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**Towards cost-effective  
tuberculosis control in the Western  
Cape of South Africa: intervention  
study involving lay health workers  
on agricultural farms**

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# ABSTRACT

## BACKGROUND

At the request of the farming community, the local public health authority in a tuberculosis (TB) high-burdened area implemented a farm-based lay health worker (LHW) project focusing on TB control. This project achieved a significantly better (15%) treatment adherence rate among adult TB patients. Management was keen to expand the intervention, but non-randomised sampling methodology had been used and could have resulted in an over-estimation of results. A more rigorous research design was requested to evaluate this project before replication; therefore this study.

## OBJECTIVE

To evaluate the effectiveness of an LHW intervention within a primary health care (PHC) framework, aimed at improving TB case finding and case holding among permanent farm dwellers, to explore the perceptions of the different stakeholders, and do a cost-effectiveness analysis, in order to contribute to TB control in South Africa.

## METHODS

This LHW model was rigorously evaluated using an unblinded, pragmatic cluster randomised control trial (RCT), while qualitative research evaluated the perceptions of the stakeholders, and a cost-effectiveness analysis established the cost-effectiveness of LHWs in conjunction with the standard TB control programme.

## RESULTS

The successful treatment completion rate in the new smear-positive (NSP) adult TB patients was 18.7% higher ( $P = 0.042$ , 95% CI 0.9%-36.4%) on farms in the intervention group than in the control group. The treatment interruption rate was 4% on intervention farms, compared to 26% on control farms. In the intervention group 8% more ( $P = 0.2671$ ) farms increased their adult NSP TB case finding, compared to farms in the control group. A cost-effectiveness analysis showed a potential saving of 59% for the public health sector in direct staff costs for clinic-based directly observed treatment of TB patients living on farms. Qualitative studies found that farmers remained positive; however, they desired recognition from the public health sector. LHWs, 95% of whom were women, were grateful for the opportunity, but feared becoming over-burdened. Among temporary farm workers the NSP TB point prevalence was 6/356 (1.7%), and the total TB point prevalence was 10/356 (2.8%).

## CONCLUSIONS

Although the focus of this study was on permanent farm labour there has been a subsequent significant change in the labour structure on farms, resulting in a shift towards temporary employment. This will require a separate study. However, the research conducted on permanent farm dwellers shows convincingly that resident, trained LHWs on farms, in conjunction with the public health sector, have the potential to substantially enhance TB control activities on farms and in similar community settings. Pivotal for success are political commitment, a dedicated project champion, an adequate budget and adoption by the health service system and other stakeholders.

**KEY WORDS**

Agriculture, Community Health Worker (CHW), Cost-effectiveness, Directly Observed Treatment (DOT), Directly Observed Treatment Choice, Directly Observed Treatment Short course (DOTS), Farming, Farmers, Farm Dwellers, Farm workers, Farm Health, Lay Health Worker (LHW), Tuberculosis (TB), and Randomised Control Trial (RCT).

## PREFACE

Permit me to start on a very personal note by relating the impact that a farm worker had on my family just a few months ago. My 26-year-old son Samuel and a Swiss friend Claudia, while on a tour of South Africa, were involved in a serious car accident in a remote farming area, 70 km from help. A vehicle transporting farm workers, one of whom was trained in first aid, stopped to assist. After fitting gloves from our first aid box (as a barrier in case of HIV infection), he immediately attended to Claudia, who was unconscious and bleeding profusely from her head. The man stopped the bleeding and made splints for Claudia using Samuel's shirt, newspapers and magazines he found in the car, immobilising her neck and supporting other suspected fractures. As it turned out, Claudia suffered 6th and 7th cervical vertebrae fractures. Today she is fit and well, and studying medicine. But for this farm worker, Claudia might have been a quadriplegic and her future very different. We will forever be thankful to him.

In 1969 I was a very junior member of the highly trained theatre nursing team in Groote Schuur Hospital during open-heart surgery, later working with sophisticated equipment and technology in the cardio-thoracic and neurological intensive care units.

In 1986, while a community developer on farms, I was informed that within a single month seven children under five years of age on one of the farms had died of gastro-enteritis; this among only 35 families (269 people). The farm dwellers knew and trusted me because I had previously worked there as a registered nurse in a mobile clinic as part of the government's family planning programme. On my arrival at the Mpumalanga farm, a distressed amaGogo (wise old lady of the community) told me that there was currently a child ill with the same signs and symptoms. She believed that they were bewitched and that was why the children were dying. I was taken to a home where I was confronted with a severely dehydrated six-year-old girl. Before seeing her I could smell what the problem was – gastro-enteritis!

Due to the heat, the long trip to hospital was out of the question. I needed to stabilise her first with homemade oral rehydration fluid. I thought that would be easy, since all we needed was a clean cup, sugar, salt and pre-boiled water. I soon discovered the difficult reality of living in this harsh environment.

First I had to contend with the flies. There were no clean utensils that the child could drink from. Water drawn that morning was finished. I was told that the water borehole would be dry at this time of the day because of the drought. I explained the urgency of the matter, and that we did not need much water. At my bidding, the amaGogo started a wood fire to boil the water, while others went to try to draw water. Thankfully we got some water, cleaned a pot and started the boiling process. We washed a cup and got the sugar and salt. Cooling the water down without access to a refrigerator was another challenge.

The child's mother started to administer the rehydration mixture in small quantities, and after about an hour there was a positive response from the child. Having arranged with the farmer for a farm vehicle to be on standby in case the child needed to be transported to hospital, we prayed together and I left, promising to return early the next

morning to evaluate the situation. On my return the amaGogo received me with such a smile that I knew the child was on her way to recovery.

This experience led to a paradigm shift in my thinking on health care; I recognised that the strict biomedical health care approach I had used during intensive care nursing was insufficient, and that a comprehensive health care approach that is contextually relevant was also required. The latter was no less life-saving.

The farm dwellers thought that I had done something very special, but I quickly told them that I could train them to do exactly what I had done. They were keen, and we agreed that they select two people to be trained who, in turn, would transfer their newly acquired knowledge to all the mothers in the community. This eventually led to a lay health worker (LHW) care project on all the farms where I worked. This project expanded to national level and functioned in both rural and township settings.

I discovered that there were often wonderful but unrecognized and untapped resources within the farming communities that had the potential, with appropriate guidance and support, to effectively address their own health needs. This process is described in my Master's dissertation: *The Lay Health Worker as a member of the Primary Health Team* (Clarke, 1992).

While working in the Western Cape Province, the burgeoning TB problem there came to my attention. I postulated incorporation of farm health workers alongside the health team as a means of controlling TB on farms. However, lack of evidence-based research evaluating the effectiveness of farm health worker interventions made it difficult to convince decision- and policy-makers.

Hence this study, which seeks to establish the feasibility of expanding a farm health worker intervention in the high TB prevalence area of the Cape Winelands, South Africa, and to understand the processes involved, together with an analysis of the cost-effectiveness of such an intervention.

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## **LIST OF ABBREVIATIONS**

<b>AIDS</b>	Acquired immunodeficiency syndrome
<b>DOH</b>	Department of Health
<b>DOT</b>	Directly observed treatment
<b>DOTS</b>	Directly observed treatment short course
<b>FGD</b>	Focus group discussion
<b>HBC</b>	High-burden country
<b>HIV</b>	Human immune deficiency virus
<b>IUATLD</b>	International Union Against Tuberculosis and Lung Disease
<b>LHW</b>	Lay health worker
<b>NGO</b>	Non-governmental organization
<b>NSP</b>	New smear-positive
<b>NTP</b>	National Tuberculosis Control Programme
<b>PHC</b>	Primary health care
<b>RCT</b>	Randomised control trial
<b>TB</b>	Tuberculosis
<b>WHO</b>	World Health Organization



# BACKGROUND

## LAY HEALTH WORKERS

The World Health Organization (WHO) defines community-based health care workers as individuals chosen by their community to be involved in health activities in their own community, and to whom they are answerable; they have shorter training than professional workers, and should be supported by the health system although not necessarily a part of its organisation, and may or may not be remunerated (WHO, 2003 (a); Kahssay *et al.*, 1998).

This study will use the umbrella term lay health worker (LHW) to embrace the variety of community-based health care workers, classifying an LHW as “any health worker delivering health care, trained in the context of the intervention, and having no formal professional certificated or dereed tertiary education” (Lewin *et al.*, 2004).

## Historical overview

In an attempt to address the basic health needs of their marginalised populations, low-income countries such as India, China and Vietnam introduced various community-based health worker initiatives in the 1950s and 1960s (Walt, 1990). After independence from colonial power during the 1960s and 1970s, many, especially in Africa, inherited medical health care systems that they could not afford, and they were unable meet the health needs of the majority their populations, who are poor and lived in rural areas. Efforts to improve health status using the medical health care approach were ineffective and often deteriorated (Macdonald, 1992; Hall and Taylor, 2003).

Developments such as community-based volunteers administering oral re-hydration solutions reduced hospital admissions. These volunteers organised effective immunisation campaigns, which in turn addressed some causes of illness and death within these hard-to-reach communities. These and various other successful comprehensive primary health care (PHC) initiatives in Tanzania, Sudan, Venezuela and Papua New Guinea, and specifically the ‘bare foot doctor’ programme in China, influenced the development of the community-based health care worker concept (Walt, 1990; Hall and Taylor, 2003; Huang, 1997). The relevance of the top-down, biomedical, disease-specific approach to health care delivery as well as the role of medical profession in these countries was questioned. Medical health care requires individuals to follow directions given by the medical professionals to reduce individual illness, whereas comprehensive PHC incorporates community participation to mobilise and empower people to actively participate in the delivery of health care within their community.

Community participation is associated with community development activities, aimed at improving their social, political and economic situation (Macdonald, 1992; Dick, 1994). PHC initiatives among poor rural populations led to discussions within the WHO on the need for fundamental change in health care delivery in low- and middle-income countries. The emphasis was on how these governments could make basic health care equitably available, accessible, affordable and appropriate to the majority who live in poverty (King, 1966; Walt, 1990).

## *Alma Ata PHC Conference*

The Declaration of Alma Ata unanimously adopted PHC in 1978 (see Box I) as the means to provide a comprehensive, equitable and affordable health care service for all countries to achieve ‘Health for All’ by the year 2000 (WHO, 1978; Walt, 1990). This conference promoted the LHW strategy to implement PHC. Many governments, especially in low- and middle-income countries, either started or extended existing LHW programmes in an attempt to provide basic health care to the majority of their population who live in poverty.

The PHC definition, principles and core activities, as adopted in 1978, were validated 25 years later at the WHO global review of PHC (WHO, 2003 (b)).

Health and funding experts were unable or unwilling to accept the community participation core principle of comprehensive PHC, which led to the development of the selective, vertical, disease-specific PHC approach (Macdonald, 1992; Dick, 1994). In South Africa the National TB Control Programme (NTP) activities are managed as a vertical health programme and could be regarded as a selective PHC programme.

### **Box I. PHC: Definition, Principles and Core Activities**

#### **Definition**

“Essential health care based on practical, scientifically sound and socially acceptable methods and technology; universal access to and coverage of health services based on health needs; commitment, participation and individual and community self-reliance; intersectoral action for health; cost-effectiveness and appropriate technology, as the available resources permit; health service provision and health promotion”.

#### **Core principles**

- “Reflect and evolve from the economic conditions and socio-cultural and political characteristics of the country and its communities, and are based on the application of the relevant results of social, biomedical and health services research and public health experience,
- Address the main health problems in the community, providing promotive, preventive, curative and rehabilitative services accordingly,
- Involve, in addition to the health sector, all related sectors and aspects of national and community development, in particular agriculture, animal husbandry, food, industry, education, housing, public works, communications and other sectors; and demand the coordinated efforts of all these sectors,
- Promote maximum community and individual self-reliance and participation in the planning, organization, operation and control of PHC, making fullest use of local, national and other available resources; and aim to develop through appropriate education, the ability of communities to participate,
- Should be sustained by integrated, functional and mutually supportive referral systems, leading to the progressive improvement of comprehensive health care for all, and giving priority to those in need,
- Rely, at local referral levels, on health workers, including physicians, nurses, midwives, auxiliaries and community workers as applicable, as well as traditional practitioners as needed, suitably trained socially and technically, to work as a health team and to respond to the expressed health needs of the community”.

## Box I. PHC: Definition, Principles and Core Activities (continues)...

### Core activities

- “Education concerning prevailing health problems and the methods of preventing and controlling them,
- Promotion of food supply and proper nutrition,
- An adequate supply of safe water and basic sanitation,
- Maternal and child care, including family planning,
- Immunization against the major infectious diseases,
- Prevention and control of locally endemic diseases,
- Appropriate treatment of common diseases and injuries,
- Provision of essential drugs”.

Sources: WHO, 1978; WHO, 2003 (b)

### Roles and functions of LHWs

LHWs were seen as a mechanism to fill the gaps in communities where the health service could not provide accessible basic health care to poor and marginalised communities. They provided a way to ensure that a ‘client-centred’ approach to health care for individuals continued (Walt, 1990; Dick, 1994).

Their activities differ considerably according to the country and/or circumstances, and are influenced by the geographical situation, socio-economic status, culture and availability of professional health care. A global systematic review of the effectiveness of LHWs showed that they were involved in a broad spectrum of health activities, i.e. promoting nutrition, growth monitoring, breast-feeding, immunisation, family planning methods, and oral rehydration activities (Lewin *et al.*, 2004). LHWs also became involved with intersectoral issues such as poverty relief, food, security, water and sanitation, income generation, obtaining child maintenance, various social grants and documents such as birth certificates, literacy education and working with disabled children. Further, they proved to be important during efforts to control epidemics, e.g. cholera (Friedman, 2003). LHWs assisted with some of the most difficult tasks, being involved in controlling and improving treatment adherence in chronic conditions such as TB, human immune deficiency virus/acquired immune deficiency syndrome (HIV/AIDS), diabetes, hypertension and sexually transmitted infections, as well as preventable cancers and drug and substance abuse and rehabilitation (Friedman, 2003; Lewin *et al.*, 2004).

LHWs were also expected to act as advocates to improve health, to mobilise community members to determine their health needs, taking responsibility for their health, and to access appropriate health resources. Further, they were expected to provide counselling services, to disseminate health information, carry out health promotion activities, and transfer health and wellness skills to the community members (Kahssay *et al.*, 1998; Friedman, 2003). A study in El Salvador found that community members did not value the preventive and promotive activities of LHWs, and preferred curative care (Lewis *et al.*, 2004).

LHWs work in a variety of capacities, which include functioning informally as volunteers as well as operating more formally as frontline health care workers (Walt, 1990; Macdonald, 1992). The most important development/promotional role of LHWs is to act as a bridge between the community and the public health sector (Kahssay *et al.*, 1998; Friedman, 2003). For some physicians and nurses, PHC is synonymous with the LHW concept (Mburu, 1994). In many ways, LHWs are seen as the panacea for health problems – able to achieve what health professionals cannot.

## **LHWs in South Africa**

LHW programmes have been established in one form or another in different parts of South Africa since the Alma Ata Conference. The role of LHWs has been discussed since the early 1990s as part of implementing PHC. LHWs have been described as the cornerstone of the health system and their incorporation into TB control programmes is encouraged, although they have not been recognised as part of the PHC team (Pillay *et al.*, 2000; WHO, 2003 (c)).

The South African Nursing Council was not willing to get involved in the statutory control of LHW practice since there are too many pitfalls in LHW selection, training and functioning, but recommended that they should function in close cooperation with the health team (Clarke, 1992; Searle *et al.*, 1992). Nursing leadership considered that nurses and not LHWs should be trained to address the health needs of the population. Therefore nursing training started to include community-based nursing; moving from a purely curative to a promotive health care approach (Searle *et al.*, 1992).

Before the democratic transition in 1994, the non-governmental sector took the lead in implementing LHW projects. These programmes received tentative recognition by the Department of Health (DOH) in the early 1990s, although little attempt was made to develop common standards of practice.

Early drafts of the African National Congress health plan referred to LHWs as an important resource to expand and improve existing health services. They were seen as catalysts for community development and to mobilise community members around basic needs such as clean water, sanitation, etc. It was envisaged that LHWs could empower communities with essential health knowledge, forming part of the decentralised health service, and be remunerated. This created the understanding that there may be a career pathway for LHWs in future (Friedman, 2003). During 1992-1994 Dr Manto Tshabalala-Msimang (currently Minister of Health) held national workshops to bring LHW programmes together and to advocate the application of more formal support (Friedman, 2003). After the first democratic transition in 1994 the official policy on LHWs was watered down, stating that although LHW programmes would be encouraged where they were integrated into local health services, there would be no national LHW programme (Friedman, 2003).

In 1995 a national task force (funded by the Health Systems Trust) produced a report '*Assessing the Feasibility of Greater State Support to Community Based Health Programmes*'. This report recommended that a three-phase model be considered for adoption by the national government. These phases included: (i) providing financial, political, structural and other support to strengthen existing programmes; (ii) evaluation of existing programmes to establish their effectiveness and the development of an accredited core curriculum, with LHW training carried out locally; and (iii) that health

personnel be orientated to understand PHC and the role and function of LHWs, and that LHWs be paid by local management structures (Friedman, 2003).

As a result, strong lobbying followed in 1996, and the generally unsupportive national policy position changed slightly, with the National DOH delegating the decision on the deployment of LHWs to provincial and local health authority levels. However, the role of LHWs at both local and national levels remained uncertain.

