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TUBERCULOSIS SURVEILLANCE IN CAPE TOWN, SOUTH AFRICA: EVALUATION AND DEVELOPMENT OF A TRIAL PROTOCOL

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Thesis submitted to the School of Graduate and Postdoctoral Studies Research in partial fulfillment of the requirements for the MSc degree in Epidemiology

Epidemiology and Community Medicine

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Abstract

The need to consistently evaluate surveillance systems is vital; without periodic evaluation, decisions informed by surveillance information may be based on incomplete or erroneous data. This evaluation of Cape Town's tuberculosis surveillance system was based on the CDC's *Updated Guidelines for Evaluating Public Health Surveillance Systems*, modified to reflect the specific context of a high burden of tuberculosis in a Middle-Income country, and emphasizing the importance of public health action that is informed by surveillance data. Findings indicate that: limitations regarding tuberculosis-human immunodeficiency virus as well as drug resistance data exist; increased availability and integration of electronic data would enhance the assessment of control efforts; and that system operations could be improved by increasing software flexibility. The development of a protocol for a trial of system changes builds upon the findings of the evaluation, and applies a logic model and an ecological health model to inform the trial design.

Executive Summary

Objectives:
1) To evaluate the current tuberculosis surveillance system used in Cape Town, including assessing how the system is perceived by its users, and identifying areas that need to be revised, added or removed. 2) To develop a protocol for a study that will aim to address a key issue identified within the program evaluation.

Methods:
1) The evaluation of tuberculosis surveillance was based on the CDC's *Updated Guidelines for Evaluating Public Health Surveillance Systems*. These guidelines were modified both in terms of elements specific to the context of tuberculosis in a developing country, as well as to increase emphasis on particular components that the CDC's *Guidelines* do not necessarily stress. These modifications included assessment of the extent to which TB data is integrated with HIV data, data regarding appropriate action for TB/HIV co-infected patients (e.g. VCT, HIV treatment follow-up, etc.), contact tracing, public health action informed by TB data, and qualitative assessment of system user perceptions. Specific evaluation questions within the three broad fields *structure and organization of the system, system performance,* and *system-informed action* were identified and addressed. Data collection sources included qualitative interviews with TB nurses, health information officers and TB coordinators; the Electronic TB Register and its paper forms; National TB Control Programme and WHO TB documents and guidelines; and personal communication.
2) Based on outcomes of the evaluation, the protocol was designed to produce a trial that would answer the research question: **does the mode of delivery of surveillance system changes improve user acceptability of these changes and satisfaction with the system itself?** A logic model was employed to demonstrate the hypothesized steps between user acceptance and satisfaction (the primary outcome of the trial) and clinical TB outcomes: treatment success and mortality rate (secondary outcomes). The intervention within this protocol was the mode of delivery of system changes, and the PRECEDE-PROCEED model was used to develop this intervention using a participatory approach.

Results:
1) System users were very accepting of Cape Town's TB surveillance system as a whole, and were committed to seeing it achieve its purpose within the broader public health context. Some individuals expressed concerns about the rigidity of the Electronic TB Register software and its analysis capabilities. Furthermore, some were frustrated with the limited extent to which their feedback about these issues was heard. Integration of TB and HIV data is currently poor, and elements of multi-drug resistant tuberculosis surveillance should be strengthened; the South African Tuberculosis Control Programme is currently developing initiatives to improve these areas. Electronic integration of data within the system itself – that is, networking databases so that access to a larger volume of TB data at regional, provincial and national levels is greater – would increase the capacity for evidence-based control and prevention decisions to be made. Lastly, dissemination of TB data and data-based action within the Cape Metro region are strong attributes of Cape Town's TB surveillance; there is ample communication and interaction between users at various levels of the system, which is key to ensuring that surveillance data is applied.

2) Because of the population of interest – TB surveillance system users – and the nature of the intended intervention, it was determined that the trial protocol developed should be a cluster-randomized trial, employing matched-pairs. The primary outcome was user acceptance and satisfaction with system changes, and the secondary outcomes selected were treatment success and mortality rate. Developed through the PRECEDE-PROCEED model, the areas of consideration of the intervention were identified as analysis and dissemination of data; data capture; and clinical practice, and specific intervention targets were identified as adequate training and explanation of rationale for system changes; perception that feedback is heard; timing of system changes; and access to resources for assistance. F.AT.E. is the acronym chosen to capture these targets: **F**eedback is taken into consideration; technical **A**ssistance is easily accessible; **T**iming of system changes considers system operations and user deadlines; and a comprehensive **E**xplanation regarding the role of changes in system improvement is provided.

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Dedicated to the memory of Dr. Andréa Toepell,

for her inspiration and infectious enthusiasm

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List of Abbreviations

AFB	Acid-fast bacilli
ANOVA	Analysis of variance
BCG	Bacille Calmette-Guérin (immunization)
CDC	Centers of Disease Control and Prevention (United States)
CIHR	Canadian Institutes of Health Research
COD	Cause of death
CONSORT	Consolidation of Standards for Reporting of Trials
DHIS	District Health Information System
DOTS	Directly-observed treatment, short course
F.A.T.E.	Intervention: **F**eedback; technical **A**ssistance; **T**iming of changes; comprehensive **E**xplanation
EPT	Extrapulmonary tuberculosis
ETR	Electronic tuberculosis register
HCW	Health care worker
HIO	Health information officer
HIV/AIDS	Human immunodeficiency virus/Acquired immunodeficiency syndrome
ICC	Intraclass/intracluster correlation coefficient
ICD	International Classification of Diseases
IUATLD	International Union Against Tuberculosis and Lung Disease
IWS	Index of Work Satisfaction
MDR TB	Multi-drug resistant tuberculosis
MSAT	Multi-Sectoral Action Team
NGO	Non-governmental organization

NHISSA	National Health Information System of South Africa
PDR	"Plan, do and review" meeting
PVP	Predictive value positive
RCT	Randomized controlled trial
TB	Tuberculosis
VCT	Voluntary counselling and testing
WHO	World Health Organization
XDR TB	Extensively drug resistant tuberculosis

Chapter 1: General Introduction

1.1 Rationale

Surveillance is a fascinating, often behind-the-scenes, component of public health. So many of the prevention and control decisions that impact community health are based on surveillance data or comparable health information, and as long as a system is performing as it should, surveillance may not immediately come to mind as a core element of public health.

Often considered a disease of the past in Western nations, tuberculosis (TB) is very much a threat to health both in industrialized countries (often in immigrant and aboriginal populations), and to a much greater extent in the developing world. The enduring HIV pandemic and proliferation of drug-resistant strains of tuberculosis have only served to exacerbate the threat and complicate prevention and control efforts. This thesis was developed out of an appreciation of the importance and severity of these two distinct public health issues, and explores their interrelatedness. The first component of the project is an evaluation of TB surveillance in the Cape Metro Region of South Africa's Western Cape Province, followed by the application of the PRECEDE-PROCEED model to develop an intervention based on needs identified in the evaluation. The third component is the development of a trial protocol, based on this intervention. This aspect of the thesis demonstrates an approach for improving user acceptance through system change. The study population is comprised of individuals who are regularly involved with tuberculosis data collection and analysis (nurses, health information officers (HIOs), and TB coordinators), and the intervention is the mode of delivery of tuberculosis surveillance system changes. The primary outcome considered is user acceptance of and satisfaction with system changes, and a group of health workers, health

information officers and TB coordinators who receive system changes in the typical manner will serve as a control.

1.2 **Objectives**

1. To perform an evaluation of the current tuberculosis surveillance system used in Cape Town, including assessing how the system is perceived by its users, and identifying areas that need to be revised, added or removed.
2. To develop a protocol for a study that will aim to address a key issue identified within the program evaluation.

1.3 **Thesis Layout**

The thesis is organized into five chapters, the first of which is this introduction, and the last is the conclusion. Chapter Two provides a background on the transmission, epidemiology, diagnosis and treatment of tuberculosis, and outlines the role of surveillance and the importance of evaluation. It subsequently describes the process followed and the results of an evaluation of Cape Town's surveillance system, including qualitative interviews with system users from various levels of surveillance. Lastly, based on the findings of the evaluation, recommendations for system improvement are presented. Chapter Three draws on insights gleaned primarily from the qualitative component of the evaluation, regarding the way in which system changes are approached and implemented, to describe the development of an intervention to improve user satisfaction with and acceptance of system changes. Chapter Four outlines the development of a trial protocol to examine effects of this intervention.

Chapter 2: Evaluation

This chapter describes tuberculosis and its context in Cape Town, South Africa, and outlines the evaluation questions that were drawn from the Centers for Disease Control and Prevention's *Updated Guidelines for Evaluating Public Health Surveillance Systems.* The evaluation process is described, followed by the evaluation of findings and a summary of the recommendations for strengthening surveillance.

2.1 **Background**

2.1.1 **Tuberculosis**

2.1.1.1 **Introduction**

Tuberculosis is a communicable disease caused by the bacterium *Mycobacterium tuberculosis*, for which human beings are the only reservoir (1, 2). Other bacilli in the genus *Mycobacterium* can also elicit morbidity in humans; e.g. *Mycobacterium bovis* primarily infects cows, but can lead to extrapulmonary tuberculosis in humans when unpasteurized milk is consumed, and *Mycobacterium leprae* is the bacillus responsible for leprosy (2). The most common and severe form of *M. tuberculosis* is pulmonary tuberculosis, which affects the respiratory system and is transmitted from person-to-person by the inhalation of droplet nuclei expelled from infected individuals during talking, singing, sneezing or coughing (3, 4). Extrapulmonary tuberculosis (EPT) is much less common and is not infectious unless the individual is also infected with active pulmonary tuberculosis (5). Tuberculosis can spread to any part of the body to cause EPT; the pleura, lymph nodes and spine are commonly infected in these cases. Disseminated, or miliary, tuberculosis describes ETP that is not limited to a single body site (6, 7).

Approximately ten percent of healthy individuals infected with *M. tuberculosis*

– latent tuberculosis – will go on to develop the active form of the disease at some point in their lifetime; TB only causes illness and is transmissible to others in this active stage (3). Immunocompromised individuals infected with TB have a greater than ten percent chance of developing the active, communicable form (3). It is important to differentiate between active tuberculosis – TB disease – and latent tuberculosis.

2.1.1.2 **Transmission**

Exposure to droplet nuclei is required for transmission of *M. tuberculosis*. As a result, close contacts of an individual infected with active disease are at highest risk of becoming infected themselves. *Close contact* entails prolonged or recurrent contact, most often experienced by household members, coworkers, friends or family members (3). Again, contacts infected with the tuberculosis bacterium will not necessarily develop the active disease. On average, an untreated individual with active disease can infect ten to fifteen other people per year (8).

There are a number of molecular and environmental factors that relate to transmission of and subsequent infection with tuberculosis disease. The number of droplet nuclei expelled into the air by an infected individual, the concentration of these organisms in the air (which is influenced by the volume of space into which the organisms are expelled, as well as the ventilation of this space), the exposure duration (that is, the length of time an individual is in the space inhaling the organism), and the virulence of the strain of tuberculosis, all play a role in the likelihood that exposure to an infected individual will lead to tuberculosis transmission (3, 5).

Symptoms experienced by patients with active pulmonary tuberculosis include persistent coughing for several weeks, bringing up sputum (with or without blood), weight loss, loss of appetite, fever, fatigue, night sweats, chest pain and shortness of breath (9).

2.1.1.3 **Tuberculosis Epidemiology**

Over a decade ago, the World Health Organization (WHO) identified tuberculosis as a global health emergency (10). Since that time, tuberculosis has continued to pose a significant threat to global health, infecting eight million individuals with active disease and killing two million every year (11). Approximately one third of the global population is infected with latent tuberculosis (12).

The global burden of tuberculosis is carried predominantly and disproportionately by low- and middle-income countries; the highest rates of new infection as well as prevalence are in Africa, South-East Asia and the Western Pacific (8). About 80-90% of active TB cases occur in individuals between 15-49 years of age – the working population (4).

TB morbidity and mortality trends persist despite the implementation of the WHO-endorsed DOTS (directly-observed treatment, short course) program, which is an attempt to improve cure rates and curb the development of drug resistance by having patients receive all treatment in the presence of a health care worker or member of the community (13).

Within South Africa, as globally, tuberculosis is certainly a disease of the poor. The risk of developing TB in South Africa is highest among those who live in poverty. People who live in crowded, poorly ventilated homes or who have been incarcerated are more likely to be exposed to tuberculosis (14), and factors such as positive HIV-status, malnutrition, drug and alcohol abuse and mining work – all of which are correlated with low socioeconomic status – increase the likelihood of development of active TB disease (4, 15, 16).

2.1.1.4 **Diagnosis and Treatment**

Left untreated, approximately fifty percent of individuals with active tuberculosis will die within two years (4). The case fatality rate is much higher among HIV-positive patients (11). Conversely, once a treatment regimen has been started and adhered to, infected individuals will experience relief from their physical symptoms within weeks, and will cease to be infectious usually after a few weeks (5).

There are several approaches used to diagnose tuberculosis. As described in the sections below, the applicability of each depends on the population, type of tuberculosis, and patient characteristics involved.

In areas of low tuberculosis prevalence, a tuberculin skin test measuring hypersensitivity to a tuberculin purified protein derivative is the first stage of tuberculosis diagnosis. A reaction to this intradermal injection indicates exposure to tuberculosis, but exposure may be a result of Bacille Calmette-Guérin (BCG) immunization[1] or latent tuberculosis infection, and further testing is required to diagnose active tuberculosis disease (5). In areas of high tuberculosis prevalence, skin tests are not informative because of the large proportion of people with latent tuberculosis infection who will have a positive test. Additionally, as a result of immunosuppression, skin tests may yield false negative results for individuals with HIV (5, 18).

In areas where tuberculosis is widespread, sputum microscopy is the primary, and most cost-effective, diagnostic technique (19). In a clinic (and usually a second time at home the following morning), tuberculosis suspects are asked to produce a sputum sample, which is sent to a laboratory for smear microscopy (5). The appearance of acid-fast bacilli (AFB) in a suspect's sputum smear reveals that he or she has active

[1] BCG vaccination is recommended for children to protect against severe types of childhood tuberculosis, but its efficacy in protecting against adult pulmonary disease is inconsistent (17).

tuberculosis (5). The absence of such evidence, however, is not an absolute indication that an individual is negative. The sensitivity of the AFB smear test can vary greatly, and has been estimated to be between 50-80%, a value that increases with the number of smear tests performed (20, 21). Many more acid-fast bacilli are necessary to detect tuberculosis with a smear test than a culture, so in cases of paucibacillary tuberculosis – in which a patient's sputum has few bacilli – results are likely to be smear-negative (20). The occurrence of smear-negative results is particularly problematic in areas with high TB/HIV co-infection rates; HIV-infected tuberculosis patients often have fewer bacilli in their sputum (5).

While much more sensitive than smear microscopy, culture testing for tuberculosis is also a more expensive approach to diagnosis, and requires a long period of time to produce useful results (20). It should be used in cases where tuberculosis is suspected on clinical grounds but smear tests have been negative, as well as for patients for whom drug susceptibility testing is required to detect multi-drug resistance, including retreatment cases and patients with unsuccessful courses of treatment (5).

Chest radiography, in which an X-ray is examined for lesions on the lungs, is another diagnostic technique. Despite being a quick test, the use of chest X-ray also has many limitations. There are many conditions that produce similar pulmonary patterns, and as a result this technique can lead to incorrect diagnoses of tuberculosis (5). Additionally, it does not reliably detect tuberculosis among HIV+ tuberculosis patients; pulmonary lesions can be observed for approximately one third of co-infected TB/HIV cases (18). It is a useful tool for diagnosing patients who are unable to produce sputum.

Due to the site of bacterial infection, and therefore the lack of bacteria in a patient's sputum, extrapulmonary tuberculosis is more difficult to diagnose than pulmonary TB. Diagnostic evaluation includes assessment of clinical characteristics,

including swelling at the infection site, indications of fluid in the chest and heart, and signs of meningitis, as well as patient symptoms, including night sweats, fever and weight loss (6, 7). Depending on the site of disease, aspiration, biopsy, or chest radiography may assist in confirming a suspected case of EPT.

Today, the standard recommended treatment regimen for new smear-positive cases is comprised of two phases. The first is a two-month intensive phase, consisting of daily (or sometimes three times weekly, although there is insufficient evidence to suggest that one regimen is superior to the other (22)) administration of isoniazid, pyrazinamide, rifampicin and often a fourth agent – usually ethambutol. In the second, continuation phase, the chemotherapy is pared down to (usually) rifampicin and isoniazid, and is taken for four months (5, 23). The intensive phase is intended to kill the majority of tuberculosis bacilli in the body, and the continuation phase ensures that any remaining bacilli are destroyed. In the absence of drug-resistant tuberculosis, and when treatment regimens are correctly adhered to, tuberculosis therapies are very effective, and most patients, while not cured, should be smear-negative at the end of the intensive phase (5). Treatment regimens for individuals who have previously been treated but not cured, or for those with drug-resistant or multi-drug resistant (MDR) strains of tuberculosis, are longer than the recommended six-month regimen (24) and involve combinations of different, often less effective and more expensive, agents (5, 23).

Subsequent to the successful completion of tuberculosis treatment, it is still possible for an individual to redevelop active disease; tuberculosis cure is not equivalent to lifelong immunity (25).

Options for prevention of active TB include treatment of latent disease and vaccination. Individuals who have been exposed to TB and are considered to be at high risk of developing active disease (e.g. HIV+ patients or others with compromised

immune systems) can be treated with a first-line anti-tuberculosis chemotherapy as a prophylaxis (3). Inoculation with the Bacille Calmette-Guérin (BCG) vaccine is another approach used to prevent tuberculosis. Its efficacy in preventing pulmonary tuberculosis is variable, but studies have shown that it is very effective in preventing more serious extra-pulmonary infection (80% effectiveness, or greater) (17). BCG immunization is recommended for children under one year of age in South Africa.

2.1.1.5 **Multi-Drug Resistance**

Over the past several years, drug resistance has become an additional complication of tuberculosis control. There are currently numerous strains of multi-drug resistant (MDR) tuberculosis (13, 26), and recently, extensively drug- resistant (XDR) cases have emerged (27-29). The development of this resistance is due in part to the intense treatment regimen required to treat tuberculosis, demanding months of regular chemotherapy with which it is often difficult for patients to comply. When treatment is interrupted before an individual is cured, it can provide tuberculosis bacilli with the opportunity to adapt to the antibiotic and mutate into a strain that the antibiotic is less effective at fighting, and which can also be transmitted to others (30). A patient is diagnosed with MDR when the strain of the bacillus that he or she is infected with is found to be resistant to at least rifampicin and isoniazid (31). Treatment regimens for MDR involve any first-line drugs to which an individual is susceptible, combined with second-line drugs; again, these regimens are less effective and require longer courses of treatment (23). Cases of XDR are resistant to all first-line anti-tuberculosis agents, as well as several second-line drugs (32).

2.1.1.6 **DOTS**

Directly observed treatment, short course (DOTS) is the approach to tuberculosis treatment currently endorsed by the World Health Organization (29). Because of the

importance of strict adherence to treatment for active cases to be cured, as well as to reduce the risk of multi-drug resistance, it has been deemed necessary that patients be observed while taking TB medication. While increasing numbers of areas have community programs in which employers, community health workers or family members can be trained to be DOTS supporters and observe patient treatment, these programs do not exist in all areas. Individual employment and family circumstances, as well as barriers such as distance from residence to communities and clinics and availability of resources result in inequitable access to both clinic-based DOTS services and community-based alternatives. The small number of trials that have examined the effect of direct observation on treatment success, compared with self-treatment, do not provide sufficient evidence to suggest that DOTS should be a blanket policy for essential tuberculosis treatment (33).

2.1.1.7 **Treatment Incompletion**

The use of the term 'patient noncompliance' should be avoided. It is a term that essentially blames the victim. It insinuates that a patient is at fault for neglecting to follow the treatment regimen, when in actual fact there are many factors that are out of patients' control that can lead to treatment incompletion, especially in the context of tuberculosis.

Variable accessibility of treatment services, both as a result of available operating resources as well as changing personal circumstances that may prevent travel to and from treatment centres, is one reason why patients may be unable to successfully complete treatment regimens. As described above, patients must be observed taking each (often daily) dose of chemotherapy, and there are many factors that may prevent a patient from meeting this criterion and thus receiving full treatment, especially when treatment must be observed in a clinical setting.

Despite its high prevalence in some areas, there can be a strong stigma associated with having tuberculosis, especially because of the known relationship between TB and HIV/AIDS. Consequently, to be seen receiving anti-tuberculosis therapy may put individuals in a (perceived and genuine) difficult position among their peers.

As discussed earlier, once receiving regular tuberculosis therapy, patients will soon begin to feel well. Coupled with other factors that make access to treatment difficult, renewed strength and absence of symptoms may make it difficult for patients to recognize continuation of therapy as important.

2.1.1.8 **TB/HIV Co-Infection**

One of the reasons for the global persistence of TB, despite the availability and effectiveness of relatively inexpensive drugs, is the ravaging HIV pandemic. TB is one of HIV's most common opportunistic infections. TB is the leading cause of death for individuals with HIV, with approximately 13% of AIDS-related deaths due to tuberculosis (8).

While healthy individuals have a 10% risk of developing active tuberculosis over the course of their entire lifetime, HIV-positive individuals have a risk of approximately 10% *per year* of developing active disease (4). This is due to the HIV-infected immune system's compromised ability to fight the bacilli and prevent latent tuberculosis from developing into active disease (34). The rate of recurrent TB is also increased in individuals with HIV; this could be reactivation of a former infection or re-infection with a new strain of TB (5, 35, 36). Furthermore, as indicated earlier, individuals with HIV are more likely to be infected with smear-negative pulmonary or extra-pulmonary tuberculosis, and a lack of rapid diagnostic tools for these types of tuberculosis can result in delayed diagnosis and commencement of treatment (7).

2.1.1.9 **Tuberculosis in South Africa**

Incidence of tuberculosis in South Africa is among the highest in the world and the number of new, smear-positive cases detected increases every year (37). In 2005 the estimated incidence was 600 cases for every 100,000 members of the population, and 245 smear positive cases for every 100,000 members of the population (37). Much of the increase in tuberculosis burden is a result of the escalation of HIV infection (1). South Africa also has one of the highest levels of HIV/AIDS-tuberculosis co-morbidity in the world, with 2 million individuals coinfected in 2000 (11).

In the Cape Town region of South Africa, the number of reported cases of TB has greatly increased; between 1998 and 2004 this value increased by 66% (although it should be noted that this is a result of both increased case load as well as population growth and improved case detection) (38). In 2005 there were 19,366 new cases of tuberculosis reported in the Cape Metro region, and throughout the sub-districts of this region the incidence[2] ranged from roughly 360 to 1200 cases per 100,000 people in the population of all cases (39).

The South African Department of Health affirms in its *Primary Health Care Package for South Africa* document that patients presenting with clinical indications of TB will be tested for the disease, and treated when positive (40). As with every other high-incidence country, South Africa has adopted the DOTS program, described previously (13, 38).

2.1.1.10 **Public Perceptions of Tuberculosis in Cape Town**

While individual interviews with TB patients were not possible within the scope of this project, qualitative interviews with health care workers who interact with patients

[2] As this value was computed using the number of new *detected* cases, rather than an estimation of the total number of new cases in the region, it is likely an underestimation of the true incidence.

were able to provide insight about perceived views of TB held by members of the general population. Participants' responses illustrated the range of public perceptions that exist within Cape Town regarding TB. Some felt that patients were ill-informed and needed more education to understand the severity of the disease, while others observed patients becoming overloaded with an abundance of information. Participants articulated that, for many people, tuberculosis symptoms or a diagnosis of TB are not considerable problems compared with the other challenges of their lives.

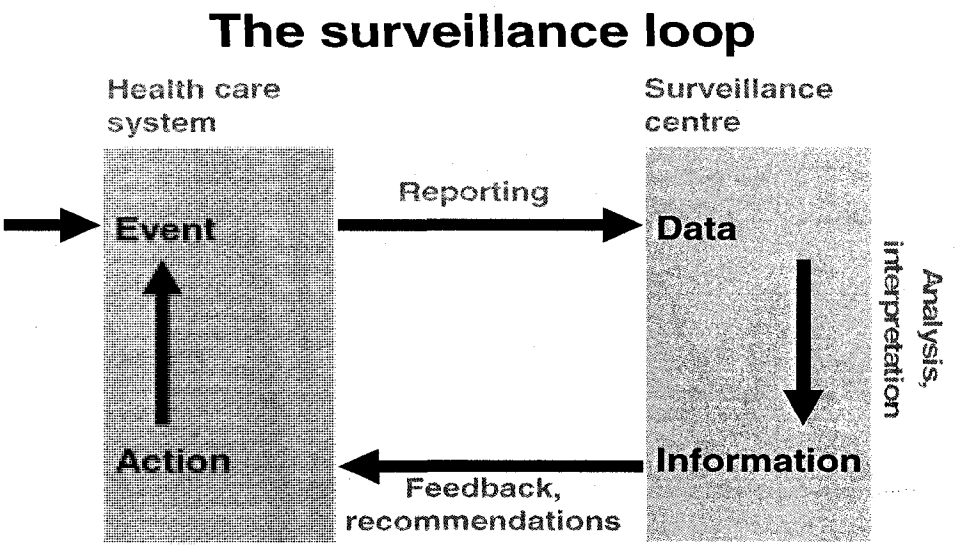
Respondents identified the problem of TB-HIV misconceptions. People understand that there is a relationship between the two diseases, but some erroneously believe that TB will lead to HIV or that by getting tested for TB, one will become infected with HIV. Fear and stigma are produced by these misunderstandings.

