A META-ANALYSIS OF THE EFFECTIVENESS OF TUBERCULOSIS PROGRAMS:
THE INFLUENCE OF PROGRAM COMPONENTS ON OUTCOMES

by

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A thesis submitted in conformity with the requirements
for the degree of Master of Science
Graduate Department of Nursing Science,
University of Toronto

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Abstract

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The purposes of this meta-analysis were to identify components of TB programs, and to determine the extent to which these components affected the outcomes. Factors that may influence effectiveness of TB programs were also examined. The substantive and methodological variables of 27 studies were abstracted and coded. The scientific quality of thirteen studies indicated that these particular studies could be used to subsequently address the research questions. The results of this study indicated that direct observed therapy and incentives components were most frequently evaluated and found to be effective in reducing the incidence of TB. For three studies, according to the Mantel-Haenszel method, the average effect size for adherence to and completion of TB treatment was 2.2. Overall this meta-analysis indicated that all program components produced the desired effect; however, there was limited ability to specify the effects of particular factors on the program components' effectiveness in producing the desired outcomes.
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CHAPTER I
INTRODUCTION

Background

"Tuberculosis was Canada’s leading cause of death at the turn of the century, with a mortality rate in 1900 of about 200 per 100,000 population. By 1944 mortality was reduced to about 20 per 100,000" (Zilm & Warbinek, 1995, p. 66).

Tuberculosis is a disease caused by a bacterium called tubercle bacillus or mycobacterium tuberculosis. The bacillus enters the body through the air and causes infection, usually in the lungs but sometimes in other parts of the body. There are two types of TB, TB infection and TB disease. Infection means that the bacillus has entered the body, but the is not doing any harm. The bacterium lies dormant, and this is considered inactive TB. TB disease means that the bacteria are spreading quickly, damaging the lungs or other parts of the body. This type of TB may be contagious, and is considered active TB.

TB infection can be treated very effectively with two drugs that kill the bacillus and make sure that the person does not develop TB disease later (Canadian Lung Association, 1996). TB disease can also be treated effectively through a combination of antibiotics. Treatment usually takes between 6 to 12 months to cure the illness. Modern drugs are effective in curing TB as long as the drugs are taken as prescribed. Several programs have been designed to help patients take these drugs as prescribed, and to manage their illness.

World-wide, in 1994, tuberculosis (TB) was considered a disease of the past, and it was believed that we would never again have to face this problem. Ineffective and incomplete treatment of the disease, declines in public funding for TB control, HIV infection, crowding, homelessness, and immigration of people coming from countries where TB is
TB is endemic have contributed to a resurgence of TB world-wide (Chaulk & Kazandjian, 1998). "It is estimated by the World Health Organization (WHO) that one third or about 1.7 billion of the world's population is infected by the mycobacterium tuberculosis" (Kochi, 1991, p. 2). In 1995, the reported TB incidence rate was 1.9 per 100,000 for Non-Aboriginal Canadian-born individuals, whereas those for Status Indians, all Aboriginal peoples and foreign-born residents were 44.5 per 100,000, 29.4 per 100,000 and 20.4 per 100,000 respectively (Health Canada, 1997). In Toronto, the incidence of TB (23 per 100 000 in 1995) was among the highest in Canada (Kerbel, 1997).

TB is a preventable and curable disease. However, effective TB management programs are imperative in order to control this disease. "The recent increases in TB morbidity have placed additional demands on state and local TB control programs, which already had been substantially weakened by inadequate staffing and funding support" (CDC, 1995, p.1). Health professionals have a responsibility to develop effective TB programs to meet the challenge the resurgence of TB creates. Freudenberg (1995) suggests that effective TB control must focus on: (1) identifying people with active TB; (2) ensuring that these individuals complete medical treatment; and (3) addressing the broader social factors that contribute to the resurgence of endemic TB.

According to Kerbel (1997), effective TB programs must include directly observed therapy (DOT) in TB control because supervision of patients taking medication to cure or prevent TB is crucial. DOT consists of administering TB drugs to patients during a face-to-face encounter. In the 1960s, treatment for individuals diagnosed with TB or infected with the disease was transferred from hospital-based programs to the community (Kerbel, 1997). Patients were instructed to self-administer the recommended antibiotics as prescribed for
periods lasting six to nine months. The lack of patient support and the laissez-faire attitudes of the health care system may have contributed to the resurgence of TB and to the multi-drug resistance of the mycobacterium. “According to the World Health Organization (WHO), an unprecedented level of neglect during the 1970s and 1980s helped to create this situation” (Pilheu, 1998, p. 697). Patients following TB drug regimens were often unable to complete the entire drug course due to lack of supervision and support.

Pozsik (1993) suggested that successful TB programs should be patient-centered and include DOT for individuals infected with TB and for those who have active disease. Directly observed therapy contributes to the effectiveness of TB programs, as patients are supervised taking anti-TB drugs. In outpost areas of Canada, DOT is one of the most important components of TB programs that produce up to 100% success.

Kohn, Arden, Vasilakis, & Bnenker (1996) contended that successful TB programs in school settings must include DOT. The authors believed that DOT increased patient compliance to TB treatment. Fujiwara & Larkin (1997) reported that as the use of DOT increased in New York City, the number of new cases of TB decreased steeply. In Baltimore, a 61.7% decline in TB incidence was reported after the implementation of a community-based DOT program (Chaulk & Spies-Pope, 1997).

Arguello (1990/1991) stated that control programs based on short-term vs long-term chemotherapy were more successful in obtaining a high cure rate among TB patients living in unfavourable socio-economic and organisational conditions.

According to Concato & Rom (1994), the treatment of TB raises issues related to public health and civil rights. Because predicting non-compliance for individual patients may be inaccurate, direct observed therapy was advocated for all patients with TB (Bayer,
Neveloff-Dubler, & Landersman, 1993; & Iseman, Cohn & Sbarbaro, 1993). Concato & Rom contended that DOT is an intrusion on personal privacy and liberty since DOT is provided to patients without choice.

In 1990, McAdam, Brickner, Scharer, Crocco and Duff reported that the success of a TB program with the homeless population was attributed to the consistent presence and support of physicians, nurses and social workers at the shelters. The authors suggested that the efficiency and success of the TB program were influenced by the comprehensive local patient-centered interventions directed at managing and controlling TB.

A study conducted in Toronto by the TB pilot subcommittee (1996) suggested that a constellation of health care resources for TB patients contributed to providing care that was more effective. The subcommittee found that giving patient information regarding TB that includes prevalence rates, incidence rates, groups at risk, and treatment, appears to influence positive patient outcomes in TB programs. Here, three components increased the effectiveness of TB programs: (1) a one-to-one approach to patient care; (2) effective communication among health care professionals; and (3) incentives such as food and clothing offered to both patients and staff.

The Toronto TB pilot subcommittee proposed that effective TB programs should focus on prevention and control of TB. The subcommittee recommended: (1) identification, comprehensive evaluation, and treatment of all persons infected with TB; (2) adequate reporting of persons infected with TB; (3) comprehensive contact tracing; and (4) screening of at-risk populations. The subcommittee contended that “[Integral] to these strategies, and perhaps the most important, is health education, health promotion, advocacy, and coalition-building” (TB pilot subcommittee, 1996).
These observations imply a pressing need to devise programs for improving the care provided to people infected with TB. In 1993, the WHO declared TB a global emergency. It is imperative that health care professionals are provided with research-based data that can assist them in developing effective TB programs (Kerbel, 1993).

One possible way to gain such data was to assess how effective TB programs were in achieving the desired outcomes. Four components of TB programs were identified from the literature. Program components are strategies and activities that compose a TB program (CDC, 1995). The components are directly observed therapy, assessment services, education services, and incentives. Two program outcomes were identified from the literature. The outcomes are incidence of TB, and adherence to and completion of TB treatment. It is important to examine the effects of TB program components, since up to half the people with TB do not complete their treatment (Volmink & Garner, 1998). “Completion of treatment of active cases of TB is the most important priority of TB control programs” (Wobeser et al., 1999).

In the current study, the four program components were not compared to each other. The objective of this meta-analysis was to assess the effects of four components on incidence of TB or on adherence to and completion of TB treatment.

This meta-analytic study provided a critical review of the research literature on components of TB programs and the extent of their effect on program outcomes. The results of the analysis, which synthesised empirical knowledge, will assist health care professionals to provide evidence-based health care for patients with TB. Furthermore, the findings of this study could inform policies that pertain to the delivery of TB-related care.
Problem Statement

World-wide, *mycobacterium tuberculosis* claims more lives each year than any other single human pathogen. Despite the availability of effective drugs, the incidence of tuberculosis is re-emerging as a public health problem in industrialised countries (Young & Duncan, 1995). In Canada, TB in foreign-born residents has increased from 35% in 1980 to 57% in 1994, and TB in the aboriginal population from 14% to 19% (Statistics Canada, 1994). For the Canadian-born, the proportion has declined from 50% to 21% between 1980 and 1994. In Canada and other countries, TB programs have recently been revived due to the continued increase of TB rates world-wide. There has been an attempt to model these programs to best fit the present health care system. Since many TB programs are not producing the desired outcomes, attention to the effectiveness of these programs is increasing. According to Stephens et al. (1998), drug resistance, breakdown or lack of control programs, and HIV infection are contributing factors to the re-emergence of tuberculosis. TB program workers report low patient adherence rates with TB treatment, and difficulties in delivering the program in its entirety. They also have difficulty reaching and communicating effectively with high-risk communities (El-Sadar, Medard, & Barthaud, 1996).

Standards and guidelines provided by Health Canada and the Canadian Lung Association have been extremely important for the development of TB programs. However, to improve existing programs and develop new ones, research into the effectiveness of TB programs is crucial. In numerous reports (Adhikari, & Menzies, 1995; Chaulk & Kazandjian, 1998; Freudenberg, 1995; Kohn, et. al., 1996; Pozsik, 1993; Yuan, Richardson, & Kendall, 1995) researchers proposed components for TB programs. As TB becomes more
threatening to public health, it is imperative that the extent to which TB program components affect the outcomes be determined based on empirically demonstrated effects.

TB programs vary in nature both nationally and internationally. Recently, expert TB health care professionals exchanged information regarding protocols observed in Canadian provinces and territories to develop a national policy to guide future development and implementation of TB programs. "If worldwide control of tuberculosis does not improve, it is predicted that 90 million new cases and 30 million deaths are expected in the decade 1990 through 1999" (WHO cited in Kerbel, 1997, p. 81). To meet this challenge, we need well designed TB programs to effectively manage TB. We also need to identify components of TB programs that influence positive program outcomes. Research could assist health care professionals to improve present TB programs. According to Fox, "the greatest current problem concerning tuberculosis chemotherapy does not lie in the introduction of either new schemes or new drugs, the point is to know how to apply the available knowledge successfully" (cited in Pilheu, 1998, p. 698).

This meta-analytic study, by using available empirical knowledge, identified TB program components that could most likely affect the success of the program.

Purpose

The purposes of this meta-analysis were to identify components of TB programs, and to determine to what extent these components affected the outcomes of interest. This study also examined factors that may enhance or impede the effectiveness of TB programs.

Significance of Problem

It is already 50 years since the first antituberculosis drug, streptomycin, was discovered; for 25 years we have had effective treatments available which can cure
patients in 6 months, and the result is failure plus a growing mortality curve at the beginning of the twenty-first century (Pilheu, 1998, p. 701).

Research-based knowledge of TB program components is essential. The knowledge can be used to develop and design new programs and to revise current programs so they produce the desired outcomes.