In 1999 the South African Qualifications Authority (SAQA) approved a standardised core curriculum for 'Auxiliary Health Workers' (valid until 2005) for generalised LHW training (Friedman, 2003; SAQA, 1999).

The Minister of Health's announcement in 2003 of government's intention to give LHWs in the health system a minimum monthly stipend (USD160) exacerbated the debate associated with incentives for LHWs (Dick, 2004; Reuters, 2004).

The issues that have confronted LHW programmes for two decades remain unchanged and are now complicated by maturing of the HIV/AIDS/TB epidemic (Friedman, 2003). Despite many difficulties, there is agreement that LHW programmes have a role to play.

### **Effectiveness of LHW interventions**

Evaluations of the LHW concept and various similar programmes have been well documented (Walt, 1990; Kahssay *et al.*, 1998).

Evaluating the effectiveness of these programmes is difficult. Often the objectives are unclear and/or not measurable (Lewin *et al.*, 2004). Such programmes ideally encourage intersectoral collaboration in addressing broader community developmental issues, so it is problematic to determine the health care outcomes and to isolate these effects from those of other developmental activities (Brender and Pitkin, 1987; Friedman, 2003).

Further, most LHW programmes are in remote rural areas where the educational and literacy levels of those involved are low, complicating the gathering of quality data for the baseline information needed in order to formulate appropriate, measurable study outcomes. Using observational visits to collect data is an option, but is time-consuming and carries the risk of observational bias (Walt, 1990).

Small-scale LHW projects that addressed the problem of having only facility-based health services were successful (Walt, 1990). However, these were expensive, only reaching a small proportion of the population and providing symptomatic and curative care rather than preventive and promotive health services (Kahssay *et al.*, 1998; Friedman, 2003).

LHW community-based activities to enhance TB control in various settings in TB high-burdened countries (HBCs) were found to be cost-effective where they worked in support of NTPs alongside other health providers (WHO, 2003 (a)). A TB-specific project in Tanzania found TB treatment supporters were particularly useful among remote subsistence farmers (Lwilla *et al.*, 2003).

A global systematic review identified 43 randomised control trials (RCTs) undertaken over a 38-year period to establish the effectiveness of LHW programmes. That study concluded that although LHWs showed promising effects in immunisation

promotion and the management of some infectious diseases, there was insufficient evidence to make policy recommendations (Lewin *et al.*, 2004).

An evaluation in sub-Saharan Africa found that countries that used LHW programmes to implement PHC did not achieve the 'Health for All' goal (Chatora and Tususime, 2004). This finding should not be seen in isolation from the changes in the political and economic sectors, civil wars, and unfolding of the HIV/AIDS/TB and malaria epidemics during the period of evaluation.

Policy-makers and funders should be encouraged to use rigorous research to evaluate the consultative processes required for successful LHW interventions and the specific health care outcomes.

### **LHWs effecting community participation**

Community participation is central to the PHC concept. History shows that health providers find it very difficult to stimulate and sustain broad-based community participation during the planning, implementation and evaluation phases of health care. This is especially so in South Africa, with its culturally diverse population and political history and transformation. The literature describes three approaches that health planners have with regard to community participation, viz. the medical approach, in which individuals and/or groups follow the instructions of the medical professionals for the reduction or treatment of disease; the health services approach, where the health authority delivers health services; and the community development approach, where community members become actively involved in decisions about how to improve their social, economic and political development (Dick, 1994; Maher *et al.*, 1999; Hadley and Maher, 2000).

The first two models regard health-specific concerns as being the most important factors in improving health status, while the community development approach focuses on the perceptions of the community regarding health and its motivation to change social, political and economic factors.

LHW programmes, by their very nature, encompass and promote the key principles of comprehensive PHC, i.e. community participation and involvement, intersectoral collaboration, equity, prevention of poor health, and the use of appropriate technology (Kahssay *et al.*, 1998; Bender and Pitkin, 1987; Barrett, 1996).

### **LHW programmes: Some lessons**

Costa Rica, Nicaragua and Columbia are three Latin American nations that adopted the PHC model, using LHWs as their strategy. A study exploring the role of LHWs as part of implementing PHC in these countries concluded that national commitment to PHC and their recognition of the important role LHWs play in realising community participation, are central to LHW's success (Brender and Pitkin, 1996).

LHWs not meeting the challenges set before them is usually the result of the health services failing to provide commitment and support, and is not a reflection on the potential value of LHWs themselves (Hadley and Maher, 2000; Friedman, 2003). It appears that it was not the LHW concept per se that failed, but rather that the LHWs were starved of resources at all levels. This resulted in the discontinuation of projects or in poor performance by LHWs, as seen in Zambia (Stekelenburg *et al.*, 2003).

Conversely, the level of ongoing performance of these workers depends on the setting in which they function, the support of the health services and the communities where they work, access to and availability of resources, and clear objectives (Lewin *et al.*, 2004).

A Namibian study found when the project aims and expectations of the residents were incongruent, LHWs became frustrated and as a result performed poorly (Wayland, 2002). Developing clear objectives for LHW programmes as well as detailed planning of the implementation strategy are vital (Low and Ithindi, 2003).

The question of incentives/payment for LHWs has been contentious ever since the inception of this cadre (Kahssay, 1998; Friedman, 2003). Research found that the payment and the hope of future remuneration were the strongest motivating factors for LHWs involved TB programmes in areas where there is high unemployment (Kironde and Klaasen, 2002). Using behavioural theory in an attempt to establish whether or not LHWs should be paid, a study stated that the “debate continues” (Kironde and Bajunirwe, 2002).

Very little documentation is available about health development initiatives in the agricultural sector, although a health intervention in the Philippines found that co-operation with farmers was important for success (Kahssay *et al.*, 1998).

In South Africa an NGO implemented a successful farm LHW project during the 1980s and 1990s. This project found that LHWs successfully bridged the gap between farm-dweller communities and the public health sector at many levels, irrespective of the cultural and language background of the clinic nurse (Clarke, 1992). Similarly, a successful farm LHW programme in Zimbabwe ended on the conclusion of the donor-funding period, even though farmers absorbed most of the project costs, because it was impossible to integrate the project management at central governmental level (Forsberg and Öjemark, 1999; Swedish Ministry of Health and Welfare, 1999). Many LHW projects are too dependent on donor funding to survive beyond the pilot phase (Kahssay *et al.*, 1998).

One ought to be cautious of the simplicity ascribed to the LHW concept, since it might cloud the complexity of its actual implementation (Mburu 1994).

## **SOUTH AFRICA**

The Republic of South Africa, the southernmost part of Africa, stretches latitudinally from 22<sup>0</sup> to 35<sup>0</sup> south and longitudinally from 17<sup>0</sup> to 33<sup>0</sup> east, with an area of 1.2 million km<sup>2</sup>. About 13% (22% high potential) of the surface area can be used for crop production. Agricultural exports contributed 9% to the total exports in 2002 (<http://www.info.gov.za>, 2004). South Africa is one of the 14 Southern African Development Community countries, having the most developed economy, generating a Gross Domestic Product (USD 156.9 billion in 2003): nearly ten times that of the other countries combined (<http://www.eia.doe.gov/emeu/cabs/sadc.html>). About 10% of the total government expenditure is spent on health care (McIntyre and Gilson, 2002). Although having an advanced economy and infrastructure, it faces a spectrum of problems symptomatic of a middle-income country. (See Box II.)

Emerging from a turbulent colonial history into a multi-party democracy in 84 years (1910-1994), the country's first free elections in 1994 ended nearly four decades of colonial domination and another four decades of white-minority (apartheid) rule. The

policy of apartheid resulted in unequal provision of infrastructure, funding and facilities in all social sectors, including health. Health status indicators exhibit major disparities, with inequalities and severe levels of poverty along racial lines (McIntyre and Gilson, 2002). The new government faces a formidable task to narrow these disparities, complicated by the maturing HIV/AIDS epidemic. Traditionally the economy was based on agriculture and mining, but has diversified into industrial, technological, manufacturing and tourist sectors.

### Health care

In 1994 the new health ministry inherited a highly inequitable, fragmented and urban-biased health care system using a biomedical approach. They selected a comprehensive PHC approach to transform it into an equitable and unified health system capable of delivering quality health care (DOH, 1997). This process and progress made in the last decade is well documented elsewhere (McIntyre and Gilson, 2002; Benatar, 2004). The strategy included decentralising health service management with the locus of implementation at district level, where municipalities are the local public health care authorities responsible for rendering PHC services (DOH, 1997).

Women and child health services are emphasised, with specific focus on the rural and urban poor and farm workers (DOH, 1997). These most vulnerable population groups continue to have least access to health care, with urban communities benefiting over rural populations (McIntyre and Gilson, 2002). It is difficult for the health service to cope with a 300% increase in workload and a major transition in the health service and political arena without any increase in resources (Wilkinson and De Cock, 1996).

### BOX II. South Africa: Population, Health Status and Agriculture (for 2001)

<b>Population</b>	
• Total:	44.8 million (48% male; 52% female)
• Race groups:	80% Black, 9.6% White, 8.9% Coloured, 2.5% Indian/Asian
• 0 – 15 years age:	Approximately 30%
• 60 years and older:	7.3%
• Women and children:	73%
• Living in rural areas:	53% (75% of whom live in poverty – in 1994)
• Living in poverty:	35% - 55% (in 1994)
• Unemployment rate:	42%
• No formal education:	>20 years: 18%
<b>Health status indicators</b>	
• Life expectancy:	55 years (male 56 years; female 43 years)
• Infant mortality rate:	59/100 000 live births
• 0-5 years mortality rate:	100/100 000 live births (40% due to HIV/AIDS)
<b>Commercial Agriculture</b>	
• Contribution to national GDP:	Primary 3% and total sector 15%
• Formal employment:	approximately 9% (18% in Western Cape)

Sources: DOH, 1997; Bamford, 2004; <http://www.info.gov.za>

## Areas of concern

Major concerns are the high rate of HIV and TB infections, crime and unemployment. About 50-60% of the TB cases reported in South Africa are HIV co-infected (WHO, 2004). Mortality statistics among adults are consistent with the HIV/AIDS epidemic, having reached the level of 1 in 9 people being infected in 2001 (Bamford, 2004). An estimated 40-50% of the workforce will die from AIDS during the next decade. Furthermore, there are currently about 800 000 orphaned children under the age of 15 years due to AIDS (Benatar, 2004).

During 1998-2002 most deaths occurred in the 20-50-year age group (total population). HIV/AIDS accounted for 39% of the total premature mortality burden, with almost 4.7 million years of life lost. TB ranked third, accounting for 5% of the total premature mortality burden, with almost 600 000 years of life lost (Bamford, 2004).

The out-migration of health professionals (doctors and nurses) to high-income countries strains the health system at a time when it can ill afford to lose much-needed competencies (Martineau *et al.*, 2004).

It is a formidable task for the public health sector to provide equitable health care, especially in the vast remote rural areas of South Africa.

## Agriculture in the Western Cape Province

Commercial agriculture in the Western Cape is economically important, contributing 6% or R7.4 billion (approximately USD 1.2 billion) in 2000 to the income generated in this region, contributing a wide variety of produce for the domestic and export markets. However, in the study area the main products are fruit and wine for export. Nearly 71% of all goods exported from the Western Cape in 2002 were agricultural produce (Vink, 2003).

Farm workers constitute about 9% of all those who are employed in the Western Cape, and while the province has 12.4% of the cultivated land in South Africa, it employs about 18% of the labour force in the agricultural sector (Vink, 2003).

Life for farm-dweller communities throughout South Africa is hard:

*“They are among the poorest citizens in South Africa and are still socially and politically isolated and oppressed. There is a tremendous imbalance of power on (white) commercial farms, with landowners having almost complete control over every aspect of farm dwellers’ lives. This situation also characterizes the commercial farming areas of the Western Cape” (Fast, 1997.)*

### *Farm workers*

Permanent farm workers live with their families on the farms where they are employed, forming small farm-dweller communities. Farms are geographically far apart. Farm dwellers in the Western Cape are generally poor, with low levels of education (25% of those older than 13 years have completed primary school education) and a lifestyle socially and economically dependent on the farmers. Recent research has shown that the farm-worker population is chronically malnourished,

despite a large proportion of income being spent on food, and has an exceptionally high incidence of TB (Fast, 1997).

Farm-dweller communities living in the Winelands of the Western Cape have over generations had a paternalistic relationship with the farmers and have become locked into dependence, isolation, poor literacy, alcoholism and violence, from which it is difficult to break free:

*“The transport situation in the rural areas has a profound impact on farm workers. The distances are great, especially in stock-farming areas, and there is often no access to public transport. This limits their access to social activities and employment opportunities. More importantly, farm dwellers depend on their employer for transport, which reinforces the farmers’ power and leaves workers feeling isolated. This in turn makes it difficult for farm workers to organise themselves to press for better conditions” (Fast, 1997.)*

Thus, farm dwellers have traditionally been entirely dependent on the farmer and the public health sector to meet their health needs, since they are unable to attend a doctor or visit a pharmacy. They have to rely on the farmer, call an ambulance or wait for the next mobile clinic visit.

Since 1994 farm workers have enjoyed considerably more social and tenure security than before. However, casual employment is increasing faster than permanent job opportunities within the commercial agricultural sector, and this trend is expected to become more prominent (Ewert and Hamman, 1999).

Alcohol abuse and tobacco smoking is common among men and women. A study among women attending public antenatal clinic facilities in 1999 found that 40% ingested enough alcohol to produce foetal alcohol syndrome in their infant (Croxford and Viljoen, 1999).

The situation for women is the worst. Women have a lower literacy rate and endure a high level of domestic violence. Male workers are given preference for housing tenure, forcing women into relationships with males for accommodation. Female farm workers receive lower wages and have poorer job security. Despite perhaps being employed, women are also responsible for the maintenance and care of their household (Fast, 1997; Sunde and Kleinbooi, 1999).

### *Temporary farm workers*

The pattern of sporadic employment of temporary farm workers, together with their low wages, limited access to education, lack of transport and housing, and poor living conditions, makes them a potentially high-risk group for contracting TB.

Very limited information is available about the health needs and utilization of health services by temporary farm workers (Personal communication on 22 May 2002 with Mrs. Sandra Theron, PO Box 100, Stellenbosch, 7599, South Africa).

Current legislation is attempting to transform labour relations in the commercial agricultural sector in order to improve legal protection of the labour force. Unexpectedly, these legislative changes have acted as a disincentive to farm owners to employ permanent staff. Permanent farm workers living on the farms now, have the legal right to demand land tenure (Restructuring of Land Rights Act No. 22 of 1994).

Consequently, the number of temporary farm workers is increasing at double the rate of permanent workers (Van Rooyen *et al.*, 1998).

## **TUBERCULOSIS**

### **Global situation – a major scourge**

Globally the TB situation is so grave that the WHO declared TB a public health emergency in 1993. Twenty-two TB HBCs account for 80% of the new cases of TB each year (Dye *et al.*, 2003). The ongoing TB scourge is fuelled by the HIV/AIDS pandemic. An estimated one-third (2 billion) of the world's population is infected with the TB bacillus, of whom 95% live in low- and middle-income countries (Grange and Zumla, 2002). In sub-Saharan Africa about half of the population is infected with the TB bacillus, 40-60% of these being co-infected with HIV (WHO, 2004). In 2002 TB accounted for 9% of the global disease burden, contributing an estimated 28 million disability-adjusted life-years lost in the 15-59-year age group (WHO, 2003 (c)).

Statistically the burden of TB is immense, but numbers alone fail to convey the human suffering linked to this disease.

Public health seeks to establish strategies that create healthy communities (Institute of Medicine, 1988), and needs to find appropriate ways to control TB, i.e. TB case finding and case holding activities. TB case finding refers to all the activities aimed at reducing the time interval between the onset of clinical and/or bacteriological overt TB and the start of treatment in order to arrest further transmission. TB case holding refers to all the activities aimed at ensuring that TB patients complete their entire treatment regimens. These activities are also referred to as TB case management. From a public health perspective, the key to TB control is finding and successfully treating all smear-positive cases in all subsets of the public at an early stage of the disease. NSP TB cases are seen as the index cases, pointing to an unidentified, untreated source of TB infection.

TB is curable using inexpensive anti-TB treatment that is available and can cure more than 95% of cases if taken conscientiously for 6-8 months (Frieden, 2003). The recent emergence of multidrug-resistant TB underlines the urgency of improving TB management (Hebling, 2003; Weyer *et al.*, 2003). Health services-based and exclusively health professional-oriented services, on their own, are unable to improve the TB status of the population (Walt, 1999; Stephens, 1999). Sociologically, TB is caused by poverty, inequity, injustice and conflict (Grange and Zumla, 2002).

Seven of the eight United Nations' Millennium Development Goals aim to reduce poverty in all its forms by 2015. Three goals are health-specific, focusing on HIV/AIDS, TB and malaria, giving the impression that a vertical biomedical approach is planned. The TB control activities proposed, support the WHO DOTS strategy (WHO, 2003 (c)). Funding will be made available through the Global Fund to fight AIDS, TB and Malaria. However, additional funding alone is not the answer - countries must have the capacity to put the additional resources to effective use (Lee *et al.*, 2004). A prerequisite for successful and sustainable TB control programmes is an accessible and effective public health system (Mahendradhata *et al.*, 2003).

