limited input from their DOTS worker.

5.4 Data output from SIMpill computer server

When the output data from the SIMpill computer server is aggregated for the patient cohort as a whole it shows that there were a total of 6,476 medication taking events expected during the course of the project. This data suggests that adherence levels averaged 83% with no SMS reminders being sent (72% on time openings, and a

further 11% opened within the tolerance period). This adherence was increase by a further 9%, taking it to 92% when SMS reminders were sent. Interestingly, there continued to be an 8% adherence failure rate even when SMS reminders were sent.

The level of adherence without being reminded (83%) may have been influenced by the enthusiasm generated by participating in a research study, or by the fact patients knew they were being monitored by the system. One or two participants appeared to say that they were complying due to fear that they might lose their grant if they did not adhere fully – presumably based on a fear that the social services department may have access to the adherence data. The fact that the majority felt that using the SIMpill was a good thing rather than a bad thing is encouraging for future use – praise is a better reinforcing technique than punishment (Skinner, 1956).

5.5 Conclusion

The socio-demographic profile of patients enrolled in the SIMpill project showed a cohort that had slightly more males than females, who were mainly over the age of 30 years, mainly living in multi-occupation houses, and who were predominately poor. In view of the fact that 48% of the general population in the District are male, compared with 56% in the study cohort suggests that TB affects males more than females in this part of South Africa, possible as a result of the predominantly mining industry in the area.

In the sample population the majority of the patients were over 30 years suggesting that TB is a disease that predominantly affects the middle and older age groups.

There was high unemployment rate with the majority of the study cohort unemployed, and salaries for the few employed participants ranged from R1000 to R3800. The majority of patients were recipients of social grants, pension or child maintenance. These findings suggest that TB impacts more on low/no income individuals and as such is a disease of poverty.

The level of acceptability of the SIMpill device to patients who were enrolled in the project was high and the vast majority of patients felt the system was helpful and they would recommend it to friends and family.

The level of TB medication adherence among patients using the SIMpill device was high from the data recorded by computer and patients recollections. It should be borne in mind that the level of adherence without being reminded may have been influenced by the enthusiasm generated by participating in a research study, or by the fact they knew they were being monitored by the system.

Therefore the study concludes that the SIMpill system increased medication adherence and that using the system was highly acceptable to the vast majority of study patients.

Study limitations:

The most important limitation of this study is recall bias, the study was conducted way after the project was completed. The use of data generated by the SIMpill computer was one of the ways to mitigate recal bias especially on an important aspect as medication adherence

Drawbacks of SIMpill include:

- Requires good cell phone signal coverage and the patient to have personal access to a cell phone, on a continual basis during treatment
- There is a potential for a breach of confidentiality if reminders are read by other people
- Patients may ‘cheat’ the system or feel intimidated by the electronic monitoring system (overbearing, policing, ‘big brother’).
- The cost of the system may be prohibitive (hardware and communication charges).

Positive aspects of SIMpill include:

- Many patients appeared to be familiar with cell phone usage and liked the prompting that the system provided
- It is likely, as with other reported studies, that simply being part of a research study, or using new technology, has a positive impact on adherence.

- When patients did forget, the SMS reminder increased adherence by a further 9% (cumulative result of all pill taking events in this study).

5.6 Recommendation

Although there is no evidence that poor medication adherence can be ‘cured’, efforts to improve adherence must be maintained for as long as the treatment is required.

It is unlikely that SIMpill is the final solution to eliminating poor TB medication adherence. However, in the right setting, SIMpill may be another important weapon in the armory to increase TB medication adherence.

In each setting, a value for money analysis should be undertaken to see if a potential 9% increase in adherence justifies the increased cost of the SIMpill system. This will need to take into account any reduced cost associated with other adherence methodologies that can be stopped or reduced (including a reduction in DOTS supervision), as well as the potential reduced costs resulting from a 9% increased cure rate

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Appendix 1a: Patient Questionnaire

User acceptability and effectiveness of the SIMpill device as a strategy to improve treatment adherence among TB patients enrolled in the SIMpill project – a pilot project in the Frances Baard district, Northern Cape Province

Demographic data: Patient Identifier		
What is your age in years?		
What is your gender?		
What is your marital status?		
What is your religion?		
What is the highest standard you passed at school?		
Are you staying in your own family house?	Yes	No
What kind of construction is the house?		
How many people live with you?		
Were you employed at the time of the SIMpill project?	Yes	No
If employed what kind of employment is it?		
What was your monthly income?		
If not employed do you have another source of income?	Yes	No
What was your source of income?		
Area of residence		