Appropriately developed and implemented TB programs are necessary for maintaining or improving population health and for maintaining the efficient use of resources. The development of tuberculosis programs needs to be addressed in a scientific manner as the disease continues to plague population health. Programs that provide care based on empirical evidence will assist nurses in their endeavour to fight TB. If TB clinicians know which components affect outcomes, they can use them for TB management and control.
REVIEW OF RELEVANT LITERATURE

"Recognising that tuberculosis is one of the most neglected global health problems and that the tuberculosis epidemic is out of control in many parts of the world, WHO declared tuberculosis to be a global health emergency in April 1993" (Raviglione, Snider, Kochi, 1995, p. 225). This statement is significant for countries accepting immigrants and refugees from countries where TB is endemic and uncontrollable, and for countries with large populations of First Nations people.

TB continues to flourish in many Canadian communities. In 1994, for example, Ontario reported 831 TB cases and Quebec reported 361 cases. Canada is not recognised as a country with many TB cases. However, the disease continues to proliferate, and pockets of the population have very high rates (Kerbel, 1997). "Globalization is taking place, [...] nowadays no country lives in isolation [...] there can be no tuberculosis-free oasis anywhere in the world as long as there are foci with millions of patients in other regions" (Pilheu, 1998, p. 699). According to Pilheu (1998), TB is still being transmitted and people are still dying from the disease for one reason: therapeutic mismanagement.

The following section will review the literature on TB programs. The substantive variables of interest in this study will be examined in this section. The focus is on program components, outcomes, and other variables (skills of intervener, cultural experience, mode of program delivery, setting, program length, participant involvement, demographic data) that may enhance or impede the effectiveness of TB programs.
Substantive Variables

Program Components

Four components of TB programs were identified from the literature. These are directly observed therapy (DOT), assessment services, education services, and incentives. The following sections will describe each of these components.

Directly Observed Therapy. Directly observed therapy (DOT) consists of contracting the individual TB patient, to observe the patient take the doses of prescribed medications. The goal is to enhance adherence to and completion of TB treatment.

El-Sadr, Medard, & Barthaud (1996) used a surrogate family model in their TB program. The program consisted of at-home and clinic DOT, development of a sense of family among the program staff and patients to facilitate treatment supervision and completion, group activities, incentives for participation, education, and support groups. They found high rates of treatment completion and visit adherence.

Assessment Services. Assessment services include screening of patients at risk of acquiring TB, following them up, providing prophylaxis treatment, and following up patients being treated for active TB. The goal of this component is to enhance adherence and completion of TB treatment. Assessment services were evaluated in Korea in both rural and urban health centres (Jin et al., 1993). In the study, 1,300 patients were assigned randomly to one of two groups. Patients in the intervention group received intensified supervisory activities, such as improved assessment services. Patients in the control group received the usual care. The staff working with the intervention group was closely motivated by the health centre director and sub-section chief to provide intensified assessment services. Staff working with the intervention group performed increased baseline assessment services, such...
as sputum collection and chest X-rays. Follow-up assessment services, such as sputum exams and chest X-rays were performed almost perfectly. Patients in the intervention group were more regular with their drug collection practices, and the proportion of patients completing treatment was clearly higher in this group.

**Education Services.** This service provides health education for the community, for TB patients, and for staff working with TB patients. The goal is to provide knowledge and information to increase awareness and understanding of TB. Lee & Price (1995) evaluated a TB program and found that health education was particularly important resulting in improved adherence to and completion of TB treatment.

Morisky et al., (1990) evaluated the education services and incentive components and found that education sessions influenced adherence to and treatment completion rates. In this study, 88 low-income adult patients with active TB were assigned randomly to the intervention group, where patients received special intervention, or to the control group, where patients received usual-care. The special intervention consisted of a tailored health education counselling session addressing compliance enhancing strategies. There was also a $10 monetary incentive at each monthly visit to the TB clinic. The counselling session consisted of tailored educational messages based upon initial interview and subsequent assessments, written instructions about the regimen, educational reinforcement about TB, enlistment of family and friend support, positive verbal reinforcement for adherence to regimen, and contingency contracting using the monetary incentive (Morisky et al., 1990). In the study, appointment-keeping, medication-taking practices, and adherence to and completion of TB treatment were improved. More patients from the usual-care group defaulted.
Incentives. Incentives are one component of TB programs that aim to facilitate patients’ participation in TB programs and adherence to treatment. Various types of incentives have been reported: treatment provided on-site for shelter patients, accommodation, meals, coffee, transportation, and support and supervision with TB treatment.

Diez et al., (1996) evaluated a TB program targeting homeless TB patients. These patients had poor adherence to treatment and concurrent multiple social and health problems. Incentives consisted of residence, food, and incidental money. The authors observed a significant decrease in the TB incidence rate among patients in this program compared to an unchanged rate in other regions.

Torres et al., (1990) evaluated a TB program provided in shelters for the homeless. On-site treatment was considered an incentive. The authors found that such programs were successful in maintaining a high degree of compliance to TB treatment provided weekly at the shelter.

McAdam et al., (1990) described a program that included incentives such as a consistent presence of physicians, nurses, and social workers at the clinic sites in shelters. In addition, transportation to shelter clinics and to more convenient shelter areas were important incentives. The authors reported improved treatment compliance due to the use of incentives.

Health Canada has encouraged incorporating incentives in TB programs. However, empirical evidence that supports including incentives, as a TB program component would benefit program planners by specifying the nature and effectiveness of this component.
Outcomes

Two outcomes were identified using TB standards: Incidence of TB and adherence to and completion of TB treatment were the outcomes of interest in this study.

According to the Canadian Lung Association (1996), effective TB programs should produce and secure a progressive reduction in the annual incidence of the disease among risk groups. The annual incidence of TB refers to the number of new cases in a year divided by the number of people at risk for TB (Streiner & Norman, 1996). This outcome represents a change in the numbers of persons diagnosed with TB in a one-year period. According to McDonald & Ma (1987), the aim of TB programs is to reduce the annual incidence rate of TB. Therefore it was important to assess the effect of components on the incidence of TB.

According to the CDC (1995) effective TB programs should promote adherence to and successful completion of TB treatment. This outcome represents a change in patient health status that is, patients that adhere to and complete their TB treatment can effectively be cured from TB (WHO, 1997). “Noncompletion of treatment has serious consequences, including ongoing infectiousness and development of drug-resistant Mycobacterium tuberculosis” (Wobeser et al., 1999). Therefore, it was important to assess the effect of components on adherence to and completion of TB treatment.

It was anticipated that the examination of additional variables related to study characteristics would permit the identification of factors that enhance or impede the success of TB programs. Based on the literature on TB programs and on available practice guidelines, participant and context characteristics that have been suggested as affecting implementation of TB program components or the effectiveness of these components, were identified and considered as substantive variables in this meta-analysis. These variables
were selected to gain a better understanding of the effectiveness of TB programs. The variables are skills of intervener, cultural experience, mode of program delivery, setting, program length, participant involvement, and demographic data. Ethnic background of participants was another variable of interest, but it was excluded due to the lack of patient information in the primary studies. These variables along with program components and outcomes represented the substantive variables, that is, variables that relate to TB program design.

**Skills of Intervener**

Wilkinson, Davies & Connoly (1996) evaluated a DOT program offered by health workers, community health representatives, and volunteer community representatives such as storekeepers. The study took place in a resource-poor setting. The results indicated that patients who received DOT by volunteer community representatives achieved the highest treatment completion rates. Many TB programs require funds to deliver the components. For example, health care professionals must be paid. Therefore, using volunteers to deliver DOT addressed the resource issue.

Chaulk, Moore-Rice, Rizzo & Chaisson (1995) evaluated a TB program that used outreach nurses to provide DOT. The researchers reported that using outreach nurses was effective since, TB treatment completion rates increased among patients with poor medical and social conditions.

McAdam et al., (1990) described a program that included a consistent presence of physicians, nurses, and social workers at clinic sites in shelters. The authors reported improved drug regimen compliance in homeless persons, since TB patients were cared for by health care professionals.
Volmink & Garner (1999) contended that interventions to improve adherence to TB treatment should be implemented by health care providers where appropriate. For example, DOT provided by RNs should be implemented in a setting for which there is evidence that DOT by RNs is more effective than self-supervision. In their review, Volmink & Garner found that DOT implemented by clinic nurses in a resource-poor setting achieved outcomes equivalent to self-supervision. The researchers also recommended studies to determine the effects of supervision by professional and lay workers in community settings, since using professionals can be costly.

Studies on TB programs identified that outcomes are influenced by skills of interveners. Therefore, it was important to examine categories of interveners and assess their influence on program effectiveness.

**Cultural Experience**

Some reports discuss interveners. Some imply that interveners must have a socio-economic background similar to that of program participants. Some recommend cultural training.

Chaulk & Kazandjian (1999) assessed adherence to and completion of TB treatment. The researchers suggested that successful programs included culturally appropriate outreach and bilingual staff. Cultural sensitivity is important in TB care, since most often TB patients are foreign born, or are from a lower socio-economic background (Volmink & Garner, 1999; & Chaulk & Kazandjian, 1998).

Staff that reflect the community cultural and socio-economic background, or persons trained to work in multicultural settings influence the effectiveness of TB programs (CDC, 1995; Etkind et al., 1991). It is believed that interveners who receive cultural sensitivity
training, or are of similar background to their TB population can better relate to clients and positively influence the program outcomes (CDC, 1995).

Studies identified that program outcomes are influenced by cultural experience of interveners. It was important to assess the cultural experience of interveners, since this factor influences the effectiveness of TB programs.

**Mode of Delivery**

Some programs are delivered one-on-one, and some may be delivered to groups of patients. Morisky et al., (1990) assessed a TB program that improved adherence to and completion of TB treatment. The researchers stated that one-on-one tailored health education sessions influenced the effectiveness of TB programs. The CDC (1994) contended that health education sessions delivered to entire communities influenced program outcomes.

Studies on TB programs identified that outcomes are influenced by mode of delivery. Therefore, it was important to examine this factor and assess its influence on program effectiveness.

**Setting**

According to Chaulk & Kazandjian (1998), “building TB treatment regimens around patients' lifestyles appears to be not only more effective in terms of treatment completion, but also more acceptable to patients” (p. 946). The authors also suggested that if components are delivered where the patient is found, the outcomes might be affected. To reach large sections of the population, programs delivered components in various settings (Chaulk & Kazandjian, 1998; El-Sadr, Medard, & Barthaud, 1996; McAdam et al., 1990; Morisky et al., 1990; Mushtaque et al., 1997; and Seetha et al., 1981; and Torres et. al., 1990). For example, settings included methadone clinics, churches, health posts, refugee
camps, homeless shelters, patients' workplaces, health centers, and community-based organizations.

Volmink & Garner argued that, to ensure that interventions are relevant to settings in which the bulk of the TB caseload occurs, studies in low-income countries are a priority. Other researchers contended that drawing conclusions from international literature can be fraught with pitfalls, since the definitions of DOT can vary from one country to another, depending on resources (Chaulk, 1994; & Liu et al., 1992 as cited in Chaulk & Kazandjian). Chaulk & Kazandjian (1998) also recommended that research studies examine more closely the effectiveness of various incentives among different populations.

Studies identified that outcomes are influenced by location. Therefore, it was important to examine this factor and assess its influence on program effectiveness. In relation to setting, it was important to examine the country in which the program was offered.

**Program Length**

TB has a long treatment period. The CDC (1994) and the Advisory Council for the Elimination of Tuberculosis (1992) recommended that treatment last six to twelve months to achieve at least 90% cure rates. Some studies report that patients are not completing their treatments (Concato & Rom, 1994; Wilkinson & Davies, 1996). The researchers suggest that program length influenced program outcomes. Therefore, it was important to assess the influence of program length on the program's effectiveness.