## **Directly observed treatment short course (DOTS)**

The WHO introduced the TB control strategy known as directly observed treatment short-course (DOTS) in 1996/97 (WHO, 1998). By 1998 all 22 TB HBCs agreed to introduce the DOTS strategy (WHO, 1998). In total, TB control in the HBCs cost about USD 850 million in 2002 (WHO, 2004). DOTS implies governmental commitment to sustained TB control; using sputum smear microscopy to detect the disease in self-reported cases (passive case finding); having directly observed treatment (DOT) for at least the initial treatment phase in all smear-positive cases; using the standardised short course anti-TB regimen for 6-8 months; ensuring a regular, uninterrupted drug supply; and applying a monitoring and reporting system to evaluate the treatment outcome for each patient (DOH, 1996). The global detection rate of 32% smear-positive cases (target 70%) is an obstacle to worldwide TB control, even though an 82% successful treatment rate (target 85%) has been achieved for the 2001 NSP TB cohort (Dye, 1998; WHO, 2004).

The DOTS strategy prioritises completion of the entire anti-TB treatment regimen by NSP TB cases. Squire and Tang (2004) noted that wider implementation of DOTS comes with careful and critical appraisal of what is needed to make DOTS work, especially where people, health infrastructures and human resources are poor.

The biomedical approach applied by WHO to control TB during the past 50 years was successful in high-income countries, although it failed in low- and middle-income countries. The key to global TB control requires a pragmatic, multisectoral approach, building on global and national partnerships (Raviglione and Pio, 2002; Brewer and Heymann, 2004).

### *DOTS and TB control*

Theoretically, implementing DOTS should reduce TB prevalence. However, this hypothesis is based on active TB case finding, whereas the WHO strategy is based on passive case finding (Brewer and Heymann, 2004). Passive case finding is influenced by three groups of interrelated factors, i.e. the individual (knowledge, perception, belief), the health care system (availability, accessibility and quality), and socio-economic factors (poverty, stigma, cultural issues) (Long, 2000).

Studies in Vietnam recommend an extension to the DOTS strategy, by introducing “a context specific and feasible system of active case finding” as part of the national TB care (Hoa, 2004). There is a call to go beyond DOTS using multiple stages, and providing quality individual case management in every location, including the hard-to-reach subsets in each country. This would require the entire health sector (private, public, academic and military) and the community to be mobilised to adapt DOTS to suit their particular situation, using lessons learnt through new innovations and operational research (Enarson, 2003).

The adequacy of DOTS for controlling TB in areas with high HIV/AIDS prevalence, e.g. sub-Saharan Africa, is questioned (De Cock and Chaisson, 1999). Unless TB case detection and cure rates urgently improve, TB cases will increase by 41% globally from 7.4 million to 10.6 million cases due to HIV during 1998-2020 (Grange and Zumla, 2002; Dye *et al.*, 1998).

## **TB a chronic condition**

TB and HIV/AIDS are regarded as chronic conditions that are challenging to manage in low- and middle-income countries (WHO, 2002; Swartz and Dick, 2002). The WHO report, *Innovative Care for Chronic Conditions: Building Blocks for Action*, presents a comprehensive framework, referred to as the Innovative Care for Chronic Conditions Framework, to control chronic conditions in resource-poor settings (WHO, 2002). This framework entails a triad partnership between the patients and their families, health care providers and community supporters; this functions optimally if all are fully informed and motivated to actively participate in the management of the condition. However, it needs support from the health system, the community and the policy environment (WHO, 2002). This report underlined the urgent need for a paradigm shift from the acute and reactive model of health care when dealing with chronic conditions.

The chronic-care model was developed to improve the management of chronically ill patients cost-effectively (Wagner, 1998). This model is patient-centred, focusing on the person and their context and not purely on the disease (Swartz and Dick, 2002). The chronic-care model has six interrelated and interdependent components: community resources and policies, the structure, goals and values of the health organisation, which in turn forms the foundation for self-management, the design delivery system, decisions supported by standardised guidelines, and clinical information systems. Some of the components were tested in a variety of settings, including a poorly resourced clinic, where they proved successful. Start-up funding was needed to appoint suitable individuals for implementation (Bodenheimer *et al.*, 2002).

## **Implementing TB innovations**

New innovations to ensure TB treatment adherence are called for (Volmink, 2003). Implementing innovations requires the various partners to adopt and assimilate the new methodology. An innovation needs to suit the values, norms and context, making it “system-fit”, allowing all participants to make a rational decision to adopt and incorporate the new idea (Greenhalgh *et al.*, 2004). Disseminating an innovation is a planned process of advocacy, leading to the acceptance and assimilation of the new way of operating until it becomes sustainable, institutionalised and routine (Rogers, 1995; Greenhalgh *et al.*, 2004). There needs to be a champion to drive the process, and health authorities need to be open to change and willing to take the risk to implement the innovation (Greenhalgh *et al.*, 2004). About a quarter of those approached can be expected not to adopt and implement new ideas (Rogers, 1995). Thus, not all stakeholders accept changes of institutionalised care modalities.

## **Directly observed treatment (DOT)**

Patient adherence to anti-TB treatment regimens is pivotal to TB control. DOT is the recommended standard of care for enhancing anti-TB treatment adherence (WHO, 1998). DOT requires a second person (staff member or volunteer) to take the responsibility to ensure that patients swallow each dose of anti-TB medication.

Where patients live close to a clinic facility, the implementation of clinic-based DOT is reasonably straightforward, but the vast majority of people in HBCs do not

have the daily access required. New strategies such as peer support are needed in TB HBCs (Volmink, 2003). Community participation and peer group education (Maher *et al.*, 1999; Hadley and Maher, 2000) may be especially relevant in long courses of treatment such as that required for TB, where culturally sensitive support in or near a patient's home is essential.

In instances where TB patients chose a DOT supporter in their community, the treatment outcomes improved, especially in resource-poor settings and among re-treatment cases (Lienhardt and Ogden, 2004; Kironde and Meintjies, 2002).

The impact of DOT on TB treatment outcomes remains unclear (Zwarenstein *et al.*, 1998, Walley *et al.*, 2001, Kamolratanakul *et al.*, 1999). A RCT that compared DOT and self-supervision in South Africa found that the two were equivalent for new patients in terms of treatment outcome; among re-treatment cases DOT produced significantly poorer results (Zwarenstein *et al.*, 1998).

There are those who question whether the weakening health systems in settings with high TB prevalence can maintain the implementation of DOT (Walt, 2003). A clinic on the outskirts of Cape Town oversees 300 TB patients receiving DOT (Dick, 2004). It costs three times more to have a patient receive anti-TB treatment under DOT at the clinic than for them to supervise their own treatment (Dick, 1998). In the light of this and the need for cost-containment, health managers have a strong case for reviewing the existing DOT policy.

### **TB among farm workers**

Control of TB among farm workers seems challenging. A survey conducted in the United States of America in 1985-1989 noted that the risk of farm workers developing overt TB was six times higher than among the general public (Centers of Disease Control and Prevention, 1992). Among African American farm workers the incidence of active TB was 300 times that of the general population. The number of years worked on a farm was found to be the most significant risk factor for infection with the TB bacillus; therefore TB is classified as an occupational risk for farm workers (Ciesielski *et al.*, 1991).

A study among migrant farm workers in Pennsylvania in the mid-1990s found them to be a group at high-risk of developing active TB once infected with the TB bacillus. This group remains a significant reservoir for TB and sexually transmitted infections (Much *et al.*, 2000).

### **TB situation in South Africa**

South Africa has also witnessed a dramatic upsurge in TB cases over the past decade and this is expected to continue, largely attributable to co-infection with HIV (Grange, 1999). HIV prevalence reached 27.9% in pregnant women attending public health antenatal facilities in 2003 (DOH, 2003).

Failure to control TB (before 1994) reflects the apartheid legacy of poverty, discrimination along racial lines, and a fragmented public health system (Wilkinson and De Cock, 1996). A process of restructuring of the public health system into an integrated, comprehensive PHC system to address the racial segregation, is still under way.

South Africa ranked ninth highest on the TB HBCs list, notifying a total TB incidence rate of 481 per 100 000 population (215 120 cases), of which 59.5% were NSP. It is estimated that about 50% of the TB cases in the 15-49-year age group are HIV co-infected (WHO, 2004). TB was declared a national priority in 1996 (WHO, 1998; DOH, 1996). Substantial progress has been made since implementing DOTS in 1996, yet there is little sign that the epidemic is abating: during 1995-2001 pulmonary TB cases more than doubled (NTP, 2003). DOT has been implemented widely in urban areas.

The high treatment interruption rate was given as the main reason for the poor performance of the NTP (Dick, 1999). Short-course anti-TB therapy utilising a combination of drugs, recommended by the International Union Against Tuberculosis and Lung Disease and the WHO, is the standardised protocol of treatment in South Africa. Drugs are issued free to patients with TB (Dick and Henchie, 1998; DOH, 1996).

All TB patients are diagnosed by standard WHO procedures and criteria and receive standard courses of therapy, preferably under DOT, for five days per week during the whole treatment period. Most TB patients receive ambulatory care for six months (new cases) or eight months (re-treatment cases) from primary level community health centres. Definitions of TB treatment outcomes are presented in Box III and the TB treatment regimens in Box IV.

Providing DOT to all TB patients requires an innovative approach, especially to provide DOT to people living in scattered rural communities.

### **Box III. TB Treatment Outcomes: Definitions**

Standard definitions of TB treatment outcomes were applied:

**‘Successfully treated’** included the sum of patients who completed their treatment and were cured;

**‘cured’** applied to those patients who were initially smear-positive and who had a negative sputum smear in the last month of treatment;

**‘new smear-positive’** referred to patients who had never had treatment for TB, or had taken anti-TB drugs for less than a month, and had been diagnosed with active pulmonary TB by the treating medical officer;

**‘treatment completed’** referred to patients who completed treatment but did not meet the criteria for cure or failure;

**‘failed’** applied to smear-positive patients who remained smear-positive, or became smear-positive again, at least 5 months after the start of treatment;

**‘interrupted treatment’** referred to patients who did not collect drugs for 2 months or more at any time after registration;

**‘transferred out’** referred to patients who were transferred to another reporting unit and for whom treatment results were unknown;

**‘re-treatment patient’** is a patient previously treated for TB whose treatment failed, who defaulted or who relapsed; while

**‘died’** referred to a patient who died during treatment, irrespective of the cause.

Sources: WHO, 2004; IUATLD, 2001.

## **Box IV. TB Treatment Regimens**

All patients were diagnosed by standard WHO procedures and criteria, and received standard courses of therapy under the DOTS policy. New patients received weight-adjusted rifafour-E (rifampicin, isoniazid, pyrazinamide and ethambutol) five times per week during the intensive phase of 8 weeks. If they were smear-negative at 8 weeks, they received rifinah (rifampicin and isoniazid) five times a week for the following 16 weeks. If the patient remained smear-positive at 8 weeks, the intensive phase was continued to 12 weeks. Smear-positive retreatment patients received the same regimen with the addition of weight- and age-adjusted streptomycin and rifafour-E for the first 8 weeks and, during the continuation phase, a weight-adjusted rifinah and ethambutol regimen five times per week. At the end of the third month, pyrazinamide was discontinued. It was only possible to administer streptomycin if the travel routes of the clinic nurse coincided with where the patient lived. When this was not possible, Streptomycin was omitted if the patient was not hospitalised; only giving the oral part of the anti-TB medication as per the prescribed policy.

Source: DOH, 1996.

### *TB in the Western Cape Province*

TB was declared a provincial emergency during 1997, and is the most common communicable disease in the Western Cape (WHO, 1998). This province has 11% of the country's population, but carries the third greatest burden of TB disease, notifying 19% of total national notifications, and in 2001 reporting an NSP incidence rate of 359/100 000 (NTP, 2003; Dick and Henchie, 1998).

### *TB in the study district*

The TB situation is even worse in some rural agricultural areas of the province. The Cape Winelands District Municipality is the local authority responsible for the health care of people living on farms in the Boland health study district. This public health authority reported an NSP TB incidence rate of 519/100 000 in 2001 (391 cases), compared with 359/100 000 at provincial and 188/100 000 at national level respectively (BDM, 2003; NTP, 2003). In 2001 HIV prevalence reached 8.3% in pregnant women attending public antenatal health facilities in the study district (DOH, Western Cape, 2001). In 2003 HIV prevalence in antenatal health facilities in the Western Cape stood at 11.93% (DOH, 2003). Implementing DOT on farms is very difficult and is also resource-intensive.

## **RATIONALE FOR THIS STUDY**

At the request of the farm communities, the Cape Winelands District Municipality implemented a farm LHW project in a small part of their district, the Klein Drakenstein area. An evaluation of this project showed the treatment adherence rate among adult TB patients was significantly better (15%) on the intervention farms (with LHW) (I). This project used a non-randomised ('promising sites') sampling methodology, which could have resulted in an over-estimation of the evaluation results. Because of this, the health services management requested a more rigorous

research design before widening the extent of the programme. This study is the response to their request.

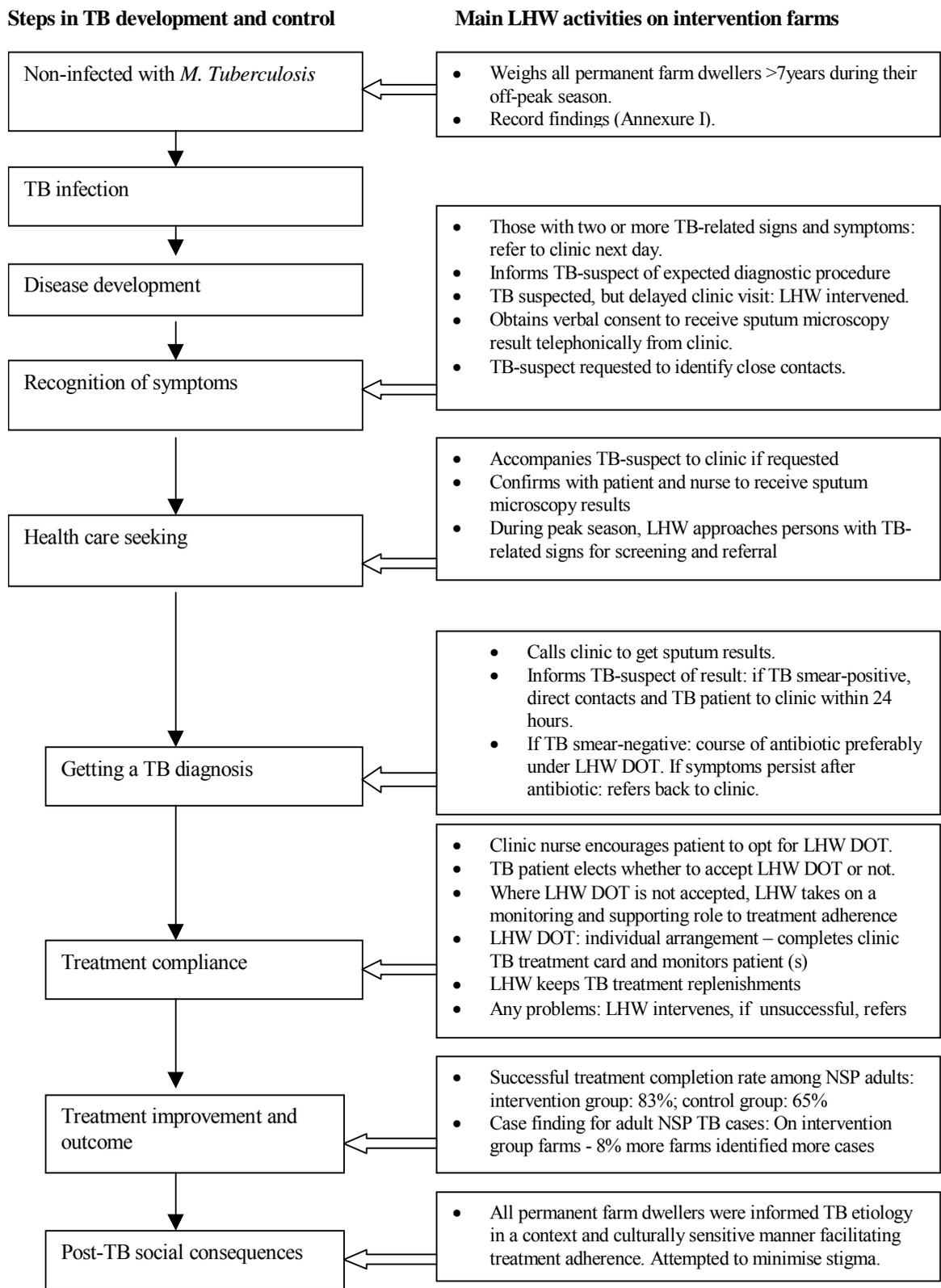
This study responds to the urgent need to improve TB control activities regionally and nationally and to find new, innovative ways of improving TB management outcomes. It focuses on agricultural communities who have been disadvantaged and who have relatively poor access to health care. This study describes an intervention using LHWs to enhance TB control among farm dwellers in South Africa.

## **CONCEPTUAL FRAMEWORK**

The aim of health systems research is to enhance the efficiency and effectiveness of the health system as an integral part of the overall socio-economic development process (Varkevisser et al., 1991). One approach used in health systems research is to provide action responses to areas of concern in order to ensure that context-bound real life problems are resolved. A basic function of any health system is the delivery of health services, which involves resource generation, financing and stewardship. This is a recent notion in health policy that requires national governments to set guidelines on health delivery for the public and private sector (Lindstrand *et al.*, 2003).

This thesis used the conceptual framework entitled ‘Steps in TB development and control’ (Long, 2000; Uplekar *et al.*, 2001). Major LHW activities related to the TB development and control framework are presented in Figure I.