2.1.2 **Surveillance**

2.1.2.1 **Definitions of Surveillance**

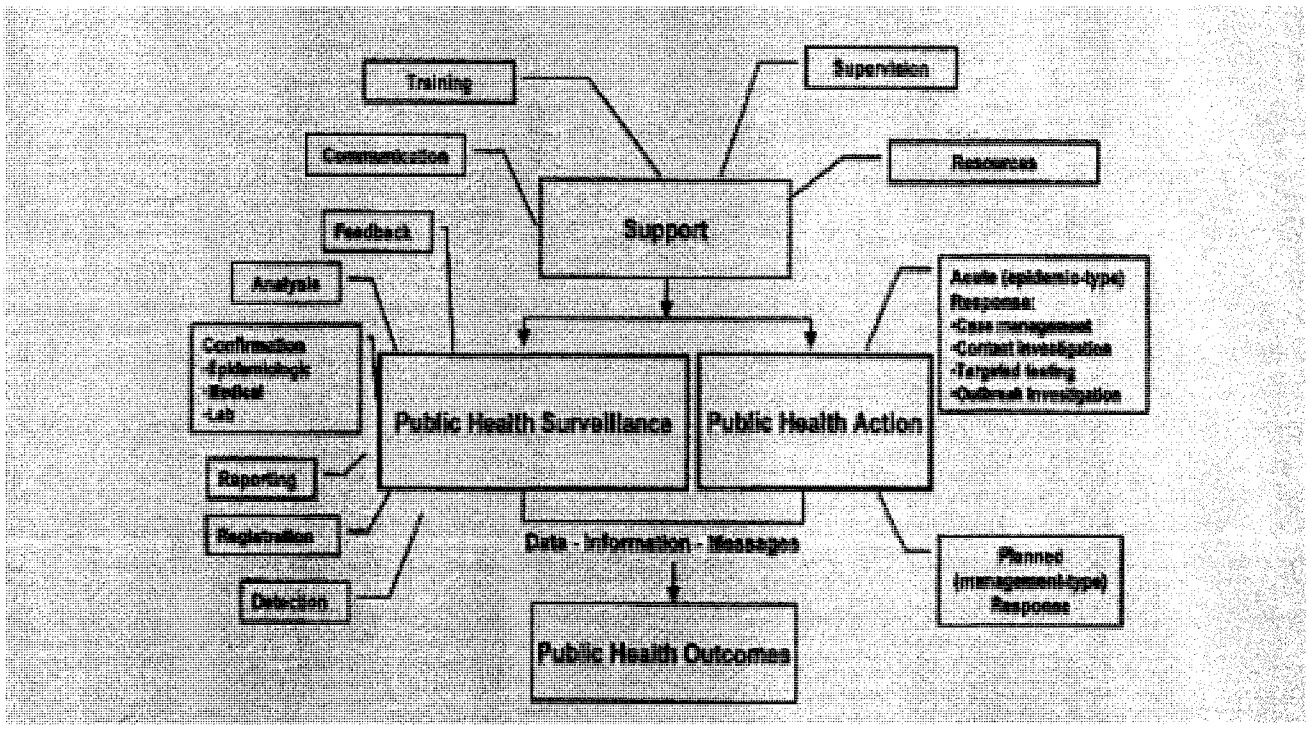
Disease surveillance is sometimes solely, and erroneously, considered the collection of data. In fact it is, or at least should be, a continuous, cyclical sequence of data collection, assembly, analysis, followed by interpretation and appropriate action. This cycle can be visualized as a surveillance loop (41), or as a broader framework (42). (See Figures 2.1 and 2.2.) There is some discord regarding the inclusion of action in the definition of surveillance, but it is agreed that action should be an interdependent process if it is not indeed a component of surveillance itself (42).

FIGURE 2.1 The Surveillance Loop



(Aavitsland et al. 2003)

FIGURE 2.2 Conceptual Framework of Public Health Surveillance and Action



(McNabb et al. 2004)

2.1.2.2 **Importance of Surveillance**

Disease surveillance has the potential to be used for more than case detection, tracking and management; it also involves analysis, interpretation and application of data findings (43-45). A surveillance system will be most valuable if it can also be used to inform decisions about health funding and service application and allocation, and these capabilities require more than the presence of adequate data fields. The collection and analysis of case data not only assists in magnitude estimation, outbreak detection, and the evaluation of control strategies, but can also highlight areas where further research is needed, and guide program planning and policy-making (44-46). These require the involvement and cooperation of health-care workers, health planners and policy-makers; people who are very close to the health issue and see it every day, as well as those who are more removed. Indeed, surveillance does not exist in a vacuum; it is integrated with every aspect of disease control, from patient management following presentation and positive diagnosis at the level of the individual patient, to policy development at a much more macro level. All of these stages must be taken into consideration for a surveillance system to operate optimally. Figure 2.2, McNabb et al.'s Conceptual Framework of Public Health Surveillance and Action (42), illustrates the amalgamation of all of these components.

Any analysis or action based on epidemiological data is dependent on the quality of a surveillance system. Public health efforts are much less valuable and may in fact be a waste of time and resources if the applicable surveillance system is inadequately designed for the needs of the particular disease and population, or not sufficiently maintained (47). Surveillance data not only suggests areas in need of intervention, research and policy change, but also indicates whether or not these actions are effective (48). Stroup,

Brookmeyer and Kalsbeek assert that disease surveillance is "the essential activity that allow [*sic*] other public health actions to have effect" (49: p. 11).

2.1.2.3 **Important Components of a Surveillance System**

In order for a surveillance system to offer its full potential, there are a number of elements and capabilities that should be present:

- It is vital that disease classification and case diagnosis definitions are standard, both to ensure consistent patient treatment and to maintain the reliability of between-patient data, as well as to facilitate the electronic integration of data from multiple regions (43, 47).
- Data verification processes should be carried out at multiple stages of data management, and measures to ensure system security and patient confidentiality must be in operation (43).
- System user training should be reflective of skills required to operate efficiently, and accompanied by appropriate procedural documents for operating and maintaining the system (43).
- Functions that facilitate appropriate data analysis and subsequent dissemination to a wide audience of stakeholders (including administrators, policy-makers and health managers) should be available (4).

There are additional components specific to tuberculosis that, in ideal circumstances, should be present in a tuberculosis surveillance system. There are many individual data field requirements for a tuberculosis surveillance system that extend beyond basic demographic information. These include: documentation of infection type and treatment outcome; susceptibility testing and resistance (including MDR) data recorded in conjunction with the data of respective cases; mechanisms that allow for

contact tracing in order to establish a disease network, valuable for both identifying individuals in need of prophylaxis (where resources exist) or regular treatment, as well as establishing patterns relating to transmission; and incorporation of HIV data (when available) with TB case information – patients who do not know their HIV status should be offered voluntary counseling and testing (VCT). While not essential for tuberculosis surveillance, collection of data pertaining to the identity of DOTS supporters could be very helpful for the development of policy in this controversial area.

2.1.2.4 **Evaluation of Surveillance**

When evaluating a surveillance system that is so intricately fused with disease control, such is the case with this tuberculosis surveillance evaluation, it is important to note the difference between evaluating surveillance and evaluating the success of control measures. The evaluation discussed here has *not* assessed actual performance of the TB control programme, but rather has considered, among other things, the capacity of the surveillance system to facilitate performance assessment.

2.1.3 **Rationale for Evaluation and Use of CDC Guidelines**

Periodic evaluation of a surveillance system is necessary to determine whether or not it is serving the needs of the area based on the health event and the affected population, as well as meeting its objectives (44, 45). The great potential of a surveillance system as a public health tool was emphasized earlier; if systems of surveillance are not regularly evaluated, the data produced and action taken in response to findings may be compromised. To ensure that the value of an evaluation is maximized, it is important to produce and disseminate recommendations for improvements after an evaluation has been conducted (45).

2.1.3.1 **CDC Guidelines**

In 1988, the United States' Centers for Disease Control and Prevention (CDC) published *Guidelines for Evaluating Surveillance Systems* to guide investigators through evaluations to ensure that health surveillance systems are operating efficiently and effectively. Six years ago these guidelines were updated to reflect some of the changes that have occurred in public health within the past several years: increased use of electronic data; integration of surveillance systems with health information systems; establishment of standards for data, and emerging and re-emerging threats to health (45). The new version of the guidelines is called *Updated Guidelines for Evaluating Public Health Surveillance Systems*, and it is this version upon which the present evaluation was based. The CDC *Guidelines* indicate the broad components that should be considered in an evaluation; they are not specific to one type of surveillance system or type of health events. As such, there are several published evaluations for varying types of surveillance systems that have been based on the *Guidelines*, including evaluations of surveillance systems for tuberculosis (50); outpatient diseases (51); congenital anomalies and malformations (52, 53); vaccine adverse events (54); and general infectious diseases (55).

A lack of focus on public health action within the CDC *Guidelines* was identified by McNabb et al. in their evaluation of tuberculosis surveillance in a county in Florida (50). These investigators apply an enhanced conceptual framework of public health surveillance, proposed elsewhere (42), which incorporates components of the *Guidelines* but which also enables the analysis of action performance and cost measurement (50).

As emphasized by authors of one of these evaluations, it is unlikely that any one system of surveillance will meet all of the evaluation criteria outlined in the CDC (or any other) guidelines, and it is therefore important for investigators to focus on the components that are of importance to the specific system being evaluated (53). These

studies demonstrated this through the inclusion and exclusion of particular components depending on applicability to the health event as well as availability of data. Some studies supplemented quantitative data collection methods with qualitative data; interviews and focus groups were conducted with key players within the surveillance system under evaluation (50-52).

The CDC *Guidelines* were selected for use within this evaluation because they appeared to be a sound basic framework, comprehensive and straightforward. This decision was reinforced through the adaptability and usefulness demonstrated through the wide-ranging applications described above. They are modified within this Cape Town evaluation to reflect the components identified by McNabb et al. (50) as important areas for improvement.

The CDC *Guidelines* outlines six tasks that an evaluation should follow. These tasks are:

a) **Engage the stakeholders in the evaluation**, because they will be able to advise about particular areas of focus for the evaluation, with respect to the specific health-related event: tuberculosis. The CDC defines stakeholders as 'those persons or organizations who use data for the promotion of healthy lifestyles and the prevention and control of disease, injury or adverse exposure.'

b) **Describe the surveillance system to be evaluated**, including:
   i. Describe the public health importance of the health-related event under surveillance.
   ii. Describe the purpose and operation of the system.
   iii. Describe the resources used to operate the system.

c) **Focus the evaluation design**, to ensure the efficient use of time and resources.

d) **Gather credible evidence regarding the performance of the surveillance system.** This involves describing the activities and decisions that have occurred as a result of the data obtained from the surveillance system, and describing each of the following attributes in terms of the surveillance system of focus: simplicity, flexibility, data quality, acceptability, sensitivity, predictive value positive, representativeness, timeliness, and stability.

e) **Justify and state conclusions, and make recommendations.**

f) **Ensure use of evaluation findings and share lessons learned;** the appropriate dissemination of the results and recommendations of the evaluation.

2.1.3.2 Modification of the CDC Guidelines: Development of Evaluation Framework

As indicated above, the CDC *Guidelines* are designed to be broad so that qualities specific to the health event under evaluation, as well as those based on the geographic, demographic and contextual characteristics of the study area, can be integrated (45). Accordingly, it was necessary to make several modifications to these guidelines to make them applicable to the context of tuberculosis surveillance in Cape Town, South Africa. The following sections briefly describe the modifications that are discussed in greater detail throughout this paper.

The need for public health surveillance and public health action to be viewed as interrelated activities has been addressed by the development of a conceptual framework that encompasses both of these elements (42). As described earlier, McNabb et al. (50) identify the lack of emphasis placed on the public health action that is informed by surveillance activities in traditional surveillance evaluations, and have applied this framework to tuberculosis surveillance evaluation in Florida, USA. In accordance with this framework, and modeling some of the contextual tuberculosis components used in the North American setting, the present evaluation augmented the CDC *Guidelines* with items examining both acute responses (case management, active and passive contact tracing, and responses regarding TB/HIV co-infection) and planned responses (long-term prevention and control efforts) (50), as well data dissemination approaches to facilitate these responses. These modifications made within the thesis framework ensured that the evaluation would be able to assess the public health action activities that are (or are not) present in tuberculosis surveillance in Cape Town.

Many components of the CDC *Guidelines* (public interest in TB, ease of operation of the system, system flexibility, acceptability and stability) depend on the insight and experiences of the users of the surveillance system. As a result, collection and analysis of qualitative data was deemed essential for this evaluation and incorporated into the project. Semi-structured, open-ended interviews were conducted with health care workers, health information officers, TB coordinators and health managers from across the Cape Metro health region's eight sub-districts. These individuals were able to provide their perceptions about the initial introduction of the electronic system, everyday use, and the extent to which data is used for planning and research.

The rampant spread of human immunodeficiency virus (HIV) throughout South Africa over the past few decades has drastically amplified occurrence of active tuberculosis; a recent study estimated that there are two million adults co-infected with TB and HIV in South Africa (11). The World Health Organization's Stop TB Department and Department of HIV/AIDS have made policy recommendations regarding collaboration between TB and HIV programs and activities, including surveillance (56). In order to investigate the extent to which these recommendations have been followed, this evaluation incorporated consideration of electronic integration of TB and HIV data and collection of data regarding appropriate action for TB/HIV co-infected patients (voluntary counseling and testing and HIV treatment follow-up for positive TB patients).

The South African National Tuberculosis Control Programme has recently converted from a paper to a new electronic system of data organization and management (38), but data is still documented in a paper record prior to being captured into the electronic system. This fact made it important to add an additional component to the thesis evaluation: the extent to which data in the paper record is transferred into the electronic record was assessed.

Modifications were made to the evaluation guidelines for use within this project to reflect specific clinical components of importance to tuberculosis surveillance and control. In most cases, if smear-positive patients have not undergone smear-conversion three months into a course of treatment, it is an indication that treatment has not been adequately adhered to, or that the patient is infected with a strain of tuberculosis that is resistant to the particular antibiotics he or she is receiving (57). This evaluation was augmented with the examination of data collection and records pertaining to smear-conversion data.

Although Africa has not been as heavily struck by multi-drug resistant (MDR) strains of tuberculosis as other areas, drug resistance is introducing further threats to tuberculosis and TB-HIV equations (11). It is vital that cases of MDR-TB are identified and monitored, and evaluation items were modified to include investigation into this type of data within this thesis project.

Lastly, economic capacity is an important factor that must be taken into account in health system evaluation. The lack of resources available in high case-load areas within the Cape Metro region was taken into consideration within this evaluation and subsequently when recommendations were made.

2.1.4. **Selection of the Research Setting for the Evaluation and Description of the Electronic Tuberculosis Register**

2.1.4.1 **Selection of Cape Town**

South Africa has a large volume of tuberculosis cases and consequently, tuberculosis control and management is crucial. The country has recently completed the implementation of a nation-wide electronic tuberculosis register, which serves as a patient management tool as well as a source of surveillance data. These characteristics made South Africa an apt setting for surveillance evaluation. The Cape Metro region in Cape Town was selected as the study site because of the supervisory and other forms of support that was already established in that area. It was deemed appropriate to limit the scope of the evaluation to the Cape Metro region for the interests of feasibility and time; to evaluate the surveillance system throughout the local to national levels would have required a great deal more time and resources than were available for this project – project support was provided by the Institute of Population Health at the University of Ottawa and the Primary Health Care Directorate at the University of Cape Town.

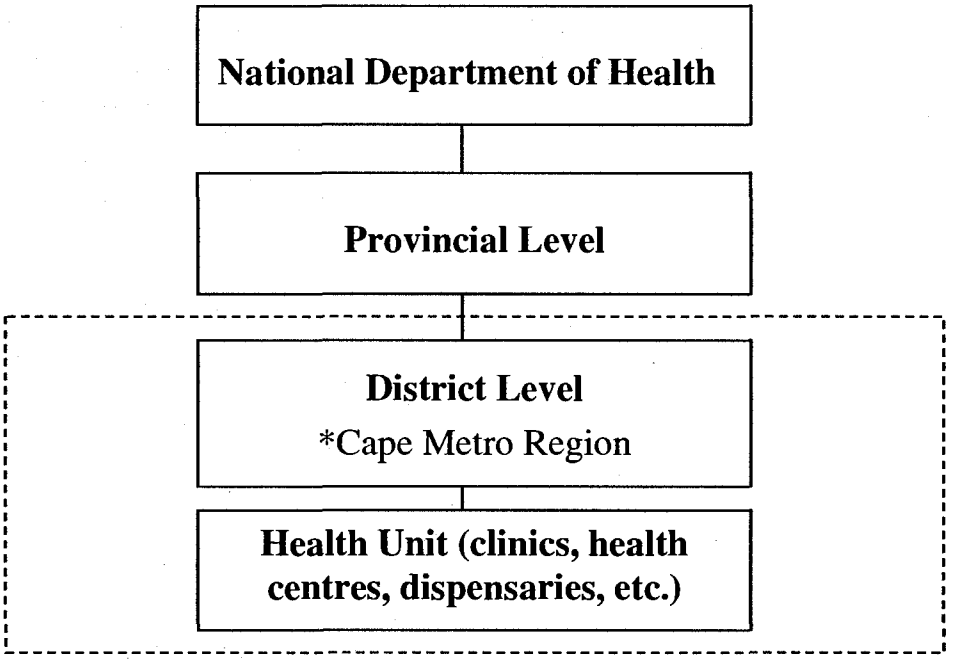
The Cape Metro region is in South Africa's Western Cape province, and has a population of close to three million people. Figure 2.3 illustrates the South African National Tuberculosis Control Programme and where the Cape Metro health region falls within its structure. The dashed box indicates the levels upon which this evaluation focused.

2.1.4.2 **The Electronic Tuberculosis Register**

Prior to use of electronic systems in South Africa, the analyses and respective summaries necessary to provide adequate feedback within tuberculosis surveillance were all based on paper records and calculated manually. This not only consumed a great deal of time and could hinder the completion and delivery of reports by the time they were

needed, but due to potential transcription inaccuracies the calculations were also subject to error (58, 59).

FIGURE 2.3 Structure of the National Tuberculosis Control Programme



(South African Department of Health 2004)

Currently, a great number of TB surveillance activities in Cape Town are facilitated by the National Electronic TB Register (ETR), which was established nation-wide in 2004. The electronic system is based on the ETR first developed in 1995 for use in Botswana – initially called 'BOTUSA software' – through a collaboration between Botswana's Ministry of Health and the United States' Centers for Disease Control and Prevention (58).

In 2000, the BOTUSA software was implemented on a pilot basis in two of South Africa's nine provinces: Mpumalanga and North West (Carina Idema, November 8, 2006). This operating system was based on EpiInfo with a Visual Basic application and a Microsoft Access database (60). As a result of feedback from system users in pilot provinces, the ETR has undergone considerable transformation in the time since its initial

implementation. The DOS-based system was menu-driven and designed to be user-friendly, but as Windows operating systems gradually became more prevalent, ETR users experienced increased familiarity and fluency with Windows over DOS. Consequently, when South Africa's National Health Information System (NHISSA) decided to officially accept the system in 2001, it was with the provision that it be converted from DOS to Windows (59). The system was rolled out in the remaining provinces between 2001 and 2004, throughout which time software changes continued to be made (Carina Idema, November 8, 2006). The current Windows version is called the ETR.net.

Across South Africa, the ETR.net is a tool that facilitates tuberculosis surveillance activities at the district level. It primarily encompasses features of a disease registry, in that data is obtained at various stages of disease management (61), but plans are in place to develop a function within the ETR.net that will allow tuberculosis data to be exported into a new national system of electronic notification; currently there is no set date for when this operation will be possible (Carina Idema, August 6, 2006; Carina Idema, November 8, 2006). (Currently notification is independent of the ETR.net.) Tuberculosis is a notifiable disease in South Africa and as such is subject to the regulations set in the Republic of South Africa's 1977 *National Health Act* regarding recording and reporting of cases and deaths (62). At the time of a patient's diagnosis, health officials submit notification forms to the South African disease notification system.[3] While notification data provides information about national tuberculosis trends, the district-level ETR.net is in many ways superior to this national surveillance system; it is the most comprehensive source of TB data in the Cape Metro region; it includes data beyond case confirmation (such as smear conversion, treatment completion, etc.) and within the Cape Metro it

[3] In addition to using TB data for its own national surveillance purposes, the National TB Control Programme must provide certain data to the World Health Organization annually (63).

informs more extensive surveillance purposes such as program planning and development.

Another notable planned augmentation to national tuberculosis surveillance in South Africa is the incorporation of ETR.net data into the District Health Information System (DHIS), a national health database. The ETR.net is a management tool for the sub-district and district levels, and currently, data from the ETR.net is inconsistently entered into the DHIS (Carina Idema, March 29, 2006). The new intended electronic linkage would facilitate direct export from the ETR.net to the DHIS, increasing reliability and value of national TB data (64).

TB surveillance in Cape Town consists of the integration of collection of data, data capture, organization and analysis of data, and dissemination of results to provide feedback and on which to assess performance and base action. The ETR.net also serves as a patient management system, but not at the clinic level (where in electronic format it would arguably be more useful than the current paper registry system). TB nurses are currently limited in access to the paper-based records that they create when meeting with patients. Patient data is accessible in electronic form to TB coordinators and health information officers at the sub-district level; their role with this data from a patient management perspective will be described in a subsequent chapter. Individual patient data is not transferred to regional, provincial or national levels.

As indicated above, the ETR.net software is a *tool* (59). Successful surveillance results and application require high-quality data collection, capture and analysis, all of which can be facilitated by the ETR but human input and attention are essential complements.

2.1.5 **Evaluation Objectives**

The ETR is the central component of tuberculosis surveillance in Cape Town, and the primary tool for capturing tuberculosis data. As indicated in an earlier section, however, disease surveillance is broader than data collection and management, and thus this evaluation considered the paper record, data analysis, dissemination of results and data informed public health action, in addition to the ETR. Furthermore, there are some types of surveillance data that are not adequately obtainable through the ETR alone. These limitations within the ETR are discussed, and when existing, alternative sources are described.

The CDC Guidelines pose a large and comprehensive set of questions for an investigator to examine when conducting an evaluation. It is vital to consider the needs of the particular surveillance system under evaluation and to select the key questions that will be able to assess the system in the best way, given these needs. Consequently, while the majority of items in the CDC's Guidelines were taken into consideration during the course of the evaluation, the following questions were deemed to be of particular importance for evaluation of the TB surveillance system in Cape Town. It is upon the assessments of these items that the evaluation report provided to stakeholders in Cape Town will be based.

Structure and Organization of the System:

1) What is the flow of data in the system? How simple is the structure? How easy is it to operate? How flexible is the system?
2) What is the level of acceptability among the participants (health care workers (HCWs), health information officers (HIOs), etc.)?

Performance of the System:

3) Does the system adequately address the contextual issues for tuberculosis control in Cape Town, South Africa? (e.g. MDR, HIV/AIDS, etc.)
4) Is contact tracing (and treatment) a component of the system?
5) Is the system meeting operational targets and epidemiological objectives? Does the system provide estimates of morbidity and mortality related to TB?
6) How high is the quality of system data?

Action Informed by the System:

7) Are activities and/or decisions related to prevention and control of TB informed (at least in part) by data collected by the system?
8) Are decisions regarding funding informed (at least in part) by data collected by the system?
9) Does the system permit assessment of the effect of prevention and control programs?
10) Does the system lead to improved clinical, behavioural, social, policy or environment practices?
11) Does the system stimulate research intended to lead to prevention or control?

2.2 Methods

2.2.1 Following the CDC Guidelines

The CDC *Guidelines* specifies several areas of investigation for each of its six broad tasks (identified in Section 2.1.3.1), and throughout the course of this projects these areas served as a roadmap for research with particular focus placed on the questions above designated as being of key importance to the evaluation.

A number of evaluation items required qualitative data to be adequately explored; the qualitative data collection process is described below. The sources and approaches used for data collection of non-qualitative information varied broadly.

2.2.2 Sources of Information

2.2.2.1 Literature: Publications, Reports, Presentations and Guidelines

Approximately 25 per cent of data required to conduct this evaluation thoroughly was obtained through literature published by individual researchers, international health agencies, South African NGOs, the South African Department of Health and the Cape Metro Region. Some of this literature was supplementary to data that was collected through other means, and some of it served as the only source of such information.

Both peer-reviewed and gray literature provided information regarding the development and history of the Electronic Tuberculosis Register. World Health Organization (WHO), Centers for Disease Control and Prevention (CDC) and International Union Against Tuberculosis and Lung Disease (IUATLD) documents and

reports provided information about current tuberculosis control and surveillance standards. *The South African National Tuberculosis Control Programme Practical Guidelines 2004* and *Mobilising Against Tuberculosis: South African Plan for TB Control for 2002-2005* (also called the *Medium Term Development Plan*) were published by the South African Department of Health. These documents outlined the official processes involved in tuberculosis control in South Africa, including patient diagnosis and treatment, directly-observed therapy, multi-drug resistance (MDR), co-infection of TB and HIV/AIDS. They also described targets, objectives and indicators that the Tuberculosis Control Programme strives to meet.

Lastly, presentations prepared by the TB Programme Regional Coordinator and TB coordinators described tuberculosis statistics and trends within the health region, and also demonstrated the form and detail in which data is disseminated to other users of the system (other TB coordinators, health information officers, health workers, NGOs and researchers).

2.2.2.2 **ETR.net Software**

A copy of the ETR.net software, as well as an updated data set, were provided by Cape Metro personnel for the purposes of this evaluation. This software served as an extremely valuable research tool. The range of data and outcome reports that the system is capable of producing was explored, as well as the different ways that both patient and aggregate data could be viewed and structured. The complexity or simplicity involved in performing all of these operations and analyses was assessed. Investigation into the scope of patient data recorded in the electronic system was also possible.

2.2.2.3 **Patient Data Documents**

Hard copies of documents comprising the paper record – prior to data capture in the Electronic TB Register – were also made available by Cape Metro personnel. The

Patient Clinic/Hospital Card, Patient Treatment Card, TB Suspect History Sheet, and the TB Register carbon form contributed to comprehension of the data flow within TB surveillance in Cape Town, and also illustrated the range of patient data collected, including the content that was recorded in the ETR and that which was obtained in the paper record but not transferred to the electronic record.

2.2.2.4 **Personal Communication**

Individuals involved in various capacities in TB surveillance at both the regional and national level in South Africa were approached and took time to answer queries, clarify ambiguities, and provide documents that were necessary to answer evaluation questions that remained when other sources of information had been exhausted. There are some routine operations that are not documented in detail in general guidelines or other publications, and similarly there were some TB data and standards about which there was not sufficient detail within the literature. The individuals who provided information with respect to these areas included the national TB coordinator, technical support personnel, health researchers, NGO staff, and health managers and coordinators (beyond the scope of the qualitative interviews).

2.2.3 **Qualitative Interviews**

A vital component of this evaluation was the qualitative data, which was obtained through semi-structured interviews with health care workers, health planners and heath coordinators. Ethics approval was granted by the University of Cape Town Research Ethics Committee and the Ottawa Hospital Research Ethics Board. A system evaluation and the findings that emerge would be ineffective if the community in which the system exists was not included as a primary data source. The individuals interviewed provided their perceptions about overall strengths and weaknesses of the system, everyday use, and the extent to which system data is used for planning and research.

The study population for the qualitative component of the evaluation was comprised of health care workers working in the Cape Metro area, health information officers, TB coordinators, and health managers whose decisions impact the health of tuberculosis patients in this area.

2.2.3.1 **Participant Selection and Recruitment**

In order for the sample to be reflective of the population of interest, it was determined that participants in the qualitative interviews should be individuals who were able to comment on the way the system operates, either because they work directly with the system in terms of handling patient care and data, or because they use, would like to be able to use, or should be able to use the system for policy-making or more general decision-making.