Studies identified that outcomes are influenced by program length. Therefore, it was important to examine this factor and assess its influence on program effectiveness.
Participant involvement

According to Concato & Rom (1994), the treatment of TB raises issues related to public health and civil rights. Because predicting non-compliance for individual patients may be inaccurate, direct observed therapy was advocated for all patients with TB (Bayer, Neveloff-Dubler, & Landersman, 1993; & Iseman, Cohn & Sbarbaro, 1993). Concato & Rom contended that DOT was an intrusion on personal privacy and liberty, since DOT is provided to patients without choice. Some researchers found that forcing patients to participate in inconvenient methods of treatment, such as DOT may produce adverse outcomes (Dick & Pekeur, 1995; Steyn et al., 1997).

Studies identified that outcomes are influenced by participant involvement. Therefore, it was important to examine this factor and assess its influence on program effectiveness.

TB programs have enlisted individuals from various categories (McAdam et al, 1990, Neher et al, 1996). Researchers usually report demographic data of participants, such as age, gender, and homelessness (Chaulk & Kazandjian, 1998). It was important to examine demographic variables since there might be differences in the outcomes related to age, gender, and homelessness (Fortin, 1996). These demographic variables are also important as they can influence whether the study results can be generalized. According to Stephens et al (1998), each of these demographic variables can influence calculation of the incidence of TB.

Age and Gender

Buri et al., (1984) noted a pattern of noncompliance and differences in treatment completion rates among younger female patients. Since age and gender influence the
outcomes, it was important to examine these factors and assess their influence on program effectiveness.

**Homelessness**

The CDC (1995) suggested complex social and medical factors, such as homelessness caused TB morbidity to increase from 1985 through 1993 in the US. This population group, due to poor adherence to treatment and concurrent multiple social and health problems, continues to be at higher risk for TB (McAdam et al., 1990; CDC, 1994). Homeless persons are at greater risk for failing to complete treatment (Wobeser et al., 1999). McAdam et al., (1990) described a program that included homeless persons in which the homeless persons complied with the TB treatment. Incentives such as, transportation to clinics seemed to be important to the success of this program. The authors suggested that program components are more effective for some patients, than for others. Studies demonstrated that outcomes are influenced by homelessness. Therefore, it was important to examine this factor and assess its influence on program effectiveness.

In conclusion, there is evidence that different combinations of program components and different ways of delivering those components can lead to different results. There is also evidence that some factors (skills of intervener, cultural experience, setting, program length, participant involvement, age, gender, and homelessness) may enhance or impede the success of TB programs.

**Summary of Empirical Literature**

The examination of TB program components and their effectiveness can assist health care professionals to develop and implement evidence-based TB programs that can achieve the desired outcomes.
Although the literature on TB programs is vast, meta-analysis and synthesis pertaining to TB program effectiveness could further clarify and improve our knowledge of TB program planning and evaluation.

The results of this meta-analytic study could assist health care providers in developing more effective programs. Program planners would be provided with findings based on empirical evidence of the components that are most effective. Lee & Price (1995) state that explicitly defined and developed TB program components would improve service delivery and consistency, thus making it possible for TB programs to meet their goals. In addition, the results of this meta-analysis would begin to identify the potential influence of participant and context characteristics on outcome achievement. This influence has not been examined in previous studies related to TB programs.
CONCEPTUAL FRAMEWORK

Conducting this meta-analysis required data on substantive variables (variables related to program design) and methodological variables (variables related to evaluating studies). The substantive variables included TB program components, program outcomes, and selected factors (skills of interveners, cultural experience, setting, program length, participant involvement, age, gender, and homelessness) that may enhance or impede the success of programs. The methodological variables, such as study design, sample size, and response rates represent the characteristics of studies that evaluated the effectiveness of TB programs. The substantive and methodological variables may be responsible for differences in the results across the studies reviewed. Therefore, their influence was examined, then two objectives were addressed: (1) to explore various components of TB programs that demonstrated positive or desired outcomes; and (2) to examine factors that enhanced or impeded effectiveness of TB programs. A framework that summarizes the relationships among the substantive variables of interest guided this meta-analytic study. The framework was derived from the literature and is represented in figure 1.
Conceptual Framework

Figure 1.

<table>
<thead>
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<th>Program Components</th>
<th>Context</th>
<th>Participants</th>
</tr>
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<td>Direct Observed Therapy</td>
<td>Skills of intervener</td>
<td>Participant involvement</td>
</tr>
<tr>
<td>Assessment Services</td>
<td>Cultural experience</td>
<td>Demographic Characteristics: age - gender - homelessness</td>
</tr>
<tr>
<td>Education Services</td>
<td>Mode of delivery</td>
<td></td>
</tr>
<tr>
<td>Incentives</td>
<td>Setting</td>
<td></td>
</tr>
<tr>
<td>Program length</td>
<td>Outcomes</td>
<td></td>
</tr>
</tbody>
</table>

- Incidence of TB
- Adherence to and completion of TB treatment
Substantive Variables

The substantive variables of interest to this study were:

1. Components of TB programs: The four components of TB programs extracted from reports and included in this study.
   
a) Directly Observed Therapy: This refers to a health professional, a health care worker or a community worker observing the patient taking the dose of anti-TB medication. The patient can be directly observed at home or at clinic (CDC, 1995; & the Canadian Lung Association, 1996). For the purpose of this study, data on DOT were extracted from the study reports as to whether or not DOT was a component of the TB program.

   b) Assessment Services: This refers to the tracing, screening, surveillance, and treatment of people who have been in contact with TB, are at risk, or have developed TB (the Canadian Lung Association, 1996). It has been recommended that assessment services be provided in community settings that are readily accessible to targeted populations (CDC, 1995; & El-Sadr et. al., 1996). For the purpose of this study, data on assessment services were collected as to whether or not assessment services were provided.

   c) Education Services: This refers to information provided to TB patients on various topics that pertain to TB. Content could include the causes and effects of TB; how it is diagnosed; how it can be prevented; the dosage of medication and possible adverse reactions; available services (CDC, 1995). For the purpose of this study, data on education services were collected as to whether or not this component was provided.

   d) Incentives: This refers to goods and services provided to the target population to enhance adherence to TB therapy and to increase successful completion of TB drug regimen. Incentives range from simple approaches (transportation to a clinic, coffee, access to health
care providers) to complex approaches (obtaining food and housing for homeless persons) (Diez et al., 1996; El-Sadr et al., 1996; & McAdam et al., 1990). For the purpose of this study, data on the use and type of incentives were extracted from the study reports.

Data pertaining to the following variables were also extracted from the studies:

2. Program Outcomes: Two categories were selected: community outcomes and patient outcomes.

   a) Community Outcomes: According to the Canadian Lung Association (1996), effective TB programs should produce and secure a progressive reduction in the annual incidence of the disease among all risk groups. For the purpose of this study, data pertaining to the incidence of TB among the specific population targeted by the program were abstracted from study reports.

   b) Patient Outcome: According to the CDC (1995), effective TB programs should promote adherence to and successful completion of TB treatment. For the purpose of this study, data on adherence to and completion of TB drug treatment were abstracted.

3. Skills of Intervener: Three categories were selected: health professionals, health care workers and community workers. For the purpose of this study, data on skills of various interveners were abstracted.

4. Cultural experience: Multicultural training and socio-economic similarity of interveners with their TB patient population was recommended. For the purpose of this study, data on cultural experience were abstracted.

5. Mode of Delivery: Two categories were selected: one-on-one and community-wide. For the purpose of this study, data on modes of delivery were abstracted.

6. Setting: Three settings were selected: patient’s home, clinic, and another community
location. In addition, data were collected regarding the country in which the programs were delivered. For the purpose of this study, data on location and country of programs were abstracted.

7. Length: The length of TB programs varies across programs and individual patients. For the purpose of this study, data on the time required to provide the program components were abstracted.

8. Participant Involvement: TB patients may be forced to receive DOT. There is conflicting evidence for providing DOT without choice, or for making DOT the standard of care for all patients. Four categories of participant involvement were considered: voluntary response to an advertisement, referral to programs, commitment to programs without choice and recruitment by a researcher. For the purpose of this study, data on participant involvement were abstracted.

9. Demographic characteristics: This information described attributes of the samples that comprised each of the studies included in the meta-analysis. For the purpose of this study data on age, gender, and homelessness were extracted. These variables are important as they can influence the results and generalizability of the results (Fortin, 1996).

Methodological Variables

The methodological variables in a study reflect important considerations of research design (Glass, McGaw and Smith, 1981). Methodological variables provide indication of the study’s validity. Analysing the variables provides information on the quality of the study.

1. Study Design: This refers to the plan for addressing the research questions. For the purpose of this study, data on the type of research design used to guide the study were collected. Randomized control trials, cohort analytic, case control, and descriptive studies
were included in the analysis.

2. **Sample Size**: This refers to the number of patients included in a study. Sample size of a study influences the power for detecting significant effects. For the purpose of this study, data on the number of participants included in the study were collected.

3. **Response Rates**: This refers to the number of subjects in the final sample divided by the number of subjects approached for the study. This information influences internal and external validity of a study.

4. **Publication Status**: Studies were coded in terms of published or unpublished reports. Journals tend to publish findings that are positive or significant (Glass et al., 1981).

5. **Measurement Time**: This refers to the time at which the outcomes (incidence of TB or adherence to and completion of TB treatment) were measured, that is, end of treatment.

6. **Quality of Study**: Overall quality of study was considered and coded based on Naylor and Guyatt’s (1996) guide to reading reports of variations in the outcomes of health services. To assess quality, six aspects of each study were examined: design (actual design of the study included); response rate (percentage of final sample out of total patients approached); inception cohort (attempt by researcher to control for disease progression); prognostic variables controlled (attempt of researcher to account for variations among participants pertaining to age, gender, and homelessness); clear objective outcomes (attempt of researcher to use valid and reliable outcome measures in their study); and comparative groups matched (attempt of researcher to match groups being compared based on characteristics as an aggregate).
Research Questions

The research questions that this meta-analysis addressed were:

1. What TB program components (DOT, assessment services, educational services, and incentives) are effective in a) reducing the incidence of TB, or b) increasing adherence to and completion of TB treatment?

2. What are the effects of skills of intervener, cultural experience, setting, program length and participant involvement on the program components’ effectiveness in a) reducing the incidence of TB, or b) increasing adherence to and completion of TB treatment?

3. What are the effects of patients’ age, gender, and homelessness on the program components’ effectiveness in a) reducing the incidence of TB, or b) increasing adherence to and completion of TB treatment?
CHAPTER II
METHODS

Overview of Study Design

This study was a meta-analysis. Meta-analysis is a methodology for synthesizing findings from several completed studies to determine what is known about a particular phenomenon (Burns & Grove, 1997; Wolf, 1986). “As a method for making sense out of research data, meta-analysis can be a critical step between individual studies and application of findings to practice” (Brown, 1991, p. 352). Meta-analysis synthesizes empirical knowledge relevant to a particular topic, intervention, or program, and this knowledge is then available to clinicians. Meta-analysis is used to build a body of knowledge that is applicable to clinical practice (Brown, 1991). The synthesis of findings is guided by a rigorous process and yields reliable answers upon which to base practice and policy (Wolf, 1986). This meta-analysis of findings related to the effectiveness of TB programs consisted of the following steps: (1) searching and collecting reports of studies addressing the effectiveness of tuberculosis programs; (2) abstracting data pertinent to substantive and methodological characteristics of the studies; (3) critically reviewing the reports of interest in this study for validity; (4) determining the significance and direction of the relationship between the independent variable and dependent variable using the vote-counting method.