**Figure I Main LHW activities linked to ‘Steps in TB development and control’ conceptual framework (Long, 2000; Uplekar *et al.*, 2001).**



# **OBJECTIVES**

## **GENERAL OBJECTIVE**

The overall study aimed to assess the effectiveness of a farm community-based LHW intervention within a PHC framework to improve TB case finding, case holding and cure rates on farms, and to explore and describe the perceptions of the different role players, and to do a cost-effectiveness analysis in order to contribute to TB control in South Africa.

## **Specific objectives**

- To describe and evaluate an LHW project designed to enhance the effective control of tuberculosis in a rural/farm setting (I);
- To estimate the point prevalence of sputum smear-positive TB among temporary farm workers who live elsewhere but work on farms in the study district, and to determine whether those diagnosed with TB have access to anti-TB treatment (II);
- To evaluate the effect of LHWs on TB control among permanent farm workers and farm dwellers in an area of South Africa with a particularly high TB prevalence (III);
- To explore and describe the perceptions farmers have about having a trained LHW on the farm (IV);
- To explore and describe the perceptions of the LHWs of a community-based intervention to improve TB control on farms in South Africa (V);
- To establish the cost-effectiveness of LHWs in conjunction with the current local TB control programme, amid health service contraction (VI).

## ETHICS AND CONSENT

Our approach was guided by the four ethical principles: respect for autonomy, beneficence, non-maleficence and justice (Beauchamp and Childress, 1993). Approval for the study was granted by the Interim Research Ethics Committee of the Faculty of Applied Sciences of the Cape Technikon, Cape Town, and the Ethics Committee for the Karolinska Institute, Stockholm, Sweden.

This research sought to ascertain whether the introduction of farm-based LHWs with a PHC approach would improve TB control on farms in the Boland health district, working in conjunction with the local TB control programme. Our exploratory study had indicated that this may be effective; apart from this we had no prior information (I). The lack of rigour in having a non-randomised and ‘promising sites’ sampling methodology during this evaluation made these results insufficiently robust as a basis for a decision to replicate the intervention. We had to test the intervention in a ‘real world’ situation.

People who would benefit most from this research study were the underprivileged farm dwellers, for whom health care is regarded as a development issue. The initial request and suggestion for the intervention came from the farming community itself, to help them in their plight to control TB. Representatives of the stakeholders were engaged during the development of the process.

The local public health authority was keen, as part of their efforts to ensure healthy communities, to identify and treat TB sufferers to reduce the pool of infection and provide equitable health care to the population for which they are responsible, i.e. the permanent farm dwellers living in their area of jurisdiction.

The local health authority management provided informed system consent for the study, with the commitment to provide all TB-related care to every individual (permanent and temporary farm workers) identified with and/or suspected of having TB. Furthermore, this undertaking would be extended to the control group farms, which would receive the intervention after the data for the RCT of the intervention had been collected. The farm dwellers that lived on farms enrolled into the control group of the RCT received TB care offered by the local TB control programme. System consent included permission that our research assistant could access the data captured in the official TB registers of the district. This research assistant was the only individual that was not blinded as to which TB patient was enrolled into either the intervention or control group. Lastly, the local health authority agreed to inform their staff members, the farm dwellers and farmers of the study.

Access to farm dwellers requires the cooperation of the farmer on whose property they live and work. Informed consent was obtained from each participating farmer to gain access to farm-dweller communities as well as the farmers acceptance of the project. Once access was secured, randomisation of farms followed, with enrolment into either the intervention or control group of the RCT.

Adult farm-dweller communities living on those farms enrolled into the intervention group of the RCT were informed individually of the extent of TB in the district, the results of the exploratory study (I), the intended research project, some guidelines for the LHW selection process, their training programme and expected activities, and what

it meant to be enrolled into the intervention group. Questions were fielded and these farm dwellers were given three weeks in which to decide whether to participate or not.

Direct observation of anti-TB treatment taken was not prescribed, although TB patients and LHWs were encouraged to regularly communicate with each other to enable LHWs to monitor treatment adherence, possible side-effects, the patients' clinical and social situation, and to provide the required support. Each patient was given the choice of whether or not to receive LHW DOT, and this did not imply that their decision was irreversible for the whole treatment period. The LHW in turn contacted (with the patient's knowledge) the trainer or clinic nurse for support and advice when any problems or side-effects were experienced.

No invasive investigations were required. The monthly screening sessions could invade privacy, but participation was completely voluntary and participants were informed of this in advance. All LHWs were trained to keep health information confidential, only sharing this with the other project team members and clinic nurses. If patients agreed to LHW DOT, others living on the farm could become aware of their TB status; the choice remained the individual patient's. The LHW took more of a monitoring and supportive role.

Verbal, audiotaped informed consent was given by all participants in the qualitative research at the beginning of each interview and/or focus group discussion.

Informed consent was obtained from each respondent during the TB point prevalence cross-sectional study among the temporary farm workers.



# **SUBJECTS AND METHODS**

## **STUDY SETTING**

The study reported on in this thesis was conducted in the rural farming communities of the Boland health district, situated in the Winelands, about 65 km northeast of Cape Town (see map). This health district comprises 14 health areas, numbered 1-14. This study included the health areas numbered 6-14, and the farming areas situated around the three towns of Paarl, Franschhoek and Wellington.

The local public health authority changed its name at the end of the study period from the Boland District Municipality to the Cape Winelands District Municipality. During the study period political transformation took place and the local leadership in the public local health authority changed four times. The study area was about 1661 km<sup>2</sup>, had an estimated population of approximately 73 000 in 2002, and reported an estimated 2.5% annual population growth rate (Boland District Municipality, 2003).

The commercial agricultural economy of the area is based on deciduous fruit growing and wine making, mainly for export. Each farm is an individual agricultural business unit that is run by a farm owner or farm manager. Farms are private property and therefore access to workers and farm dwellers by the public health sector is dependent on the consent and cooperation of the farmer (employer). Traditionally, farmers accepted the responsibility for the health care needs of the farm dwellers living on their farm property. Labour is provided by people living permanently on the farm with their families and by external casual workers that live elsewhere. Permanent employees on each farm ranged in number from 2 to 200 (median 18).

## **Intervention Process**

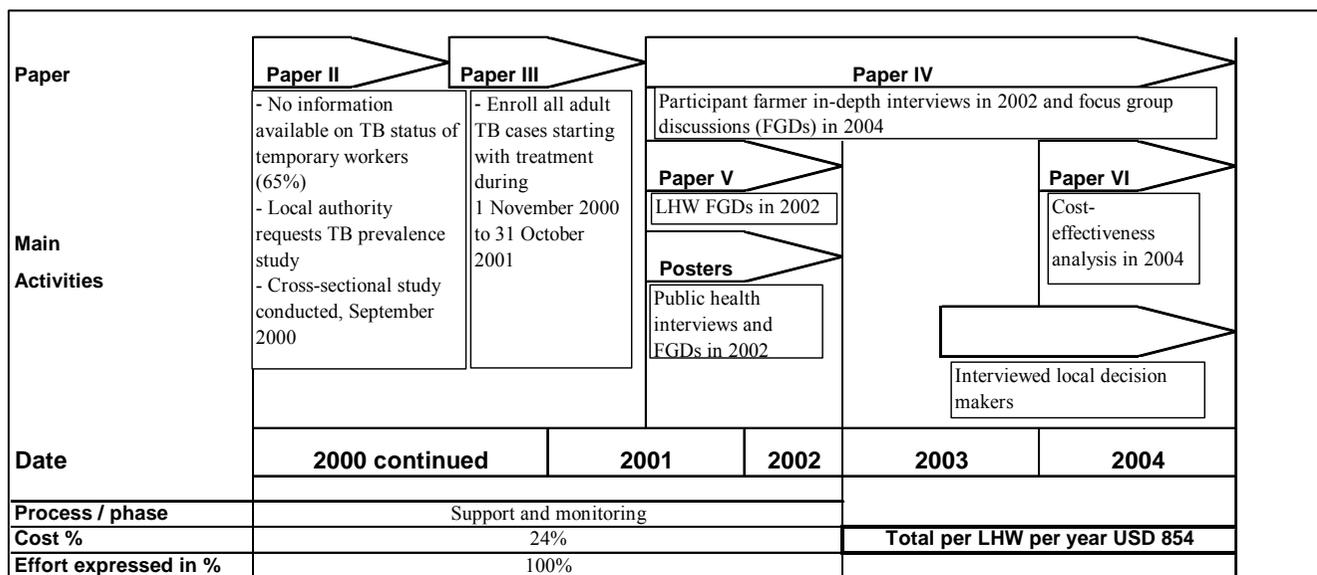
The intervention was a comprehensive strategy to empower farm communities to select, appoint and utilise LHWs trained in PHC. LHW training emphasised the importance of the early detection and treatment of TB within a comprehensive programme promoting the health of farm dwellers (Dick *et al.*, forthcoming).

Figure II presents an overview of the implementation process, its timeframe, main activities and different phases, the effort it took, and the publications that emanated from this study. The cost of the intervention was studied as a Master's thesis, and a brief summary is provided at the end of this section (Rörich, 2002).

**Figure II. Intervention: Overview of Implementation Process**

<b>Paper</b>	<b>Paper I</b>									
	<ul style="list-style-type: none"> <li>- Exploratory project: 1 January 1993 to 31 December 1995</li> <li>- Evaluated in 1996</li> <li>- Participation voluntary</li> </ul>				<ul style="list-style-type: none"> <li>- Based on exploratory study evaluation, local authority request to expose intervention to rigorous research</li> <li>- Collect baseline data</li> <li>- Form research group</li> <li>- Research methodology and protocol developed</li> <li>- Research partnerships and funding secured</li> </ul>	<ul style="list-style-type: none"> <li>- Project launched</li> <li>- Access to farm dwellers via farmers to participate</li> <li>- 211 agreed to participate</li> <li>- Randomised into study groups on 3 March 2000</li> </ul>	<ul style="list-style-type: none"> <li>- Appoint two LHW trainers</li> <li>- Inform farm dwellers on intervention group farms of study and facilitated LHW selection: March/April</li> </ul>	<ul style="list-style-type: none"> <li>- Adult farm dwellers select LHWs</li> <li>- Prepare training equipment based on exploratory study training materials</li> <li>- Train trainers in the process of preparation</li> </ul>	<ul style="list-style-type: none"> <li>- Train LHWs</li> <li>- Five x one-week modules</li> <li>- Monthly farm support visit part of training</li> <li>- 84 LHWs</li> <li>- May to September 2000</li> </ul>	
<b>Main Activities</b>										
<b>Date</b>	<b>1993</b>	<b>1994</b>	<b>1995</b>	<b>1996</b>	<b>1997</b>	<b>1998</b>	<b>1999</b>	<b>2000: Period of intervention</b> (2000 continues below)		
<b>Process / phase</b>								Marketing, preparation and access		Training
<b>Cost %</b>								32%		44%
<b>Effort expressed in %</b>								80%		60%

**Figure II. Intervention: Overview of Implementation Process (continues)...**



## PROJECT TEAM

A clinic nurse was seconded from the Cape Winelands District Municipality to act as the project manager of the LHW intervention. The function of the project manager was to lead the intervention through all phases of implementation and provide a link between the role-players, such as the employers, public health sector, LHWs and their trainers, farming community and research team. The project team consisted of this clinic nurse and two contracted trainers, one of whom was a male clinic nurse, the other a woman who had previously worked in the NGO sector as a co-coordinator of community TB DOT workers.

The two trainers were tasked to find suitable training venues. The logistics of planning the attendance and transport to ensure that each LHW attended each module was complex. Often the farmer brought the LHW from his site to the training. On completion of each training module LHWs were given supervision and support by their trainers.

The project manager maintained links with the public health sector, giving them regular feedback on the progress of the intervention. Similarly, coordinated information and feedback sessions were held with the farmers to ensure that they were kept well informed. It was more difficult to ensure all farm dwellers remained informed. However, most farm dwellers attended the annual LHW certificate ceremony, during which project feedback was given.

Concurrently with gaining access onto the farms, a training curriculum was developed. This curriculum was based on PHC principles, and has subsequently been published for general use (ABE Development Trust *et al.*, 2003 (a) and (b)). Development of the curriculum was combined with the design of training materials suitable for use by LHWs who ranged from being 'functionally illiterate' to having completed Grade 12 schooling.

### *Launch of the intervention*

A launch of the intervention, initiated by the Cape Winelands District Municipality Council and the Medical Research Council, was held in July 1999. Farmers, farm employees, provincial, regional and local policy-makers and NGOs and community-based organisations attended. The goal of the launch was to recruit voluntary participants, to communicate the results of the exploratory study (I), to introduce the research team, and to explain what the intended RCT would imply, i.e. during the first year the intervention would take place on farms randomised into the intervention group of the study and during the second year it would be conducted on the farms included in the control group of the study. The expectations of the farmers and the proposed role and function of the LHWs were also discussed. This created a framework for the development of intersectoral collaboration to meet the holistic needs of individuals in the community.

### *Phases of the intervention*

The intervention was organised into three phases, outlined below.

**Phase one:** The preparatory phase involved gaining access and informing each farming community of the aim of the study, giving them some basic TB information, and outlining the selection process when identifying peers to be trained as the LHW.

**Phase two:** Training of the LHWs included five one-week modules offered during the five-month off-peak season of May-September 2000. Training was offered on a decentralised basis, on a centrally situated farm, to 6-10 trainees per session.

**Phase three:** During training and after completion of training each LHW was visited monthly on the farm where they worked, by their particular trainer.

### *Gaining access*

Gaining access turned out to be the most complex and time-consuming part of the process. It had to be addressed with sensitivity and achieved at four different levels: local policy-makers, farm employers (farmers), farm dwellers and community resources.

#### Local policy makers

Access to the local policy makers was obtained through various means, e.g. by disseminating the results of the exploratory project through the local and national media. These policy-makers were invited to attend the annual LHW certificate ceremonies, where they were often guest speaker or guest/s of honour. The frequent change of leadership has been referred to.

#### Farm management

The project leader met with each farmer individually to discuss the intended RCT and to clarify any issues of concern. A letter (Annexure II) informing farmers of the reason for the study preceded this meeting. Each farmer was given the option of participating in the study or not.

Farmers were willing to participate since the project would address the TB problem they had referred to the local health authority. This health authority funded and managed the project, providing farmers with a sense of sustainability. Farmers had been informed of the findings of the exploratory project (I). Gaining access onto farms took eight months.

Participation in the project required farmers to provide: LHW transport to attend training, payment of LHWs whilst being trained and absent from their work on the farm, the infrastructure for LHWs to conduct the monthly weighing sessions, and payment of the first-aid module which had become a legal requirement.

#### Farm dwellers

Access to the farm dwellers could only commence once permission was secured from the farmer, and once randomisation of the farms was completed. Only farms randomised into the intervention group of the RCT were included. LHW trainers

conducted information sessions on each individual farm in order to allow the trainer to bond with the farm dwellers from the beginning.

All adult farm dwellers were included in these sessions, at which information was given on the extent of the TB problem, and the training, support, role and function of the farm LHW, as well as the selection criteria to be used to choose a suitable individual for training. These sessions were attended by various role-players envisaged as participating in the project at some or other stage, e.g. staff members of the relevant NGOs and social workers.

This part of the process took two and a half months. Farm dwellers were given the choice of whether to participate or not.

### Community resources

Gaining access to resources in the community was relatively easy, since the project leader had worked in the area for many years, knew the community resources, and had worked with them on the exploratory project.

## **Lay health workers**

### *Selection process*

During introduction of the project to the farmers and the adult farm dwellers, the following selection criteria for LHWs were discussed: the LHW must be acceptable to the farm dwellers, should have rudimentary literacy (i.e. Grade 3-4), and should preferably not hold a key position on the farm.

### *Roles and functions*

The primary functions of the LHWs were to weigh and screen the farm workers each month (Annexure I) for clinical features suggestive of TB, documenting these details, and to refer all farm dwellers (aged seven years and older) presenting two or more TB-specific signs and symptoms to the nearby clinic facility with a note, for further diagnostic tests. Further TB-specific tasks of the LHWs were to explain the sputum specimen collection procedure, the results of which are available at the clinic within 48 hours, and obtain verbal consent from those suspected to have TB, to phone the clinic nurse for sputum laboratory results on behalf of the suspected TB case and inform the patient accordingly. LHWs asked the farmers to provide transport to the clinic.

In addition, they interacted with TB patients, asking to meet with their close contacts to ensure that they also went for further TB diagnostic investigations. Nurses encouraged TB patients to accept direct supervision of treatment from the LHW, and if the laboratory sputum results were TB smear-negative, to accept antibiotics preferably under LHW direct supervision DOT. LHWs were expected to refer individuals back to the clinic should symptoms and the clinical picture of the individual not improve after completing the antibiotic treatment.

In terms of TB direct observation of treatment activities, the LHWs or the patient (according to the patient's wishes) kept the medication. LHWs were expected to inform the clinic nurse telephonically (often having to ask the farmer to use his telephone)

within 24 hours of any problem in terms of TB treatment adherence being identified. LHWs recorded treatment adherence on the clinic-provided TB treatment-adherence card.

Secondary functions included advising farm dwellers about and treating minor ailments, and referring to the appropriate public health facility, providing first aid, advising and supporting families on home-based care, and providing health education about basic health issues to the communities.

### *Training programme*

After an evaluation of the educational level of the trainee LHWs, it was decided to base the training programme on adult basic education training principles (Johnston and Rifkin, 1987; Favish, 1997). Training was tailored to the needs of the participants and emphasised issues leading to improved self-efficacy and gender empowerment. The identification and support of NSP TB cases was emphasised.