There are eight sub-districts in the Cape Metro health region, each of which has one or more TB coordinators[4] who analyzeff data, and an information officer who is responsible for data management. These individuals typically work very closely together. Across the eight sub-districts there are approximately one hundred clinics where patients can receive tuberculosis treatment. Each of these clinics has at least one TB nurse (sister) who is responsible for diagnosis, initiating treatment, and often, treatment supervision. The TB Programme Regional Coordinator, TB Manager, and an individual from the Cape Metropole Health Information Group play a key role in surveillance at the district level. Appendix 1a illustrates the organization of TB personnel within the Cape Metro Region.

It was determined that these three groups of individuals met the above criteria for interview participants, and would be recruited for the qualitative component of the evaluation.

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[4] Depending on the size of the sub-district, this individual may also be responsible for coordinating HIV and STI activities. The TB Regional Coordinator is distinct from the sub-district TB coordinators.

Each sub-district dyad consisting of TB coordinator(s) and a health information officer was approached to participate in a qualitative, in-person interview. Over the telephone, potential participants were introduced to the investigator, and the purpose of the study and the role that they would have as a participant were explained. If the dyad agreed to participate, an interview was scheduled. In the majority of cases, interviews were scheduled and conducted with both the TB coordinator(s) and the health information officer concurrently. In one sub-district, the health information officer was absent at the time of the scheduled interview as a result of illness, so the interview was conducted solely with the TB coordinator and a separate interview was scheduled and conducted with the health information officer at a later time. In another sub-district, it was not possible to meet with the health information officer, so an individual interview was conducted with the TB coordinator. This sub-district was the only one of the eight in the region for which both TB coordinator and health information officer did not participate.

A convenience sample of four health care workers – TB nurses – was selected from tuberculosis clinics across the Cape Metro region. Again, individuals were approached over the telephone, at which time the purpose of the project and their role as a participant were explained. As a result of the high tuberculosis case load in the region, especially in certain sub-districts, TB nurses in the Cape Metro region are extremely busy, and it was necessary to approach several individuals before finding four who were in a position to take time away from their multiple tasks to participate in an interview. In order to capture the likely differing experiences and perceptions of nurses based on case-load, participants were recruited from sub-districts and clinics with varying case loads and patient populations.

The three individuals from the Cape Metro regional level were approached and asked to participate in the same manner described for the TB coordinators, health information officers and tuberculosis nurses. Each agreed to participate and individual interviews were scheduled.

2.2.3.2 **Development of Interview Schedule**

Interview schedule items were derived from the list of evaluation questions presented earlier in this chapter. All questions that related to TB personnel and their experiences were included as items to be investigated through qualitative data. Draft interview schedule items were constructed by rephrasing evaluation questions into items that reflected the intent in a clear and straightforward manner. An expert in qualitative research and analysis[5] was consulted, and she advised on areas related to appropriate piloting, establishing theme areas and objectives within target questions, approaches to engage respondents, flow of questions, and techniques to ensure that participants' responses have been correctly interpreted (Lynne Leonard, January 12, 2006). She also provided advice on the development of an appropriate consent form. The interview schedule was revised to reflect this qualitative expert feedback.

In order to verify question comprehensibility and clarity in an interview setting, an interactive pilot test was conducted with a colleague with extensive experience in both qualitative interviewing as well as tuberculosis in the South African context[6]. Questions were posed to her as though an interview was being conducted, and she provided feedback regarding specific probes that could be beneficial in eliciting more detailed responses, breakdown and phrasing of questions and general suggestions to minimize interviewer and respondent bias (Salla Munro, February 23, 2006; 65).

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[5] Lynne Leonard, Department of Epidemiology and Community Medicine, University of Ottawa.
[6] Salla Munro, Primary Health Care Directorate, University of Cape Town.

The pilot test results were applied to the development of the final interview schedule. Because the involvement with and responsibilities relating to surveillance in general and the ETR specifically varied between clinic-level, sub-district level and Metro level respondents, the final interview schedule was modified to create three individual schedules (Appendix 2).

2.2.3.3 **Data Collection and Analysis**

Participants took part in semi-structured, open-ended interviews, in which the interviewer guided the discussion to cover particular topics and issues. With the participants' permission, each interview was tape-recorded to facilitate analysis. Participants were informed that if they were not comfortable with this, note-taking rather than electronic recording was certainly an acceptable alternative. All respondents agreed to be recorded with the exception of one member of a TB coordinator-health information officer dyad. In this case, the recorder was stopped each time the participant was asked a question or otherwise initiated a response, and written notes were made.

The interviews with City-level participants and TB nurses were one-on-one, while the interviews with TB coordinators and health information officers were small group discussions consisting of the interviewer and the sub-district level dyad. In three cases one-on-one interviews were held with sub-district level participants as a result of participant availability.

Prior to the beginning of each interview, participants were provided with a consent form outlining the project and what their role as a participant would be, and containing the contact information of the investigator should they have questions after the interview had taken place. Participants each signed two copies of this form; one was retained by the investigator and one could be kept for participants' own records.

Qualitative data was analyzed using thematic content analysis (66). The tape-recorded interviews were transcribed and read before being coded by themes and issues. Transcripts were visually coded freely by the investigator, without reference to the components of the evaluation that were to be answered using qualitative data, in order for codes to be developed as they emerged from the data. An ongoing list of codes was maintained and updated throughout the coding process. These visual codes were then inserted into the text of the electronic transcripts to facilitate analysis. Once all of the interview data had been coded, the codes were thoroughly examined and the resultant trends and themes were identified; comparisons were made between transcripts to identify commonalities and broad themes between groups. Validity of this approach was increased by the investigator's extensive past experience applying thematic content analysis to qualitative work in areas of end-of-life care, bereavement, and place perceptions.

2.3 **Results**

2.3.1 **Structure and organization of the system**

2.3.1.1 **Reporting Documents**

At the core of the structure of a system that manages, analyzes and disseminates data, are the mediums and mechanisms for obtaining this data. The contents of a system's reporting documents reveal the type of data that is collected and the level of detail that is gathered. Within Cape Town's surveillance system the paper recording documents are of particular importance because not all of the data contained therein is transferred to the electronic record. To examine only the data fields in the ETR would be to misinterpret the extent of the data that is collected. The following section describes the reporting documents used within the Cape Town TB surveillance system, and the stages of patient contact at which each is employed.

2.3.1.1.1 **TB Suspect History Sheet** (Appendix 3a)

This form documents the individual's name; any contact with known TB cases; previous TB treatment; skin tests; results from voluntary counseling and testing (VCT) for HIV; TB symptoms; and smear, culture or chest X-ray tests and results. (BCG immunization is not recorded within the paper record.) If the suspect tests positive for TB, this same form contains further patient information such as treatment plan, medical history, whether or not the patient has ever worked in a mine or spent time in prison, whether or not the patient is using contraceptives or is currently pregnant, and physical observations. This data remains in the paper record; data for TB suspects whose test results are negative are not recorded in the Electronic Tuberculosis Register.

2.3.1.1.2 **Patient Clinic/Hospital Card** (Appendix 3b)

This form is completed after a patient is identified as a positive case, and it contains a greater level of detail about a patient's personal, clinical, treatment, case contact and outcome information. Full communication information – both home and work addresses and phone numbers – are obtained, as well as the patient's race; sex; age; and date of birth. The role and identity of the patient's treatment supervisor, be it a relative, employer, community health worker or clinic nurses, is recorded. Patient category (new, retreatment after cure, retreatment after completion, retreatment after failure, retreatment after interruption); site of disease (according to the International Classification of Diseases (ICD)-10); sputum results; treatment regimen for both the intensive and continuation phases (including full treatment schedule); chest x-ray images (when taken) and treatment outcome comprise the clinical information contained within this file. Patient contact information – name, relationship, age, and results of TB testing – is also recorded on this form, along with the total number of contacts traced and the number of contacts treated.

2.3.1.1.3 **Patient Treatment Card** (Appendix 3c)

With the exception of some communication information and patient contact information, this smaller card contains the same data as the Patient Clinic/Hospital Card. This card is carried with each patient to improve the quality of treatment transition should a patient move within or between sub-districts.

2.3.1.1.4 **District Tuberculosis Register** (Appendix 3d)

This carbon-paper document is separated into three sections: case finding, smear conversion and outcome. The case finding component of the form contains: patient registration number; registration date; whether or not the patient has moved or transferred; first name(s) and surname; sex; age; race; address; patient category; site of disease; treatment start date; and pre-treatment smear results. The smear conversion section documents the results of smear tests taken at the end of the two-month intensive phase and the three-month intensive phase. Finally, the outcome component includes the results of end of treatment smear tests; culture results for non-converters and retreatment cases (including any drug resistance that is discovered); the treatment stop date and the final outcome.

2.3.1.2 **Data Flow**

Appendix 1b illustrates the flow of data and the health personnel that are involved with the data at each stage. The hatched outline indicates the area upon which this evaluation focuses. (Please also refer to Appendix 1a as an illustration of the region's health personnel involved with data collection and analysis.)

2.3.1.2.1 **Detection, Registration and Management of Cases**

The point at which an individual's data first enters the Cape Metro tuberculosis surveillance system is when he or she presents to a health worker with symptoms of TB,

as a contact of a patient with confirmed active tuberculosis, or is referred to a TB clinic from a hospital or other health facility. At this stage the individual is considered a TB suspect and a **TB Suspect History Sheet** (Appendix 3a) is completed.

Case finding, in which individuals infected with active tuberculosis are detected, is a passive process in Cape Town. Public health interventions such as posters and open information forums aim to educate individuals about symptoms that characterize tuberculosis, and encourage those experiencing such symptoms to visit clinics for testing. There is currently no mechanism, however, for actively seeking out and testing symptomatic or at-risk individuals. Cases are detected when an individual chooses to visit a clinic, or is brought to a clinic by friends or relatives.

As emphasized earlier, it is extremely important for standard case definitions to be employed if surveillance data from various areas is going to be electronically integrated (43). TB case definitions in the Cape Metro follow the classification system used nationally, set by the ICD-10 (67). Appendix 1c presents the case definitions of the South African Tuberculosis Control Programme according to disease site, diagnosis of pulmonary TB and patient type.

2.3.1.2.2 **Case Confirmation**

Health care workers adhere to algorithms set by the National TB Control Programme to guide diagnosis and treatment management (5), and the drug regimen followed is the standard course described earlier. Nurses obtain sputum samples from suspected cases on two consecutive days for both new and retreatment cases; a third sputum specimen for culture and sensitivity in retreatment cases is also taken. These samples are transported to a laboratory for smear microscopy testing. As described above, an individual must have two positive smear tests (or a positive culture or X-ray) to be considered a TB case. Two sputum samples are collected and tested at the end of a

patient's intensive treatment phase to assess *smear conversion*, and two final samples are collected and tested after treatment completion to discern *treatment outcome*.

2.3.1.2.3 **Reporting Sources: TB Nurses (Sisters)**

Once an individual's positive TB status has been confirmed, he or she is given a registration number and the clinic's *TB nurse* enters information into the **Patient Clinic/Hospital Card** (Appendix 3b). The majority of this information on the Patient Clinic/Hospital Card is also recorded on a **Patient Treatment Card** (Appendix 3c), which each patient carries. This ensures that, should he or she transfer to another clinic, sub-district or region, health workers are informed about treatment status, and treatment can remain current and consistent. Smear conversion and treatment outcome are also recorded on both of these documents at applicable stages of treatment.

Much of the data contained in the three paper documents (described above) and recorded in a patient's folder is not recorded in his or her file in the ETR. The individual patient data that does get transferred is limited to the contents of the **District Tuberculosis Register**, a form with tri-coloured carbon layers to facilitate data use at various levels. (Appendix 3d) *This document is the key linkage between the paper and the electronic record.* The TB sister in each clinic completes the District Tuberculosis Register form based on the information contained in the Patient Clinic Card and forwards it to the sub-district level for capture and analysis.

2.3.1.2.4 **Data Transfer and Capture**

Once recorded from Patient Clinic Cards, the data in the District Tuberculosis Register is transferred to the sub-district health office. The frequency of this transfer depends on the case-load of each clinic; in some areas it occurs weekly and in others where patient loads are much lower quarterly data transfer is sufficient. The District Tuberculosis Register forms are collected in-person by *TB coordinators*, who make

regular clinic visits not only to collect data but to oversee and provide support for treatment and data collection processes. (Again, depending on the sub-district, TB coordinators also serve as HIV/STI coordinators; their responsibilities extend to areas beyond tuberculosis control.)

Health information officers (HIOs) then input, or capture, data from the paper records into the ETR.net. Each sub-district health office has its own ETR.net database, and while others at each facility may access the database to view data and run analyses, only the health information officer (a system **user**) is authorized to input and change data. Once all of the clinic data is captured within the ETR.net, the dataset is transferred back to the TB coordinator for analysis.

2.3.1.2.5 **Storage of Data and System Security**

TB Suspect History Sheets and Patient Clinic/Hospital Cards are kept on file in patient folders at the TB treatment facility, while the District Tuberculosis Register forms are filed at the sub-district health office after data capture. No data, paper or electronic, has yet been formally archived since the implementation of the ETR.net.

When updates are made to the ETR.net, two backups of data are made: 1) on the City Health's network server and 2) on an external data drive. Within the ETR.net itself, security of data is preserved through several means. Individual user names and passwords are required to enter the database, and as described above, there are different degrees of access. System **users** are permitted to input and edit data, while system **administrators** may only view data and run analyses. Furthermore, access to patients' HIV status and other related data (where available) is further restricted to particular users and administrators. Patient identifying information is only intended to be visible at the first (sub-district) level of electronic data – data is encrypted to ensure that names and other personal data are not included in the data that gets transferred to higher levels of the

system – but in practice other health personnel within the Metro can access this information (albeit with the possession of a valid username and password).

With respect to legal authority for data collection and privacy, the National Tuberculosis Control Programme, including TB surveillance, complies with the **South African Patient's Rights Charter**, which states:

> Your right to confidentiality and privacy refers to the way in which all information concerning your health, including information relating to any treatment, or stay, in a health establishment will be dealt with. This information may only be disclosed with informed and appropriate consent, except when required in terms of law or duty (68).

2.3.1.2.6 **Data Analysis and Dissemination**

Data analysis within the Cape Metro is carried out at various levels and disseminated in ways to meet the needs of various audiences.

At the sub-district level, the TB coordinator conducts quarterly **outcome reports** that illustrate: a) case finding; b) smear conversion; c) treatment outcome. These three types of data provide the essential information required to make program and policy decisions to improve TB prevention, care and management. As one TB coordinator described,

And it's like a holistic approach, ok? For example it's the case finding, the smear conversion and the outcome. So you need to keep track of those three elements. [They're] not to be separated. That's important.

Sub-district-wide analyses are carried out, and individual facility reports are also conducted, to enable comparisons between clinic performance to be made and overall area trends to be observed. Within these, some data can be disaggregated by age and sex. After the TB coordinator has conducted a final verification of comprehensiveness, each sub-district's health information officer sends the quarter's raw data to an officer of the Cape Metropole Health Information Group. This individual compiles all of the Metro data for transfer to the regional TB coordinator for Metro-wide data analysis. He also

performs his own analyses for presentation at a Metro-level health meeting that the regional coordinator does not attend, at which TB results are discussed quarterly.

Once the regional TB coordinator receives the complete dataset, she carries out sub-district and Metro-wide analyses, comparable to those performed by TB coordinators. Throughout the Cape Metro region, it is apparent that there exists repetition of analyses by various system users. Although it is important that independent analyses are conducted to verify the inter-user reliability of results, it is likely not necessary that replication occurs to this extent. Regional TB data is transferred to the provincial level on an annual basis, and from there is disseminated to the national level. Table 2.1 outlines the analyses that are presented quarterly, but there are others that the ETR.net is capable of running. Appendices 4a, 4b and 4c are examples of Case Finding, Outcome and HIV Reports; these illustrate the more detailed analyses that the ETR.net can compute. The ETR.net is not capable of calculating the total number of active cases at a given time, because the designation "not evaluated" is given to both current (i.e., active) patients and former patients for whom data is missing.

TABLE 2.1 Tuberculosis Case Finding, Smear Conversion and Outcome Analyses: Data Presented Quarterly

New cases registered	New smear positive cases
Smear conversion rate	Cure rate
Case load (by sub-district)	Default rate
Treatment completion rate	DOTS coverage
VCT among TB patients	Sputa lab turnaround time
Treatment success[7]	

TB sisters can see the progress that other clinics have made and discuss strategies that have been successful in achieving improvements. Each facility is provided with

[7] Discussed in a subsequent section, treatment success rate is the combined value of both cured and treatment completed cases, and outcome results are sometimes described in terms of treatment success rather than cure or treatment completed individually.

tables and graphs that demonstrate their case finding, smear conversion and treatment outcome performance, and also illustrate their current standing with respect to national TB targets. TB nurses expressed the view that this feedback and discourse (as well as the light-hearted competition that is sometimes created) is valuable and encourages improvements in performance.

Participant: *We get it* [results from analysis of facility data] *from the TB coordinator. And then all the clinics on that particular district, meet together to discuss with the reports. That is where you can see that your clinic is doing well, is not doing well. There's a slight competition when it comes to that.*
Interviewer: *Oh, ok. So you want to have your facility doing well.*
Participant: *Yes, yes. And even the stats that, the way they demonstrate, over projected, then you can see that you didn't do well, or did do well. That is what they're encouraging... Because if I see your clinic can obtain 90%, why can't mine?* [TB nurse]

Participant: *Whenever they discuss these indicators like the cure rate, the smear conversion rate, things like that, they always refer to us* [all of the clinics within the sub-district] *as one, because we are a district.*
Interviewer: *Ok, so all of [name of sub-district]?*
Participant: *Yeah, all the facilities [unclear] there for these meetings. So the rates, they determine, the rate of [name of sub-district]. So we always motivate each other. If this clinic is high and that one is low, each will affect the whole district. So we always meet at these meetings, we discuss things like that.* [TB nurse]

At the sub-district level, sub-district and individual facility performance is also presented at monthly or quarterly meetings with health personnel who are involved with TB control but in most respects are less involved with raw data. These individuals include the sub-district program manager, facility managers, health promotion officer, and environmental health officer. Because data is discussed with personnel whose roles are of a more managerial nature, these meetings can serve as a forum for broader sub-district program planning.

The City of Cape Town Health Department assembles Multi-Sectoral Action Teams (MSAT) comprised of groups from a variety of sectors within the city (community, faith, NGOs), to encourage the development of interventions to combat

HIV/AIDS and tuberculosis. Within each sub-district, MSAT meetings are held monthly, at which TB data from the ETR.net is presented and considered (Ria Grant, April 26, 2006).

A member of the Cape Metropole Health Information Group presents data at a regional PDR ("Plan, do and review") meeting held monthly, at which TB data is presented quarterly. The TB Programme Regional Coordinator is responsible for presenting tuberculosis data at the remaining regional health meetings.

Appendix 1d outlines the frequency, attendees and focus of the various assemblies at which TB data is discussed. It is worth noting again that the frequency and content of sub-district meetings vary depending on health management personnel and within-district organization. What is important, however, is that within each sub-district there are regular meetings with all involved system users to keep them informed about data trends and to discuss ways to better meet goals and objectives.

2.3.1.3 **Simplicity of Structure and Ease in Operation**

The data flow and organization of reporting within the Cape Metro region is relatively simple. Users typically have only one level or party to which they are expected to report, and the management of patient data once it has been obtained is straightforward.

Because of the nature of tuberculosis treatment, however, operation at the data collection level is more complex. Health workers must be cognizant of the various tests and drug regimens required at distinct points in time for patients with different TB profiles (new cases, retreatment cases, cases with MDR TB), and the particular data that must be collected to correspond with each of these. In order to make the process more manageable, the National TB Control Programme has developed an instrument called a "sputum wheel". By selecting a TB profile on this cardboard tool, a nurse is instructed on

the timing of requisite tests and treatment changeover and completion. The tri-coloured District Tuberculosis Register carbon sheets are folded in correspondence with each phase of treatment – pre-treatment, intensive phase and treatment completion, facilitating the patient data entry process. The TB nurses interviewed had all been specifically trained in using the sputum wheel, and expressed ease with applying to their clinical practice, but the TB coordinator and information officer from one sub-district voiced concern with the quality of some of the data collected as a result of incorrect or inadequate application of the tool.

Users of the ETR in the Cape Metro region had varying opinions regarding the availability of technical support when there are malfunctions in the software (usually as a result of the software updates and revisions discussed below). The company that operates the system offers support over the phone and some individuals felt that this support was available and ample for their needs. Others were under the impression that they were not to call this company directly, but rather had to go through other individuals at managerial level in the Cape Metro region, a process that was often time-consuming and frustrating.

2.3.1.4 **System Flexibility**

In principle, the system software is quite flexible and has the capacity to adapt to changing information needs, but there is question among users regarding the extent to which the needs they themselves feel are the focus of these changes. New versions of the ETR are developed and implemented often, sometimes in response to feedback from information officers and coordinators, but also partly to their aggravation, because sometimes newer versions will leave out advantageous qualities that they appreciated. Additionally, the information officers and coordinators work under restrictive quarterly deadlines, and sometimes the implementation of updated versions will be ill-timed

rendering it difficult for users to produce the results needed for approaching meetings and presentations.

Participant *To be very honest with you, we were not part of the program, the planning of the program. We just, we get the program, we need to implement it. Ok? And that's a problem, because we are out in the field, we are on the ground, so perhaps that could be added.* [TB Coordinator]

Interviewer: *Ok, so they do ask you for feedback about [software]...*
Participant: *Yes. But a lot of the things that get asked for never get done...*
...So it works fast on everything, the only thing is that some changes they make sometimes without consulting us, and the input, and by that, they've slowed it down... For instance [unclear] you're busy in a record, you finish it and you want to go to the next one [patient], you just have a little arrow, you click on it and you get to the next one. They've taken that away... [Health Information Officer]

Some users expressed dissatisfaction with the rigidity of the available analyses within the ETR.net software, and indeed it is not possible to compute some statistics that would be valuable. Furthermore, the software enables users to produce reports comprising set statistics; it is not possible to customize analyses.

Participant 1: *You know, there are some other things that I would like to change about the system. The system is not manipulative enough for us, to run certain reports.*
Interviewer: *Ok, what kind of reports would you like to be able to run?*
Participant 1: *I just want to run,* [for] *example, smear positive reports. And list them. Because I want to be able to do just that. And it can't do that for me...It can't give me exactly what I want...* [TB coordinator]
Participant 2: *Two or three versions ago, we had an option where we could ask for certain fields, and get the report, and get the patients, so we could make up a little one... [could produce customized reports]. But then the next version comes out, and it's gone. It's been taken away.* [health information officer]

System integration is currently poor. Firstly, it would be valuable if the ETR.net software had the capability to be more integrated with *itself.* The system is not networked between health officers; when results are compiled for analysis at any level (regional, provincial, national), they must be independently assembled. Networking the system between sub-districts and provinces (and even clinics if data capture eventually takes place at that level) would be extremely

helpful for detection of overall trends as well as patient management. User interviews exposed strong feelings about the impact that an integrated system would have on transition of treatment for patients who move in and out of areas and essentially become lost to the system:

Participant: *Or maybe linking up with Home Affairs or something, once you put in the patient's ID and then that can say "this patient has been on TB", just for them to ask "did you finish your TB treatment?" and whatever. You know, something must come out about these clients...because we lose our clients so much.* [TB coordinator]

The District Health Information System (DHIS) is a national database which contains some information from the ETR, but because not every province has embraced this integration of data, its value as a national TB surveillance, or patient management, resource is currently limited. Furthermore, it does not contain the patient data components that would be necessary to facilitate the transfer of patient management between regions and provinces. Incorporating ETR.net data electronically within the DHIS, for which plans are currently being developed, would improve capacity for a general depiction of national, provincial and regional health status. At a more specific illness level than the DHIS, which encompasses a broad range of health events, it is important for TB and HIV data to be incorporated. The integration of this data would enable valuable analyses of control efforts to be carried out (69). Although patient HIV status is intermittently recorded within the ETR.net, the incorporation of HIV and TB data is still in the process of development.

Users were emphatic about the inaccuracies that result from the ETR.net classification of cases as completed or cured. Rather than these designations being based solely on clinical evidence, a case is electronically labeled as either completed or cured (or sometimes not evaluated) depending on the exact number of days between the beginning of treatment and when final sputum tests are taken. (Documented smear

conversion, achieved through sputum tests part way through treatment and again after treatment is completed, is necessary to classify a case as cured.) This can sometimes be an arbitrary designation because of the many reasons, including clinic and laboratory occurrences, that sputum tests could happen a few days earlier or later than system design prescribes. When TB coordinators and health information officers detect discrepancies with respect to treatment completion in the patient register they will bring them to the attention of the relevant TB sister, but there are times when this designation error is not discovered and thus it affects the cure rate. (Another distinct challenge with respect to differentiating between treatment and cure relates to clinic follow-up with patients for the final sputum evaluation, and is discussed in a later section.)

2.3.1.5 **Level of Acceptability Among Users**

The level of system acceptability among users was evaluated through analysis of qualitative data, as well as assessments made during the interviews; rather than specifically inquiring about acceptability in interview questions, this attribute was more suitably discerned through general observations. The system users who participated in this study all appeared very willing to participate in the surveillance system. They expressed a need for system success, as well as personal meaning associated with their roles within the system. For the most part they were strongly committed to seeing improvements in tuberculosis control and surveillance, and doing their part to make them happen. Although some felt that this fell on deaf ears, workers at various levels within the system would approach personnel in higher levels of the system to provide feedback and suggest changes that they thought could benefit the program.

One of the roles of the TB coordinators is to visit the clinics, both to collect patient data for capture and to ensure that clinic operations are moving smoothly as far as the paper record is concerned. Some of these individuals expressed how important that

support is, and that they wanted to make things easier for the staff, demonstrating a desire for the system to operate smoothly and a willingness to contribute so that this would happen. Similarly, respondents at the managerial level within the Metro expressed this role of support to the coordinators, information officers and health care workers. One individual in this position was particularly emphatic about her desire to be available to staff whenever they needed assistance. Additionally, the importance of encouraging staff to make improvements not only for the success of the system but for their own sense of meaningfulness within the system was stressed. Statements from staff indicating that they are recipients of this support corroborated these expressions.

TB coordinators and health information officers need to work very closely together to ensure that the data gets captured properly, comprehensively and on time, and for the most part it seemed that coordinator and HIO dyads (or triads in the case of sub-districts with high case loads) are committed to working well together and respecting the team effort that is required.

In order for data capture to be conducted accurately, in a manner that allows errors to be detected and corrected, health information officers require good background knowledge of TB diagnosis and treatment procedures. Several of the HIOs in this district recognized that their knowledge wasn't at the level where they thought it should be, and took the initiative to request training to help improve this.

Several respondents indicated how important it was to them that the system was performing well, stating that their responsibility went beyond [just] a job:

Participant:... *this is how I feel about my work, [I can't] just to capture and forget about what happens; I want to see results!... But I feel as an information officer, you don't just capture. You need to look at the information: does it make sense? Has there been an improvement? What in your little corner can you contribute to making it better or to improving it?*
Interviewer: *And it's important, too, because it's your job and you just can't sit back...*

Participant: *Exactly. How can you.... you know that your cure rate is so low, you're a part of the team here...but you're saying "I'll just capture", irrespective of what they're doing, how they do it.* [health information officer]

One individual expressed how vital the cooperation and communication between various members of the team within her sub-district was to contributing to the meaningfulness of both the data and the work.