SIMpill information		
Did you have a cell phone prior to your enrolment in the SIMpill project?	Yes	No
Did you use your own cell phone during the SIMpill pilot?	Yes	No
If you didn't use your own phone, whose phone was it?		
Did you regularly use a cell phone prior to your enrolment in the SIMpill project?	Yes	No
If not did you find it easy or difficult to use a cell phone during the SIMpill project	Yes	No
Did the clinic staff explain how the SIMpill device works?	Yes	No
Was it easy to open the SIMpill bottle?	Yes	No
Did you receive any SMS reminders during the SIMpill project?	Yes	No
How often did you receive reminders during the project		
Did the reminders help you to take your pills regularly?	Yes	No
Did you use the SIMpill device all the time you were taking your TB treatment	Yes	No

If no, why did you decide to stop using the SIMpill device?

_____

How long did you use the device before you stopped?

_____

What was so good about using the SIMpill device?

_____

What was not so good about using the SIMpill device?

_____

What would you change about the project and the SIMpill device?

_____

Would you recommend the SIMpill device to any of your family and friends?	Yes	No
TB Information		
Was this the first time you were treated for TB?	Yes	No
Were there times when you missed taking your medication on time?	Yes	No
Where there times when you did not take your medication at all?	Yes	No
If yes what were the reasons?		
Did you take your treatment for the duration of six months	Yes	No
Did you drink your pills in the presence of your DOT worker?	Yes	No
If you contracted TB again would you like to use SIMpill?	Yes	No

Appendix 1b: (Afrikaans Translations)

Demographic data: Patient Identifier		
Wat is jou ouderdom?		
Wat is jou geslag?		
Wat is jou huwelikstatus?		
Wat is u geloof?		
Wat is u hoogste grraad geslaag op skool?		
Bly jy by jou eie huis?	Ja	Nee
Watter tipe konstruksie is die huis?		
Hoeveel persone is woonegtig by jou?		
Was u werksaam met tye vandie SIMpill projek?	Ja	Nee
Indien werksaam watse tipe werk?		
Wat was u maandelikste inkomste?		
Indien werkloos, het u ‘n ander bron van inkomste?	Ja	Nee
Wat is u bron van inkomste?		
In waste gebid woon u?		
SIMpill information		
Het u ‘n selfoon gehad ten tyde van die inskrywing vir die SIMpill projek?	Ja	Nee
Het u, u eieselfoon gebruik ten tyde van die SIMpill projek?	Ja	Nee
Indien u nie u eie foon gebruik het nie, wie se foon was dit?		

Het u gereeld u selfoon gebruik ten tyde van dieinstrywing van die SIMpill projek?	Ja	Nee
Indien nie het u dit moelik of maklik gevind om ‘n selfoon te gebruik gedurende die SIMpill projek	Ja	Nee
Het die kliniek personnel aan u verduidelik hoe die SIM Pill toerusting werk?	Ja	Nee
Was dit maklik om die SIMpill bottle oop te maak?	Ja	Nee
Het u enige SMS ontvang om u te herhinner om die SIMpill projek?	Ja	Nee
Hoeveel keer was u in kennis gestelgedurende die projek		
Het die herhinner boodskappe u gehelp om pille gereeld te gebruik?	Ja	Nee
Het u die SIM Pill toestel gebruik terwyl u die TB behandeling gekry het?	Ja	Nee

Indien nie , hoekom het u besluit om die SIM Pill toestel te los?

_____

Hoe lank het u die toestel gebruik voordat u dit gelos het?

_____

Watwas goed omtrent die SIMpill toestel?

_____

Wat was goed om die SIM Pill toestel te gebruik nie?

_____

Wat sou u verander omtrent die SIM Pill toestel?

_____

Sal u die SIM Pill toestel vir u familie en vriende voorstel?	Ja	Nee

TB Information

Was dit die eerste keer wat u vir TB behandel is?	Ja	Nee
Was daar kere wat u vergeet het om u medikasie te neem?	Ja	Nee

Was daar tye wat u glad nie onthou het om u medikasie te vat nie?	Ja	Nee
Indien ja wat was die rede?		
Het u, u medikasie vie die tydperk van ses maande gevat?	Ja	Nee
Het u, u pille geneem in die teenwoordigheid van u DOT werker?	Ja	Nee
As u weer TB ontwikkel sal u die SIM Pill gebruik?	Ja	Nee

Appendix 1c: (Xhosa Translations)