It was possible to conduct additional quantitative analysis on those study reports that included data needed to calculate an effect size. The effect size is a measure of the strength of the relationship or effect of the independent variable on the outcome variable reported in a study. The following steps were applied to the sub-sample: (5) transforming the findings of individual studies into a common unit, the effect size; (6) estimating the mean effect size for
studies reporting on the same program outcome; (7) estimating the variance of mean effect size; and (8) estimating the 95% confidence interval.

**Method for Collecting Sample**

The sample for this meta-analysis consisted of studies that evaluated the effectiveness of tuberculosis programs, where effectiveness is defined in terms of, a) reducing the incidence of TB, or b) increasing adherence to and completion of TB treatment. The incidence of TB consists of the number of new cases in a fixed time period (usually one year) divided by the number of people at risk for the disease (Streiner and Norman, 1996). According to the Canadian Lung Association (1996), effective TB management programs should produce and secure a progressive reduction in the annual incidence of the disease among risk groups, or promote adherence to and successful completion of TB drug therapy (CDC, 1995).

A librarian was hired to conduct an extensive literature search. Medline, Cumulative Index of Nursing and Allied Health Literature, health databases, and dissertation abstract databases were used to identify appropriate studies. Key words such as tuberculosis, program, programme, success, effectiveness, studies, TB, and meta-analysis were used to search the various databases. The number of studies identified was 587. The selection criteria set for this meta-analysis required that studies: (1) include a sample of patients involved in a TB management program; (2) examine the effectiveness of a TB program that focused on management of the disease; (3) report on the relationship (for example, significant positive relationship; significant negative relationship; or no specific relationship) between the independent variable (the program component) and the dependent variable (incidence of TB or adherence to and completion of TB treatment); 4) be written in English;
and, for the quantitative analysis, (5) report statistical data that permitted calculation of an effect size. Twenty-seven published studies successfully met the first four inclusion criteria, and five of the twenty-seven reported statistical data that permitted calculation of the effect size.

The references from sixty studies and ten books were also checked for citations not identified by the computer databases. The Canadian Lung Association, the Ontario Lung Association, the Ontario Ministry of Health, the Toronto Public Health Department, the Alberta Lung Association, and the NWT Health Protection Unit were contacted about unpublished reports. One unpublished source was provided by the Toronto Public Health Department, but it did not meet the inclusion criteria for this meta-analysis.

**Method for Abstracting Pertinent Data**

Of interest in this study were substantive (program components, outcomes and factors), and methodological variables (design, sample, response rate, publication status, measurement time and quality). Every variable was coded by the investigator. To examine the reliability of data, the investigator’s coding of three studies was compared with the coding of the thesis supervisor. The reliability coefficient, representing the agreement between the two raters, was 92.5%. The coding scheme presented in Appendix A guided data abstraction.

**Substantive Variables**

**Program component.** The program component evaluated in each report was coded as DOT, assessment services (AS), education services (ES), or incentives (I). It was anticipated that some programs would include multiple components. Even if a report did not say the TB programs contained more than one component, the researcher described these
components in the comment section reserved for this purpose. The researcher organised data by listing the components included in the program and stating the number of components included in each program.

**Program outcomes.** The program outcomes were coded as community (incidence) or patient (adherence to and completion of TB treatment). In this section the researcher coded whether the program components influenced the community or patient outcome.

**Skills of intervener.** Intervener were coded as health professional (nurse, physician, or social worker), health care worker (community health representative, outreach worker), or community worker (storekeeper, church representative, community agency staff). When programs used more than one category of intervener, the researcher coded for all categories used. Results were then organised by the type of intervener and the number of intervener categories used to deliver the intervention.

**Cultural experience.** Based on explicit information provided in research reports, multicultural training or socio-economic similarity of intervener to program sample was coded as: 1 = yes; or 0 = no. For example, when researchers reported that program staff received multicultural training or that staff and research participants were from the same cultural background, a code of 1 was used.

**Mode of delivery.** The delivery of program component was coded as one-on-one instructions and care or as community-wide intervention.

**Setting.** The setting in which the TB program was delivered was coded as patient home, clinic, or other community location. When programs delivered the intervention in more than one location, the researcher coded all the settings used. The different settings were then arranged by type of setting and number of different settings used for the program.
The name of the country in which the program was delivered was also abstracted.

**Program length.** The length of programs was coded as the number of months required to provide all the components of the program.

**Participant involvement.** The participant's involvement in the TB program was coded in terms of voluntary response to an advertisement, referral to program, commitment to program without choice, or active recruitment by a researcher.

**Demographic data.** Data about age, gender, and residence status of the samples were abstracted. Measures of central tendency, such as the mean values for the total sample or the mode value and the associated percentage, were extracted.

**Methodological Variables**

**Design.** The specific design of each study was coded as randomised control trial, cohort analytic, case control, or descriptive without comparison.

**Sample size.** The sample size was the actual number of patients who participated in and completed the study.

**Response rate.** The response rate was the final sample out of the total number of the patients approached and was coded as a percentage.

**Publication status.** Studies were coded as published (P) or not published (NP).

**Measurement time.** Measurement time (follow-up time for measuring the program outcomes) was coded as the time researchers measured the outcome of interest, community or patient.

**Quality of study.** A quality rating was completed for each study. This rating measures whether threats to internal validity were minimized. Internal validity is defined as the extent to which effects detected in the study are a reflection of the intervention impact.
instead of a reflection of extraneous variables (Burns & Groves, 1997). Overall quality of each study was coded on a scale of zero to eight. According to Petitti (1994), “Rating study quality implicitly assumes that studies of higher quality scores are more likely to yield valid information than studies with lower quality scores” (p. 85). A score of five, being the middle point, was considered an adequate cut-off score for inclusion in this analysis. This value of five indicated an acceptable level of internal validity, where threats to validity were minimized experimentally. Studies with an overall rating lower than five were considered of poor quality, since the study design and methods were not successful in reducing threats to validity. These studies were not used, as lower levels of validity lead to biases, which compromise the accuracy of the findings.

Abstracting and coding variables in a permanent and well-organised record of the results of data collection permitted to examine the program effects related to these variables. In order to address the research questions of this meta-analysis, the record of results was critically examined for similarities and differences.

**Method for Critically Reviewing the Reports**

An estimate of the effect of TB program components is valid if it measures what it was intended to measure. According to Petitti (1994), studies of poor quality may yield information that is not valid. For example, a study meant to evaluate the effectiveness of a program component may yield invalid results because of initial differences among patients chosen for the study. “Taking the quality of studies, and implicitly their validity, into account in a meta-analysis has the potential to enhance the validity of the meta-analysis” (Petitti, 1994, p. 84). After obtaining study reports, the investigator read them carefully to determine the quality of each. In this meta-analysis, quality was defined in terms of the
validity of the conclusions reached.

**Quality rating.** The development of quality rating systems begins with a listing of criteria that define good or poor quality in the research reports (Petitti, 1994). According to Petitti, this listing may be based on a published set of criteria defining quality, or it may consist of items that experts believe measure quality. After careful consideration and consultation with a nurse researcher experienced in the evaluation of quality of studies for meta-analysis, a rating system was developed. Naylor and Guyatt (1996), developed a guide to assess the validity of interventions in producing desired outcomes in health services. This guide was consulted to determine the adequacy of the rating system developed for this meta-analysis.

**Criteria.** After the items defining quality were developed and agreed upon, the criteria were translated into a data abstraction form. Six criteria were used to evaluate the quality of the studies included in the sample of this meta-analysis: design, response rate, inception cohort, prognostic variables controlled, clear objective outcomes, and comparative group matched. These criteria are indicators that provided information about the degree to which internal validity was maintained in each study.

**Scoring system.** Next, for each quality item, a scoring system was developed by the nurse expert and the researcher. The total score for the highest quality study was defined. A numerical weight was assigned to each item, reflecting the contribution of that item to quality. The choice of weight for each item was determined by the expert nurse. “The choice of weights has historically reflected the judgement of the developer of the scale” (Petitti, 1994, p. 85). The scoring system was used for each study included in this meta-analysis regardless of study design. According to Petitti (1994), it is possible to develop
scoring systems that rate studies of different designs fairly in relation to one another.

In this study, the investigator rated the extent to which each of the six criteria was met within all studies included in this meta-analysis.

A. **Rating Study Quality**

A.1. **Study Design.** For the design criteria, a value of zero was assigned to a study that did not include a comparison group. A value of one was assigned to a case control study. A value of two was assigned to a cohort analytic study. A value of three was assigned to a randomised control trial.

A.2. **Response rate.** For the response rate, a value of zero was assigned to a study reporting less than 80% and a value of one was assigned to a study reporting more than 80%.

A.3. **Inception cohort.** For the inception cohort, a value of zero was assigned when researchers did not attempt to control for disease progression, and a value of one was assigned when researchers attempted to control for disease progression. For example, researchers might attempt to control for disease progression by enrolling participants in their study at the time of diagnosis, or by enrolling only newly diagnosed TB patients. By eliminating patients with widely varying physiological states, we increase the likelihood of maintaining the homogeneity of the sample, thus creating a more level playing field for comparisons (Naylor & Guyatt, 1996).

A.4. **Prognostic variables.** Prognostic variables were selected, since in research reports information on these variables often is provided. Age, gender, and homelessness are variables that can influence the outcomes of interest in this meta-analysis. For example, each of these variables can influence calculation of the incidence of TB (Stephens et al., 1998). However, researchers are unlikely to know all the prognostic variables that interact with
treatments to affect outcomes (Naylor & Guyatt, 1996). For the prognostic variables, a value of zero was assigned when researchers did not account for variations among participants pertaining to age, gender, and homelessness. A value of one was assigned when researchers accounted for variations among participants pertaining to age, gender, and homelessness. Researchers can account for prognostic variables by controlling for their potential effects either statistically by using them as covariates in an analysis of covariance, or experimentally by using a block design and analysis.

A.5. **Outcome measurement.** The criterion of clear objective outcomes refers to the objective (not subjective) measurement of the outcomes important to patients and health care professionals (Naylor & Guyatt, 1996). For this criterion a value of zero was assigned when researchers did not use valid and reliable measures of patient and community outcomes, a value of one was assigned when researchers used valid and reliable outcome measures.

A.6. **Comparative groups.** For the comparative groups, a value of zero was assigned when researchers did not attempt to match participants from the groups compared. A value of one was assigned when researchers attempted to match participants from the groups compared. Failure to match participants can create groups of patients that cannot be compared. This confounds any outcome comparisons (Naylor & Guyatt, 1996). The term matching in this meta-analysis refers to the general strategy for selecting a control group (Streiner and Norman, 1996). According to Streiner and Norman, matching refers to selecting a control group that has characteristics similar to those of the experimental group. For example, participants in the control group can be patients drawn from the same community. “Control subjects, however, are not matched to experimental subjects on a one-to-one basis” (Streiner and Norman, p. 48).
After all the reports were rated, the ratings for report were summed. The total rating score, ranging from zero to eight reflected the overall quality of the study. The overall score was used to determine which studies would be used to address the research questions. Studies with a score greater or equal to five were used to answer the three research questions.

**Vote-Counting Method for Determining the Relationship Between Variables**

For this meta-analysis, the vote-counting procedure (Light and Smith cited in Bushman, 1994) was used to examine the relationship between the independent variables (program component) and the dependent variables (community or patient outcomes) of interest across studies. All 27 studies that reported information on the relationships between the variables of interest were examined.