Participant: *I'm actually getting more involved now than I ever was in the past. All we did was just capture, capture, all the time. Now with these meetings with the district manager, we've become part of a team, it makes the information more meaningful. So you're actually more aware of what's happening now...*[health information officer]

Receiving feedback about the system and the progress it is making (or not making, as the case may be) was also helpful to respondents, especially the nurses who had less contact with the data once they'd entered individual patient details into the paper record.

2.3.2 **Performance of the system**

Based on contextual needs as well as more general surveillance criteria, the following section assesses the performance of Cape Town's TB surveillance system. The primary areas of focus of the performance evaluation are the questions identified in section 2.2.1, but as indicated earlier, other elements of the CDC *Guidelines* were also considered, including sensitivity, predictive value positive and early detection.

2.3.2.1 **System Consideration of Contextual Issues for Tuberculosis Control in South Africa**

The South African National TB Programme emphasizes the need for VCT to be a component of tuberculosis clinical care for all patients, but within surveillance data it is difficult to discern how often VCT is actually offered in practice. While individual HIV data is not accessible to many ETR.net users, aggregate data pertaining to HIV (including VCT) is available. It is possible to calculate the proportions of TB cases who received counseling, agreed to be tested, tested positive, and began co-trimoxazole preventive

therapy (as prophylaxis for other opportunistic infections (56)), but within the electronic record it is not possible to discern to how many patients VCT was initially *offered.* Among the number of cases who did not receive counseling and testing some may have declined to receive the service and others may not have been offered VCT at all.

In the context of growing numbers of resistant strains, including extensively drug resistant tuberculosis (32), it is essential that surveillance of TB drug resistance is strong. Susceptibility testing within a laboratory is necessary to diagnose cases of multi-drug resistant (MDR) tuberculosis, but results take several weeks to obtain. Nurses and physicians are advised to follow this testing procedure for patients who do not convert to smear-negative status after the intensive treatment phase, treatment failure cases and individuals who default from treatment (5), but it is not clear whether or not this is always done consistently. When these tests are performed, susceptibility results are recorded in a patient's paper record and also transferred to the electronic record. Broader MDR data is collected at provincial and national levels (70) from MDR-TB units (to which patients diagnosed with MDR-TB are transferred, usually within a larger hospital or other health facility), but obtaining routine data has been problematic (Carina Idema, January 29, 2007), and this does not contribute to the base of TB information at regional levels. In response to the need for higher quality MDR TB data (29), routine surveillance tools are being developed and piloted, and it is anticipated that an MDR component will be added to the ETR.net (Carina Idema, January 29, 2007).

The way in which TB treatment and management is approached is under deliberation, out of recognition that traditional clinic-based DOTS limits patient accessibility to treatment (71, 72). There is evidence that patients who receive treatment from community health workers have cure and completion rates that are equivalent to patients supervised by family members (71), and studies suggest that there is no

significant difference in treatment success between patients who are directly observed and those who self-administer treatment (73). Models for administration of tuberculosis treatment are also changing in Cape Town. According to TB nurses interviewed, DOTS is primarily received from clinic staff within the Cape Metro region, but family members, employers and volunteers within the community also provide DOTS support to some TB patients. This information is collected and recorded within a patient's paper records, but is not transferred into the electronic record. This data is collected, collated and presented in summary form by the Regional Coordinator, so it is possible to make decisions using this information, but having it consolidated in one source – that is, within the ETR.net, or an integrated electronic system – would be beneficial.

Another surveillance element specific to the context of tuberculosis is the need for investigation of smear conversion. As indicated earlier, the first set of drugs taken in the intensive phase of treatment rids the body of the majority of the tuberculosis bacilli, and consequently patients should be smear-negative at the end of this phase. In order to determine how well treatment is being managed, as well as detect potential cases of MDR (apparent if smear conversation has not taken place by the end of the intensive phase), it is necessary for tuberculosis surveillance to include data on smear conversion. The ETR.net produces sputum conversion reports, which can provide data for all smear-positive cases, as well as disaggregated data for retreatment smear-positive and new smear-positive cases.

Lastly, turnaround time for lab results is a critical component to TB care, and the recording of such information can help to monitor and improve performance. This data is available by clinic, but is not contained within the ETR.net.

2.3.2.2 **Contact Tracing**

Like case finding, contact tracing is currently a primarily passive practice in the Cape Metro region. When patients are diagnosed with tuberculosis, they are asked to identify individuals with whom they have had close contact. (This deems the process slightly more active than not inquiring about contacts at all, but as will be described below, the practice used to be completely active.) Patients are asked to inform these persons of the symptoms of tuberculosis, and to appeal to them to come to a clinic if they experience any symptoms. The exception to this is in the case of patient contacts who are under the age of five years old. Regardless of whether or not they exhibit symptoms, patients are asked to bring children under five years of age to a clinic to be tested and to receive treatment because young children, especially those two years of age and younger, are at high risk of developing active disease after exposure to an infected individual (5). In the past, active contact tracing – in which health workers obtain the names and addresses of case contacts from patients and go into the community to seek them out for testing – was a feasible practice in some areas of the Metro and was thus carried out. The increase in case volume over the last several years, however, has meant that active contact tracing is prohibitively time- and resource-consuming. The number of contacts identified by patients, as well as the number of those contacts who were traced and subsequently treated is recorded within patient paper records but not transferred to the electronic record.

Mechanisms for contact tracing, as well as diagnostic approaches for TB in HIV+ patients and cases of MDR, serve as examples of components that undoubtedly constitute tuberculosis control activities but that to some extent also comprise surveillance endeavors. The surveillance data upon which program and policy actions are based is itself rooted in the types of disease control and management activities that are carried out.

2.3.2.3 **Sensitivity and Predictive Value Positive**

As a result of the range in severity of symptoms, variable access to health services, stigma and diverse knowledge and understanding about the disease and its symptoms, many individuals infected with tuberculosis may not seek medical care. Additionally, both human error and clinical and laboratory ambiguities and inaccuracies are realities in testing for and diagnosing tuberculosis (74). It is thus important to be able to ascertain how precisely a surveillance system is identifying cases, and of all existent cases, how many are being identified. Sensitivity and predictive value positive (PVP) are two measures that serve this purpose. Sensitivity reflects the proportion of all true cases in the population or community that are detected by the system, and PVP indicates the proportion of cases detected by the system that are true cases (74, 75). Low sensitivity can suggest that there are health needs that are not being met, while low PVP can suggest that public health resources are being wasted or misdirected by providing treatment to patients who do not need it, as well as potentially initiating larger public health responses to perceived but incorrect shifts in disease occurrence (74).

In order to measure both sensitivity and predictive value positive, external data representing a "gold standard" must be available. A gold standard data source for sensitivity of tuberculosis must be able to reveal the frequency of tuberculosis infection within the population, and to determine PVP gold standard data should enable the confirmation of all system-detected tuberculosis cases (74). Currently, no external gold standard data source exists in Cape Town that can meet these requirements, nor was it possible to collect data of a sufficient quality to meet this purpose within the context of this evaluation. Although studies that consider the sensitivity and predictive value positive of diagnostic techniques in various populations within the region have been conducted (76, 77), none have evaluated these measures within ETR.net data. While not

specifically examining sensitivity, one study of tuberculosis within children in Cape Town found that of the 443 children treated for TB during the study period, fifty four cases (12.2%) were not recorded in the clinic (District Tuberculosis) register (78). Because the children observed in this study were *treated*, clinically this does not present as considerable a problem as children with tuberculosis who were not detected by the system at all, but these data discrepancies do indicate severe surveillance concerns.

2.3.2.4 **Estimates of Morbidity and Mortality**

The ETR.net includes all patients who present (or are referred, from a hospital or other health facility) to clinics for TB testing and are diagnosed with active disease. It therefore presents a broad but not comprehensive picture of TB morbidity in the Cape Metro Region. The cases that are not included are those patients diagnosed with and treated for tuberculosis while serving time in correctional facilities, a population in which TB prevalence is relatively high (14). Data regarding incarcerated cases of TB is reported directly to National level (Geraldine Pienaar, March 22, 2007). There are some districts within which prison TB data is entered into the ETR.net as separate sub-districts, but this is inconsistent and thus very incomplete (Carina Idema, March 22, 2007). Furthermore, beyond numbers of infected individuals, the ETR.net alone does not have the capability to provide measures of morbidity such as years of life lived with disability (79).

TB mortality is not well captured by the ETR.net. The electronic register only contains mortality information for patients who die while on treatment (as well as, to a small extent, those who had recently been receiving treatment); cases are not followed up indefinitely post-treatment. These deaths contained in the ETR.net are not confirmed tuberculosis deaths, but rather deaths of any cause that occurred while an individual was receiving tuberculosis treatment. Moreover, because they have presented to a TB clinic and are receiving treatment, the patients whose data is captured within the ETR.net are

less likely to die from tuberculosis. It is those individuals who do not receive treatment that comprise a much larger group more likely to succumb to the disease. TB mortality is one of the areas of surveillance that must be supplemented by other sources of data. TB mortality data of a more comprehensive nature can be obtained from South Africa's national vital registration system. When a death occurs, a death notification form is completed by a practitioner, onto which he or she records the cause of death (COD) (80). This information is coded using ICD-10[8] and compiled at local council levels (81). Data specific to TB deaths can then be extracted from this system. Discrepancies within both death notification forms (missing or incomplete data, misclassified or inconsistent causes of death) as well as coded data (coding inconsistencies) can compromise the quality of TB mortality data (80).

Because there is not a link between TB mortality data and the ETR.net (i.e. detected cases), it is not possible to obtain a high-quality estimate of the case fatality ratio for tuberculosis.

2.3.2.5 **System Objectives**

The extent to which a surveillance system is able to meet its own system objectives and/or provide strong indicators to measure the operational objectives of the broader health programme in which it functions, is a strong indication of its performance. Outside of its patient management mandate, there are no officially documented objectives specific to the ETR.net, but as a component of the South African TB Control Programme, its purpose is to serve as a programme management tool (at the sub-district and district levels) and to provide data to support assessment of TB control efforts (5). The epidemiological targets of South Africa's TB Control Programme are to (70):

[8] In the Cape Metro region a short list to correspond to ICD-10 was developed, based on the causes of death that are more prevalent in this area, in order to improve reliability in coding practices. Individuals who code cause of death information were trained in the use of this short list (81).

- cure 85% of newly detected cases of smear-positive tuberculosis
- detect 70% of all tuberculosis cases
- reduce interruption rates to less than 5%

The ETR.net is able to provide information about interruption and cure rates, but estimation of case detection requires supplementary data and cannot be computed using the ETR.net alone. The case detection rate is the proportion of all true cases that are detected, and thus requires an approximation of the area's overall incidence, which is difficult to estimate (82). As outlined in an earlier section, the values for incidence produced by analysis of ETR.net data use the number of newly *detected* cases as the numerator – rather than new cases *total*, or more realistically, an estimate thereof – which is not a correct use of the term. South African case detection rates are calculated at the national level, although there is acknowledgement that this is problematic as a result of the difficulty in determining true overall incidence (70).

2.3.2.6 **Treatment Completion and Cure Rate**

Cure rate and the rate of treatment completion are vital measures in tuberculosis surveillance (83). Data pertaining to treatment completion and cure rate is comprehensive, if not always well-defined (described earlier, with respect to the difference between completion and cure), and as such serves as a measure of system performance. Cure rate and treatment completion rate are two routinely collected outcome measures; treatment success rate is the combined value of both cured and treatment completed cases.

One challenge voiced by interview participants related to the calculation of cure rates is that some patients do not return for final sputum tests. These final smears are required in order to designate a case as cured; if an individual does not return he or she can be considered *completed*, because clinic staff know that the DOTS supporter was

provided with a sufficient amount of anti-TB medication, but they cannot confirm whether or not the case was *cured.* This again can lead to the calculation of erroneous, most likely underestimated, cure rates.

2.3.2.7 **Early Detection**

Health workers are able to determine at what stage in the disease process cases are being detected by the amount of tuberculosis present in the sputum of a smear-positive patient. At the time of a laboratory confirmation of tuberculosis disease, each patient's sputum receives a ranking, through the designation of a number of [+]s, which indicates the amount of bacilli present in the lungs. The greater the number of [+]s, the greater the amount of bacteria that is present and the further along the disease progress is. These values are not transferred into the electronic record, however, and consequently it is not possible to examine broad trends relating to case detection and stage of disease. (It is of course arguable that these pluses are not necessarily a standardized designation, which would limit their applicability in terms of studying broad trends.)

2.3.2.8 **Data Quality**

Several measures are taken to ensure the quality of patient data and subsequent analyses. As a first phase of verification of data quality, TB coordinators check the paper register for missing data as well as incorrectly entered data. When necessary to acquire missing information or clarify areas of ambiguity, the TB coordinator follows up with facility personnel. Completeness of data is also assessed by the health information officer throughout the data capture process, and the greater his or her understanding of tuberculosis management, the more comprehensive this examination will be. The final phase of data quality verification takes place when the TB coordinator conducts quarterly analyses. Discrepancies within the sub-district and/or individual facility report (for example, 'non-evaluated patients' – patients for whom there is no outcome recorded) are

examined. As necessary, the TB coordinator goes back to the electronic record or patient folders to determine where the error happened and what needs to be input or changed to restore the data.

A folder audit process recently initiated to examine the contents of patient files can serve as a supplementary, though not at all comprehensive, source of data quality information. In the past, external folder reviews were periodically conducted at randomly selected facilities, but those involved in TB management found that unless reviews were internally driven, the results would not be applied. Now, facilities that are interested in carrying out this type of performance assessment perform folder audits internally. Ten folders from each of these initiating facilities are randomly selected, and the data contained within is and (depending on the patient's health status) examined for a number of factors relating to tuberculosis, HIV, sexually transmitted infections, etc. Facilities use this information to inform action planning. (At the time of the evaluation, it was hoped that the more enthusiastic facilities that had initiated these audits would transmit lessons learned to other facilities, who could then follow suit.) While not generalizable because of the very small sample size, this information can identify performance gaps of which health workers and TB coordinators should be aware. This audit is a Metro-specific initiative.

2.3.3. **Action Informed by the System**

As previously emphasized, it is vital that surveillance data be used to inform public health and policy action. An extremely comprehensive and well-managed system of data collection would be of no value if its function stopped at data collection. This section will explain the ways in which analyses of TB data are used to inform public health action. Post-analysis, system data is disseminated in a broad range of forums to individuals at all levels of TB involvement in the region, facilitating decisions and

courses of action regarding TB prevention and control to be made. Because prevention and control activities take a variety of forms within the Metro – from posters and information sessions at the clinic level to decisions and approaches to improve completion and cure rates at the City level, as well as broad-reaching NGO activities – the wide dissemination of TB findings is extremely valuable. (Of course, policies and regulations nation-wide are implemented by the National TB Control Programme, but this evaluation was limited to the Cape Metro region.)

As funding decisions are made at a variety of levels (and consider a plethora of factors), it is less straightforward to quantify the extent to which these are made using Cape Metro system data. Through quarterly meetings at the City level, ETR.net data is taken into consideration when decisions regarding targeting and distribution of resources are made. Policy recommendations are established based on ETR.net findings at quarterly meetings, and thus bear some weight in policy-making.

As far as it produces data on the National TB Control Programme's objectives, the system does permit broad assessment of prevention and control activities. Within the constraints of its current operation, however, the capacity of the TB surveillance system to assess the effect of *specific* prevention and control activities within the Cape Metro is limited (although the system does provide information about broad trends that can paint an overall picture of TB control). There are several factors that play a role. It is not possible to determine the overall number of people who come for testing[9], nor the proportion of people tested who are positive. These figures could be indicative of the success (or failure) of public health efforts encouraging TB testing as well as those providing education about prevention. The disease stage at which infected individuals

[9] While a paper record of all individuals tested is maintained at the facility level, and thus absolute numbers are available at each clinic, this information is not transferred to the electronic record from which it could be used to assess prevention efforts.

present for testing and treatment could also provide an idea of how well education campaigns are working, and this information is available within smear-positive patients at the clinic level (recall the taxonomy of [+]s for rating the bacteria levels at the laboratory), but again does not get transferred to the electronic record for broader analysis. Smear-conversion at the end of the intensive phase, and overall treatment success rate are well-documented elements of the ETR.net; analysis of changes within these values could provide insight into the effect that control efforts such as patient education at the clinic level as well as within the community are having on disease outcomes. Regardless of the variable considered, however, it is very difficult to determine that an observed effect is causal and can be attributed to any single factor.

Clinical practices are certainly improved by the dissemination of and frequent discussion surrounding ETR.net data with health care workers who see and supervise TB patients. When discussing performance between facilities in terms of treatment failure and success rates at regular TB meetings, interview participants noted that they bring back lessons learned from more successful clinics to their own practice. It is much more difficult to ascertain whether broader-reaching practices (behavioural and social), however, are improved as a result of system operation and data.

Lastly, while a very important area of action that could potentially be based on system data is research. Certainly at least some researchers follow and use TB trends produced by the system to inform their work, as evidenced by the attendance of researchers at TB Clinical Working Group Meetings. Beyond this, however, it is difficult to determine the extent to which research is stimulated by the Cape Metro region's specific TB data. It is well known that TB is a major health problem within the area, so many research projects may be initiated using this knowledge, without relying on specific reports.

2.4 **Discussion**

A key responsibility undertaken by any investigator carrying out an evaluation is the appropriate dissemination of the results and recommendations emerging from the evaluation (45). The following sections form the basis of the evaluation report, which will be disseminated to key stakeholders in the Cape Metro region, individuals within South Africa's National Tuberculosis Control Programme, as well as ETR.net system users who participated in the qualitative component of the study.

2.4.1 **Conclusions of the Evaluation**

In Section 2.2.1 of this document, eleven question areas were posed, divided into three elements. A previous section describes detailed findings relating to each of these areas, and the following summarizes the strengths and weaknesses detected.

2.4.1.1 **Structure and Organization of the System**

The structure of the system and the flow of data are not extremely straightforward, but the number of levels and therefore individuals involved is necessary to ensure proper organization of data and data management. What would increase simplicity of the structure would be the implementation of data capture mechanisms at the facility level; that is, data would be entered into the ETR.net at the same place where the data itself is obtained. This option was recommended by several interviewees but they also acknowledged the reality that this would require more resources than are available and it was primarily an "in an ideal world..." suggestion.

Earlier, the importance of verification of data – especially within a system which contains several levels of data management – was stressed. Within the levels of the Cape Metro region, this verification appears to be sound.

While the structure of the system may not be particularly simple, it is well-understood by all users; individuals at all levels understand their role and where their

work fits into the larger system. Moreover, the operation of tasks required at each level is clear and manageable. Data flow and operation of the system are thus strengths.

An area of weakness is the system's flexibility. While software changes are possible and updates occur regularly, this flexibility is not always optimized. While not all users felt this way, some individuals working within the system felt that the recommendations for changes that they perceived as necessary were not heard, let alone carried out. A lack of response to (some) user feedback, as well as a sometimes perceived lack of opportunity to provide feedback, are limitations of the system that impacts on its flexibility.

One of the clearest messages received during this evaluation, and one of the system's strongest assets, was the level of acceptability among system users. Everyone interviewed was passionate about their work and committed to improving the context of TB in Cape Town. Acceptability was extremely high despite the frustrations with some components of the system; users were invested in working towards changes to improve the overall operation of the system.

In order to adapt to changing needs, regular software changes are made to the system. These changes are usually small, but often users are not consulted about features that are added or removed. Inconsistency between users regarding whether or not user feedback is sought when changes are made was also detected in this study. Lastly, the timing of software changes can be poor, often conflicting with report deadlines for monthly or quarterly meetings.

2.4.1.2 **Performance of the System**

With respect to the key contextual issues of concern in TB surveillance, there is certainly room for improvement but for the most part gaps are identified and approaches to meet the needs are being discussed and/or planned. Complete HIV data is not

integrated with the ETR.net, which is a large limitation, but plans are in place for this to be possible. Included in this integration should be more detailed data about VCT and applicable follow-up, and appropriate TB testing for individuals with HIV. Similarly, high-quality, routine MDR data should be available at the regional and sub-district levels, and should be integrated electronically with other TB components. Routine MDR surveillance tools are currently being developed and piloted, with plans to incorporate this data into the ETR.net. Smear conversion data is a very important element specific to TB surveillance and this is a strong component of the ETR.net.

Again as a result of resource constraints, contact tracing within Cape Metro is limited, which can have a potentially great effect on the number of cases of active tuberculosis detected. Regardless of whether or not the approach to contact tracing changes, electronic data about the proportion of contacts who are traced and treated would be valuable, and currently this information stops at the paper record.

There is currently no mechanism for assessing the sensitivity and predictive value positive of the ETR.net; this information would be very helpful in considering surveillance performance.

TB mortality data is not available through the ETR.net but relatively comprehensive data is obtainable by accessing death notification data at the regional level. The quality of this data can be compromised by incomplete or inconsistent data recorded on the notification forms themselves or discrepancies in the coding process.

In order to provide adequate and relevant data with which to assess whether or not the TB Control Programme's targets and objectives are being met, the ETR.net should be able to provide comprehensive data about interruption rates, cure rates and treatment completion, and case detection. The system is able to produce data about the first two of these, although there is sometimes discrepancy and disagreement about the way

'completion' is classified, which can impact the cure rate. Calculation of a case detection rate, however, is not possible; this is not because of a weakness of the ETR.net but because of a lack of estimated true incidence.

There is a very sound, multi-stage process for preserving the quality of data collected – both missing and inconsistent data – from the data capture stage through to the data analysis stage. Users are trained in the TB management course of action, which enables them to more easily spot discrepancies (e.g. a sputum date that is not possible, or a missing treatment outcome when a patient has provided final sputums.) Folder audits are a relatively new initiative that seem to be helpful at individual facility level for identifying gaps and areas of required action.

As has been highlighted throughout this report, there are many components of TB control for which data is recorded in the paper record but does not get transferred to the electronic record. Much of this data would be valuable for identifying trends, if it were possible to analyze it at higher levels.

2.4.1.3 **Action Informed by the System**

Another very strong element of Cape Town's TB surveillance is the wide dissemination of system data – essential to any surveillance system in order to maximize the applicability of system outputs. With the exception of researchers, a group whose use of TB surveillance data is difficult to determine, there is a broad range of groups (health workers, TB coordinators, health information officers, TB managers, city health personnel, NGOs) across the Cape Metro who use the data in regular decision-making, and for whom there are regularly scheduled forums for dissemination. These meetings are intended for not only presentation of data, but for discussion and planning as well. Policy practices are thus influenced at least in part by system data. Through the regular dissemination of data to health workers, and the motivation and hints provided by peers

when regular meetings are held, clinical TB practices are certainly improved. Social and behavioural practices are much less direct and thus it is more difficult to attribute changes within these to the system.

It is possible to broadly assess the effect of prevention and control activities using system data (e.g. interruption rates and cure rates), but effects of very specific interventions are not easily evaluated.

This last component is something that is vital to strong surveillance; if data is not used appropriately to inform decision-making and public health action, the other components, however strong they are, will be useless.

2.4.2 **Evaluation Informed Recommendations**

Several recommendations for system improvement have emerged from this evaluation, and are presented below.

2.4.2.1 **HIV and MDR Data: Increased Integration within the ETR.net**

HIV and MDR data represent vital components of tuberculosis surveillance which, in order to improve TB control and prevention efforts, need to be integrated directly within ETR.net. In particular, detailed electronic information records regarding VCT (including when it is offered) and HIV testing and status among cases of TB, TB testing and status among individuals with HIV, and MDR susceptibility testing and results, should be routinely maintained. *Plans for further electronic development and integration of these components are currently being made within South Africa's TB Control Programme.*

2.4.2.2 **Integration and Increased Availability of Electronic Data**

There are some elements of data that do not pertain specifically to an individual patient's treatment course and outcome, but that are valuable for assessing components of the control programme and with which future prevention and control efforts can be

developed (certainly components of action-oriented surveillance). There is thus a need for a broader, integrative electronic system that includes these components and can be linked with individual patient data. (To incorporate this into one database would be too complex a process and would make analysis of the key surveillance data within the ETR.net unnecessarily complicated.) Much of this type of information is already routinely collected but remains within the paper record and is thus not available for examination at other levels within the National TB Programme. The supplementary data that would be valuable in an electronic format, and integrated with the ETR.net, includes:

- DOTS: type of supervisor upon whom patients are relying (clinic, employer, community, family)

- Sputum:
  a) allow data from ALL patients who were investigated to be recorded in a sputum register, regardless of whether they tested positive or negative (currently the electronic system only includes the positive patients); this in turn would assist in being able to determine whether initiatives are encouraging more people to come in to be tested, whether there's a change in the proportion of those tested who test positive, etc.
  b) lab turnaround times recorded

- Disease stage: record the number of [+]s that each person's sputum receives at the lab (or translate those [+]s to a scale), so there is an indication of what proportion of patients are coming in a what stage of the disease process

- Case contacts: record contacts identified and treated

2.4.2.3 **Technical Changes within the Existing ETR.net**

Several recommended software modifications would enable users to more efficiently and accurately carry out their duties with respect to data capture and analysis:

- Interface changes:
  a) fewer 'pages' within the computer program; because there are several 'pages' per patient, it makes data capturing much more time consuming
  b) similarly, the ETR.net should have the capability to display all of a patient's information on one page (e.g. whether he/she has received treatment before, what the outcome was, etc.); currently HIOs and coordinators have to look through earlier data to obtain previous records for the same patient

- Analyses: the software should have the capability to allow users to do more specific and custom analyses; currently there are a limited number of set analysis 'packages' that can be run, and sometimes users are interested in different, more specific things

- Criteria for 'cure': the flexibility for this should be increased; system users should be able to override the default designation that is given based on the number of days between treatment completion and smear test. The software programme has specifications for when final smears must be done in order for a patient to be considered a 'cure' as opposed to just 'completed'; this is sometimes not relevant to a particular case, and means that it can make the cure rate seem lower than it actually is.

2.4.2.4 **Implementation of System Changes in a Manner Acceptable to Users**

In addition to findings concerning the operation and performance of the system, and although change implementation was not a direct evaluation question, this evaluation of Cape Metro's tuberculosis surveillance system revealed dissatisfaction among some system users regarding the way in which system changes are currently made. Frustration over perceived lack of consideration for feedback that users provide was also expressed. The personnel that work with TB data at various levels are critical to the operation of the system, and attempts need to be made to ensure that system changes are implemented in a manner that is acceptable to users, in terms of the nature of the changes themselves, their perceived usefulness, and the logistical details surrounding the implementation (timing, training, etc.). This non-technical component may be less straightforward to implement, but it can play a vital role in the success of other surveillance components; the PRECEDE-PROCEED section below describes how this type of intervention could be developed.