Development of an individual picture manual during each module helped the LHWs to inform their communities about what they had learnt. The five training modules were: Becoming a community LHW (including capacity building skills), TB (using the standardised provincial training manual), Family health (including HIV/AIDS, minor ailments, foetal alcohol syndrome), First aid, and Home-based care (personal capacity building in bereavement stages). LHWs were trained to keep detailed records of their client contacts, providing data regarding their caseload and type of activities.

LHWs were trained to share health knowledge with people; help to prevent illness; conduct monthly voluntary weighing screening sessions for TB; treat minor common illnesses; and refer health problems to appropriate public health facilities.

The training programme covered areas such as the management of TB, HIV/AIDS infection in the community, the principles of growth monitoring, oral rehydration, breast-feeding, immunisation, female education, family spacing and food supplementation, using group discussions, demonstrations, visual aids, posters, and role-play. Psychosocial aspects such as the role of the woman in the family and the development of positive self-esteem were important parts of it. Each training module was offered over a one-week period between 08h00 and 14h00. Farmers provided transport for the LHWs, which had to fit into the transport system for getting children to school. Training was offered outside of the peak harvest season, at eight different venues central to the three village areas. The two trainers trained two groups of learners simultaneously.

LHWs were evaluated at the end of each training session, discussing how they experienced the training session. Final individual LHW evaluations were conducted either by a written test or orally by the project team members, according to the particular LHW's preference.

### *Monthly support*

Trainers visited each LHW on the farm where they were working in a four- to six-week cycle to establish any problem areas that the LHWs experienced, to review and discuss the monthly weighing reports, collect the monthly report reflecting what

health-related issues the LHW had attended to since the previous visit, and encourage the LHW to persevere.

### **Cost of the intervention**

The logistical and cost structures of the Cape Winelands LHW intervention were compared with those of four similar interventions in the province, which had non-urban facets to them. The project comparing best with the Cape Winelands LHW project in terms of size, area of operation, health service structures, and the use of part-time LHWs was that conducted by the Rural Foundation (an NGO) (Rörich, 2002). The main difference between that programme and the Cape Winelands LHW programme, was that the Cape Winelands did not pay incentives to LHWs. This important aspect was taken into account in comparing the cost data of the different programmes.

The average cost of the Winelands programme was R5318 (USD 854) per LHW per year, as opposed to R8418 (USD 1351) per LHW per year in the Rural Foundation programme (Rörich, 2002; Reuters, 2004). However, when adjusted to exclude the LHW incentive payment, the cost of the Rural Foundation programme dropped to R3630 (USD 583). According to Rörich (2002), differences in cost could relate to either implementation procedures or, more likely, economies of scale, i.e. the percentage of the total cost per LHW is independent of the number of LHWs in training or fully trained LHWs active and being supervised as part of the training programme. The ratio of population to LHW was 83:1 in the Rural Foundation study and 70:1 in the Cape Winelands LHW project (Rörich, 2002). All costs were calculated in 2001.

The marketing phase absorbed 32% of the total implementation cost, the training phase 44% and the maintenance phase 24%. See Figure II. The supervision costs were fixed and should remain constant unless the number of LHWs exceeds the capacity of the supervision structure, in which case expansion of this structure would have additional cost implications. Training costs should remain the same, irrespective of the number of LHWs trained, because the LHW trainers were fully employed by the local health authority. Specialised areas of training carried their own costs, such as first aid (funded by farmers) and life skills (payment to NGO included in this calculation) (Rörich, 2002).

### **Health services in the study district**

The local public health authority, the Cape Winelands District Municipality, is responsible for rendering health care to the people who live and work on the farms within their area of jurisdiction. Health care in the study district is nurse-driven, and both the TB DOTS and PHC approach were introduced in mid-1997. The public regional hospital is situated in the study district. Private physicians' fees are too high for regular use by farm dwellers.

The health service operates on limited resources. Due to health budget cuts, health authorities centralised their health care delivery. Mobile clinic visits fell from 11 000 visits at 552 points (where the mobile clinic would stop, i.e. at a farm) in 1997 to 4000 visits at 173 visiting points in 2000 – a 64% drop (Boland District Municipality, 2003). Farm dwellers now have to walk up to 5 km to attend either a mobile clinic on a

centrally situated farm or a fixed clinic facility operating on weekdays during office hours. This leaves little room for services such as home visits or health promotion to be offered by the clinic nurses.

Strategies such as DOTS are very hard to implement because of limited capacity of the nursing staff to reach TB patients daily. In more remote areas of the district no public transport is available, and access of farm dwellers to public health care facilities is dependent on transport provided by their employers. Services have shifted from preventive to comprehensive, combining curative and preventive health care activities. The consequence has been that preventive care is over-shadowed by the curative needs of the patients.

Table I depicts a summary of the local TB control programme and compares it with the TB control programme undertaken in combination with LHWs on farms.

**Table I. Summary of components of alternative TB management strategies to control TB among permanent farm dwellers**

<b>Strategy</b>	<b>Case finding</b>	<b>Pre-diagnosis</b>	<b>Laboratory results</b>	<b>Treatment</b>	<b>No. of visits by patient</b>	<b>Supervision</b>	<b>Programme management</b>
<b>Strategy 1</b> (Current)	<ul style="list-style-type: none"> <li>- Passive case finding as part of DOTS strategy</li> <li>- Self-referral when unwell</li> </ul>	<ul style="list-style-type: none"> <li>- Individual presents him/herself on being sick</li> <li>- If clinic nurse suspects a person attending the clinic, may have TB, two sputum specimens are taken 90 minutes apart</li> <li>- Sputum is sent for laboratory microscopy (WHO procedures followed)</li> </ul>	<ul style="list-style-type: none"> <li>- Microscopy results are available at the clinic in 48 hours</li> <li>- TB suspect is requested to return after one week for results</li> <li>- The clinic nurse informs patient of sputum laboratory result</li> <li>- If the result is smear-positive, treatment commences and patient is requested to refer all direct contacts to clinic for TB screening</li> <li>- If the result is smear-positive and patient does not return for result (10%), the clinic nurse recalls patient</li> <li>- If the result is smear-negative, antibiotics are given; with a request to return if symptoms persist.</li> </ul>	<ul style="list-style-type: none"> <li>- Standard WHO treatment – see note* below</li> <li>-The clinic nurse informs the patient of preferred option: clinic-based DOT</li> <li>- If patient lives too far from the clinic to attend daily DOT, they are issued with 1 – 4 weeks’ supply of drugs, depending on distance from clinic.</li> </ul>	<ul style="list-style-type: none"> <li>- Five days per week for both initial and continuation treatment phases</li> <li>- In the six month treatment period there are 120 doses / visits to the clinic for DOT or for whatever the arrangement with nurse is.</li> </ul>	<ul style="list-style-type: none"> <li>By the clinic nurse at the clinic if clinic-based DOT has been chosen by the patient, otherwise the clinic nurse working in the mobile unit will monitor during the monthly visits on that farm</li> </ul>	<ul style="list-style-type: none"> <li>Cape Winelands District Municipality.</li> </ul>

**Table I. Summary of components of alternative TB management strategies to control TB among permanent farm dwellers (continued)**

Strategy	Case finding	Pre-diagnosis	Laboratory results	Treatment	No. of visits by patient	Supervision	Programme management
<b>Strategy 2</b> (Current in combination with LHW)	- Active monthly TB sign and symptom screening during off-peak season - During peak season screening is done on an individual's request or if the LHW notices clinical changes, i.e. weight loss / cough for more than 3 weeks	-LHW refers farm dweller with two or more TB-specific signs and symptoms to clinic with a note - LHW prepares the person referred of the possibility of a sputum specimen being requested, explaining the collection procedure - LHW obtains verbal consent to phone the clinic nurse for sputum results - The person presents him/herself at the clinic with the LHW note, then as for strategy 1. -Clinic nurse confirms with the person whether the LHW may be informed of sputum result	- LHW telephones clinic nurse after 48 hours to get sputum results - LHW meets patient and conveys the sputum result - If the result is smear-positive, the person goes to the clinic immediately (within 24 hours) together with all direct contacts for their TB screening - Patient commences treatment - In most cases patient asks LHW to accompany him to the clinic - If the result is smear-negative, antibiotics are given under LHW DOT – LHW refers the person back to the clinic should symptoms persist.	- Same as for strategy 1 -Clinic nurse discusses LHW DOT as preference with patient. - Patient selects DOT option - Medication replenishment is via the nurse tasked to supervise treatment: this is either the clinic nurse in mobile unit or the the clinic nurse at the fixed clinic.	- As for strategy 1 except DOT on farm is provided in facility supplied by the farmer or in a home or place as agreed with the patient	- LHW resident on the farm - Clinic nurse working in the mobile unit meets the LHW and patient monthly during farm visits - LHW has telephone details of clinic nurse working in the mobile unit so that she/he can be contacted if needed.	Project team employed by the Cape Winelands District Municipality manages intervention together with community stakeholders, in conjunction with the Cape Winelands District Municipality.

\**Treatment regimens:* New patients receive weight-adjusted rifamprazole (rifampicin, isoniazid, pyrazinamide and ethambutol) five times per week during the intensive phase of 8 weeks. If they remain smear-negative at 8 weeks, they receive rifinah (rifampicin and isoniazid) five times a week for the following 16 weeks. If the patient remains smear-positive at 8 weeks, the intensive phase is continued to 12 weeks.

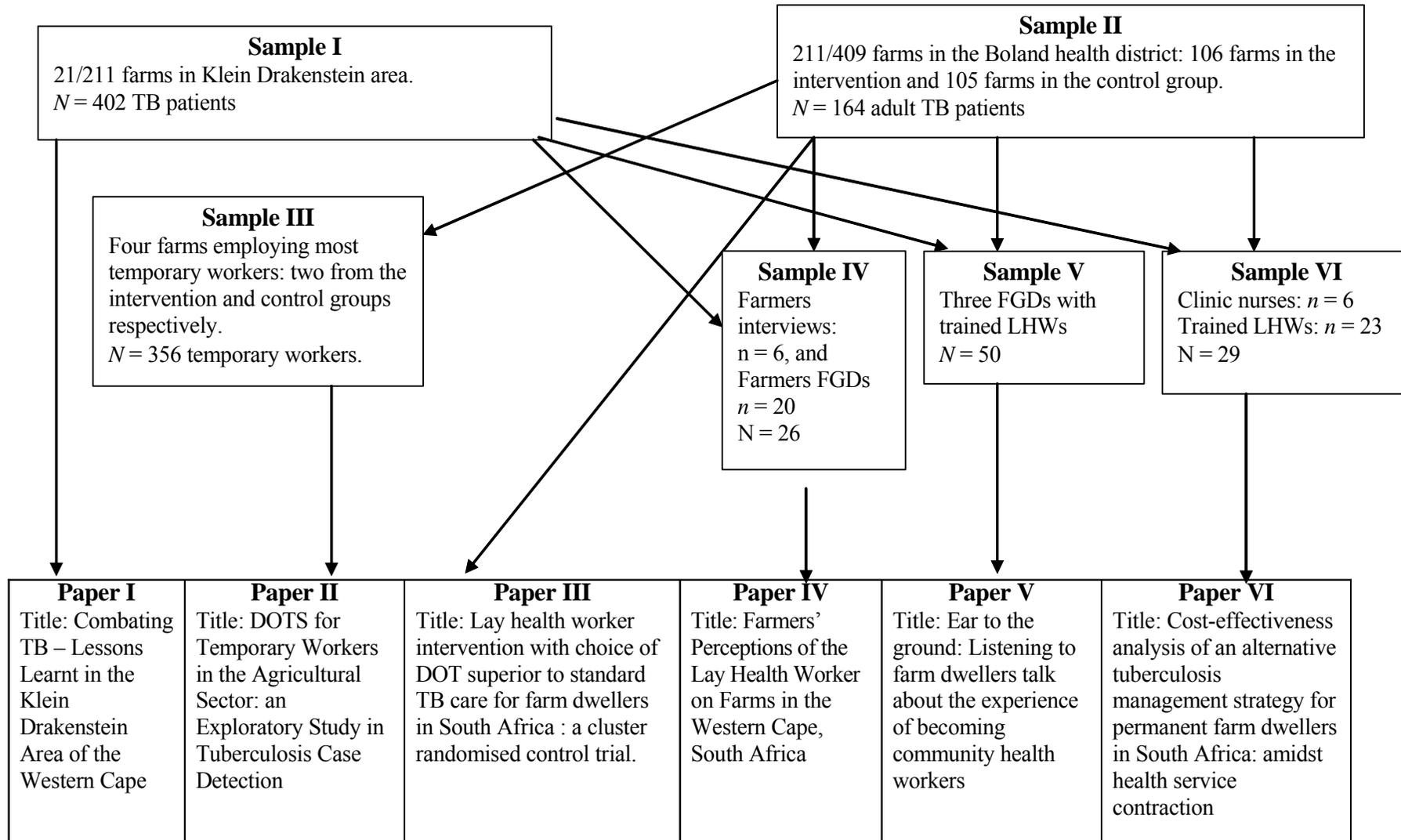
## **STUDY POPULATIONS**

An overview of the study population sampled and that for each study, is presented in Figure III. A summary of the study designs, samples and data collection techniques is presented in Table II.

The pattern of temporary employment of farm workers became evident during the baseline (pre-intervention) data collection in preparation for the RCT (Shoeman and van Zyl, 2000). Health managers in the Cape Winelands District Municipality subsequently requested information on the prevalence of TB in this group as well as their access to the standard TB care. It was decided to include the findings of this study in the thesis as it enriches the description of the complex and changing context in which the study took place.

In addition, access to the study population to identify key informants and participants for the in-depth interviews and focus group discussions (FGDs) was only possible via the project manager (IV, V, and VI).

**Figure III. Illustration of study samples: Papers I–VI**



FGD = Focus Group Discussions

**Table II. Summary of various studies: Designs, data collection methods, samples and data collection periods**

<b>Study</b>	<b>Study design /data collection methods (italics)</b>	<b>Sample</b>	<b>Data collection period</b>	<b>Paper</b>
Evaluate farm-based LHW effect on TB control	Cohort study <i>Public health authority database</i>	402 TB patients	01 January 1993 to 31 December 1995	I
Temporary farm workers: estimate smear-positive TB point prevalence and determine access to TB care	Cross sectional <i>Structured interviews using trained interviewers and questionnaire</i>	356 temporary farm workers	28 September 2000	II
Establish effect of farm-based trained LHW on TB case finding and case holding among farm dwellers	Pragmatic unblinded, cluster randomised control trial <i>Official TB registers</i>	Total 164 TB patients of whom 89 were NSP TB cases	01 November 2000 to 31 October 2001	III
Perceptions farmers have of trained farm-based LHW	Qualitative exploratory <i>In-depth interviews and Focus Group Discussions</i>	Six in-depth interviews and two Focus Group Discussions N = 26 Informants	June 2002 and May/June 2004	IV
Perceptions of trained farm-based LHWs of intervention	Qualitative exploratory <i>Focus Group Discussions</i>	N = 50 trained farm-based Lay Health Workers	September 2001	V
Cost-effectiveness analysis comparing alternative TB control strategy with LHWs in conjunction with local TB control programme on farms	Cost-effectiveness analysis <i>Direct communications, group discussions to verify information and salary structures information</i>	Six clinic nurses 23 trained LHWs N = 29	April and May 2004	VI

## **Quantitative studies: Papers I – III**

### *Paper I*

#### Subjects

The exploratory study included 402 TB patients (Sample I in Figure III) to evaluate the adherence rates on intervention farms (with LHWs) and non-intervention farms (without LHWs). These intervention farms were ‘promising sites’, having been non-randomly selected; farmers voluntarily agreed to participate. All TB patients notified during the period 1 January 1993 (when the intervention started) and 31 December 1995 were included in the study (see Table II).

#### Method

A cohort study design (Beaglehole *et al.*, 1993) was used to evaluate the TB treatment adherence rates in the intervention and non-intervention groups. Demographic and treatment adherence data were obtained from the database of the Cape Metropolitan Council, which at the time provided health services to the farm dwellers in the study health district. The registered clinic nurse validated this information using individual patient records (see Table II).

### *Paper II*

#### Subjects

This study included 356 temporary farm workers (Sample III in Figure III) who worked on the four largest study farms that participated in the RCT on 28 September 2000, who were transported to work by the employer every day of the week. Two of these study farms were randomised into the intervention group and the other two farms were randomised into the control group of the RCT.

#### Method

This cross-sectional (Beaglehole *et al.*, 1993) active TB case finding study aimed to estimate the point prevalence of TB sputum smear-positive cases among temporary farm workers in the Boland health district, and to determine whether temporary farm workers have access to anti-TB treatment (see Table II).

To simplify the logistics of this study, the four largest farms (Schoeman and Van Zyl, 2000) that were included in the RCT (III) were selected for this study. At the time of the study, 244 permanent farm workers lived on these four farms and up to 1110 temporary farm workers were employed on these farms during the peak season. A convenient random sampling method was used to finalise the study sample, using two inclusion criteria; (i) participants had to be temporary farm workers at work on any of the four study farms on the specific day, and (ii) were not living on the farm.

The project manager coordinated the date to suit all stakeholders involved. Data were collected using questionnaires that were completed by eight trained interviewers. Together these interviewers were able to accommodate all language preferences of the participants. The questionnaires were available in English, Afrikaans and Xhosa.