These results were represented in three possible categories. Plus (+) indicated a significant relationship between the independent and dependent variables in the hypothesised direction. Minus (-) indicated a significant relationship between the independent and dependent variables opposite to the hypothesised direction. Zero indicated no specific relationship between the independent and dependent variables. The number of studies falling into each of these categories was then tallied.

The modal category was identified and provided an estimate of the presence and direction of the true relationship between the independent and the dependent variables. “Although vote-counting is not always the method of choice, in some cases the meta-analyst might not have a choice” (Bushman, 1994, p. 212), since studies do not always report statistical data that permit calculation of an effect size. In this meta-analysis, 20 studies out of 27 did not report test statistics, but all studies reported the direction of results; therefore, the vote-counting procedure was quite appropriate (Bushman, 1994).
**Method for Calculating Effect Size**

One goal of analyzing data from several studies is to estimate a summary measure of the effect size (Petitti, 1994). The first step involved in such analysis is to identify the type of statistics reported in the studies. The second step is to decide which method to apply. For this analysis, the Mantel-Haenszel was chosen.

**Mantel-Haenszel Method**

The studies provided odds ratio statistics. The Mantel-Haenszel method, which summarizes data, was used to calculate an effect size. It was possible to calculate an effect size for a sub-sample of studies in this meta-analysis. "The Mantel-Haenszel method is a well-known method for pooling data across strata [and] since studies identified for a meta-analysis are strata, the Mantel-Haenszel method is an appropriate method for analysing data for a meta-analysis" (Petitti, 1994, p. 96).

The Mantel-Haenszel method was used to: (1) compute the effect size for each study; (2) average the effect size; (3) estimate the 95% confidence interval for the mean effect size; and (4) estimate the variance of the mean effect size. As suggested by Petitti (1994), the method of Robins, Greenland, and Breslow (1986) was used to estimate the variance of the mean effect size.

**Strengths and limitations.** The major strength of the Mantel-Haenszel method is that the test based on the Mantel-Haenszel chi-square has optimal statistical properties. It is uniformly the most powerful test (Petitti, 1994). Usefulness of the method, however, is limited. Application of the Mantel-Haenszel method requires data for each study to complete a 2x2 table. That is, values of outcome by treatment or exposure by disease are
available for computing the effect size. "If data that would allow construction of a 2×2 table for a study are unavailable, the study must be excluded […] exclusion has the potential to result in bias" (Petitti, 1994, p. 99).

**Estimating Effect Size**

In this meta-analysis, five studies provided data that permitted calculation of the effect size based on the Mantel-Haenszel method. Another study provided test statistics, but a cell of the 2×2 table contained a zero value, so it was impossible to calculate the effect size. Five steps were followed to estimate the effect size.

(1) Arranged data and table notation for application of the Mantel-Haenszel method for each study:

<table>
<thead>
<tr>
<th></th>
<th>Exposed</th>
<th>Not Exposed</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Positive Treatment Outcome</td>
<td>a</td>
<td>b</td>
<td>g</td>
</tr>
<tr>
<td>Negative Treatment Outcome</td>
<td>c</td>
<td>d</td>
<td>h</td>
</tr>
<tr>
<td>Total</td>
<td>e</td>
<td>f</td>
<td>n</td>
</tr>
</tbody>
</table>

In this table, *exposed* meant that patients participated in a particular TB program that offered DOT, AS, ES, or I as a program component. *Not exposed* meant that patients were not offered DOT, AS, ES, or I. These participants formed the control group. *Positive treatment outcome* meant that TB programs demonstrated a decrease in incidence of TB or an increase of adherence to and completion of TB treatment. *Negative treatment outcome* meant that TB programs were not able to demonstrate a decrease in incidence of TB or an increase of adherence to and completion of TB treatment.
(2) The odds ratio (effect size) for each study was computed:

\[ \text{OR} = \frac{a \times d}{b \times c} \]

The odds ratio represents the likelihood that those exposed to the program would demonstrate a positive outcome. In other words, this ratio estimates the relative effectiveness of the program for a given study.

(3) The variance of the odds ratio for all the studies was estimated:

\[ \text{variance} = \frac{n}{b \times c} \]

By estimating the variance of the odds ratio, it was possible to determine the accuracy of the estimate of the effect of a program component within a study.

(4) The contributory weight for each study was computed:

\[ \text{weight} = \frac{1}{\text{variance}} \]

This value is used to weigh each study's estimated effect size by taking into account differences in sample size.

(5) The OR for each study was then modified by the contributory weight:

\[ \text{product} = \text{OR} \times \text{weight} \]

This strategy permits later computation of the mean effect size in a manner that accounts for differences in the study sample sizes.
**Method for Calculating Mean Effect Size**

To provide an overall estimate of the effect of a TB program in producing the desired outcome, it was necessary to calculate the mean effect size across studies that evaluated TB programs. To accomplish this, two values were calculated: (1) the sum of weights across studies; and (2) the sum of the product of the weight and the ORs across studies. The mean effect size was obtained by dividing the sum of the products (OR x weight) by the sum of the weights (1÷ OR variance).

**Method for Calculating Variance of Mean Effect Size**

To determine the variability of the effect sizes based on the deviation from the mean, an estimate of the variance in the mean effect size was calculated using the Robins, Greenland, and Breslow method as cited in Petitti (1994, p. 113).

**First step.** This step consisted of calculating mathematical values (F, G, H, R, and S) to estimate the variance in the mean effect size.

1. Calculated the F value for each study where
   \[
   F = \frac{a \times d \times (a + d)}{n}
   \]

2. Calculated the G value for each study where
   \[
   G = \frac{[a \times d \times (b + c)] + (b \times c \times (a + d))}{n}
   \]

3. Calculated the H value for each study where
   \[
   H = \frac{b \times c \times (b + c)}{n}
   \]
(4) Calculated the R value for each study where

\[ R = \frac{a \times d}{n} \]

(5) Calculated the S value for each study where

\[ S = \frac{b \times c}{n} \]

**Second step.** This step consisted of estimating the variance of the Mantel-Haenszel summary odds ratio across studies, using the formula as described by Robins, Greenland, and Breslow (cited in Petitti, 1994). The variance is calculated to determine the homogeneity of the effect size. Homogeneity of effect sizes reflects higher confidence in the estimate of the mean effect size. If the effect size is not homogenous, other factors, for example methodological and substantive variables must be examined, to see if they account for the variability.

\[
\text{VARIANCE}_{\text{mh}} = \left( \sum F \right) + \left[ \sum G \right] + \left( \sum H \right) + \frac{2 \sum R}{2 \sum S} \left( 2 \times \sum R \times \sum S \right) + \frac{2 \sum S}{2 \sum S}
\]

**Method For Estimating The 95% Confidence Interval**

\[
\text{CI} = e \ln \text{OR} +/- (1.96 \times \sqrt{\text{variance OR}_{\text{mh}}})
\]

The 95% confidence interval was calculated to determine the accuracy of the mean effect size estimate.
Summary of Study Methods

This meta-analysis synthesised empirical knowledge on the influence of components on community outcomes (incidence of TB), and patient outcomes (adherence to and completion of TB treatment). The goal was to add to this body of knowledge. The following steps were taken:

To determine the sample of this meta-analysis, a literature search was conducted. Studies reporting on TB program components and their effectiveness were collected. The substantive and methodological variables of studies were abstracted from the reports and coded in a data collection form. These variables were critically examined for similarities and differences, and were used to address the research questions. Each report was critically reviewed and assigned a quality score. This score was used to identify the studies of higher quality, which were then used to address the three research questions. Using the vote-counting procedure, each study was examined to determine the relationship between the independent variable of interest (program component) and the dependent variable of interest (community or patient outcomes).

For a sub-sample of this meta-analysis, it was possible to calculate the effect size for individual studies using the Mantel-Haenszel method. The mean effect size for TB programs was calculated. The variance of the mean effect size and the 95% confidence interval were also estimated.

In the following section the results found in this meta-analysis will be presented.
CHAPTER III

RESULTS

The results of this meta-analysis are presented in two sections: a description of the sample, and a report of the results.

Sample

Of the 587 studies identified through the computer database search, the manual search, and contacts with regional, provincial, and federal health agencies for unpublished reports, 27 published studies successfully met the inclusion criteria. The following points explain why only 27 studies were included in the sample. First, the key words used for the literature search could not distinguish between programs for patients with active TB and programs for patients on prophylaxis TB treatment (34%). Second, studies did not evaluate the effects or relationships between program components and outcomes (17%). Third, studies were published in languages other than English (28%). Fourth, studies examined different independent and dependent variables to the ones of interest in this study (3.4%). Fifth, there were repeated entries, or identical studies were published under different titles (17%).

Of the 27 studies, five (18%) reported data for calculating the effect size. Of these five studies, one (20%) was given a quality score lower than 5, and in another study (20%) the effect size was an outlier. Therefore, these two reports were not included in the sub-sample used in the quantitative analysis. Of the five studies, three (60%) comprised the sub-sample on which additional quantitative analysis was performed. Substantive and methodological characteristics of the 27 studies are described in the following sections. Study characteristics for the 27 studies are also represented in table format (see appendix C).
Substantive Characteristics

Program Components

The four TB program components of interest in this meta-analysis were directly observed therapy, assessment services, education services, and incentives. Of the 27 studies, ten (37%) evaluated programs with one component and seventeen (63%) evaluated programs with more than one component. Table 1 represents the distribution of program components for the twenty-seven studies. The direct observed therapy component was most frequently evaluated.
Table 1

Program Components of The Twenty-Seven Studies

<table>
<thead>
<tr>
<th>Study</th>
<th>Direct Observed Therapy</th>
<th>Assessment Services</th>
<th>Education Services</th>
<th>Incentives</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brudney &amp; Dobkin 1991</td>
<td>✓</td>
<td>✓</td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>Caminero et al. 1996</td>
<td>✓</td>
<td></td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
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</table>

Notes: ✓: indicates that the program offers the component

Table continues
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<tr>
<th>Study</th>
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<th>Education Services</th>
<th>Incentives</th>
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</tbody>
</table>

**Notes:** ✓: indicates that program offers the component
**Skills of Intervener**

In twenty (74%) studies, the TB program was delivered by one category of intervener, and in seven (26%) studies, the TB program was delivered by several categories of intervener.

Of the twenty studies reporting one category of intervener, twelve (60%) studies used health professionals (RNs, physicians, and social workers); five (25%) studies used health care workers (community health representatives, and outreach workers); three (15%) studies used community workers (store keepers, church representatives, and community agency staff).

Of the seven studies reporting a combination of intervener categories, six (86%) studies used two categories of intervener such as health professionals and health care workers, RN & outreach workers and one (14%) study used three categories of intervener, such as health professionals, health care workers, and community workers.

**Cultural Experience**

Of the 27 studies, fifteen (56%) reported data pertaining to the cultural training of the intervener or the socio-economic background of intervener and program participants. Twelve (44%) studies did not report on this factor. Several examples illustrate how studies reported that cultural training was provided or that program staff was of similar cultural background to subjects. One study reported that villages were participating in TB control activities by sending community members to be trained as community health workers for TB programs (Farmer et al., 1991). Another study reported hiring “culturally concordant” DOT staff in other words, the staff were of similar cultural background to program participants (Klein & Naizby, 1995). Curry (1968) reported that program staff became culturally
sensitive to patients' needs. For example, the staff changed TB clinic hours, received education to understand various cultural needs of TB patients, and developed a program that made TB care more convenient for culturally diverse patients. Another program was developed with the assistance of persons from a community where TB was prominent (El-Sadr et al., 1996). The staff was instrumental in shaping the philosophy of a TB program that aimed to be culturally sensitive. The program staff focused on meeting complex patient needs and fostered a surrogate family model of care for their TB patients.