2.4.2.5 **Future Research**

In order to assess the predictive value positive and sensitivity of the ETR.net, a beneficial future research project could involve the establishment of a parallel system that would involve a) TB testing within the community to estimate the number of true cases;

and b) retesting cases within the ETR.net (from the selected community) to assess the number of true positives. The chosen community (or communities) would not have to be large; very small areas would be more manageable for this type of project, and would still be able to paint a picture of system sensitivity and predictive value positive.

2.4.2.6 **Ideal System Changes**

Lastly, there are some large modifications that would greatly strengthen surveillance but that are not currently practical given resource constraints:

- Active case finding and contact tracing, in which TB personnel conduct systematic (voluntary) TB testing within communities, and similarly personally follow up with case contacts for assessment of symptoms and potential testing
- Complete networking of the ETR.net between offices and even regions and provinces; this would allow for smoother data transfer for analysis at higher levels, and would also permit improved patient management (e.g. when patients transfer out of one region or province into another)
- Data capture shifted to facility level rather than sub-district level; health workers would input data into the electronic system at the same level where it is obtained from patients

2.4.3 **Limitations of the Evaluation**

Due primarily to time and resource restraints, there are several limitations of this evaluation that should be addressed.

An economic evaluation of the operation of the surveillance system was not carried out. This would have provided information about the efficiency of the system from a financial perspective, including the resources used for data collection and analysis as well as how well data is used to inform decisions regarding resource allocation. Such a component could have contributed to the development of recommendations regarding planning and budgeting that could ultimately improve services.

As indicated previously, a gold standard for detecting tuberculosis is necessary in order to ascertain sensitivity and predictive value positive. Had resources been available

to set up a parallel system of testing – both at the community level to determine actual incidence, as well as to corroborate laboratory findings, even within a few small areas of the region, the ability to assess the case finding performance of the system within this evaluation would have been strengthened. This is certainly an area where further study would be extremely valuable.

The scope of the evaluation was limited to the Cape Metro region. Not only does this deem the findings ungeneralizable to broader areas within South Africa, it also means that certain components of tuberculosis surveillance that occur at provincial and national levels of the TB Control Programme (but not at local levels) were not examined in great detail. Examination of drug resistance, which as described earlier is not conducted comprehensively at clinic or sub-district levels, serves as an example of one such component.

Lastly, there are both strengths and limitations inherent in the fact that the investigator carrying out the evaluation was from an outside party, completely independent from South Africa's health system and government. The investigator had no biases – conscious or unconscious –stemming from loyalty to or faith in the system, which may have been factors if the investigator was employed within some component of the system, or had been specifically commissioned by the TB Control Programme to carry out the investigation. Such biases may have obscured both the initial findings themselves, and/or the presentation of findings. Conversely, the lack of intimate knowledge of the organization of the broader systems of government and health within South Africa prior to the commencement of the evaluation made the evaluation more difficult to carry out; both cultural and organizational nuances had to be deciphered in order to understand some aspects of the system operation.

Chapter 3: Intervention Development

3.1 Introduction to PRECEDE-PROCEED Model

The evaluation described in Chapter Two identifies several approaches to strengthening tuberculosis surveillance. One of these recommendations focuses on a human element of surveillance: the need to ensure that system changes are implemented in a way that is acceptable to system users. Because this issue emerged from the assessment as the most crucial problem to address, and therefore the top priority to evaluate, this recommendation has been selected for more detailed focus here, where an intervention designed to improve user acceptance and satisfaction of system changes is designed.

The PRECEDE-PROCEED model is a framework that guides the development and evaluation of health promotion programs, by focusing on the ecological context of the program (84). While often utilized in approaches of individual health behaviour modification, the PRECEDE-PROCEED model is flexible and can thus be used as a planning framework for a wide variety of interventions aimed at improving health, including policy changes and respective interventions such as the one developed for this project. Further, the elements of F.A.T.E. are the interim markers for a final health outcome, as illustrated in the logic model presented in Chapter 4 (Figure 4.1). In this case, the PRECEDE-PROCEED model is used to identify impediments to user acceptance, and, *informed by these impediments,* develop an intervention that will improve acceptance and satisfaction.

The PRECEDE-PROCEED model emphasizes the importance of looking back at the desired outcome to consider why it may be problematic to achieve (in this case, why might acceptability of changes be poor or low?), before going forward to determine what

should be done and how it should be done, in order to achieve the outcome (84). Naturally, there are many factors related to the outcome and its ecological context that may or may not be important to an intervention. Applied as a planning process, the PRECEDE-PROCEED model helps to identify which of these factors are of greatest influence to the outcome, as well as which are most modifiable (84).

Both PRECEDE and PROCEED are acronyms:

PRECEDE = *p*redisposing, *r*einforcing and *e*nabling *c*onstructs in *e*ducation/*e*cological *d*iagnosis and *e*valuation.

PROCEED = *p*olicy, *r*egulatory and *o*rganizational *c*onstructs in *e*ducational and *e*nvironmental *d*evelopment.

This model will guide the identification of activities to inform a hypothetical intervention, which will be incorporated into a trial protocol in Chapter 4. The processes required for each phase will be described in detail, but will not actually be carried out. Qualitative interviews were conducted with users of the system during the evaluation component of this project, and this qualitative data will serve as a model to illustrate the way qualitative data collected as part of a broader PRECEDE-PROCEED application could be utilized. Because the interviews used to obtain the qualitative data were not designed specifically for the purposes of this model, the data will not meet all of the needs of this model. It will, however, provide an illustration of the way that data should be applied to this type of model, as well as provide the foundation onto which a qualitative data-based intervention can be developed.[10]

[10] Elements of the hypothetical intervention are proposed, but as this is based on an illustration of how to apply the PRECEDE-PROCEED model in the development of this type of intervention, these details are provisional and would need to be revised once the model is applied using data collected specifically for that purpose.

3.2 Application of the PRECEDE-PROCEED Model

3.2.1 Modifications to the Model

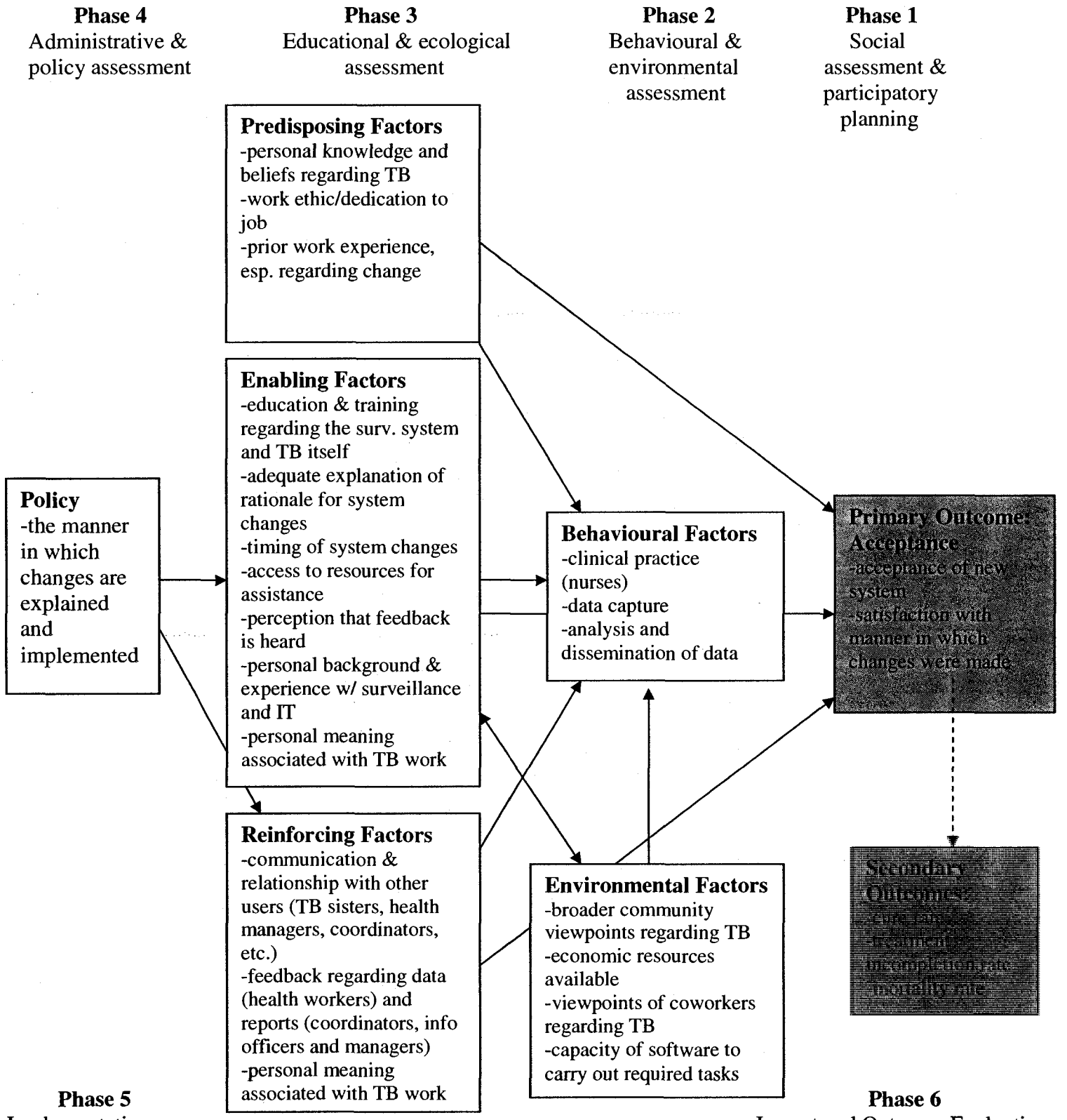
As indicated, PRECEDE-PROCEED is often used to develop and implement health promotion programs and activities. As a result, the outcome *user acceptance* is different than those outcomes most often used within the PRECEDE-PROCEED approach – usually change in health behaviour, or perhaps change in incidence or prevalence of a health outcome itself – and in order to apply the model to this type of intervention, modifications were required. An epidemiological assessment phase was unnecessary and so was removed from the model. Physiological and biochemical components do not apply to an acceptance outcome; the types of behavioural and environmental factors considered were thus quite different than would have been appropriate for a health outcome or health behaviour outcome. Figure 3.1 illustrates the model, and the following sections describe the phases the model as they fit with acceptance as an outcome.

3.2.2 Phase 1 – Social Assessment and Participatory Planning

In this adaptation of the PRECEDE-PROCEED model, social assessment refers to the examination of the social context within which the tuberculosis surveillance system operates. The target population to investigate for this component is the users of that system. The social assessment phase examines factors relating to the outcome *user acceptance* to inform the development implementation of an intervention.

One of the hallmarks of the Precede-Proceed model is participation. Green and Kreuter (84) emphasize the importance of engaging stakeholders in the process of developing and implementing an intervention. Canada Health Infoway highlights the need for user engagement and support in order to achieve acceptance of programs and processes within electronic health systems (85).

FIGURE 3.1 PRECEDE-PROCEED Model for Health Worker System Acceptance



Active involvement by members of the community in intervention planning will help to achieve a greater understanding of the perceived needs and priorities of the target population. This will help to identify factors that influence the outcome, which will facilitate the development of a stronger, more relevant and applicable intervention. The members of the community of focus for this intervention, that is, the users of the system, are TB nurses, health information officers and TB/HIV coordinators. While it is not necessary (or practical) to target participation by all members of the community, a representative sample of individuals should be sought (84).

Focus groups and questionnaires are two primary means of engaging users of the system in the project and obtaining their input. The information sought from each medium is similar, but the approaches both have strengths and weaknesses, and the utilization of both will yield a broader, more comprehensive qualitative data set. Focus groups allow users to discuss their experiences with each other, in a conversation guided by an investigator, and enable planners to observe the interaction between users at various levels of the system. These dynamics will be very important in subsequent phases of the project when considering behavioural, environmental, predisposing, enabling and reinforcing factors of user acceptance. Questionnaires yield a different quality of evidence than focus groups. They enable investigators to gain a sense of individual perceptions, and because the questionnaires are completed in isolation, users may provide answers that they might not feel comfortable revealing in a larger group.

3.2.3 **Phase 2 – Behavioural and Environmental Assessment**

The participant contribution to the qualitative research conducted in the previous phase will identify contributors and barriers to system change acceptance. This participatory component thus plays a key role in the behavioural and environmental assessments, as well as the educational and ecological assessment.

The *behavioural assessment* considers the direct and indirect action-based factors that influence the goal of fostering user acceptance of changes to the system. The *environmental assessment* is a concurrent analysis of social and physical environmental factors that may either a) impact the behaviour(s) under examination in the behavioural assessment or b) directly impacts user acceptance of system changes (84). (The qualitative social assessment can help to identify of behavioural and environmental factors, but an in-depth knowledge of the operation of the system will also be helpful. As a result, at least some of the investigators designing the intervention will be individuals with experience with the system.) As with a health promotion intervention, this phase may reveal factors that are not changeable (or at least not changeable through the proposed intervention), but it is important to be aware of all of the facets that influence the outcome. Changeability will be addressed in a subsequent section.

Again, because the outcome of focus for this intervention is not health, this phase of the PRECEDE-PROCEED model has been modified from more traditional applications to reflect user acceptance as the outcome. Behavioural and environmental factors are as important to system acceptance as they are to health, but in distinct and often less direct ways. An individual's behaviour within various parts of the system can often influence the outcome for others as well as for him or herself. Within this intervention, behaviour change is not the desired outcome. It is certainly a possible effect of the intervention that may influence the acceptance outcome, but it will not be a direct focus of the intervention. Rather than emphasizing the need for behavioural and environmental *targets* for the intervention, behavioural and environmental *considerations* should be identified. The following steps are advocated by Green and Kreuter (84) and, in keeping with the above points, modified for this intervention:

Behavioural Assessment:

1.) Outline any behavioural contributors to user acceptance
2.) Rate these behaviours in terms of importance (to outcome of acceptance)
3.) Rate the changeability of these behaviours (within this intervention)
4.) Choose behavioural considerations for intervention

Environmental Assessment:

1.) Identify which, if any, of the environmental contributors to user acceptance are changeable
2.) Rate importance of these contributors
3.) Rate the changeability of these contributors (within this intervention)
4.) Choose environmental considerations for the intervention

As previously indicated, the factors described below emerged from the qualitative interviews designed for a surveillance evaluation, not this particular process, and serve as an example only of the way that such data could be analyzed and organized. A more specific set of questions would yield a broader range of factors, but again, the purpose of these is to serve as a foundation or model, not as a comprehensive data set. In the context of this work, all of the codes and themes relating to system changes and user acceptability were used as the data from the *social assessment* phase to identify these behavioural and environmental factors. Appendix 5a indicates the importance and changeability of each factor, as well as indicates which will be considerations within the intervention.

3.2.3.1 **Description of the Factors**

3.2.3.1.1 **Behavioural Factors**

Clinical practice (nurses)

The extent to which nurses obtain and report complete patient data comprehensively impacts the tasks of HIO and TB coordinators down the line. This behaviour is potentially changeable through the proposed intervention; if sisters are comfortable with and see the rationale behind changes that influence their role (e.g. new data forms) the quality of their performance would likely be high.

Data capture

This is similar to clinical practice; if data capture is performed appropriately – because users appreciate why the changes have been made – the end product will be more efficient and valuable for the people carrying out analysis at the next level.

Analysis and dissemination of data

This factor is important because, ultimately, being able to carry out necessary tasks on time is one of the most important factors in how satisfied users will be and how acceptable they will find the changes. The role of the TB coordinators and health information officers is to produce high quality reports *on time*. If changes are not explained well, and/or are implemented at an inappropriate time in the quarter, and/or are not accompanied with sufficient support, this will not be possible.

3.2.3.1.2 **Environmental Factors**

Broader community viewpoints regarding TB

This factor may have a general impact on how satisfied a user is with the TB system in a broad sense, but it is not related to implementation of any type of system change.

Available economic resources

Again, this may have an effect on perceptions of the system and any changes that are made. If an area suffers from lack of resources and users are consequently overworked, it may impact negatively on how any type of change is viewed, but it is not changeable through the implementation of system changes.

Viewpoints of co-workers regarding TB

This factor is again similar to the two described above; negative perceptions about TB and any possibility for improvement in the current TB situation held by others in the workplace may also negatively influence users' perceptions of any component of the

system, including changes. Again, this is not a factor that can be addressed by the type of intervention proposed here.

Capacity of Software to carry out required tasks

The proposed system changes have been made with this in mind already; the actual changes *are not* the intervention. While this certainly impacts users' perception of the actual system and changes that have been made, within the proposed trial *everyone* will be receiving the actual changes. Other intervention components (such as the provision of adequate training within the context of changes; see below), however, may influence this factor and therefore acceptance of changes.

3.2.4 **Phase 3 – Educational and Ecological Assessment**

The social, behavioural and environmental assessments produce an understanding of the actions and conditions of working within the TB surveillance system that affect user acceptance. This next phase of the PRECEDE component of the model considers the behavioural and environmental conditions that are related to user acceptance to determine what causes them. The determinants of user acceptance that are isolated in this phase will become the objectives and targets of the intervention (84).

As in the previous phase, the qualitative data described here is taken from the qualitative material obtained during the evaluation component of this project. The interviews conducted during the evaluation were more broadly focused to meet the needs of the evaluation, and thus the data is limited in use for this component, but still serves as an ample proxy for the more comprehensive qualitative data that would be obtained if data were collected specifically for use in an application of the PRECEDE model.

Again similar to the last phase, several factors are identified and ranked according to importance and changeability (see Appendix 5b). Distinct from the previous process, however, is the classification of intervention *targets* rather than *considerations.* Within

the context of an intervention that is delivery system changes in a particular manner, the selected factors described below have a much more direct influence on the outcome, and so have been identified as concrete targets.

3.2.4.1 **Selecting Determinants of System Acceptance by Users for Intervention** (modified from Green & Kreuter 1999 (84))

1.) Identifying and Sorting → Develop a list of causal factors for system acceptance (identified in the previous phases) and organize into predisposing, enabling and reinforcing factors

2.) Set Priorities: which factors are the objects of the intervention and in what order?

Within the theory upon which this phase is based, the predisposing, enabling and reinforcing factors are groupings of factors that particularly influence behaviour (84). Predisposing factors are those that precede a behaviour and play a motivating role; enabling factors facilitate a behaviour or action; and reinforcing factors are those that reward and therefore encourage the repetition of a behaviour (84). As indicated by the arrows in Figure 3.1, PRECEDE-PROCEED Model for Health Worker System Acceptance, in this model these factors do influence behaviour, but they also shape user acceptance.

Some of the factors will impact directly how users accept system changes, while others are more indirect and result from broader experiences and perceptions that contribute to a system user's overall outlook on his or her role in surveillance.

3.2.4.2 **Description of the Factors**

3.2.4.2.1 **Predisposing Factors**

Personal knowledge and beliefs regarding TB

Within this project, general knowledge about TB was high, and comparable across the majority of system users interviewed, as were as personal beliefs about the severity of TB and importance of high-quality treatment. Knowledge about and beliefs regarding TB could impact user acceptability of changes. If knowledge is high and users believe that

TB poses a severe threat to health, it is possible that they would have a stronger commitment to the success of the surveillance system and be more likely to embrace changes (presuming that the changes were perceived as positive and progressive). (The converse could be hypothesized in a setting where TB knowledge is low and users do not believe that it presents a health threat.) Changeability of these factors, especially beliefs, is not high, however, and there are other factors that relate more directly to the outcome; in order to prevent the foci of the intervention from becoming too broad, this factor will not be included in the intervention.

Work ethic/dedication to job

This factor varied quite widely across participants interviewed for this evaluation. None of the system users exhibited poor work ethic but some individuals demonstrated extremely passionate dedication to their work. Similar to the previous factor, it is reasonable to suspect that users with this type of outlook would support positively perceived system changes, but again, changeability is low for this factor and this intervention will focus on other factors that are more directly outcome-related.

Prior work experience, especially regarding change

Several interview participants expressed frustration with the way that system changes had been implemented in the past: in manners that did not include very much user input (if any) and at times that made completing required tasks by their deadlines difficult if not impossible. Past experiences where change has not been approached in a responsible way could cause users to be wary of and resistant to change. This factor is an important one to consider, because of its potential to affect the outcome, but it will not be a direct component of the intervention because its low changeability.

3.2.4.2.2 **Enabling Factors**

Education and training regarding the surveillance system and TB itself

Participants described the training that was provided when the new electronic surveillance system was initially implemented. Among most respondents, this training was expressed as being adequate for users at all levels of the system, and it appeared that this training facilitated a smooth transition from the previous system to the revised one.

A small number of respondents indicated they would like to achieve greater understanding of TB treatment. These individuals were not TB nurses but users at a different level of involvement in TB surveillance and they felt that their performance could be enhanced by acquiring a more in-depth knowledge of the processes involved at other levels.

Education and training would likely have a large impact on the way that larger system changes are regarded and accepted, and the specific education and training about the system changes (described below) will be a target of this intervention, but broader TB and surveillance education are not feasible within this intervention.

Adequate training and explanation of rationale for system changes

When the ETR.net was first implemented, users received training on its use; this appeared to be quite extensive, but it was held at a central location outside of the workplace and therefore outside of the context of everyday use. Some element of training within the work setting, where real problems will crop up and have to be dealt with would be beneficial. Small software changes are made to the TB system on an ongoing, regular basis, and while sometimes the reason for the change is obvious (e.g. in circumstances where there has been glaring software malfunctioning), based on respondents' accounts, it does not seem that rationale for changes is often provided. Seeing a change as

necessary is important to users' acceptance of that change and as such, explanation of rationale for system changes will be a target factor in this intervention.

Perception that feedback is heard

Some users felt that not only was feedback on system modifications not sought, but when comments were offered anyway, they were disregarded. (Some users, however, did feel listened to, and appreciated this. This emphasizes the fact that individual experiences within the same system can differ, and approaches to improvement need to take this into consideration.) Users will likely hold more value in the system if they feel that they have a voice when experiencing difficulties.

Timing of system changes

As described above, users involved in data management and analysis expressed frustration with the timing of system changes, which did not appear to consider the deadlines for analysis and dissemination within which users must operate (see Data Analysis and Dissemination in Chapter Two). Consulting with users and timing the changes based on what is most appropriate with respect to their schedules will likely improve their acceptance of the adaptations to the system. This factor has high changeability and will be a target of this intervention.

Access to resources for assistance

There were discrepancies among user reports about access to technical and personnel support after the new system had been implemented. It is not clear whether levels of support did indeed vary across different sub-districts within the region, or whether users' needs were different and so too were their perceptions of available support. Regardless, users who felt that there was a lack of accessible support when they were experiencing system difficulties had a less positive view of the transition than those who were satisfied with the level of support.

The provision of high quality technical and personnel support across all users of the intervention group will be a target.

Personal background and experience with surveillance and IT

Users interviewed had varying levels of experience with using computers, databases and running analyses, all of which are necessary for involvement in electronic surveillance processes. With the exception of TB nurses, successful adaptation to changes in the system requires users to be technologically adept. Those who are more comfortable with information technology will likely find software transitions easier to manage, and consequently be more accepting of changes but past experience is not a factor that can be changed.

Personal meaning associated with TB work (also a reinforcing factor)

Some respondents attributed remarkable personal meaning to their involvement in TB work. They described how much hope they had for improvements in the success of TB treatment, and were grateful to play a role in this and to affect change.

Similar to knowledge and beliefs as well as work ethic, this factor will likely have an impact of user acceptance because it affects a user's overall perception of his or her role. While there are ways in which personal meaning could be enhanced, changeability is not high and this factor will not be a component of this intervention.

3.2.4.2.3 **Reinforcing Factors**

Communication and relationship with other users (TB sisters, health managers, coordinators, etc.)

Most interview participants seemed to work and communicate very well with their colleagues, but in a few coordinator-information officer dyads there appeared to be areas of disconnect. This information was not revealed as a result of any particular interview question, but was rather observed through the course of the interviews in general.

Contributing to the overall atmosphere of the work environment, positive communication and strong relationships with co-workers could also have an indirect impact on user acceptance of system changes. Because harmony or conflict between individuals depends so much on personality, however, this factor would be difficult to address in an intervention and will be excluded from this one.

Feedback regarding data (health workers) and reports (coordinators and information officers)

The work of TB nurses, health information officers, and TB coordinators is sent 'higher' up through the surveillance system, so there is always application of the data at other levels of the system that individuals do not see unless specific feedback is provided. Users both at the clinical as well as data input and management levels expressed gratification at seeing the results of their work when analyses had been performed, especially when improvements in patient adherence and cure rates had been made. It is hypothesized that receiving regular feedback on their progress in the context of a system change will improve user acceptance to these changes. Regular feedback is already a component that is quite strong in the existing system, however, so the intervention will not include this factor.

3.2.5 **Intervention**

Before examining the last phase of PRECEDE, an outline of the proposed intervention based on the products of the pervious phases should be developed so that administrative and policy assessments are appropriately informed.

Taking into consideration the behavioural factors of clinical practice, data capture and analysis and dissemination of data, several enabling factors were identified important to the outcome, changeable within this project, and therefore, as targets for the proposed intervention (in order of priority):

a) Adequate training and explanation of the rationale for system changes: Prior to the implementation system changes, users will be briefed on the components of the system that are different from what they are currently using; the need for each new component will be explained as well as how it fits in with current components. After the changes have been implemented, training will continue within the workplace setting to support users as they adjust to the system modifications.

b) Access to resources for assistance: Once training has been completed, a very accessible system of technical support will be made available to field any problems that arise; the personnel in this support role will have knowledge of the system's operation beyond the very technical components of the ETR.net software.

c) Perception the feedback is heard: A forum for official feedback (and respective responses) on system changes will be established so that users know that they have a voice and are key players in future system developments.

d) Timing of system changes: Prior to the implementation of changes, users will be involved in determining when the best time for implementation of changes within a quarter is, so that they are able to complete analyses and reports on time (while still allowing an adjustment period before deadlines).

This intervention will be referred to as F.AT.E. to reflect the above targets: **F**eedback is taken into consideration; technical **A**ssistance is easily accessible; **T**iming of system changes considers system operations and user deadlines; and a comprehensive **E**xplanation regarding the role of changes in system improvement is provided.

3.2.6 Phase 4 – Administrative and Policy Assessment

The previous phases of PRECEDE have considered the intervention elements that will (hopefully) impact the outcome; in order to improve the likelihood of this occurring, it is important to also consider the more practical context of the intervention. Potential

supports and barriers to implementation of F.A.T.E. as it has been developed should be identified so that they can be addressed if necessary (84). This last phase should examine the resources both needed and available, as well as the policies that are in place (or perhaps that should be in place) for the intervention to be successfully implemented (84). Unlike the previous phases, for which expansion was possible by applying the results of the evaluation's qualitative component, there is a lack of data regarding these specific administrative and policy components. Consequently, this last section serves only to outline the practical considerations that must be made prior to implementation of an intervention.