### *Paper III*

#### Subjects

All adult (15 years and older) permanent farm dwellers that lived on any of the 211 study farms (106 farms in the intervention group and 105 farms in the control group) and commenced with TB treatment during the period 1 November 2000 to 31 October 2001, were included in the study (Sample II in Figure III). The multidrug-resistant TB patients were excluded.

In total 164 adult TB patients were recruited into the study, of whom 89 were NSP TB cases. We estimated that a sample of at least 180 farms (90 intervention and 90 control) was required to detect a 15% difference with a power of 80% at a significance level of 0.05%. A sample size of 211 farms (17.2% over sample) was achieved (III).

#### Method

The aim of this pragmatic (Swartz and Lelouch, 1967), unblinded cluster RCT (Beaglehole *et al.*, 1993) was to evaluate the effect of LHW recruitment, training and deployment on successful treatment completion by NSP TB patients among permanent farm dwellers. Subsidiary aims included assessment of the impact on TB case finding and re-treatment cases (see Table II).

TB treatment outcomes of adult patients on farms with the LHW intervention were compared with those on farms with no LHW intervention. This trial measured the successful treatment completion rate of NSP adult TB patients on 106 farms randomised into the intervention group, and compared it with outcomes in patients on 105 farms randomised into the control group. Farms were the unit of randomisation, and analysis was by intention to treat (Newell, 1992) for clusters in a completely randomised design using individual level data on rate differences between intervention and control groups, and a chi-square test adjusted for clustering within farms.

A research assistant collected data (Annexure III) using the official TB registers held in the clinics situated in the study district. This information included the patients' name, gender, age, clinic number, notification date, origin, TB type, sputum-smear results at diagnosis and at two and five months, and whether a new or a re-treatment case. The baseline TB data were collected from 01 January 1998 to 31 December 1998 (Schoeman and Van Zyl, 2000).

### **Qualitative studies: Papers I, IV and V**

#### *Paper I*

#### Subjects

Purposive sampling was utilised to make contact with a variety of informants (Sample I in Figure III). Redundancy of descriptions, a means of determining sample size in qualitative studies, was assessed at around the seventh or eight interview.

#### Method

This qualitative study explored the perceived acceptability of the project from the perspective of the TB patients, the LHWs, the farmers, and the health providers. These qualitative data were collected using in-depth interviewing techniques (Denzin

and Lincoln, 1994). Interviews were conducted by a qualitative researcher together with the principal researcher to explore the perceived acceptability of the project from the perspective of the TB patients, the LHWs, the farmers, and the health providers.

#### *Paper IV*

##### Subjects

Six farmers, three of whom participated in the exploratory study (I) and three who participated in the intervention group of the RCT (III) were the key informants. Purposive sampling was used to identify these key informants, who had all implemented the intervention on their farms with varying degrees of success. They were identified and approached by the project manager based on their ability to communicate unambiguously, and their willingness to participate. The key informant sample was supplemented by a convenient sample (Ritchie and Lewis, 2003) to include more farmers from the same study frame (Papers I and III) in two focus group discussions (FGDs). Eighteen farmers (5 of whom participated in the intervention) attended the first FGD, and 18 farmers (15 of had participated in the intervention) attended the second (Sample IV in Figure III).

##### Method

The aim of this study was to explore, understand and describe the perceptions of farmers about having a trained LHW on the farm. A qualitative study design was applied. Data were collected during in-depth face-to-face interviews (Denzin and Lincoln, 1994; Ritchie and Lewis, 2003) conducted by the principal researcher during June 2002. The interviews took place in either the home or offices of the key informants at a time suitable to them. The question used to start each interview was: "Tell me about your experience in having a lay health worker on your farm" .

Findings from the key informants' interviews helped researchers to develop the aim and opening question for the two FGDs conducted during May and June 2004. The chairmen of two local agricultural groups granted the researchers access to the groups prior to the start of their monthly meetings. These FGDs were conducted at a time when the farmers were not in a buoyant mood due to the adverse exchange rate and a period of severe drought. A research specialist attended both FGDs to observe the non-verbal group dynamics during the interaction. The question used to start each FGD was: "How do you view the future of the lay health worker project offered by the Boland District Municipality?" (Table II).

After participant anonymity and confidentiality were assured and verbal informed consent was obtained, these interviews and FGDs were tape-recorded and transcribed by an approved secretary verbatim. Both in-depth interviews and FGDs were translated from Afrikaans into English by the principle researcher, who stored these tapes in a safe place.

#### *Paper V*

##### Subjects

The participants included two groups of LHWs (Sample V in Figure III) that had been

with the intervention since the start of the intervention trial the previous year (III). The third group was from the exploratory project (I) that had been running for more than seven years by then.

The three FGD groups were as follows: group one included 15 women and 2 men, group two included 12 women, and group three included 21 women. Groups one and two included LHWs from the RCT intervention study group (III), and the third group (I) included LHWs from the exploratory study.

## Method

Collecting data from LHWs was more complex to arrange, since bringing participants together in this rural setting is difficult. Convenience sampling was therefore used for this qualitative study, with three FGDs held after LHW training sessions. This was done in an attempt to ensure that as many LHWs as possible could participate in the FGDs, while causing little inconvenience to them and their employers. Two of the groups had been with the intervention since the start of the RCT the previous year (III). The third group was from the exploratory project (I). In choosing groups with different lengths of exposure it was hoped that we would capture different experiences of the intervention (see Table II).

The low literacy level of participants presented a challenge. Therefore, before each FGD started the process was explained to participants. It was ensured that they understood that their participation was voluntary, that the FGD would be tape-recorded, and that they would not be required to identify themselves during the recording. None of the participants chose to leave the venue after this explanation. The FGDs were tape-recorded and transcribed verbatim.

A qualitative researcher collected data and attempted to enter the interview with an open mind and an open heart (Smaling, 1993), allowing the participants to share their stories without being judged. The interview was structured through the process of reflection and clarification (Buskens, 1996), aiming to understand as fully as possible what the participants were sharing.

The principle researcher, although not the first author of this paper, was involved in the planning and the design of the study, as well as in aspects of the data analysis and the writing of this paper.

## **Cost-effectiveness study: Paper VI**

### Subjects

Seven clinic nurses provided information on time per activity for the clinic nursing personnel involved in TB care: one clinic nurse provided the initial information that was verified by the six other clinic nurses. Twenty-three trained LHWs provided information on time per activity performed on the farm by LHWs (see Figure I): one LHW provided the initial information that was verified by 22 other LHWs (Sample VI in Figure III).

The average salary packages for the different categories of nurses involved were provided by their employer, the Cape Winelands District Municipality.

## Methods

The aim of this study was to establish the cost-effectiveness (Drummond, 1997) of LHWs in conjunction with the current local TB control programme, amid health service contraction, to provide empirical evidence for decisions on how better to use public money for health improvements and survival. The Cape Winelands District Municipality cost perspective was applied.

The data included the direct nursing time cost from when a person suspected of having NSP TB visits the clinic until completion of the six months' treatment under clinic-based DOT, and the direct time cost to farmers of having an LHW involved with TB screening, clinic referral and NSP TB case finding and supervising six months' treatment, and applied the time costs to the measures of effectiveness based on the findings of an RCT (III).

Data were collected during face-to-face communication with a clinic nurse who, working in a fixed clinic in the study area with the project manager present, provided the first round of information from which flow diagrams were developed. The six clinic nurses working in the study district verified the data during a discussion group. An LHW with 11 years' experience provided the first round of information during face-to-face communication with the project manager present, from which flow diagrams were developed. Twenty-two LHWs verified these data during three separate discussion groups (see Table II).

Time cost estimates for clinic and enrolled nurses were based on average salaries of these staff categories, as provided by the Cape Winelands District Municipality.

Time cost estimates for LHWs were based on the mean wage using information provided by LHWs attending the data verification discussion groups.

## **STATISTICAL ANALYSIS**

TB data (Annexure III) for Papers I, II and III were entered by one research assistant operator using the software Epi Info version 6 from Epidemiology and Disease Surveillance, Centers for Disease Control in Atlanta, USA. This software is a multi-purpose computer program designed for epidemiological researchers and public health personnel.

In Paper I the adherence to treatment of the intervention and non-intervention groups was compared using a relative risk estimate with a 95% confidence interval.

In Paper II the TB smear-positive and total TB point prevalence was calculated. A TB point prevalence rate was estimated with a 95% confidence interval.

In Paper III the analysis was by intention to treat (Newell, 1992) for clusters in a completely randomised design using individual level data on rate differences between intervention and control groups, and a chi-square test adjusted for clustering within farms. A 95% confidence interval was estimated for each effect and a common intra-cluster correlation was used for all outcomes. The ACLUSTER V2 software (Donner and Klar, 2000; Pinol and Piaggio, 2000) was used for performing the statistical inference.

In terms of comparability, the population size, number of workers and the TB-related variables on the intervention and control farms were similar at baseline (III).

Quality assurance was conducted using a random sample of 15% of the clinic-held patient sputum-smear laboratory results verified against data entries made in the TB registers. Validation of clinic-based data against central laboratory-based patient records indicated 100% correlation.

## **QUALITATIVE DATA: VALIDITY AND RELIABILITY**

Qualitative research methods were used to explore and understand how farmers perceived having a trained LHW on the farm, and to understand how LHWs experienced their role as farm LHWs (IV; V).

The reliability, validity and generalisability of results refer to the trustworthiness, authenticity, dependability and credibility of the findings. In other words, how 'true' the study findings reflect what really was found, and to what extent this corresponds to reality (Hallberg, 2002). These concepts are interwoven and cannot be separated from each other (Kwale, 1996).

A content analysis qualitative research approach was used to analyse and interpret the data using the verbatim transcripts that served as the data set for Papers IV and V. To ensure correctness and credibility and enhance reliability these transcripts were read by three different researchers for (IV) and by four different researchers for (V) (Mason, 1996).

Each researcher (of various backgrounds) individually read and reread the transcripts to familiarise themselves with the content, making annotations as they did so. Each researcher analysed the data independently; the data were then triangulated during group sessions, mapping and linking categories (Pope *et al.*, 2000). The transcripts were then cut and pasted and categorically indexed (Mason, 1996).

The summaries and selected quotes drawn from these themes were written up as results. The results of (V) were also presented to a group of five researchers at a peer review session; these researchers had either worked on the project or were familiar with it.

The generalisability of the study findings refers to the extent of the use of the finding beyond the studied group. Kwale (1996) refers to 'analytical generalisation' as a reasoned judgement of the extent to which the findings of one study could guide another study, based on an analysis of the different situations.

## RESULTS

A summary of the main results from the papers and respective studies included in this thesis is presented below.

### IMPROVED TB CONTROL ON FARMS WITH LHWS

#### NSP TB case holding significantly better

After a one-year period, amidst a health service contraction, the successful TB treatment completion rate (sum of patients who completed their treatment and were cured – see Box III) of adult NSP TB patients in the intervention group with trained LHWS on the farms was 39/47 (83%), compared to the control group's 27/42 (64.3%) (See Table III). This difference was significantly different ( $P = 0.042$ ). Farm, participant recruitment and follow-up data are presented in the CONSORT flow diagram (Figure IV). The estimated intervention effect is 18.7% (95% CI: 0.9% - 36.4%). The intra-cluster correlation for this outcome is 0.023 (III).

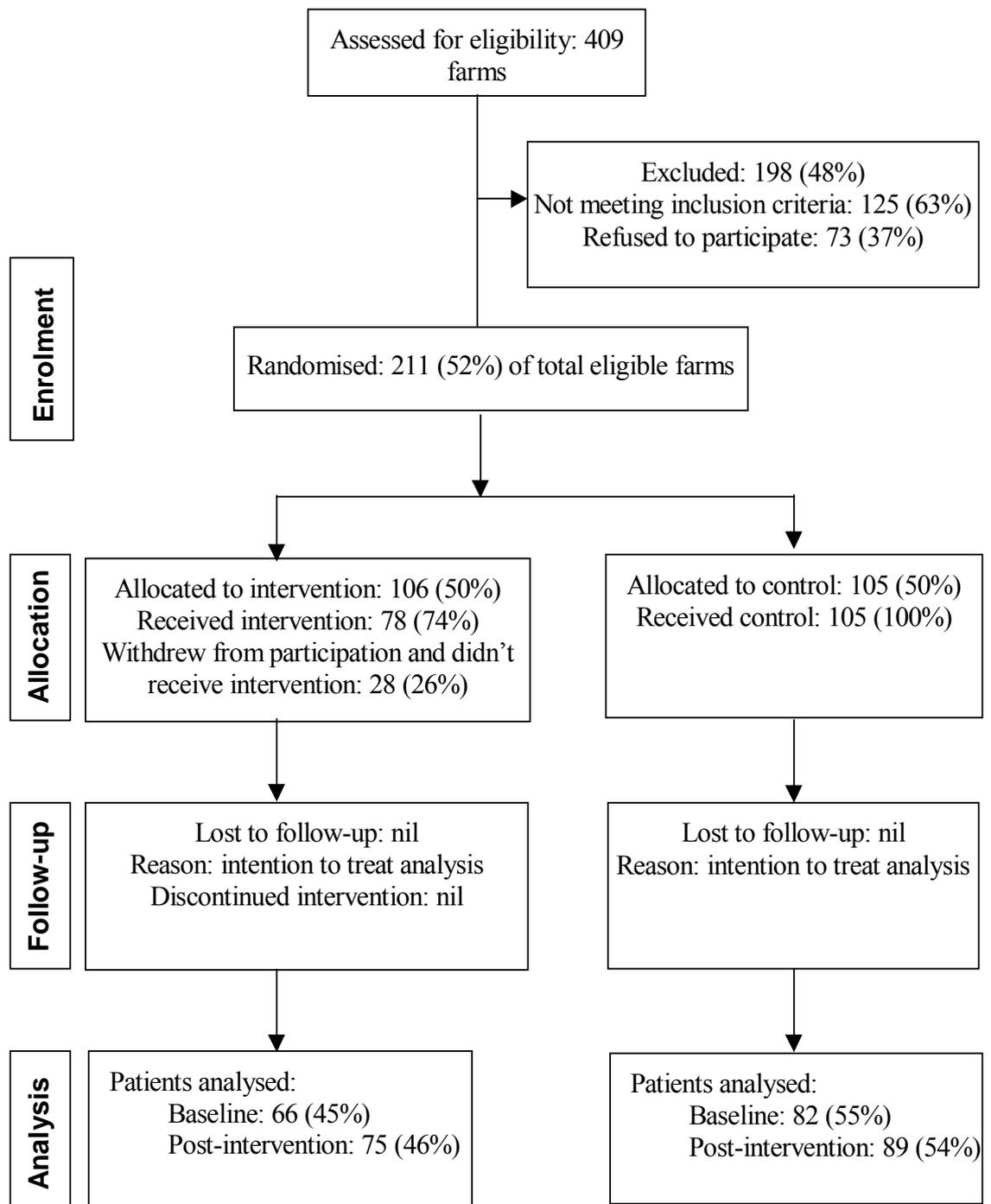
The successful treatment completion rate of adult NSP TB cases on intervention farms increased from 79% at baseline to 83%, while control farms experienced deterioration in the successful treatment completion rate, which dropped 15% from 79% to 64%. At baseline successful treatment completion rates in this population were not significantly different ( $P = 0.812$ ) (See Table III).

Post-intervention, the treatment interruption rates for the adult NSP patients were 4.2% in the intervention group and 26.2% in the control group respectively. The corresponding figures at baseline were 14.7% and 11.6% in the intervention and control groups respectively (See Table III).

**Table III. Adult NSP TB cases: Baseline and post-intervention comparisons – data on patient demographics and treatment outcomes**

Variable	Baseline			Post-intervention		
	Intervention		Total	Intervention		Total
	No.	(%)	No. (%)	No.	(%)	No. (%)
<b>Age groups (years)</b>						
15-24	5	(15)	11 (26)	16	(21)	8 (17)
25-34	15	(46)	15 (36)	30	(40)	15 (32)
35+	13	(39)	16 (38)	29	(39)	24 (51)
<b>Sex</b>						
Male	18	(55)	19 (45)	37	(49)	28 (60)
Female	15	(45)	23 (55)	38	(51)	19 (40)
<b>Total</b>	33	(44)	42 (56)	75	(100)	47 (53)
<b>Treatment outcomes</b>						
Cure	22	(67)	28 (67)	50	(67)	31 (66)
Completed	4	(12)	5 (12)	9	(12)	8 (17)
Interrupted	5	(15)	5 (12)	10	(13)	2 (4)
Failed	0	(0)	3 (7)	3	(4)	4 (9)
Transferred out	2	(6)	1 (2)	3	(4)	1 (2)
Died	0		0	0		1 (2)

**Figure IV: CONSORT Flow Diagram.**



### **NSP TB case finding improved**

The number of NSP TB cases at baseline and post-intervention was compared. On intervention farms 26/106 (25%) farms increased their case finding, compared to 18/105 (17%) control farms. This difference is not significant ( $P = 0.267$ ) (see Table IV).

**Table IV. Case finding per cluster (farm): NSP TB cases. \***

Study group	Less new cases		Same number		More new cases		Total	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Intervention	18	(17)	62	(58)	26	(25)	106	(100)
Control	20	(19)	67	(64)	18	(17)	105	(100)

\* Note: In both groups 59 farms had no new smear-positive TB cases over the study period.

### Overall adult TB case holding significantly improved

After a three-year period the overall adult TB treatment adherence rate was significantly better (15%) on farms that had participated (intervention group) compared to the farms that had not participated (non-intervention group) (RR = 1.19, 95% CI 1.08-1.31) (I). However, this study included a non-randomised sampling, which could have resulted in an over-estimation of the study results (I).