**Mode of Delivery**

The mode of delivery of TB programs was reported as a one-to-one intervention in all 27 studies included in this sample. Therefore, this variable was not included in further analysis.

**Setting**

The settings in which TB programs were delivered varied that is, patient's home, clinic, and other community location. In the 27 studies, nineteen (70%) identified one category of location for delivering the TB program, and eight (30%) identified two locations.

Of the 19 studies that reported one category of location, four (21%) delivered their intervention in the patient's home; six (32%) delivered their intervention in an ambulatory TB clinic; and nine (47%) delivered their intervention in other community locations, such as methadone clinics, churches, health posts, refugee camps, homeless shelters, patient work places, health centres, and community-based organizations. Of the eight studies that used a combination of locations, all eight (100%) reported using the patient's home and an ambulatory TB clinic to deliver the intervention.

The countries in which TB programs were delivered were organized by continent and
are distributed as such: thirteen (48%) reports were from North America, seven (26%) from south east Asia, three (11%) from South Africa, two (7.5%) from Central America; and two (7.5%) from Europe.

**Program Length**

The length of the TB programs varied across studies. Of the 27 studies, six (22%) reported that programs were delivered over a period equivalent to six months, nineteen (70%) reported that programs were delivered in a period ranging from six to twenty months, and two (8%) did not provide information about program length.

**Participant Involvement**

Participant involvement in TB programs was reported as voluntary in all 27 studies included in this sample. Therefore, this variable was not included in further analysis.

**Demographic Data**

Demographic data of interest were age, gender, homelessness, and ethnic group. Of the 27 studies, eleven (41%) reported the mean age values of their sample, and sixteen (59%) did not.

**Age.** Mean age values were classified into ten-year intervals. None of the studies reported a mean age of 0 to 9 and 10 to 19 years. One (9%) reported a mean age of 20 to 29; four (36%) reported a mean age of 30 to 39; six (55%) reported a mean age of 40 to 49; and no study reported a mean age of 50 or older.

**Gender.** Twelve studies (44%) reported on gender of the participants, and fifteen (56%) did not. Of the twelve reports, ten (83%) contained mostly men; one (8.5%) contained mostly women; and one (8.5%) contained equal numbers of men and women.
Homelessness. Of the 27 studies, five (19%) mentioned that the sample comprised homeless persons. The remaining twenty-two (81%) studies did not specify including homeless subjects. However, since some researchers conducted chart analysis and others compared their sample data to information provided in large city databases, it is possible that homeless persons were involved in programs evaluated in studies included in this meta-analysis.

Program Outcomes.

The two outcomes of interest (community and patient) were the incidence of TB and adherence to and completion of TB treatment. Of 27 studies, four (15%) reported on TB incidence and twenty-three (85%) reported on adherence to and completion of TB treatment. The following section will describe the methodological characteristics of the 27 studies.

Methodological Characteristics

Design

Four types of research designs were used in the 27 studies. Randomized control trials were reported in three (11%) studies. The cohort analytic design was reported in one (4%) study. A case control design was reported in twelve (44%) studies. Descriptive designs were reported in eleven (41%) studies.

Sample Size

Of the 27 studies, twenty-five (93%) explicitly reported on their sample size, and two (7%) did not. The sample size values were classified into categories: thirteen (52%) studies reported between one participant and 200 participants; four (16%) reported between 201 and 400; three (12%) reported between 401 and 1,500; and five (20%) reported more than 1,500.
Response Rates

In 25 studies (93%), a response rate greater than or equal to 80% was reported. This is the percentage of the final sample of the total number of patients approached. Two (7%) studies did not provide the information required to determine the response rate.

Publication Status

All 27 studies were published between 1968 and 1997. The distribution is as follows: twenty-two (81%) were published in the nineties, four (15%) were published in the eighties, and one (4%) was published in the sixties.

Measurement Time

Twenty-five (93%) of the studies reported on the measurement time of the outcome of interest in this meta-analysis, and two (7%) did not. The outcome measurement times were classified into twelve-month intervals, and the distribution across the time intervals was as follows: five (20%) studies reported measuring the outcome at 0 to 11 months; two (8%) reported measuring the outcome at 12 to 23 months; one (4%) reported measuring the outcome at 24 to 48 months; and seventeen (68%) reported measuring the outcome at the end of treatment without specifying the number of months.

Quality of Study

An overall quality score was computed for each study based on the rating for six criteria. The criteria were design, response rate, inception cohort, prognostic variables controlled, clear objective outcomes, and comparative group matched. Table 2 represents the distribution of quality scores for each study.
### Table 2

**Quality Rating of the Twenty-Seven Studies**

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>RR</th>
<th>Inception Cohort</th>
<th>Prognostic Variables</th>
<th>Objective Outcome Measures</th>
<th>Matched Groups</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brudney &amp; Dobkin 1991</td>
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<td>1</td>
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**Notes:** RR = response rates

*Table continues*
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>RR</th>
<th>Inception Cohort</th>
<th>Prognostic Variables</th>
<th>Objective Outcome Measures</th>
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<td>1</td>
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<td>1</td>
<td>6</td>
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</table>
Of the 27 studies, fourteen (52%) studies had a total quality score ranging from 0 to 4, representing a lower level of quality; thirteen (48%) studies had a score ranging from 5 to 8, representing a higher level of quality. The thirteen (48%) studies with an overall score greater or equal to five were used to address the research questions.

The second section reports the findings pertinent to each research question.

Of the 27 studies, thirteen (48%) studies that rated highly on overall quality were used to address the three research questions in this meta-analysis. These thirteen studies were included in this portion of the analysis since they were all assigned a quality score greater or equal to five, which indicated higher quality of study. The score of five represents the midpoint value on a quality scale in which values ranged from zero to eight.

Three research questions were addressed.

Research Question One

What TB program components (directly observed therapy, assessment services, education services, and incentives) are effective in reducing the incidence of TB or in increasing adherence to and completion of TB treatment?

Of the 27 studies, thirteen (48%) studies that rated relatively highly on overall quality were used to address the three research question in this meta-analysis. These thirteen studies were included in this portion of the analysis since they were all assigned a quality score greater or equal to five, which indicated higher quality of study. The score of five represents the midpoint value on a quality scale in which values ranged from zero to eight.

Of the thirteen studies, six (46%) examined programs with one component; and seven (54%) examined programs with more than one component (see appendix D).
One Component

Table 3 represents studies that evaluated programs with one component. Of the six studies examining TB programs with one component, two (33%) examined the DOT component; three (50%) examined the assessment services component; and one (17%) examined the incentive component.
### Table 3

**Studies Examining The Effectiveness of TB Programs With One Component**

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Sample size</th>
<th>Intervention</th>
<th>Outcome</th>
<th>Quality score</th>
<th>Reported relationship &amp; effect size</th>
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</thead>
<tbody>
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<tr>
<td>Jin et al. 1993</td>
<td>RCT</td>
<td>1300</td>
<td>AS</td>
<td>Patient</td>
<td>8</td>
<td>+</td>
</tr>
<tr>
<td>Klein &amp; Naizby 1995</td>
<td>CC</td>
<td>1769</td>
<td>DOT</td>
<td>Patient</td>
<td>6</td>
<td>+</td>
</tr>
<tr>
<td>Onozaki &amp; Shakya 1995</td>
<td>CC</td>
<td>428</td>
<td>AS</td>
<td>Patient</td>
<td>5</td>
<td>+</td>
</tr>
<tr>
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<td>RCT</td>
<td>235</td>
<td>I</td>
<td>Patient</td>
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<td>+</td>
</tr>
<tr>
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<td>CC</td>
<td>2426</td>
<td>DOT</td>
<td>Patient</td>
<td>6</td>
<td>+</td>
</tr>
</tbody>
</table>

**Notes:** CC = case control. RCT = randomized control trial. AS = assessment services. DOT = directly observed therapy. I = incentives. "+" = indicates a significant relationship between the independent and dependent variables in the hypothesized direction.
Outcomes

In the two studies that examined the DOT component, a significant relationship was reported between DOT and adherence to and completion of TB treatment in the hypothesised direction (Klein & Naizby, 1995; and Wilkinson et al., 1996). The three studies that examined the assessment services (AS) component reported a significant relationship between assessment services and adherence to and completion of TB treatment in the hypothesised direction (Curry, 1968; Jin et al., 1993; Onozaki & Shakya, 1995). The study that examined the incentive (I) component reported a significant relationship between incentives and adherence to and completion of TB treatment in the hypothesised direction (Seetha et al., 1981). All studies that examined programs with one component had a significant impact on the same outcome (see Table 3).

More Than One Component

Of the seven studies that examined programs with more than one component: three (43%) examined the DOT and incentive components; two (29%) examined the assessment services and incentive components; one (14%) examined the education services and incentive components; and one (14%) examined the assessment services and education services components. Table 4 represents studies that evaluated programs with more than one component.
### Table 4

**Studies Examining The Effectiveness of Programs With More Than One Component**

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Sample size</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Quality score</th>
<th>Reported relationship &amp; effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chaulk &amp; Spies-Pope 1997</td>
<td>CC</td>
<td>N/S</td>
<td>DOT I</td>
<td>Community</td>
<td>5</td>
<td>+</td>
</tr>
<tr>
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<td>DOT I</td>
<td>Patient</td>
<td>6</td>
<td>+</td>
</tr>
<tr>
<td>Farmer et al. 1991</td>
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<td>54</td>
<td>AS I</td>
<td>Patient</td>
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<td>+</td>
</tr>
<tr>
<td>Fujiwara et al., 1997</td>
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<td>DOT I</td>
<td>Community</td>
<td>5</td>
<td>+</td>
</tr>
<tr>
<td>Miles &amp; Maat 1984</td>
<td>CC</td>
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<td>AS I</td>
<td>Patient</td>
<td>5</td>
<td>+</td>
</tr>
<tr>
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<td>ES I</td>
<td>Patient</td>
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<td>+</td>
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<tr>
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<td>AS ES</td>
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<td>6</td>
<td>+</td>
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</tbody>
</table>

**Notes:**
- **CC** = case control
- **CA** = cohort analytic
- **RCT** = randomized control trial
- **N/S** = sample size not specified
- **DOT** = direct observed therapy
- **I** = incentives
- **AS** = assessment services
- **ES** = education services
- "+" = indicates a significant relationship between the independent and dependent variables in the hypothesized direction.
Outcomes

In the three studies that examined the DOT and incentive components, one study reported a significant relationship between the components and adherence to and completion of TB treatment in the hypothesised direction (Diez et al., 1996). Two studies reported a significant relationship between the components and the incidence of TB in the hypothesised direction (Chaulk & Spies-Pope, 1997; Fujiwara et al., 1997) (see Table 4).

The two studies that examined the assessment services and incentive components reported a significant relationship between the components and adherence to and completion of TB treatment in the hypothesised direction (Farmer et al., 1991; Miles & Maat, 1984).

The study that examined the education services and incentive components reported a significant relationship between the components and adherence to and completion of TB treatment in the hypothesised direction (Morisky et al., 1990).

The study that examined the assessment services and education services components reported a significant relationship between the components and adherence to and completion of TB treatment in the hypothesised direction (Werhane et al., 1989).

All studies that examined programs with more than one component had a significant impact on both the incidence of TB and adherence to and completion of TB treatment.