The following considerations for administrative and policy assessments are advised by Green & Kreuter (84) and they have been modified to be appropriate for this intervention.

Administrative Assessment

1. How much **time** will be required to implement changes in a manner that includes additional training and follow-up support – for WamTech personnel? For system users? For regional coordinators? Will the extra time taken counteract the benefits of the intervention on system operation?
2. Additional WamTech **personnel** will likely be needed to provide the more intensive training and support – is additional personnel available?
3. What impact will the above have on **budgetary allocations** for the TB Programme? Is there enough of a commitment to this intervention from various parties to make allowances within the budget for these costs?

Policy Assessment

1. What are the current **policies** (and if not policies, **general practices**) regarding system changes? Are these flexible? Is there a **forum** for the provision of (and response to) feedback subsequent to change implementation?

3.2.7 Phase 5 – Implementation

Once the administrative and policy components have been examined, and any barriers overcome, implementation of F.A.T.E. may begin. In the context of this project, there are actually two implementation elements: 1.) implementation of the system

changes (*not* the intervention, but a parallel component), and 2.) the implementation of F.A.T.E. itself (the actual intervention). As the changes will be commissioned by the National TB Control Programme, the first implementation element will be out of the hands of investigators, but it is up to investigators to plan for F.A.T.E. so that the project is ready to start whenever the programme changes are ready. Implementation of F.A.T.E. and subsequent outcome analyses will take place as it is described above in the intervention section, as well as in the protocol development sections in Chapter Four.

3.2.8 **Phase 6 – Impact and Outcome Evaluation**

The final stage of the PROCEED model is an evaluation of the project's outcomes, outlined in Chapter Four's trial protocol. The evaluation of the primary and secondary outcomes will be described in that chapter's **Planned Analysis** section.

3.2.9 **PRECEDE-PROCEED Note**

> The identification of priorities in one phase of PRECEDE leads to quantitative objectives that become goals and targets in the implementation phase of PROCEED ...[as well as] the standards of acceptability or criteria of success in the evaluation phases of PROCEED (84: p. 34).

It is important to note that not all components of the PRECEDE-PROCEED model were included in this application. It was decided that the assessment phases of the model were crucial components to this type of intervention design, so PRECEDE was chosen as a tool to inform the development of the intervention, but the PROCEED component again differs from typical applications. Phase 6 of the original PROCEED component of the model – Process Evaluation – is not specifically addressed in this discussion, and the original Phases 7 and 8 – Impact Evaluation and Outcome Evaluation – are grouped together as Evaluation. As indicated earlier, PRECEDE-PROCEED is often used to design and implement entire health (promotion) programs, in which context a more involved and long-term evaluation phase would be appropriate and necessary to assess many (potentially) complex program processes. Impact and outcome evaluation are still

components of this intervention, but they are approached in a manner appropriate to an intervention with a single outcome. Within the context of a model where patient TB indicators are the ultimate outcome (please refer to Figure 3.1), the primary outcome of this study – user acceptance and satisfaction – could be considered an immediate effect and therefore an *impact*. It was decided that, as a single intervention and not an entire health promotion programme, this project would consider the impact and outcome in one evaluation, encompassed in the trial protocol described in Chapter Four.

3.3 **Transition from Evaluation to Protocol Development**

The evaluation described in Chapter Two has yielded recommendations to improve the operation and performance of Cape Town's tuberculosis surveillance system in a variety of ways. Chapter Three has described the application of the PRECEDE-PROCEED to the development of a hypothetical intervention to correspond to one of these recommendations: F.A.T.E., modifying the delivery of system changes to improve user acceptance. Within the context of improvements to prevention, control and surveillance activities, periodic modifications to surveillance systems will be necessary, and it is hypothesized that user acceptance of these modifications plays a role in the effectiveness of any type of health system change.

Before time and resources are expended to widely implement F.A.T.E. (or a comparable intervention), it is important to first assess the impact that it has on user acceptance, and, ultimately, tuberculosis outcomes. The next chapter outlines a trial protocol to study the effect of this type of intervention on these primary and secondary outcomes.

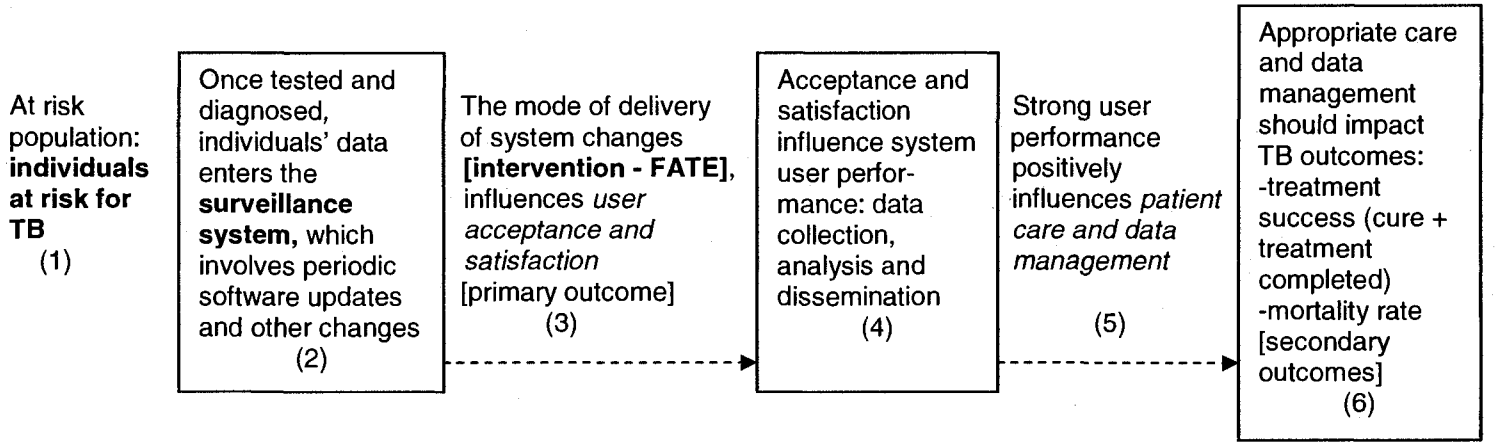
Chapter 4: Protocol Development

4.1 Background

The second and third chapters of this thesis describe an evaluation of the Cape Metro tuberculosis surveillance system and an intervention (F.A.T.E.) based on the recommendations that resulted from that investigation respectively, and it is upon this intervention that a protocol for a trial of system changes has been based. As discussed, the South African TB Control Programme is in the process of developing modifications to HIV and MDR reporting that will make it possible for this data to be integrated within the ETR.net. These changes will likely involve moderate if not extensive software modifications, as well as the incorporation of new data collection tools and the resultant increase in data transfer from the point of patient-health worker interaction to the data capture stage. F.A.T.E is designed to improve the acceptability of and satisfaction with changes within the system's operation whenever changes are made, but these larger-scale existing plans serve as a good example of how broadly adaptations can range.

Regardless of how valuable and needed proposed system adaptations are, if the changes and the way in which changes are implemented are not acceptable to users, the improvements will not be fully achieved. Ultimately, it is hypothesized, if planned improvements are acceptable to users, their performance and in turn the quality of patient care and management will increase, improving patients' clinical outcomes. Figure 4.1 illustrates this relationship; it demonstrates the chain of linkages hypothesized to be involved in the effect of surveillance activities on TB outcomes.

FIGURE 4.1 Logic Model: TB outcomes in the context of surveillance activities



This model (modified from Harris et al. (86)) is used to demonstrate the chain of linkages hypothesized to be involved in the effect of surveillance activities on TB outcomes.

1. Initial starting point: Individuals at risk for TB
2. When tested and diagnosed, individuals' data enters the surveillance system
3. Hypothesized association: characteristics of a surveillance system, including **the mode of delivery for system changes (F.A.T.E)**, influence user acceptance/satisfaction [primary outcome]
4. Acceptance and satisfaction are in turn hypothesized to influence performance
5. Strong user performance (including dissemination of surveillance findings and application of these in daily practice) positively influences patient care and management
6. Appropriate patient care and management of patient data should influence TB outcomes; specifically, treatment success rates should increase and mortality rate should decrease

In order to determine whether or not the manner in which system changes are made influences user acceptability of changes, the intervention under study is not the implementation of changes themselves, but rather *the manner in which the changes have been made* – F.A.T.E. (**F**eedback, technical **A**ssistance, **T**iming, **E**xplanation). The intention of the trial is to evaluate the effectiveness of the intervention in making system

changes more acceptable to users. The PRECEDE-PROCEED model serves as a tool for the development of F.A.T.E. (described in Chapter Three).

4.2 **Methods**

4.2.1 **RCT Protocol**

The development of this protocol was based on modifications of the guidelines for the Canadian Institutes for Health Research (CHIR) Randomized Controlled Trials Program, and augmented by the CONSORT statement suggested extension for cluster randomized trials (87, 88).

4.3 **Results**

4.3.1 **Protocol**

4.3.1.1 **The Need for a Trial**

4.3.1.1.1 **Problem to be addressed**

The surveillance evaluation revealed some dissatisfaction among system users regarding the way that changes are made to the system, particularly with respect to the timing of changes, perception that feedback is heard, and explanation of the rationale for the changes themselves.

As indicated earlier, periodic evaluation of surveillance systems is necessary to investigate whether or not a system is continuing to meet its targets and objectives; if it is not, changes should be recommended. This trial will address the need to ensure that users of surveillance systems are accepting of and satisfied with changes that have been made, so that these changes can serve their ultimate purpose: to allow the surveillance system to continue to best serve the health needs of the population.

Regular changes to the ETR are usually small. This trial proposes to implement changes relating to those that have already been proposed (incorporation of HIV and MDR-TB data), and are larger in scale, to enable observations to be made about the implementation of more weighty modifications. The changes will be made across both control and intervention groups; the intervention itself is not the changes made but rather

the manner in which the changes are implemented, with emphasis placed on the needs of surveillance system users.

4.3.1.1.2 **Research Question**

The principal research question to be addressed is: **Does F.A.T.E. improve user acceptability of these changes and satisfaction with the system itself, compared with the standard approach?** The intervention is the mode of delivery of system changes, and the primary outcome is user acceptance of and satisfaction with system changes. These elements will be expanded upon in the sections that follow. Figure 4.1 outlines the hypothesized impact that the intervention will have on the study population and the primary outcome, and how this impact will influence the secondary outcomes. An answer to the research question, be it positive or negative, will help to substantiate these linkages.

4.3.1.1.3 **The need for a trial now**

In the context of electronic systems, modifications may be required with increased frequency to keep pace with presently rapidly changing information technology. The shift in ETR interface was a large change that serves to illustrate this point. The ETR was initially developed as a DOS-based program, but was converted to a Windows-based application when it became apparent that this technology would improve usability and applicability. This trial is timely because, since the initial implementation of the ETR, only relatively small system changes have been made. This trial, conducted in the context of TB Control Programme HIV and MDR system augmentations, will provide policy-makers with insight into how to implement future larger-scale changes.

The results of this trial can be used by policy-makers, health managers, and IT personnel involved in the planning processes as well as the actual implementation of system changes. The results will be applicable both in the context of TB surveillance as well as in a broad range of other settings, in health and non-health sectors.

4.3.1.2 **The Proposed Trial**

4.3.1.2.1 **Design Architecture**

A matched-pair, cluster randomized trial was determined to be the most appropriate design for this trial, given the nature of the intervention. Randomization was deemed necessary to reduce threats to bias. Randomizing individual subjects would not be feasible because of how closely individuals within the TB system work together; contamination would most certainly be a high risk, and it would not be practical to implement system changes in different manners to individuals working in the same work environment. The cluster was thus chosen as the unit of randomization, with each cluster consisting of one sub-district and its respective TB coordinator, health information officer, and TB nurses.

Pair matching was selected as an additional component of the trial design in order to further protect from bias due to pre-trial levels of system satisfaction. With a relatively small number of clusters, it is not certain that exclusive randomization would be able to control for the biases that may exist based on pre-trial system conditions and resultant user experiences. It is hypothesized that, as a result of case load, resources, and sub-district-specific elements that impact system operation independently of the electronic system, individuals within some clusters may be more or less satisfied with the overall system. Cluster pairs will thus be matched according to score in a baseline satisfaction survey.

4.3.1.2.2 **Sample**

4.3.1.2.2.1 **Population and Control Group**

The proposed study population is comprised of individuals who are regularly involved with carrying out data collection and analyses processes for tuberculosis surveillance in the Cape Metro region. These are TB sisters who collect data and enter it into the paper record; health information officers who capture data electronically; and TB

coordinators who are responsible for data analysis and presentation of results at the sub-district and regional levels. (A second group of peers will serve as a control group.)

System changes will be experienced by both the intervention and control groups. The system changes are *not* the intervention. The *control group* will experience the standard approach to implementation of changes, which includes training where necessary, but limited explanation of changes and little consideration of the impact that the timing of system changes has on users. Prior to changes, user input will not be sought. F.A.T.E. will be applied to the delivery of system changes to the *intervention group.* (Delivery of changes will be carried out by the individuals who are normally involved – information technology specialists from WamTech: the company that manages the ETR.net – as well as regional coordinator(s), if necessary, for workshops and other training exercises.)

4.3.1.2.2.2 **Threats of Bias to the Sample**

Study subjects will be blinded as to which arm of the study they are in, to protect from placebo effect. The questionnaire serving as an outcome measurement tool (described in a later section) will be quite general; subjects will not be aware that satisfaction with the manner of system change delivery is the specific outcome that is being measured, and this should further help to protect reduce the risk of response bias. (Selection and performance biases are addressed in a subsequent section.)

4.3.1.2.2.3 **Sample Size**

Typically, previous studies with comparable interventions and/or outcomes are used to determine the intraclass (or intracluster) correlation coefficient (ICC), and within- and between-cluster variability with which to calculate the estimated sample size. In the case of this intervention, however, there aren't any studies that have looked at system satisfaction/acceptance within a cluster trial. As a result, a pilot study is necessary and

will be carried out. Part of this pilot development will be to examine variability in responses, in order to obtain estimates of variability for the sample size calculation. The pilot study will be conducted within 3-4 clusters (with approximately ten individuals per cluster). An ANOVA will be carried out in order to ascertain within- and between-cluster variance components, which will enable the calculation of sample size and the ICC.

The following formula will be used to calculate the appropriate sample size when the above components are available. In order to demonstrate use of the components, a mock calculation was carried out, using VERY rough estimates of within-cluster variability and between-cluster variability. The cluster size was fixed and predetermined by the number of appropriate potential participants in each cluster; the formula calculated the number of cluster pairs required.

$k = (z_{\alpha/2} + z_{\beta})^2 \, Var(dj)/\Delta^2$

where:

$Var(dj) = 2(\delta_w^2/m + \delta_b^2)$

k = number of required cluster pairs

m = average cluster size = 15

δ_w^2 = within cluster component of variability = 0.419^2
(estimate from study using Index of Work Satisfaction Questionnaire with nurses (89); not clustered)

δ_b^2 = between cluster component of variability = 0.472^2
(estimate from study using Index of Work Satisfaction Questionnaire with nurses (89); not clustered)

Δ = detectable difference between group means = 1 (out of score of 5; estimating that control will have a mean of 3 and intervention will have a mean of 4)

$Var(dj) = 2(0.419^2/15 + 0.472^2)$
$= 2(0.012 + 0.22)$
$= 0.424$

$k = (1.96+0.84)^2(0.424)/1$
$= 7.84(0.424)/1$
$= 3.32$

The number of pairs will be augmented by two to adjust for the undercorrection present when using a 5% type I error rate (90).

The number of pairs will be further augmented by a variance inflation factor, to account for variation between clusters (91, 92).

Variance Inflation Factor (design effect) = 1 + (m-1)ICC

$ICC = \delta_b^2/ \delta_b^2 + \delta_w^2$
$= 0.472^2/0.472^2 + 0.419^2$
$= 0.223/0.398$
$= 0.57$

$VIF = 1 + (15-1)(0.57)$
$= 1 + 14(0.57)$
$= 8.98$

The final number of pairs required:
$3.32 + 2 + 8.98 = 14.3$

In order to ensure that the sample size provides the study with sufficient power, this simulated calculation indicates that 15 pairs (30 clusters) will be required.

4.3.1.2.3 **Recruitment**

Depending on the number of clusters required in each arm of the study, the entire Cape Metro Region will be used (8 sub-districts/clusters; 4 in each arm of the study) but other regions may be included if necessary. Each sub-district has an information officer and one or two TB Coordinators, as well as an average of 10-12 TB sisters (nurses).

An approach of concurrent recruitment will be applied across all of the chosen region(s). Clusters (i.e. sub-districts) will be recruited simultaneously at the level of the health region. The lead investigator will meet with each health area(s) Regional TB Coordinator(s) and give a presentation describing the rationale for and processes that will

be involved in the proposed project. The Regional Coordinator(s) will be asked to provide consent for the involvement of their health region, with the provision that individuals will also be providing informed consent before they are recruited. This consent involves granting permission for system users to be involved in the study, as well as the IT specialists from WamTech who are involved with delivery of services; their participation is key, and will likely involve a great deal more of their time and energy. If the tuberculosis coordinator(s) at the regional level(s) do not consent to involvement, the study will be conducted elsewhere.

Given the fact that the trial will be taking place in the context of system changes, there will likely be existing involvement and awareness on the part of Regional TB Coordinators. Any changes that progress to the implementation stage will have been approved by the National Tuberculosis Control Programme, and TB stakeholders in other levels throughout the programme will be made aware of the changes that are going to take place; a situation would never arise in which a trial was based on system changes and TB stakeholders were not aware of the changes.

Individuals will be also be recruited simultaneously to complete questionnaires at the baseline and post-intervention phases of the trial. System users will be either visited or telephoned by members of the research team, who will explain the project as well as their role should they choose to participate. Once this information has been communicated, individuals will be given the opportunity to choose whether or not to participate. This study will aim to recruit *all* TB system users (TB sisters, health information officers and TB coordinators) for participation.

The baseline satisfaction and follow-up acceptance questionnaires will not be time-consuming to complete, nor will they require communication of personal

information, so it is anticipated that the high recruitment rate desired will be feasible to obtain.

4.3.1.2.4 **Compliance and Loss to Follow-Up**

The responsibilities of the trial participants are minimal; questionnaires will be administered by research team members at three points in time, when it is convenient for participants. It is thus not anticipated that there will be problems with compliance, as there might be in a trial that relied on participants remembering to undertake regular, unmonitored tasks.

In part because of the factors described above, it is unlikely that there will be many participants who are lost to follow-up. As this is essentially a workplace-based trial, the research team will be aware of where participants can be found in order to carry out the two follow-up measurements. The exception to this would be in cases where individuals make vocational changes, which is a possibility over the study period, since the last follow-up analysis will take place several months subsequent to the intervention.

4.3.1.2.5 **Inclusion and exclusion criteria**

Sub-districts within which any type of major crisis or disruption has recently occurred will be excluded; users' perceptions of the system may be impacted by such events, and it will be difficult to attribute changes in clinical outcomes to the intervention.

Within clusters, individuals will be included in the trial if they regularly work with tuberculosis surveillance in the Cape Metro region; TB sisters, health information officers, and TB/HIV coordinators. Individuals who are involved in software development and implementation, as well as TB managers will not be included in this trial.

4.3.1.2.6 **Allocation Concealment, Blinding and Randomization**

Allocation concealment will be applied in order to prevent selection bias, and, when possible, blinding will seek to reduce the risk of performance bias (in which members of treatment and control groups are treated differently) (93). Because WamTech employees involved with delivery of system changes will be spending more time with members of the intervention group – before, during, and after the changes are made – it will not be possible for them to be blinded, but they will not be aware of the outcome that is being evaluated. Investigators will be blinded when data analyses are carried out.

A computer-generated random sequence of *n* numbers, where *n* is the number of matched pairs, will be used to allocate clusters in the pair. An even number will allocate the first member of the pair and an odd number will allocate the second member of the pair to the study intervention. The study coordinator will access a box of numbered, sealed, opaque envelopes to determine allocation of the subsequent matched pair. Envelopes will be selected in sequence and one cluster within each pair will be allocated to the study intervention, according to the instruction on the card in this envelope.

Once matched-pairs have been established, the intervention group for each dyad will be randomly selected.

4.3.1.2.7 **Intervention**

4.3.1.2.7.1 **Standardization**

It is important to ensure that F.A.T.E is standardized. Because the individuals who will carry out the system changes are those who are routinely in this role, it is not likely that there will be differences in the 'normal' delivery of system changes within the control groups. In order to achieve standardization of F.A.T.E among the intervention groups, WamTech personnel, as well as regional coordinators who will be involved in

non-technical elements of the intervention, will undergo training that will describe the specific components of the 'new' approach to change delivery, as well as exactly how it differs from the 'normal' delivery.

4.3.1.2.7.2 **Threats of Bias within the Intervention**

Throughout normal operation of the system, including conventions to disseminate and analyze system results, users of the TB surveillance system – in particular, health information officers and TB coordinators – have regular contact with each other. Cointervention is a type of bias that in this context would be problematic if surveillance system changes (external to the study) were introduced to either the control or intervention groups (93). The company involved in all electronic system changes, WamTech, will be involved in the study so it is improbable that external changes will occur. Contamination bias could be introduced if participants in the control group were exposed to elements of the augmented manner of system change delivery. Because technical components of TB data management are quite separate between sub-districts, it is unlikely that this will be a problem. Further, although it is possible that individuals in the control group could become aware that their colleagues in other sub-districts are the recipients of atypical information regarding system change, the actual information (that is, the complete elements of F.A.T.E.) will be provided in information sessions that only the members of the intervention group will attend.

'History', in which external events occurring between baseline and outcome measurement impact the outcome (91), is another potential sources of bias that has been considered. It is extremely unlikely that an external event would a) impact acceptance of changes, and b) occur across an entire cluster but not within any other cluster. This type of bias may impact the secondary, clinical outcomes that will be examined (discussed below), however, and it is important that close attention is paid to the study setting

between baseline and follow-up to ensure that any such external events are detected and taken into consideration during analysis.

4.3.1.2.7.3 **Intervention Duration and Follow-Up**

The duration of the intervention will depend on the results of the PRECEDE investigation (recall that F.A.T.E. is a hypothetical model), but it is likely that the implementation of changes and the accompanying user training sessions will take place over a week to two weeks.

After the changes have been made to the system in both the intervention and control groups, time must be allowed for users to operate within the system and form an opinion of the changes. Since the primary outcome measure will be considering how the changes were made, outcome measurements must not be made too long after implementation of changes. A time period of one month will elapse after system changes have been made before the first series of measurements of user acceptance will be taken. It is possible that levels of acceptance could vary initially, but would become balanced out across the two groups over time. This study hypothesizes that greater user acceptance and satisfaction will lead to higher user performance within the system and ultimately greater patient treatment and improved tuberculosis outcomes. It is therefore important to know whether or not differences in approach to system changes have a temporary or long-term effect on user acceptance and satisfaction. In order to determine this, a second phase of outcome evaluation will be performed, four months following the implementation of system changes.

As with the primary outcome, the secondary clinical outcomes will be evaluated at baseline. The follow-up period for evaluation of these outcomes will be longer, as it will take time for change in patient outcomes to be perceptible. Follow-up measures will be made six months and one year post-intervention.

4.3.1.2.8 **Outcome Measures**

The primary outcome is user acceptance of system changes combined with user satisfaction with both changes themselves as well as the implementation of the changes. Secondary outcomes that will be considered are treatment success rate[11] and mortality. Consideration of these clinical indicators will help to determine whether or not the way in which system changes are made can also have an impact on patient outcomes, which is ultimately the goal of system intervention.

Within the outcome user satisfaction and acceptance, the specific attributes of interest will be satisfaction with the timing of system changes and available technical support, perception of ease (or difficulty) of adaptability to changes, and appreciation of the importance of the changes to system operations.

Data collection will involve administration of the acceptance measurement tool (questionnaire) as well as accessing treatment success and mortality information from the ETR.net software; both of the clinical outcomes are routinely collected and analyzed quarterly so this data will be fully available. These measures will be made at baseline, and at two points in time following the intervention (measures of acceptance will be taken at one month and four months post-intervention, while the secondary, clinical outcomes will be measured at six months and one year post-intervention). In order to minimize discussion and speculation about the questionnaire, attempts will be made to schedule delivery of the questionnaire among all system users for the same day, soon after a quarterly deadline has passed when users will be more likely to have time to complete the questionnaire.

[11] Described in Chapter 2, treatment success is an indicator that is comprised of two routinely collected measures: cure rate and treatment completion rate.

Acceptance and satisfaction will be measured by a questionnaire containing both a closed-ended scale component as well as an open-ended, qualitative component. As the exact measurement tool desired does not exist, a scale to measure user acceptance will be developed using a modified element of the Index of Work Satisfaction (IWS) Questionnaire © (94) as a framework, and will be validated in a pilot study. (The applications of pilot outcome with respect to sample size calculation are discussed above). The element of the IWS that is related to user acceptance of system changes is *organizational policies*, but even independent from the other five IWS components, it is not sufficient to measure the attributes of the primary outcome identified above. A new measurement tool will need to be developed (with the IWS *organizational policies* component serving as a primary framework). A draft version of this questionnaire, based on qualitative data and the PRECEDE-PROCEED model can be found in Appendix 6. Using Cronbach's coefficient alpha, the reliability of the *organizational policies* component of the Index of Work Satisfaction Questionnaire has been calculated to be approximately 0.73 in several studies, with a range of values spanning 0.65 to 0.83 over two and a half decades since the tool was first developed (94, 95), but a pilot would allow the reliability and validity of the modified tool to be assessed.

A baseline evaluation will be carried out in order to provide preliminary satisfaction values with which to match as well as to compare the post-intervention data; while it will not be possible to examine perception of system changes pre-intervention, this assessment can measure satisfaction with the system itself.

Treatment success rate is a value that is computed by the ETR.net by sub-district. Rather than examining both cure and treatment completion rates, this overall measure was selected as a secondary outcome because of the risk of ambiguous findings relating to treatment completion. An increase in treatment completion could represent either a

positive or negative impact. The rate may increase because fewer people are defaulting or dying (but for whatever reason some are failing to be given a final sputum test), which is certainly positive. Alternatively, the rate may increase because fewer people who have finished all of the required TB chemotherapy are undergoing final sputum tests (whether it be because of fault on the part of the patient or the clinic), which would be negative. As a measure that encompasses both cure and treatment completion, treatment success represents a more valid study outcome.

The ETR.net also computes a mortality rate for those individuals registered within the system; while this is not to be mistaken for a measure of overall community TB mortality, this value will also be considered as a potential indicator of system performance improvement.