### COST-EFFECTIVE LHW INTERVENTION

The marginal time cost of diagnosis and clinical consultation in the public health sector for the suspected TB cases referred by the LHW (intervention farms) amounted to USD 9.12 per case, yielding a total marginal cost (private and public) per case of USD 21.80 for the cases screened in off-peak season or self-referred in peak season and USD 22.03 for cases not self-referred during peak season (VI).

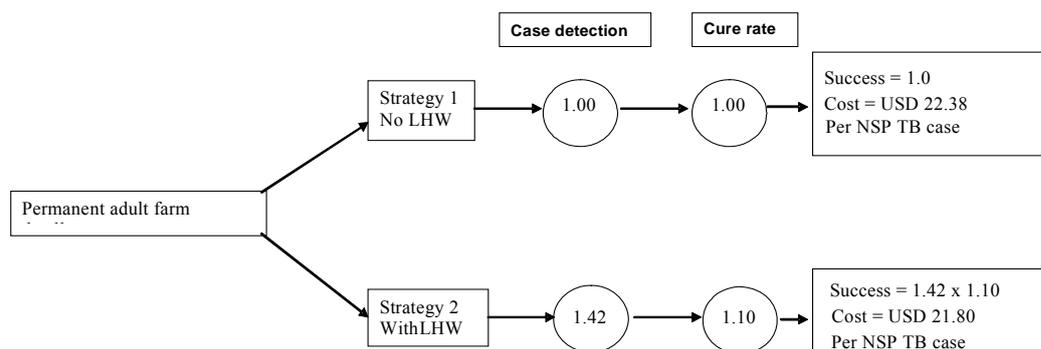
The marginal time cost of an NSP TB case on the non-intervention farms was USD 19.80 when no recall was required and USD 25.80 when recall was necessary. Recall was required in approximately 10% of the cases on the non-intervention farms, while it did not occur on the intervention farms. This yields a mean marginal time cost of USD 22.38 (19.80 + (10% x 25.80)) per NSP TB case on the non-intervention farms (VI).

The marginal time cost of the LHW to the farmer for screening, case finding, referral and treatment of an NSP TB case on an intervention farm amounted to USD 12.68 during off-peak season and for self-referral, and USD 12.91 when not self-referred during peak season.

The public health sector could potentially save 59% of their direct staff costs of clinic-based direct observation of TB treatment if TB patients who live on farms receive their treatment on the farm under LHW direct observation/monitoring instead of receiving direct supervision of treatment at one of the clinics. This saving is possibly underestimated, since only the direct staff costs were included (VI).

There is also the potential to increase NSP TB case finding by 42% and increase the cure rate of NSP TB by 10% if the momentum of the intervention can be maintained (III and VI). See Figure V.

**Figure V. Diagrammatic representation: NSP TB case detection and cure rate in the two alternative TB control strategies**



## PERCEPTIONS AND CONCERNS VOICED BY STAKEHOLDERS

### Farmers' perceptions

Farmers responded very positively to this project saying, among others, that: *“It means a lot”* and *“It was an outstanding achievement”*. The informants described the role of the LHW as more than just conducting TB work, and as *“taking a great deal of responsibility for the well-being of the families on the farm”*.

The community registered nurse responsible for implementing and coordinating the project appeared to be regarded as an icon in the area. The informants verbalised their appreciation of her and her team members. They expressed their appreciation for the community development efforts made to upgrade the community, which they thought were effective. Farm workers were encouraged to develop their own vegetable gardens, while women were taught the skills to produce a balanced diet for the family. The need for these initiatives was well recognised by the farmers, who commented: *“The nutrition of the family is often compromised by the need for alcohol”*. Employers also regarded the project as a way to deal with the minor ailments of their employees.

Farmers who agreed to participate in the RCT told us that their initial skepticism about participating in the intervention was curtailed because of their respect for the project leader and because the intervention was operationalised by the local public health authority.

Participants reported an increased level of productivity and decreased work-related absenteeism after the introduction of the LHWs. The farmers felt that having an LHW saved them time and money: *“I see a change in the productivity since having a lay health worker. Attention is given to each individual on the farm and they [the farm dwellers] are not seen as a group”*. Farm work is associated with a variety of occupational health and safety hazards. Physical injuries and exposure to chemical poisons are risks associated with the work, and LHWs are trained to deal with these

issues. One farmer commented: *“She is better equipped to deal with health issues on the farm than my wife or I.”*

Communication with the LHW increased the farmers’ insight into the health dynamics on their farm, and LHWs were able to use their knowledge of health issues to refer problem cases appropriately to local public health services. However, farmers felt that they had to be careful of being perceived as showing the LHW any favouritism, since this could lead to jealousy from other workers. This jealousy was a threat to the LHWs’ health functions, because it could result in the farming community being unwilling to co-operate. Any perception of the LHW benefitting from increased opportunities and an elevated relationship with her employer could lead to her social isolation. Farmers recognised the stress that LHW incumbents faced if other farm dwellers became jealous when they perceived the LHWs as having increased status.

The role of farmers regarding health and related issues on the farms changed, with LHWs acting as a ‘brokers’ between farmers and farm dwellers. The farmers appreciated and trusted the LHWs, relying on their judgement. Said one farmer: *“One of the benefits is that the farm has a contact person with whom you can discuss health issues and deal with them, as well as someone that gives you feedback on different health issues of the farm workers.”*

Farmers observed a number of changes in the individuals selected to act as LHWs. They commented on the LHWs’ increased self-confidence as they gained expertise in the health field. The farmers recognised that LHWs had developed the ability to communicate accurate and appropriate health information to them. The farmers also commented on a *“noticeable improvement”* in the quality of life of the LHW’s family; her home and its environs appeared cleaner and they frequently established a food garden, and became a *“role model in the community”*. The farmers reported that the LHWs brought the social needs of the farm dweller community to their attention.

### **Farmers’ concerns**

Farmers felt that their contributions, e.g. paying the LHW during their absence from work to attend training sessions, and their support of the LHW on the farm, were not acknowledged by the public health services. They would like the public health sector to recognise their contribution by, for example, *“fast-tracking”* cases referred by LHWs to the public health sector (hospitals and clinics).

Farmers reported two areas of concern: the possible over-burdening of the LHW and whether replacements could be found for current LHW incumbents should the need arise.

### **LHWs’ perceptions**

LHWs were enthusiastic about what their involvement in the project had meant to them. They expressed a humanistic motivation to do this work: *“It means a lot to me as I always want to help people. I feel so good that I have the chance to be of assistance”*.

At times being an LHW became problematic within the family dynamics. One participant described how her husband criticised her *“for speaking like that the white people”*, and especially because she discussed his alcohol problem with the employer.

LHWs gained insight into some of the psychosocial aspects of behaviour around illness, as one of the participants shared how workers sometimes pretended to have TB symptoms when they wanted advice: *“People always want to be sick to get some attention”*. The LHWs were insightful about familiar problems that could lead to non-adherence to TB treatment. The misuse of alcohol was the most common reason referred to as to why TB patients discontinued their treatment. The LHWs discussed these problem cases with the community nurse at the earliest opportunity.

The LHWs interviewed felt that their employers were supportive of their efforts. The continuous contact with the project team was particularly appreciated. They explained the process of weighing the TB patients and recording the results of the screening process. The community nurse reviewed these records each month. This continual monitoring of their work was important to them. Some did the weighing in their homes, during their free time: *“I see the people in my house, and that is difficult because it is a small place”*.

LHWs experienced their training as extremely positive and enjoyed it. They were grateful for all that they had gained. LHWs gained personally in terms of self-development and growth: *“I learned a lot that is also applicable in my personal life.”* LHWs reported learning skills that enabled them to assist their peers in managing their health, and this was perceived as important to the community. The informants described how the training process helped them to begin to understand unfamiliar concepts in detail: *“The training gave me a good idea of what to do. We weigh the people each month. If people have symptoms we then have them checked and then assist by administering the treatment”*. One LHW commented on how she appreciated understanding how her body functioned, while another described how she had been neglectful of her own TB treatment before her health care training: *“I have had TB twice myself, and I didn’t take the medication regularly. I didn’t realise how important it was”*.

Some LHWs suggested that there had been a measure of transfer of their skills to other people living on the farm. For instance, once they understood the aetiology of TB and the reason for the lengthy treatment period, they were able to transfer health knowledge to their peers. Through this interaction health promotion occurs, with LHWs teaching their communities about being healthy: *“It is mainly about health and how to live healthily, in your home, at the workplace and so on. This is how I explained it to them.”*

In terms of TB treatment, respondents related stories of how they stuck by patients who they thought had TB, convincing them to be tested and then staying with them through the process, and insisting on more tests if initial ones proved negative.

### **LHWs’ concerns**

Our data show that respondents wanted to do their best as LHWs, but in doing so had to pay a price. In one instance a respondent developed a better relationship with the farmer through the intervention, but was then criticised by the community because they thought that she *“thought she was better than them”*. Similarly, there was mistrust over the relationship between the nurses and the LHWs.

Other respondents spoke of how their families criticised them and did not understand what they were doing and why it took so long. There was acknowledgement

that being an LHW is difficult, with discussion on how they were torn between doing the job well, working full-time, and fulfilling their domestic responsibilities.

Most (95%) of the trained LHWs were women, and the multiple domestic, productive and community roles of LHWs frequently proved difficult for them. They reported that it was difficult to be an LHW on the farm. As a coping mechanism, they needed ongoing support from all the stakeholders.

However, LHWs also reported that they enjoyed being in a position to help their fellow community members, although they feared becoming overburdened by the demands put on them as LHWs.

## **TB HIGH-BURDENED TEMPORARY FARM WORKERS**

The NSP TB prevalence was 6/356 (1.7%) and the total TB point prevalence of the temporary farm workers (including the four self-reported cases) on the day of the study was 10/356 (2.8%). However, these figures exclude one respondent suspected to have TB, who refused to attend the on-site clinic facility for further diagnostic investigations. None of the four self-reported TB cases had their TB treatment clinic cards on their person, with a result that it was impossible to establish their TB type and treatment situation.

The self-reported TB cases indicated that they received treatment from a health facility outside the study health district. In terms of their access to treatment, one respondent indicated that his/her supply of medication was depleted, whereas the other three respondents indicated that they took the required treatment at home. All cases indicated that they were taking their treatment without the supervision of another person. Three of these respondents indicated that they sent family members to collect their treatment from the clinic within their communities. The remaining respondent indicated that someone who worked at the local clinic dropped the treatment off at his/her home.

We estimated the total TB point prevalence rate of 2809/100 000, with a 95% confidence interval of 1094 – 4524/100 000 among temporary farm workers. Further, the estimated TB NSP point prevalence rate was estimated at 1685/100 000, with a 95% confidence interval 348 – 3022/100 000.

## DISCUSSION

This is the first known RCT study evaluating the effectiveness of a farm-based LHW intervention, providing important data on an alternative TB management strategy among permanent farm dwellers in South Africa. (See III and Table I.)

As TB is a major health problem in South Africa and especially in this region, with projections of an increased incidence in correlation with the increasing prevalence of HIV/AIDS, it is important to test different approaches to TB management. Successful TB control depends on two essential functions - early detection, followed by effective treatment of infectious patients - to ensure a cure (Dye, 2000) (See Figure 1). The key indicator for success recommended internationally is the successful treatment completion rate in NSP cases (See Box III.)

Other studies found that it has become increasingly difficult to translate and implement joint TB and HIV/AIDS control strategies to work in a close relationship, especially in high-burdened rural settings (Harries *et al.*, 2005; Maher *et al.*, 2005). It appears that LHWs were able to assimilate and transfer their training into their cultural-social context, and in so doing satisfied public health's need for disease control.

It is becoming increasingly difficult to maintain the medical approach in providing public health care in sub-Saharan Africa. It seems that the comprehensive PHC approach suggested by King 40 years ago remains valid, and should be scaled up (King, 1966; Walt, 1990). Furthermore, the literature indicates that a strong public health sector is needed. Public-private innovative partnerships are encouraged in sub-Saharan Africa to strengthen the public health sector to be able to adequately meet health needs with the scarce resources available (Streefland, 2005).

## METHODOLOGICAL CONSIDERATIONS

This evaluation of the exploratory study (I) could not follow the methodological imperatives of a randomised trial, and therefore has potential inherent sources of bias in the study design. The TB data before 1993 were not of a quality to facilitate a before-and-after study design.

The study (III) followed a pragmatic, unblinded cluster RCT design. The unit of randomisation is the key feature of cluster randomisation since the cluster is different from the unit of analysis, as the individual subjects form the cluster (Hauck *et al.*, 1991). In this study each farm formed a cluster, the unit of randomisation. The TB patient enrolled into the study was the unit of analysis, analysed on an intention-to-treat basis (Newell, 1992). It was not feasible to randomise individual TB patients to receive the intervention for a number of reasons. Firstly, because access to the farm dwellers living on farms in the study area was dependent on the cooperation of the farmer. Secondly, the LHWs had to be trained before the study participants could be included in to the study, to ensure that the TB patients would be exposed to the intervention (Diwan, 1992). Further, contamination between the intervention and control study groups seemed unlikely for two reasons: the pattern of delivery of TB care in the intervention group required a trained LHW, and the intervention is fairly complex, involving in-depth training and support of the role players. Therefore, the intervention could not easily be transferred to farms in the control group simply by word of mouth.

Population size, the number of permanent farm workers, and the TB-related variables, i.e. TB patient categories, demographics and treatment outcomes on the intervention and control farms, were similar at baseline (III). At baseline 148 adult TB patients were resident on all 211 study farms: 66/148 (45%) lived on 46/106 (43%) of the intervention group farms and 82/148 (55%) lived on 50/105 (48%) of the control group farms. The intra-class correlation was 0.1 (III).

Cluster sampling usually gives estimates with larger standard errors than in simple random sampling, because the number of units in clusters tends to be more similar than units in general. The effective sample size is dependent upon the similarity of responses within clusters, measured in intra-class correlation. A cluster randomised design therefore requires more subjects to maintain the desired power than a simple randomised design (Hauck *et al.*, 1991). The unit in this trial was the adult TB patient living on a farm allocated to the intervention group of the study, rather than individual TB patients (once TB had been diagnosed) being randomised into either the intervention or control group of the study.

The design effect is defined as the ratio of units needed in cluster sampling to the number of units needed in simple random sampling to achieve the same precision. Design effect =  $1 + (m-1) p$ , where 'm' is the average number of units per cluster and 'p' is the intra-cluster correlation. The size of random errors in cluster sampling is increased with a factor that is the square root of the design effect compared to simple random sampling. If the clustering effect is not taken into account when analysing data, the *P* values will be too low and confidence levels too narrow. These increase the chances of misleading conclusions. For the estimates of successful treatment completion for adult NSP TB cases in this study, the design effect was 1.2 (Donner and Klar, 2000; Pinol and Piaggio, 2000) See Annexure IV. The design effect would not change the trend of results in this study, and the conclusions are valid for the particular clusters in the study.

We had to apply both qualitative and quantitative research methodologies in order to answer the question of whether or not the introduction of farm-based LHWs might be effective in terms of TB control on farms.

The purposive sampling that was done by the project manager to identify the key informants for the farmer in-depth interviews is noted as a possible study limitation.

The selection of the four study farms included in the TB point prevalence study among temporary farm workers in all likelihood created a bias in study. This because large farms are more profitable, pay higher salaries, employ fewer temporary workers and offer better access to health care; thus the study sample is likely to underestimate the proportion of temporary farm workers and the prevalence of TB.

## **COST-EFFECTIVE TB CONTROL ON FARMS**

A previous study concluded "if DOT can be achieved in rural South Africa with a scattered population, it can be achieved anywhere" (Wilkinson and De Cock, 1996). It would appear that this intervention realised this challenge, although it is a variation of the usual way of implementing DOT, inasmuch as TB patients were not randomised to receive DOT, they chose when to use DOT. Our study found that selected peers trained and supported as farm-based LHWs are able to have a substantial and statistically significant, robust, cost-effective impact on TB treatment

completion among permanent farm dwellers in the Cape Winelands of South Africa (III and VI; Figures IV and V).

This intervention achieved close (83%) to the WHO target of an 85% successful treatment completion rate for NSP TB cases. LHWs had a relatively respectable 4% treatment interruption rate for adult NSP TB farm dwellers, whereas the rate on farms without LHWs was 26% (III and Table III). Our study compares favourably with another of an LHW TB support programme in an urban setting outside Cape Town, where 19% of the NSP TB cases interrupted their treatment regimen (Sinanovic *et al.*, 2003). The successful treatment completion rate (83%) for NSP TB cases (Table III) also compares well with that of the other study, where 67% of the NSP TB cases successfully completed their treatment (Sinanovic *et al.*, 2003). Furthermore, the result in the urban setting was achieved at 30% of the costs of clinic-based DOT and based on the cost-effectiveness of that study; it was recommended that this intervention be replicated in similar settings (Sinanovic *et al.*, 2003).

In our study costs to the public health sector were USD 854 per LHW per year to implement, with 39 TB NSP cases successfully treated (Rörich, 2002; III). Our data show that these farm-based LHWs performed health-related work beyond TB care; it is therefore difficult to allocate a specific cost per NSP TB case successfully treated. However, our study resulted in a cost reduction of 59% of direct staff costs for the public health sector per NSP TB case cured on the farms in the intervention group, because farmers paid the LHW costs (VI). The external benefits/effects, including reduction of job absenteeism, are considered sufficient by the farmers to justify them paying for the LHW. Furthermore, our data and the other study undertaken in South Africa suggest that it would be a cost-effective investment for the public health sector, even if they were to fund the LHW costs (Sinanovic *et al.*, 2003).