Demographic data : Patient Identifier		
Mingaphi iminyaka yakko?		
Isini?		
Utshatile na?		
Buthini ubuhlanga bakho?		
Litini ibanga eliphezulu owaliphurmelelayo?		
Uhlala endleini yosapho lwakho?	Ewe	Hayi
Didi luni lwendlu ohlala kuyo?		
Bangaphi abuntu ohlala kuyo?		
Wawusebenza msebenza ngelixa le SIMpill?	Ewe	Hayi
Ukuba wawungasebenzi wawunayo ingeniso?		
Yayiyimalini ingeniso yakho ngenyanga?		
Ukuba wawungasebenzi wawunayo ingeniso?	Ewe	Hayi
Ukuba ewe yayiyingeniso ni?		
Uhlala kweyiphi inginqgi?		
SIMpill information		
Wawunayo imfonomfono ngoku wawubhalisela iSIMpill?	Ewe	Hayi
Wawusebenzisa imfonomfono yakho ngexesha le SIMpill?	Ewe	Hayi

Ukuba yayingeyoyakho yayiyekabani?		
Wawusebenzisa imfonomfono yakho rhoqo negexesha le SIMpill?	Ewe	Hayi
Ukuba hayi uyifumene lula okanye nzima ukusebenzisa imfonomfono ngexesha leSIMpill?	Ewe	Hayi
Ingaba abongikazi bayicacisa indlela esebenzangayo iSIMpill?	Ewe	Hayi
Kwakulula ukuyivula I SIMpill?	Ewe	Hayi
Wawuyifumana imiyalezo yem fonomfono nqexesha le SIMpill?	Ewe	Hayi
Ukuba ewe wawuyifumana kangakanani		
Yayikunceda imiyalezo leyo ukuba usele I SIMpills zakho?	Ewe	Hayi
Wawuyisebinzisa ngamaxesha onke I SIMpill yakho ngelixa wawufumana unyango lwakho lwe TB?	Ewe	Hayi

Ukuba hayi wayekela ntoni ukusebenzisa I SIMpill yakho?

_____

Wayisebenzisa ixesha elingakanani iSIMpill yakho phambi kokuba?

_____

Yintoni eyayikuehulumalisa kule SIMpill?

_____

Yintoni owawungayithandi ngale SIMpill?

_____

Tshintsho luni ongaluzisa apha kule projekti SIMpill?

_____

Akunabanangxaki ukuba usapho lwakho okanye umhlobo wakho asebenzise I SIMpill?	Ewe	Hayi

TB Information		
Yayililixa lokuqala eli lokufumana kwakho unyango lwe TB?	Ewe	Hayi
Ingaba Kwakukho amaxesha apho wawulibala ukuthatha iipilisi zakho?	Ewe	Hayi
Akhona amaxesha apho wawungaqalisa tu ukuthatha iipilisi zakho khona?	Ewe	Hayi
Ukuba kunjalo sasisithini isizathu soko?		
Ingaba Itritimenti wayithatha ixesha elingange nyanga ezinthandathu?	Ewe	Hayi
Ingaba iipilisi zakho wawuzisela umongikazi wakho ekhona?	Ewe	Hayi
Ukuba unokuphinda uhlaselwe sisifo sephepha ungaphinda usebenzisc iSIMpill?	Ewe	Hayi

Appendix 2: Data extraction tool (from SIMpill computer)

Data extraction tool: TB Patients enrolled in the SIMpill project in 2005	
Patient Demographic information	
Patient identifier	
Age	
Gender	
Area of residence	
Highest standard passed at school	
Marital status	
Employment status	
Treatment taking pattern	
Right Time	
Wrong time	
Reminded	
Missed	

Appendix 3a: Informed consent by patient

UNIVERSITY OF LIMPOPO (Medunsa Campus) CONSENT FORM

Statement concerning participation in a Research Project

Name of Project:

User acceptability and effectiveness of the SIMpill device as a strategy to improve treatment adherence among TB patients enrolled in the SIMpill project – a pilot in the Frances Baard district, Northern Cape Province

I have heard the aims and objectives of the proposed project and was provided the opportunity to ask questions and given adequate time to rethink the issue. The aim and objectives of the project are sufficiently clear to me. I have not been pressurised to participate in any way.

I understand that participation in this project is completely voluntary and that I may withdraw from it at any time and without supplying reasons. This will have no influence on the regular treatment that holds for my condition neither will it influence the care that I receive from my regular doctor.

I know that this project has been approved by the Medunsa Campus Research and Ethics (MCREC), University of Limpopo (Medunsa Campus). I am fully aware that the results of this project will be used for scientific purposes and may be published. I agree to this, provided my privacy is guaranteed.