4.3.1.2.9 **Analysis**

4.3.1.2.9.1 **Primary Outcome**

When a cluster matched-pair design is applied, it is difficult to ascertain whether observed variation is due to the intervention or due to the differences within the pair of clusters, and as a result between-stratum variability must be included in outcome analyses (90). In the context of a matched-pair cluster randomized trial, and if the cluster sizes within each pair are equal, the paired t-statistic may be used to test the null hypothesis that there is no difference between the control and intervention groups (90, 91).

Mean difference in response between clusters in the j^{th} pair:

$$d_j = \overline{Y}_{1j} - \overline{Y}_{2j}$$

$j = 1,2,\ldots,k$ *(k = # of matched pairs; j = pair/stratum)*

Sample mean:

$$\overline{d} = \sum_{j=1}^{k} \frac{d_j}{k}$$

Sample variance:

$$S_d^2 = \sum_{j=1}^{k} \frac{(d_j - \bar{d})^2}{k-1}$$

Test:

$$t_p = \frac{(\bar{d}\sqrt{k})}{S_d}$$

CI: $\bar{d} \pm t_{\alpha/2} S_d / \sqrt{k}$

Including the baseline assessment, three phases of analysis will be conducted in this trial. The baseline assessment will take place prior to the implementation of system changes, the first outcome assessment will be conducted one month after the changes have been implemented and the final analysis to determine whether satisfaction/acceptance levels have equalized over several months will take place four months following change implementation. The principal analysis of interest will be the outcome measurement one month following implementation of changes.

It may be worthwhile to conduct subgroup analyses among the clusters with high case-loads, to determine whether or not users with higher volumes of TB data to collect and manage have different perceptions of the system and changes that have been made than those who work in lower case load areas.

4.3.1.2.9.2 **Secondary Outcomes**

The secondary, clinical outcome analyses will be similar to the analysis described above, but with proportions rather than means because these outcomes are all rates. Again, a paired *t*-test can be used to test the null hypothesis that there is no difference in treatment success rate or mortality rate between the control and intervention groups (90). Mean difference in response between clusters in the j^{th} pair:

$$d_j = \ln(\hat{P}_{1j} / \hat{P}_{2j}) = \ln(\hat{P}_{1j}) - \ln(\hat{P}_{2j})$$

$j = 1,2,\ldots,k$ *(k = # of matched pairs; j = pair/stratum)*

Sample proportion:

$$\bar{d} = \sum_{j=1}^{k} \frac{d_j}{k}$$

Sample variance:

$$S_d^2 = \sum_{j=1}^{k} \frac{(d_j - \bar{d})^2}{k-1}$$

Test:

$$t_p = \frac{(\bar{d}\sqrt{k})}{S_d} \text{ with } (k-1) \text{ degrees of freedom}$$

CI: $\bar{d} \pm t_{\alpha/2} S_d / \sqrt{k}$

Follow-up measures will be made six f and one year post-intervention.

4.4 **Discussion**

This trial has been designed to test whether or not incorporating F.A.T.E. within system changes improves user satisfaction with/acceptance of the changes and overall operation of the system itself in a manner that will improve patients' TB outcomes. These individuals are the ones who are most intimately involved with the operation (and success) of the system. Their satisfaction and perceived quality of the system is therefore extremely important. Changes are made relatively often; it is important that users are committed to system management and upgrading.

Furthermore, the approach taken in this trial also demonstrates that there are many elements within a health system that can, directly and indirectly, impact health outcomes. Prevention and control efforts are essential to improving the current state of tuberculosis,

but it is important to recognize the large role that human resources play in carrying out these policies and plans. The evaluation that was carried out revealed the frustration that some system users experience.

Changes to systems of surveillance of any health event are necessary to ensure that the system continues to meet the needs of the recipient population, but it is hypothesized that user acceptance of these modifications is required in order for any type of health system change to be effective. If users are not convinced that changes are necessary or positive, or if changes are introduced in a manner that is unsatisfactory to users, it will likely affect their overall performance as well as their employment of the imposed changes, and ultimately, the effects of public health activities.

The dashed lines within Figure 4.1 indicate that these relationships are hypothesized associations. Use of the logic model facilitated the incorporation of human resource components involved with surveillance with TB outcomes in a theorized manner. Policy, administrative, or programming action should not be based on these associations until there is an evidence-base that supports it. The results of this proposed trial will help to fill in some of the gaps in this knowledge and enable health systems decisions that are complementary to public health action to be made.

The design of a cluster randomized trial requires estimates of variability to inform sample size, data that can be drawn from previously conducted, comparable studies. Because of the lack of published studies illustrating similar research it was determined that a pilot study would be required to estimate variance in order to make sample size calculations. A lack of data such as this does not present reason to refrain from carrying out research in a particular way (i.e. using clusters as the level of analysis); if anything the knowledge gap indicates an area of research that has not but should be explored. This challenge also illustrates the importance of both publishing results from this type of trial,

as well as the quality of the reporting within publications. Some protocols outlining cluster randomized trials do not account for clustering within sample size calculations, and among these, many do not report intracluster correlation coefficient and/or design effect (variance inflation factor) (96). Manuscripts should include sufficient information to enable future researchers designing similar trials to take advantage of previous work (88).

Chapter 5: Conclusion

Throughout this investigation I have learned that there are two surveillance components that are essential above all others: general acceptance of the system and appreciation of the value of its data. These are certainly not the most technical or advanced of components – indeed, while other system components can be tweaked, altered or replaced entirely, these are difficult to create and foster, but without them a system will never reach its full potential. Users at all levels of the system, from health workers on the ground to policy-makers at the national level, must generally be in support of the system and perceive value of their role within it. As vital as dissemination of data is, if its value is not appreciated within all levels of the system, as well as in broader operations, this too will fall short of its potential for public health action. Despite some shortcomings, the more broadly defined TB surveillance system within the Cape Metro region is of high quality, and I believe it is due in no small part to the strength of these components.

Out of recognition for the importance of acceptance, and to explore possible ways to strengthen acceptance, the intervention proposed in the third element of this project was selected as a means of maintaining and fostering system acceptance felt by users. Applying the PRECEDE-PROCEED model to this type of program – one with a non-health outcome but indirectly very important to health – demonstrated the model's pliability.

In multiple elements of the project, pre-existing models were used and adapted for the purposes desired within the context of this thesis. In the case of the CDC's Guidelines, the model had to be narrowed down and made more specific in order to be relevant to TB in a middle-income country setting. In order for the PRECDE-PROCEED

approach to be adapted for a different outcome as well as type of intervention than are usually the targets, however, more alterations to the model had to be made. The modifications of these tools was valuable both to serve the needs of this specific project, but also to illustrate broad applicability that may encourage other investigators to explore the uses of these models for their particular needs.

The evaluation revealed that TB surveillance in the Cape Metro region is strong. The structure of the system is slightly complex in terms of data management and flow, but this level of intricacy is necessary to meet the needs of the system in the context of high TB burden, and steps are taken to ensure that the quality of the data throughout the system remains high. As indicated above, user acceptance within the system is high (although some dissatisfaction exists regarding the implementation of system software changes, as well as lack of perceived voice with respect to feedback). A very strong element of the system is the breadth of data dissemination. Weaknesses of the system revealed by the evaluation include its relative inflexibility and current lack of integration with other systems; in particular links to HIV and MDR-TB data are necessary, and plans to incorporate these into the ETR.net are reportedly underway. As South Africa's National TB Control Programme continues to assess system needs and plan for improvements, this evaluation should serve as a helpful contribution.

While more abstract, the protocol design complements the evaluation by illustrating the development of a trial that aims to improve the acceptance of relatively large system changes to integrate HIV and MDR TB data within the ETR.net. The placement of TB surveillance in the context of a logic model helps to identify where this acceptance fits into the larger picture, and ultimate goal, of improving TB outcomes. Special considerations for cluster randomized trials are presented in the context of this

protocol design, and the PRECEDE PROCEED model illustrates how an intervention can be designed with a focus on participatory input to improve its relevance.

As the global threat of tuberculosis continues to grow, so too do the time and resources poured into the development of vaccines and combative therapies aimed at curbing this disease. These advancements are important and necessary, but the vital role of health systems, in particular surveillance systems and the human resources that drive their operations, must not be overlooked. As treatment and control efforts are enhanced, discerning their impacts will depend heavily on tuberculosis data, and the individuals who manage, analyze and disseminate this information. With this view to systems improvement in mind, the tuberculosis surveillance system of South Africa's Cape Metro region has been assessed and suggestions for system improvement have been presented; the application of a model that can be used for the design of an appropriate system user-centered intervention based on an evaluation observation has been demonstrated; and a protocol for a trial to evaluate the effects has been designed.

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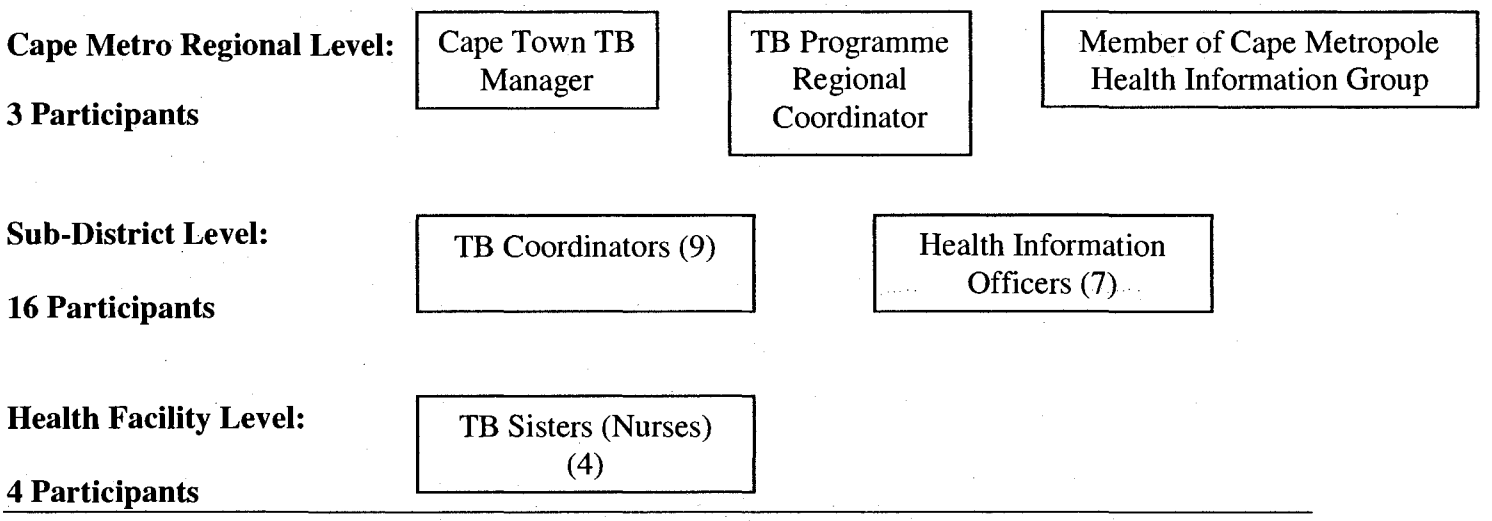
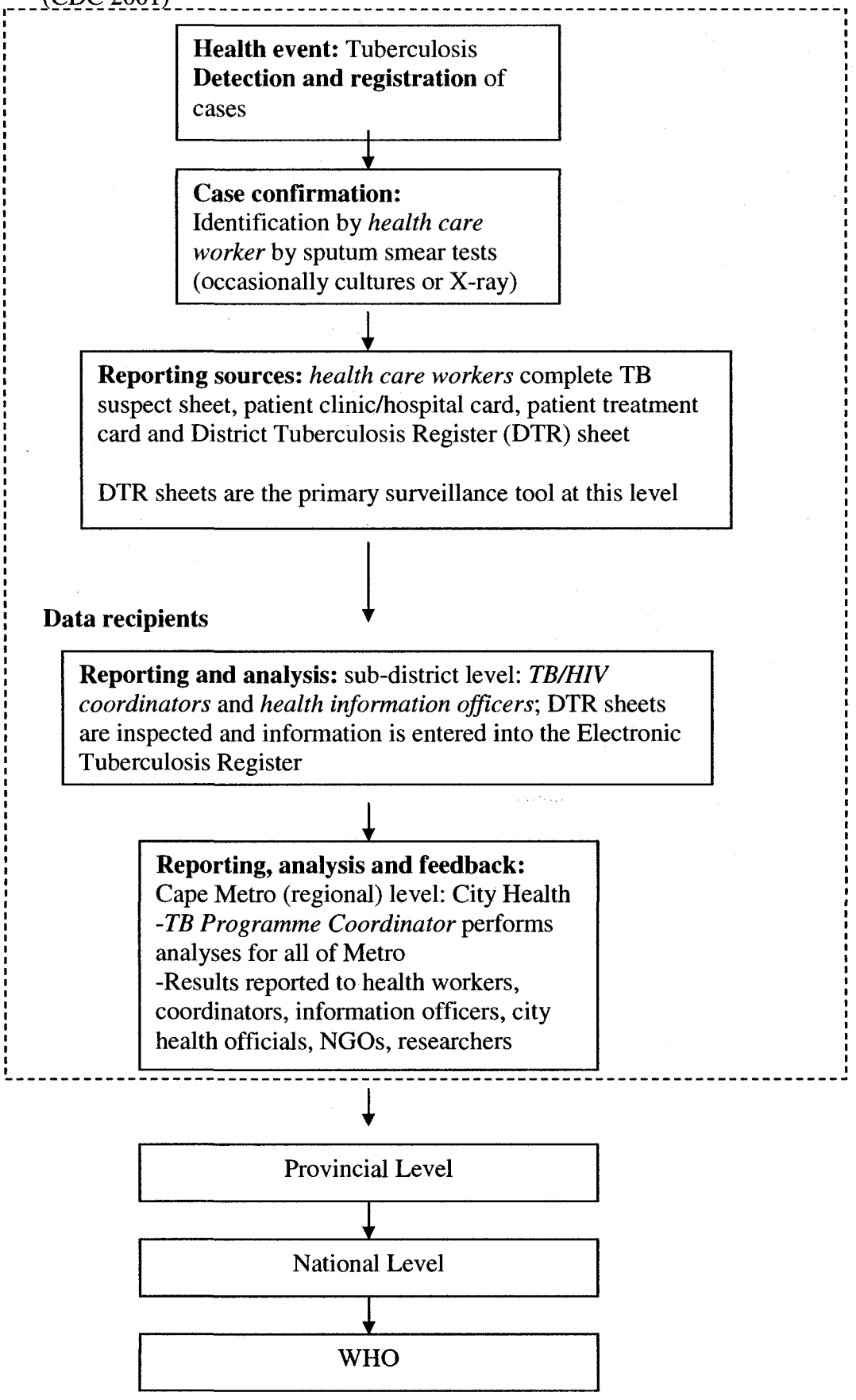
APPENDICES

APPENDIX 1: Elements of TB Data Management

Appendix 1a. Cape Metro Tuberculosis Personnel



Appendix 1b. Flow of Tuberculosis Data in the Cape Metro Region of South Africa (CDC 2001)



Appendix 1c. Case and Outcome Definitions

Type	Classification	Definition
Site of Disease	Pulmonary tuberculosis	-infection of the lungs
	Extrapulmonary tuberculosis	-infection of organs other than the lungs: pleura (membrane that covers the lungs), lymph nodes, abdomen, genito-urinary tract, skin, joints, bones and meninges (brain tissue)
Diagnosis of Pulmonary TB: Bacteriology or sputum smear result	Smear-positive pulmonary tuberculosis case	-at least two sputum smear tests are positive for acid-alcohol fast bacilli **or** one sputum smear test positive for acid-alcohol fast bacilli and chest X-ray abnormalities are consistent with active TB **or** culture positive TB **or** one sputum smear test positive and clinically ill
	Smear-negative pulmonary tuberculosis case	-at least two sputum smear tests are negative for acid-alcohol fast bacilli **and** chest X-ray abnormalities are consistent with active TB.
Patient Classifications	New case	-a patient who has never been treated for TB or who has not been on anti-TB drugs for more than four weeks.
	Relapse	-a patient who previously tested smear positive for TB, received treatment and was cured (sputum smear tested negative), and has developed smear positive TB again
	Treatment after failure	-a patient with pulmonary TB who still tested positive for sputum smear at the end of the treatment regimen and returned to be treated again
	Treatment after default	-a patient who previously completed at least one month of treatment, interrupted treatment for at least two months, and returned to be treated again.
Treatment Outcomes	Cure	-a patient who is smear-negative at the end of treatment
	Treatment completed	-a patient who has completed treatment but for whom there are no sputum results to confirm that he/she is smear-negative
	Died	-a patient who died prior to completing treatment
	Failure	-a patient who tested positive for sputum smear at the end of the treatment regimen
	Default	-a patient who completed at least one month of treatment, and interrupted treatment for at least two months
	Transferred out	-a patient who moved to a different unit of reporting and for whom there is no available outcome information

Appendix 1d. Tuberculosis Meetings in the Cape Metro Region

Name	Level	Attendees	Frequency	Content
Clinic meeting	Sub-district	facility staff, TB coordinator	Monthly	TB/HIV/STIs
Mini PDR	Sub-district	facility managers, health promotion officer, environmental health officer, health information officer, TB coordinator	Monthly	TB as well as other health issues; feedback from 'big' PDR post PDR
Health facility managers meeting	Sub-district	facility managers, program manager, health information officer, TB coordinator, health promotion officers	Monthly	TB as well as other health issues
Multi-Sectoral Action Team (MSAT) meeting	Sub-district	-NGOs, local health authorities, community-based organizations, faith-based organizations	Monthly	HIV/AIDS/TB
TB/HIV/STI Information Meeting	City	sub-district managers, TB coordinators, health information officers, Cape Town TB manager, regional TB Programme coordinator, TB Care representatives	Quarterly	TB/HIV/STIs
TB Clinical Working Group Meeting	City	TB coordinators, regional TB Programme coordinator, other groups involved with TB (e.g. academic researchers, sometimes NGOs, etc.)	Quarterly	TB
PDR ("Plan, do and review")	City	Director of City Health, health information officers, sub-district managers	Quarterly	TB as well as other health issues
Health Information Meeting	City	Member of Cape Metropole Health Information Group, city health manager, health information officers	Quarterly	TB as well as other health issues

APPENDIX 2: Interview Schedules

Appendix 2a. Interview Schedule 1: City Level TB Personnel

INTRODUCTION
Objective: Establish individual's role in Cape Metro TB surveillance system, and discuss perceived public interest regarding TB.

1. Let's talk briefly about your involvement in TB care and surveillance.

- How would you describe your role regarding TB?
- Can you talk a little bit about what you do on a day-to-day basis?

2. I'd like to know about how TB is perceived in Cape Town.

- How do you think people in Cape Town feel about TB?
- Is it seen as an important health issue, or is there not a lot of concern about it?

TRAINING AND OPERATION OF THE SYSTEM
Objective: What training was provided to users when the ETR was implemented? How smooth is the operation of the system?

3. Let's talk about the training you received.

- When the ETR was implemented in Cape Town, what was involved in the training you received?
- How long did the training last?
- Once the ETR was in place, was additional help available if you needed it?

4. I'm wondering about the flexibility of the system, as far as the software goes.

- How easy or difficult would it be to add or change fields in the ETR if necessary?
- If there were changes that required making alterations to the ETR (for example, changes in technology, or in the TB treatment process), could these be made without much difficulty?
- Is the ETR integrated with other systems? (**If no,** could it be? How easy or difficult would that be?)

5. What about the stability of the system?

- Is tech-support readily available when you have problems with the system?
- In terms of the stability from a personnel point of view, how well does the data flow throughout the ETR?
- Speaking about data flow, can you explain what data you receive, what you do with the data, and where you send it?

PERFORMANCE OF THE SYSTEM

Objective: Establish how well the system is perceived to detect and prevent TB, as well as how well it is perceived to assess the impact of prevention and control programs.

6. Let's talk a bit about the system's ability to detect and prevent TB.

- Is there an estimate of the case capture or detection rate? About what proportion of TB cases in Cape Town are captured by the ETR? (If not, is there someone I could ask who would know this?)
- Do patients seem to be seeing health care workers early enough in the disease process to make treatment worthwhile? (**If not**, is there anything you can think of that could change this?)
- What about prevention? Do you think that contact tracing is helping to prevent development of TB in others? (**If not**, is there anything you can think of that could change this?)
- From your experience, does the system allow for effects of prevention and control programs to be assessed?
- Can you see a difference in incidence in areas where you know certain programs are implemented?

DATA-INFORMED ACTION

Objective: to what extent does the collected data inform decision-making, program development and research?

7. We're getting close to the end now. I'm wondering if we could talk a bit about the action-response based on data from the ETR?

- Is the data collected used to influence changes in terms of programming? What kind of programming occurs at the City level? What about policy?
- Is there other long-term action that is based on this data? What about decisions regarding resources allocation?
- To what extent does it seem that research done in this area is based on information produced by the ETR?

CONCLUSION

Objective: Obtain final input from participants regarding the ETR.

8. This has been extremely helpful – thank you very much. I just have one more question: If you were designing a new system, what changes would you make?

- What would you like to include?
- What would you take out?
- What are the things that you like and don't like about how the system operates?

Appendix 2b. Interview Schedule 2: TB Coordinators and Health Information Officers

INTRODUCTION

Objective: Establish individual's role in Cape Metro TB surveillance system, and discuss perceived public interest regarding TB.

1. Let's talk briefly about your involvement in TB care and surveillance.

- How would you describe your role regarding TB?
- Can you talk a little bit about what you do on a day-to-day basis?

2. I'd like to know about how TB is perceived in Cape Town.

- How do you think people in Cape Town feel about TB?
- Is it seen as an important health issue, or is there not a lot of concern about it?

TRAINING AND OPERATION OF THE SYSTEM

Objective: What training was provided to users when the ETR was implemented? How smooth is the operation of the system?

3. Let's talk about the training you received.

- When the ETR was implemented in Cape Town, what was involved in the training you received?
- How long did the training last?
- Once the ETR was in place, was additional help available if you needed it?

4. I'm also wondering about the stability of the system?

- What proportion of the time would you estimate the system is operating fully?
- Is tech-support readily available when you have problems with the system?
- How much time is generally required for computer repair (when there are ETR-related problems)?
- In terms of the stability from a personnel point of view, how well does the data flow throughout the ETR?

PERFORMANCE OF THE SYSTEM

Objective: Establish how well the system is perceived to detect and prevent TB, as well as how well it is perceived to assess the impact of prevention and control programs.

5. Let's talk a bit about the system's ability to detect and prevent TB.

- Do patients seem to be seeing health care workers early enough in the disease process to make treatment worthwhile? (**If not**, is there anything you can think of that could change this?)

- What about prevention? Do you think that contact tracing is helping to prevent development of TB in others? (**If not**, is there anything you can think of that could change this?)
- From your experience, does the system allow for effects of prevention and control programs to be assessed?
- Can you see a difference in incidence in areas where you know certain programs are implemented?

DATA-INFORMED ACTION
Objective: to what extent does the collected data inform decision-making, program development and research?

6. We're getting close to the end now. I'm wondering if we could talk a bit about the action-response based on data from the ETR?

- Is the data collected used to influence changes in terms of programming? What about policy?
- Do you think that there is other long-term action that is based on this data? What about decisions regarding resources allocation?
- To what extent does it seem that research done in this area is based on information produced by the ETR?

CONCLUSION
Objective: Obtain final input from participants regarding the system.

7. This has been extremely helpful – thank you very much. I just have one more question: If you were designing a new system, what changes would you make?

- What would you like to include?
- What would you take out?
- What are the things that you like and don't like about how the system operates?

Appendix 2c. Interview Schedule 3: Health Workers

INTRODUCTION

Objective: Establish individual's role in Cape Metro TB surveillance system, and discuss perceived public interest regarding TB.

1. Let's talk briefly about your involvement in TB care and surveillance.

- How would you describe your role regarding TB?
- Can you talk a little bit about what you do on a day-to-day basis?

2. I'd like to know about how TB is perceived in Cape Town.

- How do you think people in Cape Town feel about TB?
- Is it seen as an important health issue, or is there not a lot of concern about it?

TRAINING AND OPERATION OF THE SYSTEM

Objective: What training was provided to users when the ETR was implemented? How smooth is the operation of the system?

3. Let's talk about the training you received.

- When the ETR was implemented in Cape Town, what was involved in the training you received regarding the new forms and registers?
- How long did the training last?

PERFORMANCE OF THE SYSTEM

Objective: Establish how well the system is perceived to detect and prevent TB, as well as how well it is perceived to assess the impact of prevention and control programs.

4. Let's talk a bit about the system's ability to detect and prevent TB.

- Do patients seem to be seeing health care workers early enough in the disease process to make treatment worthwhile? (**If not**, is there anything you can think of that could change this?)
- What about prevention? Do you think that contact tracing is helping to prevent development of TB in others? (**If not**, is there anything you can think of that could change this?)
- Can you tell me about DOTS? Who are patients often using as treatment supervisors or supporters? (health workers, family, friends, etc.)

DATA-INFORMED ACTION

Objective: to what extent does the collected data inform decision-making, program development and research?

5. We're getting close to the end now. I'm wondering if we could talk a bit about the action-response based on data from the ETR?

- Do you see the results of your facility's data?
- Is the data collected used to influence changes in terms of programming? What about policy?
- Is programming done at the facility level?

CONCLUSION

Objective: Obtain final input from participants regarding the system.

6. This has been extremely helpful – thank you very much. I just have one more question: If you were designing a new system, what changes would you make?

- What would you like to include?
- What would you take out?
- What are the things that you like and don't like about how the system operates?

APPENDIX 3: Data Reporting Documents

Appendix 3a. TB Suspect History Sheet (p. 1)

Ref: HTB 994

TB SUSPECT
HISTORY SHEET

PERSONAL PARTICULARS

Surname & Name:
Folder Number:

CONTACT WITH KNOWN TB CASES

None	Family	Household	Adults	Children	Work	School	Other	MDR

PREVIOUS TB TREATMENT

Yes			No	Unknown
If yes:	When		Where	

SKIN TESTS

Tine / Mantoux (circle)	Date:	Result:

VCT

Offered	Yes	No	Date	
Tested	Yes	No	Date	
Status	Neg	Pos	Not disclosed	

SYMPTOMS

	Yes	No	Comments
Cough			
Sputum Produced			
Nightsweats			
Weight Loss			Weight:
Chest pain			Tempearture:
Appetite Loss			Respiratory Rate:
Fatigue			
Other			

SPUTUM SPECIMENS

Smear	Specimen 1		Date		Result	
	Specimen 2		Date		Result	
Culture	Specimen		Date		Result	

CHEST X-RAY

Date and report:

Date given for return visit: _____ Antibiotics Yes/No

DATE: _____ Type: _____

COMPLETED BY: _____

Patient Suspect History Sheet (p. 2)

TB SUSPECT

FOLLOW-UP VISIT

Treatment Plan:

DATE: _____

COMPLETED BY: _____

CONFIRMED TB CASE

MEDICAL HISTORY

	Yes	No	Comments
Diabetes			
Epilepsy			
Operations			
Previous chest stab wounds			
Allergies			
Hepatitis			
Medication			
Smoking			
Substance Abuse			

SOCIAL / WORK HISTORY

	Yes	No	Comments
Mines			
Prison			

CONTRACEPTION / PREGNANCY

	Yes	No	Comments
Pill			
Injectables			
IUCD			
Sterilisation			
Pregnant			

PHYSICAL OBSERVATIONS

Weight		HB	
BP		Urine:	
Pulse		Other:	
Temp			

DATE: _____

COMPLETED BY: _____

Appendix 3b. Patient Clinic/Hospital Card (p. 1)

G.P.-S. 004-9186

GW 20/12
Revised

SOUTH AFRICA

NATIONAL TUBERCULOSIS CONTROL PROGRAMME

PATIENT CLINIC/HOSPITAL CARD

Registration number ☐☐☐☐/☐☐☐☐ (y y y y)

Transferred/ Moved? ☐

N = No, newly registered.
M = Moved in from facility in this district.
T = Transferred in from facility in another district.