Remuneration has been found to keep lay people motivated and to achieve sustainability (Kironde and Kahirimbanyi, 2002).

## **LHW: EMPOWERING ROLE**

Data suggest that LHWs transmitted the correct information about TB and the prolonged treatment period required in a manner that was culturally acceptable, using the appropriate language that led to TB patients being empowered to manage their own illness. Being informed, it appears that the patient was equipped to know when to interact with the LHW. Our data suggest that the TB patients and trained LHWs were able to move from the biomedical approach of the health care model to becoming empowered through understandable information being given to them. Other research found that effective health promotion leads to empowerment, which in turn involves a change of attitude of the patients and health professionals. Where patients become the experts in managing their own illness, and experts of their own lives, they consult medical professionals as experts in the medical field as a resource (Berger *et al.*, 1997).

Based on the qualitative data, it became obvious that the LHW incumbents came into their own, having become proud of themselves, their homes and environment. Despite the opposition and possible jealousy they might have to face from their peers, they continued to be agents of change on the farms where they live and work. All our information shows that this was extremely difficult, emphasising the imperative role of

ongoing support and trust between the project team and the LHWs. However, the amount of funding that this phase of the project absorbed was incongruent with the effort it required to keep the LHWs motivated and focused. (See Figure II.)

### **TB as a chronic disease**

In many TB high-burden settings, where there are high rates of TB/HIV co-infection, low treatment adherence seems commonplace (WHO, 2003 (a)). This makes one reconsider the provider-client relationship, towards viewing TB more as a chronic condition (WHO, 2002). The medical approach to health care is geared to address acute episodes of ill health, taking the shortest and most effective, evidence-based route to cure the condition, with the patient taking a passive role in accepting instructions from the health professionals to ensure cure. However, managing chronic illnesses require a paradigm shift to enable patients to participate in managing their condition, using health professionals as a resource to clarify issues pertaining to their illness when needed. Similarities to the process of empowerment are noted.

The chronic-care model emphasises client perspectives of their condition, client self-management, continuous quality improvement and collaboration that is flexible to suit the needs of the patients, in addition to the elements of the health system organisation already included in the DOTS strategy (Wagner, 1998; WHO, 2002). Further, it appears that sections of the chronic-care model were successfully transferred into a resource-poor setting (Bodemheimer *et al.*, 2002). The question is whether the chronic-care approach could be implemented within the context of a high TB/HIV/AIDS burden and the constraints that sub-Saharan Africa offers (Swartz and Dick, 2002). Our data suggest that the training and support components of this intervention prepared the LHWs to monitor, support and guide TB patients in practical ways to realise successful treatment completion. In addition, this achievement was cost-effective.

A more flexible and patient-centred approach to DOTS expands the debate beyond simplistic and polarised discussions about the effectiveness of DOTS to seeking ways to support patients during protracted treatment regimens (Garner and Volmink, 2003; Marq *et al.*, 2003). This support need not be dictated in a rigid manner, but should be tailored to the local context and the needs of specific patients. This approach would support aspects of the chronic-care model.

### **COMMUNITY PARTICIPATION**

All stakeholders appeared to be in support of the intervention, displaying a level of 'ownership' of the process (I, IV and V). This intervention started with a request from the community, indicating some level of community involvement and participation before the implementation. However, data indicate that having an LHW improved community participation on the farms, particularly for farmers, who became more informed and aware of the needs and life experiences of the farm dwellers that have lived on their farms for generations. Because of this, communication between employer and employees improved on the farm; the LHW becoming a 'broker' between the employer and the rest of the members of the community. The concept of 'broker' was recorded in Vietnam, where previous TB patients created informal structures within their communities, advising TB patients on the disease and on what treatment involves (Johansson and Winkvist, 2002).

Intersectoral collaboration is noticed, inasmuch as LHWs interact with the clinic staff. It would appear that LHWs in this project were able to incorporate community level issues pertaining to the ‘pillars of PHC’, i.e. community participation and intersectoral collaboration towards more equitable health care (Macdonald, 1992) for permanent farm dwellers.

Our data reflect that these farm dweller communities lived in poor socio-economic conditions, with evidence of alcohol abuse and related domestic and health effects. LHWs displayed an understanding of the social dynamics on the farms and also knew where, when and how to provide TB and other support and follow up. For instance, we note that they monitored TB treatment adherence as direct observers in about 50% of the cases (III and V).

LHW inputs went beyond just TB treatment adherence, since it was noted how they attempted to address social and living conditions on the farm by becoming a role model and example, while possibly being ridiculed for it. The adult peers selected the LHWs whom they trusted and in whom they saw the potential, ability and character to guide them to become healthier. They perhaps did not realise at the time that it would challenge some of their social and living practices, and call for a fundamental change in the way they lived. Despite these difficulties of trying to bring change to the community, balancing the needs and demands of their families with those of the community, these LHWs continued to promote community participation and deliver cost-effective TB health care.

During the intervention other positive spin-offs were observed: improved social conditions, reduced alcoholism, less violence and an increase in out-of-work activities, e.g. sports and gardening. Other available data suggest that LHWs have the potential to implement DOT cost-effectively (WHO, 2003 a).

## **EMPLOYER POSITION**

Farmers reflected their understanding of the complexities of the LHW situation in the community and the possibility of them becoming over-burdened. However, they appear rather unsure of how to address these problems. These export farmers are required to comply with regulations governing worker health and social well-being, and LHWs assist farmers in their efforts to improve the health and welfare of the workers, thereby contributing to more effective and profitable production. Farmers recognised that this intervention is financially mutually beneficial to both the business and the workforce in direct and indirect ways.

These employers accepted the input required from them, making their resources available and providing an infrastructure on their farms, but in return they expect recognition from the public health sector through fast-tracking of cases referred to the clinics and hospitals by the LHWs (V). This request seems reasonable, given the potential gains to public health. Furthermore, it seems that this model adds to the debate on developing a model for TB management in an occupational setting among farm dwellers in South Africa.

This intervention could become a unique private/public partnership, where the LHW employment could become sustainable without being an additional burden to the already cash-strapped public health sector.

It is further noted that farmers verbalised their concern that the LHW might become over-burdened by having to deal with the multiplicity of tasks and expectations of the farming community, clinic nurses and employers.

## **LHW POSITION**

Our data indicate that this was not an easy road for the LHWs to travel. Although LHWs enjoyed the training and found the work rewarding, as well as having their life world grow beyond the borders of the farm, it seems debatable whether they would have been able to cope without the ongoing support they received from the project team (V and Figure II). Even so, these LHWs were able to assimilate and transfer their training into their cultural-social context, and in so doing satisfied the need of public health for disease control. It seems that the LHWs were able to make DOT physically, socially and economically accessible to TB patients (Hurtig *et al.*, 1999).

The tasks of the LHWs (95% of whom were women) were additional to work they were already involved in. The LHWs also became aware of possibly becoming over-burdened. Literature shows that it is the families of women who care for others, even when they themselves are overburdened, that carry the cost (Friedman, 2003).

Studies found women are reluctant to admit to ill health, should it disrupt their care giving or domestic tasks, especially if they believe their value lies in their capacity to perform these duties. This perception is more evident in rural settings, where women are involved in a multiplicity of tasks (Sen *et al.*, 2002). Ignoring the complex situation of rural women may inadvertently exacerbate gender inequalities and reinforce the notion that they are only valued as mothers and caregivers.

It would appear that much of the cost was not in terms of financial expenses, but rather time and effort borne by the LHW incumbents and their families.

## **TB CASE FINDING**

Case finding activities should only start once a low treatment interruption rate is achieved to prevent secondary TB cases from developing (Helbling, 2003). In this study we found improvements in both NSP TB case detection and case holding that will have a multiplying effect, in addition to the cost savings we observed (Figure V and Tables III and IV). This intervention was able to identify further infectious sources of TB that were previously unknown to the health services, by doing voluntary monthly weighing of all adults (III and Annexure II). Although the number of cases found was not substantial, the positive trend in case finding is significant (Table IV). The improved case holding will have secondary preventive effects. It is estimated that between 10-15% of secondary TB cases occur per primary case left untreated: five new secondary infections every six months (Walker, 1999).

If the observed average improvements in case detection and case holding are sustained during an expansion of the intervention, it will lead to a reduction of multidrug-resistant TB, with potentially huge cost savings. Each case of multidrug-resistant TB costs up to USD 2585 in drugs alone (Pharmacy services: Provincial Administration Western Cape, 2004). South Africa is in the midst of a maturing HIV/AIDS epidemic. As the HIV epidemic unfolds in the Western Cape, a 10% increase in recurrent TB and more drug-resistant TB cases are expected (Weyer *et al.*, 2003).

## **RESULTS POSSIBLY UNDERESTIMATED**

Our results may underestimate the intervention effect, as only 74% of the farms that agreed to participate in the intervention had an LHW trained (III). However, it may be close to reality, in that other studies found that it could be expected that only a quarter of those aware of an innovation would actually assimilate the change (Rogers, 1995).

## **IMPLEMENTING AN INNOVATION**

We observe that this achievement did not come about easily; rather, it required that health system management take the risk of implementing this intervention that they believed could be effective in TB control on farms (I). The fact that the concept and the planned intervention were piloted served as preparation for the health system towards them being ready to implement and disseminate a 'system-fit' innovation onto the study farms (Greenhalgh *et al.*, 2004). However, these studies strongly suggest that the project champion played a vital role in ensuring successful implementation (I, III, IV and V).

Data strongly suggest that the implementation of this innovation required active involvement of farmers and LHWs. Further to this, it would appear that the feasibility to disseminate this innovation depends on the public health sector being able to give farmers and LHWs appropriate acknowledgement for their contributions.

## **FARM WORKER PROFILE CHANGED**

We noted that our target audience changed - permanent farm workers may have become less important in the bigger picture of farm labour, with the relative increase in temporary farm workers on farms. Legislative changes since the transition in 1994 resulted in an ongoing trend where farmers decreased their permanent work force and increased their use of temporary workers (Van Rooyen *et al.*, 1998). Very little has been published on this high-risk subset of the community, although a survey in the USA (1985-1989) found the prevalence rate of TB infection among migrant workers to be 57% (Hibbs *et al.*, 1989). The disease profile is also changing, with HIV/AIDS-related issues becoming a reality as the epidemic unfolds.

In our study we found a TB point prevalence rate among temporary farm workers that was twice that of the health district (II). Effective TB case management of this high-risk group presents a special challenge to the public health community, since the nature of temporary employment in the agricultural industry makes it difficult for these workers to access TB health care. It appears impossible for this group to receive clinic-based TB DOT near their homes during their period of employment, since their work hours are similar to those of the clinics.

Studies done in a rural community in the Northern Province of South Africa, where the families of predominantly temporary workers live, found that there is a considerable delay between the onset of TB symptoms and the start of treatment. This study also discovered that for every nine sputum-positive TB cases, there were two further undiagnosed cases of TB in the community (Pronyk, Makhubele *et al.*, 2001; Pronyk, Joshi *et al.*, 2001). Data suggest that the passive case finding aspect of the DOTS strategy might not be sufficient to identify active cases of TB at an early stage of the disease for all (Long, 2000; Hoa, 2004). Available information strongly suggests that

an active TB case finding system for temporary farm workers would be worth investigating given the HIV/AIDS/TB epidemic.

## **SOME LESSONS LEARNT**

Community-based projects cannot be left to run on their own, since they require high levels of professional support and control. Innovations should not occur faster than the public health sector can provide the necessary trained personnel and support structures.

However, successful LHW interventions should not be seen to replace the role of the public health sector; rather, this intervention has the potential to free up some of the time of health professionals who can use their expertise to reach people with quality care.

The underpinning principles of the exploratory project (I) continued throughout this study, while the pivotal role of the champion and the need for resources to implement and sustain this process become obvious. The increasingly powerful role played by local politicians has been noted. This might influence the level of community participation.

Implementing this innovation took high levels of energy and dedication amid ongoing political changes and health service restructuring. We observed that the top-down approach to health care switched to become bottom-up during the course of the project; what started with a health focus became a workers' rights project. The initial aim to improve the health status of permanent farm dwellers appears to have become distorted by politicians inadvertently undermining the input of the different stakeholders. We observed that a distortion of this model (Dick *et al.*, forthcoming) could change the focus of such an intervention. This seems to be one of the risks of such projects, although it might have positive effects for the farm dweller communities.

Participants in this project volunteered their involvement, making the project management complex. We observed that farmers acted as gatekeepers to the permanent farm dwellers; therefore access depended on the farmers' goodwill. The emergence of 'agri-villages' for farm workers, enabling them to live in off-farm premises, should solve the problem of access (Vink, 2003).

Often LHW programmes are criticised for not being effective, but the lack of robust evidence is not sufficient reason not to develop policy for LHW interventions (Lewin *et al.*, 2004). This study provides evidence-based data towards developing context-specific (Collins *et al.*, 2002) policies that should involve various decision makers at national level within health, economics and national TB control sectors. Policy recommendations have been formulated towards including community contributions to TB care (WHO, 2003 (a)).

Available data indicate that funding would be required to implement this innovation. Given the context and the cost-effectiveness of this intervention, it might be possible that funding could be obtained from the global fund, earmarked for proven cost-effective health interventions to complement and strengthen public health systems to achieve the set Millennium Development Goals (Brugha *et al.*, 2004).

Despite the participatory nature in which this LHW intervention developed, its sustainability is threatened as resources are continually being withdrawn from the

public health sector because of the restructuring of the health services. The LHW intervention is complementary to a PHC care service which is efficiently managed, but if depletion of the public health sector continues, this intervention would collapse. Secondly, politicians may use successful community-based interventions to further their own situation. Should the LHWs be utilised as political advocates, it may result in the intervention becoming a vehicle of political expediency (Dick *et al.*, forthcoming).

Reflecting on the data from these studies, it seems clear that this simplified, context-specific community participative intervention was cost-effective in TB control among permanent adult farm dwellers, providing an alternative TB management strategy for them.

Can our findings be applied more widely in the commercial agricultural sector of South Africa? The LHW model has been rigorously evaluated using an RCT; also the perceptions of those involved were evaluated using qualitative research methods, providing insight into the process required to successfully implement this strategy in a sustainable way. The LHW strategy has proved affordable within current cost constraints, and is acceptable within the current infrastructure. It therefore offers hope, being a strategy to cope with the expected increased TB caseload as the HIV/AIDS pandemic unfolds. Cost-effectiveness analyses form only part of the decision-making process. Policymakers might consider incorporating aspects of these findings; however actual implementation would need to be guided by local circumstances. One must remain mindful that inefficient allocation of scarce resources exacts a very severe penalty in terms of forgone health benefits in rural areas with high TB prevalence.

Our study points a way to a more cost-effective TB strategy to improve health and survival in resource-poor settings. How ethical would it be not to replicate this intervention on farms in South Africa, knowing that it is cost-effective - not forgetting the contributions made by these LHWs, whose remuneration and access to appropriate resources need to be addressed with urgency at policy level?

## CONCLUSIONS

This research conducted on permanent farm dwellers shows convincingly that resident, trained LHWs on farms, in conjunction with the public health sector, have the potential to substantially enhance TB control activities on farms and in similar community settings. Pivotal for success are political commitment, a dedicated project champion, an adequate budget and adoption by the health service system and other stakeholders. Provision of choice regarding TB DOT to permanent farm dwellers was well received by all the stakeholders, with significantly better successful treatment completion rates among NSP TB cases.

Further, we conclude that:

1. Farm-based LHWs, working in conjunction with the local TB control programme, enhance community participation, are cost-effective, supplementary, and able to extend but not to replace the activities of the public health sector;
2. A champion is needed to drive the intervention, together with a dedicated budget;
3. An intervention such as LHWs is not a quick-fix solution for a complex problem such as TB control on farms. Rather, it appears that an overall significant TB treatment adherence, among adult patients, was reached only after three years, although a significantly better case holding among NSP TB patients was observed already after a one year period;
4. This intervention is beneficial to the farm dwellers, farmers, public health sector and the larger community in terms of TB control;
5. LHW incentives/employment status in this instance is not a concern of the public health sector but rather of the farming fraternity, making this intervention more likely to be financially sustainable. However, the farming community needs to be recognised by the public health sector for their contribution to health care,
6. This project has the potential to be used or diverted for purposes of political expediency;
7. Temporary farm workers remain a subset in the community at high-risk of being infected with and developing overt TB without being identified and treated at an early stage of the disease having no access to TB care at their place of work; and
8. This project could become a model of a public/private partnership in an occupational setting in the agricultural sector.

## RECOMMENDATIONS

Based on the study, the following are recommended:

1. That this research be enhanced by evaluating whether the effect of this intervention could be maintained beyond a one-year period.
2. That policy recommendations, as proposed by the WHO's *Community Contribution to TB Care: Practice and Policy*, be discussed towards formulating context-specific policies for TB control among permanent farm dweller communities. These policies need to address the legal status, the scope of practice, and the principles of remunerating LHWs.
3. That project innovation champions are sought and/or developed and funding is allocated to expand this intervention onto more farms where the health system organisation is ready to take the risk to disseminate this innovation.
4. That further studies be conducted to determine the health care-seeking behaviour among temporary farm workers and to develop a 'system-fit' innovation to address their need for TB care.
5. That given the urgency and severe consequences of the HIV/TB co-infection in hard-to-reach subsets of the community, the search for other viable innovations be encouraged and facilitated by governments and the health fraternity.

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