Effect size

Of the thirteen studies, four (31%) were used to compute an effect size based on the Mantel-Haenszel method. All four studies reported on the patient outcome, that is, adherence to and completion of TB treatment. The distribution of effect size values is represented in Table 5.
Table 5

**Distribution of Effect Size Values**

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Sample size</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Quality score</th>
<th>Reported relationship &amp; effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jin et al. 1993</td>
<td>RCT</td>
<td>1300</td>
<td>AS</td>
<td>Patient</td>
<td>8</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1.99</td>
</tr>
<tr>
<td>Morisky et al. 1990</td>
<td>RCT</td>
<td>205</td>
<td>ES</td>
<td>Patient</td>
<td>8</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>I</td>
<td></td>
<td></td>
<td>2</td>
</tr>
<tr>
<td>Seetha et al. 1981</td>
<td>RCT</td>
<td>235</td>
<td>I</td>
<td>Patient</td>
<td>8</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>3.7</td>
</tr>
<tr>
<td>Werhane et al. 1989</td>
<td>CC</td>
<td>184</td>
<td>AS</td>
<td>Patient</td>
<td>6</td>
<td>+</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>ES</td>
<td></td>
<td></td>
<td>48*</td>
</tr>
</tbody>
</table>

**Notes:** RCT = randomized control trial. CC = case control. AS = assessment services. ES = education services. I = incentives. "+" = indicates a significant relationship between the independent and dependent variables in the hypothesized direction. "*" = indicates that this effect size of 48 was considered an outlier and could not be included in further analysis since it would skew the analysis.
The average effect size across all components for TB programs is 2.2. This average was calculated with data from three studies by dividing the sum of the products by the sum of the weights. The variance of the mean effect size is 0.01. This value was calculated based on the Robins, Greenland, and Breslow method as cited in Petitti (1994). The 95% confidence interval is 1.8 to 2.7. Since the value of one is not included in the confidence interval, there is statistical evidence that the true effect size is not one (where one indicates no effect).

Summary

The first research question was interested in identifying which TB program component could be effective in reducing the incidence of TB (community) or in increasing adherence to and completion of TB treatment (patient). Of the 27 studies that met the inclusion criteria, thirteen (48%) rated highly on overall quality and were used to address this research question. According to the results, all components are effective in producing the desired outcomes. In this meta-analysis, the components evaluated were as follows: (1) DOT; (2) assessment services; (3) incentives; (4) DOT and incentives; (5) assessment services and incentives; (6) education services and incentives; (7) assessment services and educational services. All studies reported a significant relationship in the hypothesised direction between the program components and the outcomes.

Of the 13 studies, four (31%) were used to compute an effect size. The effect size values ranged from 1.99 to 48. Using three studies, the average effect size across all components for TB programs was 2.2.
Research Question Two

What are the effects of skills of intervener, cultural experience, setting, and program length, on the program components’ effectiveness in reducing the incidence of TB or in increasing adherence to and completion of TB treatment?

Of the thirteen acceptable studies, nine (69%) evaluated programs that used one type of intervener, and four (31%) evaluated programs that used several categories of interveners. Nine (69%) studies evaluated programs that reported on cultural experience of interveners. Twelve (92%) studies evaluated programs that used one category of location, and one (8%) evaluated programs that used several locations. Two (15%) studies evaluated programs lasting six months, and ten (77%) evaluated programs lasting more than six months.

Table 6 represents the distribution of factors for the thirteen studies.
Table 6

**Distribution of Factors Across Studies**

<table>
<thead>
<tr>
<th>Study</th>
<th>Skills of Intervener</th>
<th>Cultural Experience</th>
<th>Setting</th>
<th>Length*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chaulk &amp; Spies-Pope, 1997</td>
<td>HCW &amp; HP (RN &amp; Outreach worker)</td>
<td></td>
<td>Home</td>
<td>6 to 8</td>
</tr>
<tr>
<td>Curry, 1968</td>
<td>HP (RN &amp; Physician)</td>
<td>✓</td>
<td>Hospital clinic</td>
<td>12</td>
</tr>
<tr>
<td>Diez et al., 1996</td>
<td>HP (RN &amp; SW)</td>
<td></td>
<td>Hospital clinic</td>
<td>N/S</td>
</tr>
<tr>
<td>Farmer et al., 1991</td>
<td>HCW &amp; HP (RN &amp; Physician)</td>
<td>✓</td>
<td>Community clinic</td>
<td>16</td>
</tr>
<tr>
<td>Fujiwara et al., 1997</td>
<td>HCW &amp; HP (Outreach worker &amp; Physician)</td>
<td>✓</td>
<td>Home &amp; clinic</td>
<td>6 to 8</td>
</tr>
<tr>
<td>Jin et al., 1993</td>
<td>HP (health centre staff)</td>
<td></td>
<td>Health centres</td>
<td>12</td>
</tr>
<tr>
<td>Klein &amp; Naizby, 1995</td>
<td>CW (Community-based agency staff)</td>
<td>✓</td>
<td>Home</td>
<td>12</td>
</tr>
<tr>
<td>Miles &amp; Maat, 1984</td>
<td>HP (Physician)</td>
<td>✓</td>
<td>Refugee camp</td>
<td>6</td>
</tr>
</tbody>
</table>

**Notes:** "*" = values represent number of months. HCW= health care worker. HP= health professional. RN= registered nurse. SW= social worker. CW= community worker. "✓" = identifies that program staff had similar cultural background to participants, or that staff received cultural training.

Table continues
<table>
<thead>
<tr>
<th>Study</th>
<th>Skills of Intervener</th>
<th>Cultural Experience</th>
<th>Setting</th>
<th>Length*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Morisky et al., 1990</td>
<td>HP (health educator)</td>
<td>✓</td>
<td>Clinic</td>
<td>6 to 9</td>
</tr>
<tr>
<td>Onozaki &amp; Shakya, 1995</td>
<td>HCW (auxiliary health workers)</td>
<td>✓</td>
<td>Health posts</td>
<td>8</td>
</tr>
<tr>
<td>Seetha et al., 1981</td>
<td>HCW (field workers)</td>
<td>✓</td>
<td>Home</td>
<td>12</td>
</tr>
<tr>
<td>Werhane et al., 1989</td>
<td>HP (RN)</td>
<td></td>
<td>Hospital clinic</td>
<td>6 to 12</td>
</tr>
<tr>
<td>Wilkinson et al, 1996</td>
<td>HCW vs CW (health care workers vs community volunteers)</td>
<td>✓</td>
<td>Home</td>
<td>6</td>
</tr>
</tbody>
</table>
Effects of Skills of Intervener

Nine studies reported one category of intervener, the most frequently reported category is health professionals (67%). Other studies used health care workers (22%), and community workers (11%). Of the six studies that used health professionals, registered nurses were the most frequently reported type of intervener (see Table 6). All studies reported a significant relationship in the hypothesized direction between the program components and the outcomes (see Table 3 and Table 4).

Effect Size

Of the 13 studies, the effect size from three (23%) studies was used to address this research question. Two studies reported using health professionals to deliver the program, and their effect sizes were 1.99 and 2 (Jin et al., 1993; and Morisky et al., 1990). One study reported using health care workers to deliver the program, the effect size was 3.7 (Seetha et al., 1981).

The influence of interveners on the effectiveness of TB program components in producing the desired patient or community outcomes was evaluated in this meta-analysis. In studies that provided data on skills of intervener, all TB program components were effective in producing the desired outcome, regardless of category of intervener.

Cultural Experience

Nine studies reported on cultural experience of interveners (see Table 6). Of these, five (56%) reported on programs with one component, and four (44%) reported on programs with more than one component. All studies reported a significant relationship in the hypothesized direction between the program components and the outcomes (see Table 3 and Table 4).
**Effect Size**

Of the 13 studies, the effect size from three (23%) studies was used to address this research question. Two studies reported on the cultural experience of interveners and their effect sizes were 2 and 3.7 (Morisky et al., 1990, and Seetha et al., 1981).

The influence of cultural experience on the effectiveness of TB program components in producing the desired patient or community outcomes was evaluated in this meta-analysis. In studies that provided data on cultural experience, all TB program components were effective in producing the desired outcome, regardless of cultural experience.

**Setting**

Twelve (92%) studies reported one category of setting; the most frequently reported category is TB clinic (42%). Other studies used the patient’s home (33%), and other community locations (25%) (see Table 6). All studies reported a significant relationship in the hypothesized direction between the program components and outcomes.

**Effect Size**

Of the 13 studies, the effect size from three (21%) studies was used to address this research question. One study reported using other community locations to deliver the program, and the effect size was 1.99 (Jin et al., 1993). One study reported using a TB clinic to deliver the program, and the effect size was 2 (Morisky et al., 1990). One study reported using the patient’s home to deliver the program, and the effect size was 3.7 (Seetha et al., 1981).

The influence of setting on the effectiveness of TB program components in producing the desired patient or community outcomes was evaluated in this meta-analysis. In studies
that provided data on program locations, all TB program components were effective in producing the desired outcome, regardless of setting.

**Program length**

Ten (77%) studies reported on TB programs that lasted more than 6 months (see Table 6). All studies reported a significant relationship in the hypothesized direction between the program components and the outcomes (see Table 3 and Table 4).

**Effect Size**

Of the 13 studies, the effect size from three (23%) studies was used to address this research question. In all three studies, program length was greater than six months. One study that evaluated the assessment services component’s influence on the patient outcome reported an effect size of 1.99 (Jin et al., 1993). One study that evaluated the incentive component’s influence on the patient outcome reported an effect size of 3.7 (Seetha et al., 1981). Another study evaluated the influence of education services and incentives on the patient outcome, and reported an effect size of 2 (Morisky et al., 1990).

The influence of program length on the effectiveness of TB program components in producing the desired patient or community outcomes was evaluated in this meta-analysis. In studies that provided data on program length, all TB program components were effective in producing the desired outcome, regardless of their length.

**Summary**

The second research question was intended to find out what factors influenced the effectiveness of program components in producing the desired patient or community outcome. Of the 27 studies that met the inclusion criteria, thirteen (48%) rated highly on overall quality, and were used to address this research question. Of the program examined in
this meta-analysis, two lasted six months, ten lasted longer than six months, and one did not report on the length. All thirteen studies reported a significant relationship between the program components and the patient or community outcome in the hypothesized direction. According to the results, all components, regardless of intervener, cultural experience, setting, and program length, were effective in producing the desired outcomes.

**Research Question Three**

*What are the effects of patients' age, gender, and homelessness on the program components' effectiveness in reducing the incidence of TB or in increasing adherence to and completion of TB treatment?*

**Age.** Of the thirteen studies, five (38%) reported age values. Three (23%) evaluated programs in which a mean age between 30 and 39 was reported; and two (15%) evaluated programs in which a mean age between 40 and 49 was reported.

Of the three studies in which mean age values were between 30 and 39, one (33%) reported a significant relationship in the hypothesized direction between the assessment services and incentive components and the patient outcome (Miles & Maat, 1984). One (33%) reported a significant relationship between the education services and incentive components and the patient outcome (Morisky, et al., 1990). One (33%) reported a significant relationship between the assessment services component and the patient outcome (Onozaki & Shakya, 1995).

Of the 2 studies in which mean age values were between the 40 and 49 interval, one (50%) reported a significant relationship between the DOT and incentive components and the patient outcome (Diez et al., 1996). One (50%) reported a significant relationship in the hypothesised direction between the assessment services and incentive components and the
patient outcome (Farmer et al., 1991).

Effect Size

Of the three studies from which an effect size was calculated, one (33%) reported on the mean age value of the sample (Morisky et al., 1990). This study evaluated the influence of the education services and incentive components influence on patient outcome, and reported an effect size of 2.

This meta-analysis evaluated the influence of age in studies on the effectiveness of TB program components in producing the desired patient or community outcomes. In studies that reported mean age values, all TB program components were effective in influencing the desired outcome.