I hereby give consent to participate in this project.

....

Patient name Signature of patient or guardian.

Signed in (town)..... on (date).....

Witnessed by .....

Statement by the Researcher

I provided verbal information regarding this project

I agree to answer any future questions concerning the project as best as I am able.

I will adhere to the approved protocol.

....

Researcher name Signature of researcher

Signed in (town)..... on (date).....

Appendix 3b: (Afrikaans translation)

UNIVERSITY OF LIMPOPO (Medunsa Campus) CONSENT FORM

Verklaring rakende die deelname in n' navorsing projek

Naam van Projek of studie

Verbruiker aanvaarbarheid en effektiviteit van die SIMPILL hulpmiddel as n strategie om TB pasiente wat deelneem aan die SIMPILL projek te laat hou by die behandeling-n' loods studie in die Frances Baard distrik, Noord Kaap Provinsie.

Ek is ingelig oor die mikpunte and doelwitte van die voorgestelde studies en het die geleentheid gehad om vrae te vrae en is genoeg tyd gegun om die kwesi te herdink. Die mikpunte en doelwitte van die studie is duidelik genoeg vermy. Ek is geensinde onder druk geplaas om deel te neem aan die studie nie.

Ek verstaan dat deelname aan die studie total vrywillig is en date ek ter enige tyd mag onttrek sonder of redes te verskaf. Dit gaan geen invloed he' op die gereelde behandiling van toepassing op my toestand nie, asook geen invloed he op die sorg wat ek van my gewone dokter ontvang nie.

Ek weet dat hierdie studie goedgekeer is deur Medunsa Kampus Narvorsing en Etiek(MKNK) Universiteit van Limpopo (Medunsa Kampus). Ek is ten volle bewus daarvan dat die resultate van hierdie studei gebruik sal word vir wetenskaplike doeleindes en moontlik gepuliseer sal word. Ek stem toe daartoe, op voorwaarde dat my privaatheid gewaarborg word.

Ek gee hiertoe toestemming om deel te neem aan die studie.

....

Naam van pasient Handtekening van pasient of vrog.

Plek..... Datum.....

Getui .....

Verklaring deur die Navorger

Ek het verbale inligting verskaf oor die studie

Ek het verbale inligting verskaf oor die studie

Ek onderneem om enige toekomstige vrae met die studie na die beste van my vermoe' te beantwoord.

Ek sal hou by die goedgekeurde protocol.

....

Naam van Navorsing Handtekening

Plek..... Datum.....

Appendix 3c: (Xhosa translation)

UNIVERSITY OF LIMPOPO (Medunsa Campus) CONSENT FORM

Indlela nomgaqo wokusebenzisa kwe SIMpill ukuphucula unyango lwe zigulana eziphila nesifo sephepha, abaxharnla kule SIMpill projekti esekwe e Frances Baard district, kwingingqi yase Northern Cape.

Bendinikwe ithuba elaneleyo lokokuba ndifunde ndazingokucacileyo malunga naleprojekti ndaza ndanikwa nethuba lokubuza imibuzo

Kunjalonje ndaze ndanikwa nexesha elaneleyo lokuba ndililalutye lomba. Injongo neminqweno yokufunda zicace gca kum. Andinyanzeliswanga nakancinci ukuba ndithabathe inxaxheba.

Ndiyaqonda ukuba ukuthatha inxaxheba ekufundeni akunyanzelekanga koko kukuzinekela ungenanjongo yantlawulo, kwaye ndinako nokurhoxa nokuba kunini na ngaphandle kokuba ndichaze izizathu. Lo nto ayiyi kuchapahazela unyango lwa rhoqo elindigcina ndisemgmgathwemi wempilo entle okanye ichaphazele uncedo endilufimana kugqirha wezonyango lwernpilo yam.

Ndiyazi okokuba ezizifundo zavunyelwa luvavanyo licandelo yezentlola le dyuniversity ekuthiwa yi Ujunivesity yase Limpopo (Medunsa Capmus)

Ndinika ugunyaziso oluqgibeleleyo ukuba iziphumo zezizifundo zingasetyenziswa zingcali khon' ukuze zibenokuphucula ezinye iziguli, ndivulemene ke ukuba incukacha zam zinokuhlala ziyirnfihlo yam .

Ndiyavuma ukuba ndiyakuthatha inxaxheba kwezizifundo

....

Igama lesigulana.....Tyikitya.

Indawo..... Umhla.....

Ingqina.....