Registration date ☐☐/☐☐/☐☐☐☐ (d d m m y y y y)

Health District..... Clinic/Hospital..... Treatment point .....

Surname..... Full name(s).....

Home address..... .....
(First)

....

Work address ....

....

Telephone (H) ..... Telephone (W)..... .....

Home address..... .....
(New)

....

Work address..... .....

....

Telephone (H) ..... Telephone (W)..... .....

Race ☐
1 = African/Black
2 = Coloured
3 = Indian/Asian
4 = White
5 = Unspecified/Other

Sex ☐ M/F

Age ☐☐ years

Date of birth ☐☐/☐☐/☐☐☐☐ (d d m m y y y y)

PATIENT CATEGORY

☐ (N) New patient

☐ (RC) Retreatment after previous cure

☐ (RAC) Retreatment after previous completion

☐ (RF) Retreatment after failure

☐ (RI) Retreatment after interruption

INTERNATIONAL CODE FOR DISEASE

☐ A16.2 TB PULMONARY

☐ A16.3 TB lymph nodes

☐ A16.5 TB pleura and other respiratory organs

☐ A16.7 TB primary

☐ A17.0 TB meningitis

☐ A18.0 TB bones/joints

☐ A18.8 TB other organs

☐ A19.9 TB milliary

NOTIFICATION INFORMATION

Has patient been notified? ☐ Yes ☐ No

Date of notification ☐☐/☐☐/☐☐☐☐ (d d m m y y y y)

Name of sister in charge ..... Telephone number .....

Patient Clinic/Hospital Card (p. 2)

GW 20/12

SPUTUM RESULTS

Pre-treatment		End of Intensive Phase (2/3 months)		Discharge		Culture **		
Smear dates(s)	Smear result(s)	Smear date(s)	Smear result(s)	Smear date(s)	Smear result(s)	Specimen date(s)	Culture results	Suscept results

** Non-converters and retreatment cases.

REGIMEN AND DOSAGES

Regimen 1—New case ☐ Regimen 2—Retreatment/Adult case ☐ Regimen 3—Children ☐

(a) INITIAL INTENSIVE PHASE

Drug	RHZE	RHZ	S
Number of tabs			

Other drugs (specify)

Weight at diagnosis
kg

H = Isoniazid R = Rifampicin Z = Pyrazinamide E = Ethambutol S = Streptomycin

* The use of fixed-dose combinations is a central part of national TB Programme guidelines.

Use one of the following symbols in the upper space of the appropriate box and initial in the lower space after the drugs have been administered:

✓ = Medication taken under supervision at clinic.
X = Patient did not collect medication.
O = Patient did not have to collect medication (e.g. weekend).
— = Medication collected for self-administration or supervision elsewhere; draw horizontal line (—) to indicate number of days supply were given.

	Day																												
Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

(b) CONTINUATION PHASE

Drug	RH	H	E
Number of tabs			

Other drugs (specify)

	Day																												
Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

TREATMENT SUPERVISOR

☐ Relative ☐ Employer ☐ Teacher ☐ Community health worker ☐ Clinic nurse ☐ Other.....

Name..... Address.....

..... Telephone No..... Code.....

Patient Clinic/Hospital Card (p. 3)

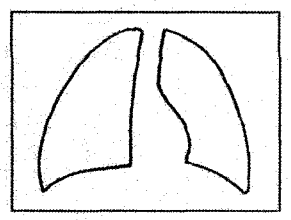
NOTES GW 20/12

Draw in pre- and post-treatment chest x-ray pictures if taken.

Pre-treatment

Date taken.....

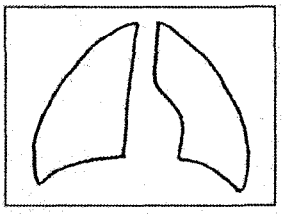
X-ray No.....



Post-treatment

Date taken.....

X-ray No.....



Date	Notes

GW 20/12

SPUTUM RESULTS

Pre-treatment		End of intensive Phase (2/3 months)		Discharge		Culture **		
Smear dates(s)	Smear result(s)	Smear date(s)	Smear result(s)	Smear date(s)	Smear result(s)	Specimen date(s)	Culture results	Suscepi results

** Non-converters and retreatment cases.

REGIMEN AND DOSAGES

Regimen 1—New case ☐ Regimen 2—Retreatment/Adult case ☐ Regimen 3—Children ☐

(a) INITIAL INTENSIVE PHASE

Drug	RHZE	RHZ	S
Number of tabs			

Other drugs (specify)

Weight at diagnosis
kg

H = Isoniazid R = Rifampicin Z = Pyrazinamide E = Ethambutol S = Streptomycin

* The use of fixed-dose combinations is a central part of national TB Programme guidelines.

Use one of the following symbols in the upper space of the appropriate box and initial in the lower space after the drugs have been administered:

✓ = Medication taken under supervision at clinic.
X = Patient did not collect medication.
O = Patient did not have to collect medication (e.g. weekend).
— = Medication collected for self-administration or supervision elsewhere; draw horizontal line (—) to indicate number of days supply were given.

	Day																												
Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

(b) CONTINUATION PHASE

Drug	RH	H	E
Number of tabs			

Other drugs (specify)

	Day																												
Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

TREATMENT SUPERVISOR

☐ Relative ☐ Employer ☐ Teacher ☐ Community health worker ☐ Clinic nurse ☐ Other.....

Name..... Address.....

..... Telephone No..... Code .....

Appendix 3c. Patient Treatment Card (p. 1)

G.P.-S. 004-1001

GW 20/15
Sept 2002

NATIONAL TUBERCULOSIS CONTROL PROGRAMME

PATIENT TREATMENT CARD

Health district..... **Treatment point**.....

Clinic/Hospital..... **Tel. No.** .....

Surname.....

Full name(s).....

Register number ☐☐☐☐☐ / y y ☐☐

Registration date d d ☐☐ / m m ☐☐ / y y ☐☐ Gender ☐ Age (in years) ☐☐

Transferred/Moved? ☐ N = No, newly registered
M = Moved in from facility in this district

PATIENT CATEGORY

☐ (N) New patient
☐ (RF) Retreatment after failure
☐ (RC) Retreatment after previous cure
☐ (RI) Retreatment after interruption
☐ (RAC) Retreatment after previous completion

INTERNATIONAL CODE FOR DISEASE (ICD-10)

☐ A16.2 TB PULMONARY
☐ A16.7 TB primary
☐ A18.8 TB other organs
☐ A16.3 TB lymph nodes
☐ A17.0 TB meningitis
☐ A19.9 TB miliary
☐ A16.5 TB pleura/other resp. organs
☐ A18.0 TB bones/joints

NOTIFICATION INFORMATION

Has patient been notified? ☐ Yes ☐ No Date of notification d d ☐☐ / m m ☐☐ / y y ☐☐

Completed by..... Tel. No. .....

REGIMEN AND DOSAGES

Regimen 1—New adult ☐ Regimen 2—Retreatment adult case ☐ Regimen 3—Children ☐ Treatment start date d d / m m / y y y y

(a) INITIAL INTENSIVE PHASE

Drug	RHZE	RHZ	S
Number tabs			

Other drugs (specify)

Weight at diagnosis
kg

H = Isoniazid R = Rifampicin Z = Pyrazinamide E = Ethambutol S = Streptomycin

* The use of fixed-dose combinations are a central part of national TB Programme guidelines.

	Day																												
Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

(b) CONTINUATION PHASE

Drug	HR	H	E
Number tabs			

Other drugs (specify)

Weight at end of intensive phase
kg

	Day																												
Month	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31

Patient Treatment Card (pp. 2-3)

Patient Treatment Card (p. 4)

SPUTUM RESULTS

SPUTUM BACTERIOLOGY RESULTS (Enter date specimen collected)								
Pre-treatment		End of Intensive Phase (2/3 months)		Discharge		Culture **		
Smear date(s)	Smear result(s)	Smear date(s)	Smear result(s)	Smear date(s)	Smear result(s)	Specimen date(s)	Culture result	Suscept results

** Non-converters and retreatment cases.

TREATMENT SUPERVISOR

☐ Relative ☐ Employer ☐ Teacher ☐ Community health worker ☐ Clinic nurse

☐ Other.....

Name..... Address.....

..... Tel. No..... Code.....

TREATMENT OUTCOME

☐ **(C) Cured:** Patient who is smear-negative at, or one month prior to, completion of treatment and on at least one previous occasion.

☐ **(TC) Treatment completed** without bacteriologic proof of cure.

☐ **(TF) Treatment failure,** patient remains, or becomes again smear-positive at 5 months or later during treatment.

☐ **(D) Patient died** (any reason).

☐ **(TI) Treatment interrupted** for 2 or more months.

☐ **(TRAN) Patient transferred** to another district; treatment outcome unknown.

☐ **(MVD)** Check here if patient **MOVED** to another facility in the **SAME district.**

NOTES

.....

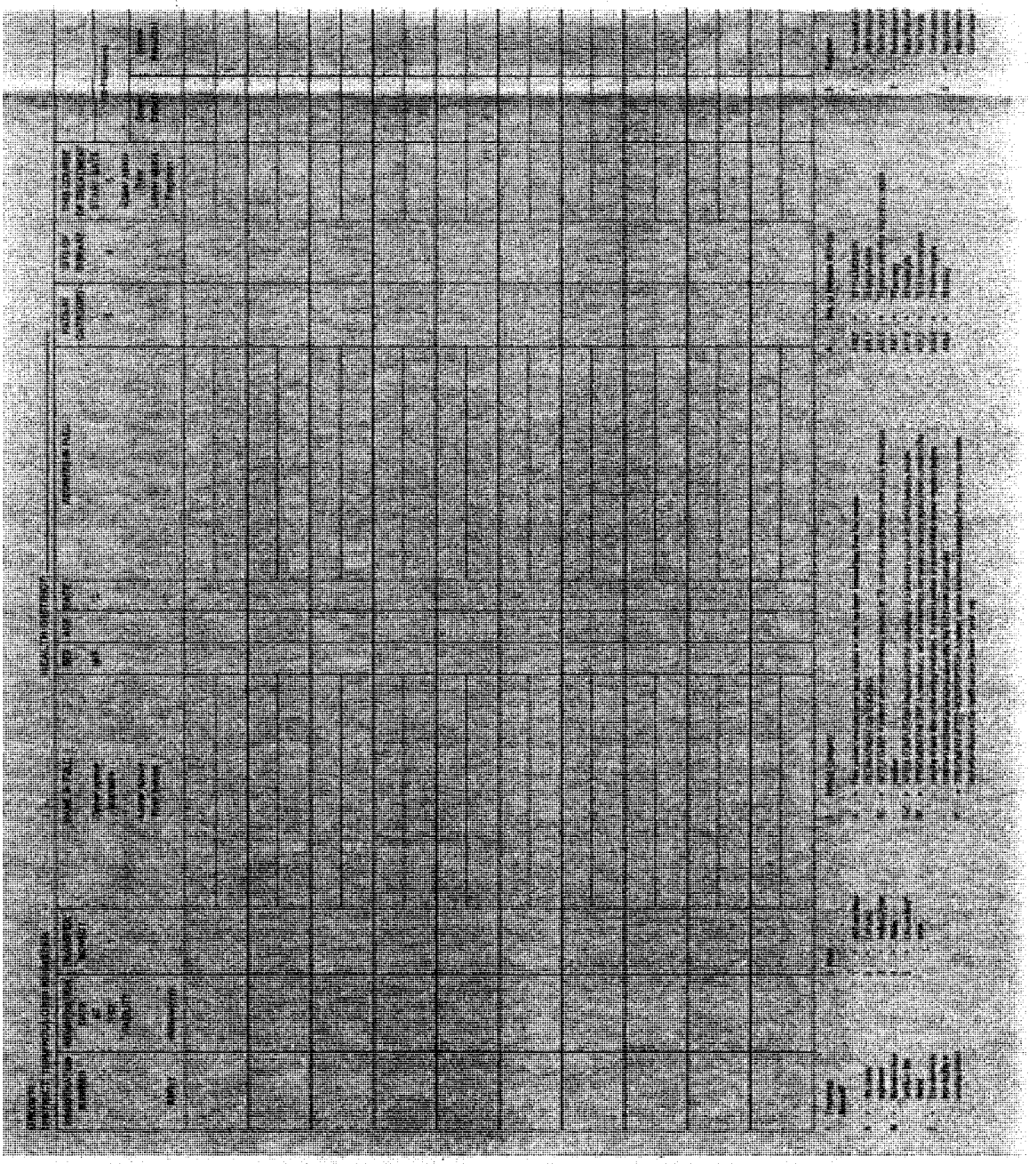
.....

.....

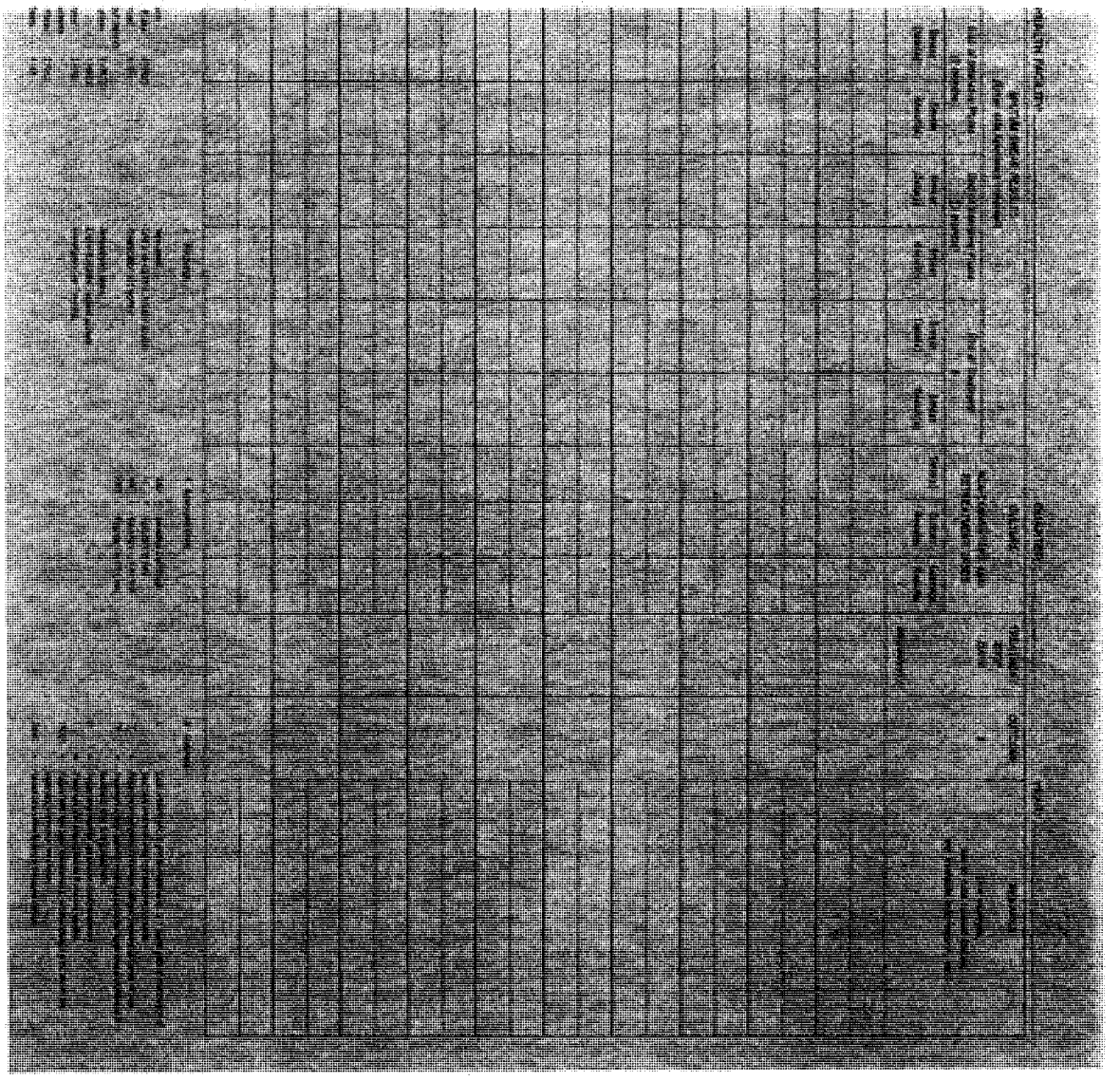
Discharged by (print name).....

Date of discharge d d m m y y ☐☐/☐☐/☐☐

Appendix 3d. District Tuberculosis Register (p. 1)



District Tuberculosis Register (p. 2)



APPENDIX 4: ETR Reports

Appendix 4a. Case Finding Report

WESTERN CAPE Tuberculosis Programme

Case Finding Report
Report on New and Re-treatment Cases of Tuberculosis
[Name of sub-district removed] Quarter 1-4 of 2004

TB Cases	Pulmonary				E P	Total	%
	Smear +	Smear -	No Smear	Total			
New cases	702	192	154	1048	309	1357	73.6%
Relapses	242	140	11	393	45	438	23.7%
After default	25	4	-	29	3	32	1.7%
After failure	11	5	1	17	1	18	1.0%
Total	980	341	166 *	1487	358	1845	100.0%
%	53.1%	18.5%	9.0%	80.6%	19.4%	100.0%	
* of which children aged 0 - 7: 117							
This report excludes - patient(s) that died before treatment started							
% smear + as proportion of Total PTB : 65.9%							

TB Cases		0-14	15-24	25-34	35-44	45-54	55-64	65-74	>74	Total	%
All TB Cases	M	75	135	327	279	150	75	17	6	1064	57.7%
	F	85	162	250	163	73	33	10	5	781	42.3%
	TOTAL	160	297	577	442	223	108	27	11	1845	100.0%
	%	8.7%	16.1%	31.3%	24.0%	12.1%	5.9%	1.5%	0.6%	100.0%	
New Smear Pos Cases	M	4	85	147	95	60	29	6	3	429	61.1%
	F	6	81	101	50	19	11	3	2	273	38.9%
	TOTAL	10	166	248	145	79	40	9	5	702	100.0%
	%	1.4%	23.6%	35.3%	20.7%	11.3%	5.7%	1.3%	0.7%	100.0%	
Re-Treat Smear Pos Cases	M	-	13	61	76	31	18	2	1	202	72.7%
	F	-	13	30	22	6	3	1	1	76	27.3%
	TOTAL	-	26	91	98	37	21	3	2	278	100.0%
	%	0.0%	9.4%	32.7%	35.3%	13.3%	7.6%	1.1%	0.7%	100.0%	
- record(s) with missing age											

Bacteriology Coverage = $\frac{\text{Total smear pos + Total smear neg}}{\text{Total PTB minus children 0-7 yrs}}$ = 96.4%

Appendix 4b. HIV Report

WESTERN CAPE Tuberculosis Programme

TB/HIV Collaborative Activities Report
Report on Counselling, Testing and Treatment

[Name of sub-district removed]

Quarter 1-4 of 2004

A. Case Finding

Total number of TB patients in this period: 1866

TB Cases		0-14	15-24	25-34	35-44	45-54	55-64	65-74	>74	Total	%
All TB Cases	M	75	138	331	283	152	77	18	6	1080	57.9%
	F	85	163	252	164	73	33	11	5	786	42.1%
	Total	160	301	583	447	225	110	29	11	1866	100.0%
	%	8.6%	16.1%	31.2%	24.0%	12.1%	5.9%	1.6%	0.6%	100.0%	
0 record(s) with missing age											

B: HIV Counselling

Number of TB patients counselled for HIV this period: 174

C: HIV Testing

	Adult male (>15)			Adult female (>15)			Child male (0-14)			Child female (0-14)		
	Tested	Pos	%	Tested	Pos	%	Tested	Pos	%	Tested	Pos	%
TOTAL	70	18	25.7%	61	31	50.8%	1	1	100.0%	2	1	50.0%
HIV positive by TB type				HIV positive by TB type			HIV positive by TB type			HIV positive by TB type		
Smear Pos		6	33.3%		13	41.9%		-	0.0%		-	0.0%
Smear Neg		5	27.8%		9	6.5%		-	0.0%		-	0.0%
Smear Not Done		1	5.6%		2	6.5%		1	100.0%		1	100.0%
EP		6	33.3%		7	22.6%		-	0.0%		-	0.0%

	Total		
	Tested	Pos	%
Total	134	51	38.1%
HIV positive by TB type			
Smear Pos		19	37.3%
Smear Neg		14	27.5%
Smear Not Done		5	9.8%
EP		13	25.5%

Indicators: Expanded HIV services for TB patients

	Percentage	
TB patients counselled for HIV	174/1866	9.3%
Of TB pts counselled, HIV tested	134/174	77.0%
Of TB pts tested, HIV positive	51/134	38.1%
TB/HIV patients starting CPT	25/51	49.0%
TB/HIV patients referred for HIV care	0/51	0.0%
TB/HIV patients starting ART	0/51	0.0%

D. HIV care and treatment

TB/HIV patients starting CPT	25
TB/HIV patients referred for HIV care	-
TB/HIV patients starting ART	-

Appendix 4c. Treatment Outcome Report

WESTERN CAPE Tuberculosis Programme

Treatment Outcome Report
Report on the Outcome of Tuberculosis Treatment

[Name of sub-district removed] Quarter 1-4 of 2004

Category	Outcome status	No	%
All TB Cases	**Treatment success**	1430	76.7%
	Treatment failure*	20	1.1%
	Treatment not completed		
	- Died during treatment	77	4.1%
	- Defaulted from treatment	141	7.6%
	Transferred to another unit	57	3.1%
	Patients not evaluated	140	7.5%
	All TB Cases	**1865**	**100.0%**
	* Of which 1 were diagnosed as MDR TB.		
New Smear Positive Cases	**Treatment success (81.9%)**		
	- Cured	537	75.4%
	- Treatment completed	46	6.5%
	Treatment failure**	9	1.3%
	Treatment not completed		
	- Died during treatment	14	2.0%
	- Defaulted from treatment	53	7.4%
	Transferred to another unit	15	2.1%
	Patients not evaluated	38	5.3%
	New smear positive cases	**712**	**100.0%**
	** Of which 0 were diagnosed as MDR TB.		
Re-treatment Smear Positive Cases	**Treatment success (64.5%)**		
	- Cured	158	56.6%
	- Treatment completed	22	7.9%
	Treatment failure***	6	2.2%
	Treatment not completed		
	- Died during treatment	17	6.1%
	- Defaulted from treatment	33	11.8%
	Transferred to another unit	8	2.9%
	Patients not evaluated	35	12.5%
	Re-treatment smear positive cases	**279**	**100.0%**
	*** Of which 1 was diagnosed as MDR TB.		

APPENDIX 5: Behavioural, Environmental, Educational and Ecological Factors of the Intervention

Appendix 5a. Behavioural and environmental factors classified according to importance and perceived changeability

Factor	Factor Type	Importance (to Outcome)	Changeability (within this intervention)	Intervention Consideration?	Level of Priority
Clinical practice	Behavioural	Medium	Medium	Yes	3
Data capture	Behavioural	Medium	Medium	Yes	2
Analysis and dissemination of data	Behavioural	High	High	Yes	1
Viewpoints of co-workers regarding TB	Environmental	Low	Low	No	
Available economic resources	Environmental	Medium	Low	No	
Broader community viewpoints regarding TB	Environmental	Low	Low	No	
Capacity of software to carry out required tasks	Environmental	High	Low	No	

Appendix 5b. Predisposing, enabling and reinforcing factors classified according to importance and perceived changeability

Factor	Factor Type	Importance (to Outcome)	Changeability (within this intervention)	Intervention Target?	Level of Priority
Personal knowledge and beliefs regarding TB	Predisposing	Medium	Low	No	
Work ethic/dedication to job	Predisposing	High	Low	No	
Prior work experience, esp. regarding change	Predisposing	Medium	Low	No	
Education and training regarding the surveillance system and TB itself	Enabling	High	Low	No	
Adequate training and explanation of rationale for system changes	Enabling	High	High	Yes	1
Perception that feedback is heard	Enabling	High	High	Yes	3
Timing of system changes	Enabling	High	High	Yes	4
Access to resources for assistance	Enabling	High	High	Yes	2
Personal background and experience with surveillance, IT and TB	Enabling	Medium	Low	No	
Communication and relationship with other users (TB sisters, health managers, coordinators, etc.)	Reinforcing	Medium	Medium	No	
Feedback regarding data (health workers) and reports (coordinators, info officers and managers)	Reinforcing	High	High	No [certainly important to the outcome but already a strong component of the system]	
Personal meaning associated with TB work	Enabling, Reinforcing	High	Medium	No	

APPENDIX 6: Draft Questionnaire

Please circle the number that most closely corresponds to your feelings and experiences.

	Agree				Disagree
Management of data is smoother now than it was prior to the changes	1	2	3	4	5
When I have concerns about the system, someone does something to address the problem	1	2	3	4	5
Once changes have been made it is easy for me to get back to my old routine	1	2	3	4	5
I preferred the old way of working with the data	1	2	3	4	5
When new system features were being developed, I felt that I had sufficient input into the planning	1	2	3	4	5
Data moves smoothly between myself and my coworkers	1	2	3	4	5
The new data collection tools are straightforward to use	1	2	3	4	5
The timing of system changes prevent me from meeting data deadlines	1	2	3	4	5
I am satisfied with the level of available technical support while the changes were being made	1	2	3	4	5
I am satisfied with the level of available technical support after changes have been made	1	2	3	4	5
I understand why the changes have been made	1	2	3	4	5
I received a sufficient amount of warning prior to the implementation of new system features	1	2	3	4	5
I have little control over system planning	1	2	3	4	5
When I have concerns about the system, there is someone to whom I can go the problem	1	2	3	4	5
The rationale for the new features was clearly explained	1	2	3	4	5
I am satisfied with the level of detail provided about how to use the new features	1	2	3	4	5
I have all of the voice in system planning that I would like	1	2	3	4	5
I feel that I play an important role in the overall TB system	1	2	3	4	5