Ingxelo yengcali

Ndinikezele ingxelo ngomlomo malunga nezizifundo

Ndiyavumelana ukuphendula nayiphi na imibuzo enokuthi ilandeliswe malunga nezizifundo

Ndiyavumelana nemithetho evunyiweyo.

....

Igama lengcali Tyikitya

Indawo..... Umhla.....

Appendix 4: Letter – Seeking permission to conduct research in the Northern Cape Department of Health

14 Heerengracht
Kimberley
8301

Cell: 0833906655
Land line: 0538324008

The Chief Director
Northern Cape Health Department
Private Bag X5049
KIMBERLEY
8301

Dear Sir/Madam

Re: Permission to conduct a project in Betty Gaetsewe clinic in the Francis Baard District

I, Deon Madyo, student No 200435795, am studying for a Master of Public Health degree at the School of Public Health, University of Limpopo (Medunsa Campus). I am required to submit a research report for the partial fulfilment of the degree.

I am writing to seek permission to undertake a project using data obtained from the SIMpill device for the treatment of tuberculosis in the Frances Baard District and also to conduct interviews with patients enrolled in the SIMpill project during 2005. The project aims to assess the effect of the SIMpill device on treatment adherence and describe the level of acceptability of the device to TB patients enrolled in the pilot project.

My project proposal is still to be reviewed by the Research and Ethics Committee of the National School of Public Health and the Medunsa Research and Ethics Committee. Permission will also be sought from the Francis Baard District Office and the Health facility Manager.

Findings from the project may result in expansion of the SIMpill project in the Province and the proven benefits can be expected to impact on greater numbers of TB sufferers (and potentially other conditions where SIMpill supported treatment adherence may be of benefit).

Yours sincerely

Deon Madyo (Mr.)

Appendix 5: Letter – Seeking permission to conduct research in the Frances Baard Health District

14 Heerengracht
Kimberley
8301

Cell: 0833906655
Land line: 0538324008

The District Manager
Frances Baard Health District
Northern Cape Health Department
Private Bag X5049
KIMBERLEY
8301

Dear Sir/Madam
Re: Permission to conduct a project in Betty Gaetsewe clinic in the Francis Baard District

I, Deon Madyo, student No 200435795, am studying for a Master of Public Health degree at the School of Public Health, University of Limpopo (Medunsa Campus). I am required to submit a research report for the partial fulfilment of the degree.

I am writing to seek permission to undertake a project using data obtained from the SIMpill device for the treatment of tuberculosis in the Frances Baard District and also to conduct interviews with patients enrolled in the SIMpill project during 2005. The project aims to assess the effect of the SIMpill device on treatment adherence and describe the level of acceptability of the device to TB patients enrolled in the pilot project.

My project proposal is still to be reviewed by the Research and Ethics Committee of the National School of Public Health and the Medunsa Research and Ethics Committee. Permission will also be sought from the Francis Baard District Office and the Health facility Manager.

Findings from the project may result in expansion of the SIMpill project in the Province and the proven benefits can be expected to impact on greater numbers of TB sufferers (and potentially other conditions where SIMpill supported treatment adherence may be of benefit).

Yours sincerely

Deon Madyo (Mr.)

Appendix 6: Approval to conduct research in the Northern Cape Department of Health

27. OCT. 2009 9:10 H O D NO. 119 P. 1

DEPARTMENT OF HEALTH

LEFAPHA LA BOITEKANELO

ISEBE LEZEMPILO

DEPARTEMENT VAN GESONDHEID

Office of the Deputy Director General
Executive Offices
Kimberley Hospital Complex
Private Bag X5049
KIMBERLEY
8300

Enquiries : DR DG THEYS
Dipatlisiso : Tel: 053-8302102
Imibuzo : Fax: 053-8334394
Navrae :

Reference :
Tshupelo :
Isalathiso :
Verwysings :

Date : 26 OCTOBER 2009
Letlha :
Umhla :
Datum :

RE: APPROVAL TO CONDUCT RESEARCH

This letter serves to confirm that Mr Deon Madyo was granted authorization to conduct a research project entitled:

"Effectiveness of SIMPILL box to increase TB patients".

The approval was granted in February 2005 by the Provincial Research Committee in the Northern Cape Department of Health.

Yours faithfully

DR DG THEYS
CHAIRPERSON
PROVINCIAL RESEARCH COMMITTEE

We are committed to achieving our vision through a decentralized, accountable, accessible and constantly improving health care system within available resources. Our caring, multi-skilled, effective personnel will use evidence-based, informative health care and maturing partnerships for the benefit of our clients and patients.