Gender. Of the thirteen studies included in this analysis, six (46%) did not specify the gender of their samples; five (38%) evaluated programs in which mostly male subjects participated; one (8%) evaluated a program in which mostly female subjects participated; and one (8%) evaluated a program in which equal numbers of male and female subjects participated.

Male. Of the five studies in which participants were mostly males, two (40%) reported a significant relationship in the hypothesised direction between the assessment services component and the patient outcome (Jin et al., 1993; and Onozaki & Shakya, 1995); one (20%) reported a significant relationship in the hypothesised direction between the DOT and incentive components and the patient outcome (Diez et al., 1996); one (20%) reported a significant relationship in the hypothesized direction between the assessment services and incentive components and the patient outcome (Miles & Maat, 1984)); and one (20%) reported a significant relationship in the hypothesized direction between the assessment
services and education services components and the patient outcome (Werhane et al., 1989).

**Female.** The study in which participants were mostly females reported a significant relationship in the hypothesized direction between the assessment services and incentive components and the patient outcome (Farmer et al., 1991).

The study in which equal numbers of males and females participated reported a significant relationship in the hypothesized direction between the education services and incentive components and the patient outcome (Morisky et al., 1990).

Of the three studies from which an effect size was calculated, two (66%) reported on gender of their sample. In the first study, which contained mostly males, the assessment component’s influence on the patient outcome was evaluated and had an effect size of 1.99 (Jin et al, 1993). In the second study, which contained almost equal numbers of males and females, the influence of the education services and incentive components on the patient outcome was evaluated, and had an effect size of 2 (Morisky et al., 1990).

The influence of gender in studies on the effectiveness of TB program components in influencing the desired patient and community outcomes was evaluated in this meta-analysis. In studies that provided data on gender, all TB program components were effective in influencing the desired outcome regardless of gender distribution.

**Homelessness.** Of the thirteen studies included in this report, twelve (92%) evaluated a program in which the homelessness status was not specified; and one (8%) evaluated a program in which participants were homeless. This study reported a significant relationship in the hypothesised direction between the DOT and incentive components and the patient outcome (Diez et al., 1996). An effect size could not be calculated for this study.
Summary

The third research question was designed to find out what factors influenced the effectiveness of program components in producing the desired patient or community outcome. Of the 27 studies that met the inclusion criteria, thirteen (48%) rated highly on overall quality and were used to address this research question. In this meta-analysis, five (38%) studies reported the mean age values of their sample. A significant relationship in the hypothesized direction between the program components and the desired outcome was reported for all age categories represented in these studies.

In this meta-analysis, seven (54%) studies reported on the gender of their samples. In these studies, a significant relationship was reported between the program components and the desired outcome in the hypothesized direction.

One study (8%) reported that their sample was comprised of homeless persons. In this study, a significant relationship was reported between the program component and the desired outcome in the hypothesized direction. According to the results, all components regardless of demographic factor (age, gender, and homelessness) were effective in influencing the desired outcome.

Overall Summary

This section is a synthesis of the major findings relative to each research question. The data used to answer the research questions consisted of information found in reports that were given a quality score greater than or equal to five.

The first research question was designed to find out what TB program components were effective in increasing adherence to and completion of TB treatment, or in reducing the incidence of TB. All the components evaluated in this meta-analysis were effective in
influencing the desired patient or community outcome.

The second research question was designed to find out how skills of interveners, cultural experience, setting, and program length influenced the program’s effectiveness in increasing adherence to and completion of TB treatment, or in reducing the incidence of TB. Programs that used health professionals were most frequently reported in this analysis, and all the components in these programs demonstrated a positive effect on the patient outcome. Cultural experience of interveners was reported in most programs, and all the components in these programs demonstrated a positive effect on the patient and community outcomes. Programs using TB clinics were most frequently reported in this analysis, and all the components in these programs demonstrated a positive effect on the patient outcome. Programs lasting more than six to twenty months were most frequently reported in this meta-analysis, and all the components in these programs demonstrated a positive effect on the patient outcome.

The third research question was designed to demonstrate the effects of program characteristics, such as patients’ age, gender, and homelessness, on the program components’ effectiveness in increasing adherence to and completion of TB treatment, or in reducing the incidence of TB. The age category 30 to 39 was most frequently reported in this meta-analysis, and all of the components in these programs demonstrated a positive effect on the patient outcome. The male category was most reported in this meta-analysis, and all of the components in these programs demonstrated a positive effect on the patient outcome. Only one study included in this meta-analysis reported a sample consisting of homeless persons. In this study the program component demonstrated a positive effect on the patient outcome.
CHAPTER IV
DISCUSSION

The purposes of this study were to determine which components of TB programs were effective in managing TB, and to identify factors that influenced the effectiveness of these TB programs. Meta-analysis of trials of program components for decreasing the incidence of TB or for promoting adherence to and completion of TB treatment have not been published. However, two recent reviews that relate to this meta-analysis will be used to guide the discussion section: 1) Volmink and Garner's (1999) systematic review of randomized trials of interventions for promoting adherence to tuberculosis treatment; and 2) Chaulk and Kazandjian's (1998) review of trials of Direct Observed Therapy for achieving treatment completion of pulmonary TB. This section will focus on the major results of this meta-analysis and discuss them in relation to these two reviews.

Influence of TB Program Components

The thirteen studies that rated higher on overall quality were used to address the three research questions in this meta-analysis. In their review, Volmink and Garner (1999) attempted to control for the quality of study by including only randomized controlled trials or trials that used pseudo-randomized methods, such as alternate allocation. Their sample comprised seven studies, of which only four evaluated independent variables similar to those studied in this meta-analysis. The researchers stated that in their sample the reporting of aspects of study methods was not adequate, making quality difficult to fully assess. In their review, Chaulk and Kazandjian (1998) included all studies, regardless of design, that assessed the effectiveness of various forms of DOT and incentives in influencing successful tuberculosis treatment completion rates. The researchers determined quality of study by
grading the evidence related to the recommendations. Their sample comprised 18 studies, of which 15 were given a higher quality score.

Three research questions were addressed.

**Research Question One**

*What TB program components (DOT, assessment services, education services, and incentives) are effective in increasing adherence to and completion of TB treatment or in reducing the incidence of TB?*

In this meta-analysis, most studies evaluated combinations of two components of a TB program. This is similar to reviews by Volmink and Garner (1999) and Chaulk and Kazandjian (1998), which included studies that mostly evaluated two components of a TB program. In this meta-analysis, the DOT and incentive components were most frequently evaluated and found to be effective in reducing the incidence rates of TB. This finding is similar to Chaulk and Kazandjian's review, in which the DOT and incentive components were most frequently evaluated and found to be effective. The reviewers found that the effectiveness of DOT appeared robust; in other words, documented efficacy in treatment completion for pulmonary TB. These researchers recommended a patient-centered strategy based on DOT. This strategy should include multiple incentives and enablers to be most effective in producing high treatment completion rates.

Zwarenstein et al., (1998) compared the effects of self-supervision and DOT. The researchers contended that low treatment completion rates were related to the increased surveillance from the intervener. Zwarenstein et al. supported their claim with findings from previous studies that is, surveillance of pill swallowing could be alienating and authoritarian
(Dick & Pekeur, 1995; Steyn et al., 1997).

For a variety of patient populations, including alcoholic patients, substance abuse patients, incarcerated patients, homeless persons, refugees, and patients infected with HIV, a combination of multiple incentives and enablers was found to be effective. Enablers included intermittent regimen designed around a patient’s life-style, that is therapy at home, school, work or a clinic two or three times per week; and relevant social and economical enablers and incentives, that is food, clothing, books, stipends, transportation, treatment contracts, bilingual staff, or reminders. As well, culturally appropriate outreach and tracking interventions were effective in producing the desired outcome (Chaulk and Kazandjian, 1998). “Moreover, this patient-centered strategy appears equally effective regardless of country or community” (Chaulk and Kazandjian, p. 946).

In Volmink and Garner’s review, each study assessed different program components. The researchers did not include randomized control trials that examined the DOT and incentive components.

**Effect Size**

In this meta-analysis, the effect sizes were computed using the Mantel-Haenszel odds-ratio method. Similarly, Volmink and Garner (1999) used the Mantel-Haenszel method to determine the effect sizes. Chaulk and Kazandjian did not compute effect sizes.

To address this research question, the effect size was computed for four studies. However, one of these effect sizes was considered an outlier, and could not be included in further analysis, since it would skew the analysis. A weak design, where historical data were used to compare program effectiveness, is a possible reason for this extreme effect size value (Werhane et al., 1989). The average effect size for the outcome adherence to and completion
of TB treatment was 2.2. This effect size was computed using studies that evaluated the effectiveness of: (1) assessment services; (2) educational services and incentives; and (3) incentives. The three effect sizes for each of these components are as follows: (1) for assessment services it was 1.99; (2) for the education services and incentive combination it was 2; and (3) for incentives it was 3.7. Following is a more detailed description of the effectiveness of these components in increasing adherence to and completion of TB treatment.

Assessment services were evaluated in Korea in both rural and urban health centres (Jin, et al., 1993). This program component was evaluated using a semi-randomized interventional study design. In this study, 1,300 patients were randomized to either the intervention group (patients who received intensified supervisory activities such as improved assessment services) or the control group (patients who received usual care). The staff working with the intervention group were closely motivated by the health centre director and sub-section chief to provide intensified assessment services, and sessions for discussion of the achievements of each worker were held at the health centre. Staff working in the intervention group was motivated to perform increased supervision activities such as sputum collection and X-rays. Staff performance was improved, that is assessment services (follow-up sputum and X-ray examinations) were performed almost perfectly. Patients in the intervention group were more regular with their drug collection practices, and the proportion of patients completing treatment was clearly higher in this group. The researchers recommended that there should be a primary focus on staff motivational activities to improve the assessment services and care offered in TB programs (Jin et al). The major problem with this study is that staff motivational strategies confounded the patient drug collection
practices. Jin et al., concluded that there was a very weak relationship between the degree of compliance of the patient and a patient's background factors, with the exception of severity of disease. The results of this study support the view that "the normal patient is the one who defaults" (Rouillon, 1972, as cited in Jin et al., 1993). To improve patient adherence to and completion of TB treatment, the researchers suggested interventions that focused on program staff.

Volmink and Garner (1999) also evaluated this study, and found that patients subjected to intense supervision (increased assessment services and monitoring) were more likely to complete treatment than were patients receiving routine supervision. However, Volmink and Garner were critical of these results, since this study was cluster randomized and the data were insufficient to correct for design effects.

The education services and incentives combination was evaluated in two health districts in Los Angeles County. (Morisky et al., 1990). This program component was evaluated using a randomized control design. In this study, 88 low-income adult patients with active TB were randomized to either an intervention group, where patients received special intervention, or to a control group, where patients received the usual care. The special intervention consisted of a tailored health education counselling session about compliance enhancing strategies. There was also a $10 monetary incentive at each monthly visit to the TB clinic. The counselling session was behaviourally oriented and consisted of tailored educational messages based upon initial interview and subsequent assessments, written instructions about the regimen, educational reinforcement about TB, enlistment of family and friend support, positive verbal reinforcement for adherence to regimen, and contingency contracting using the monetary incentive (Morisky et al., 1990). In this study,
appointment-keeping and medication-taking practices were no different for active TB patients in the special intervention group and patients in the usual care group. Only one patient from the special intervention group as compared to four patients in the usual care group defaulted treatment. The researchers concluded that the education services and incentives components were effective in increasing adherence to and completion of TB treatment. However, the researchers cautioned that it was impossible to definitely show which part of the intervention contributed to success, since the intervention was delivered as a package (Morisky et al., 1990).

Volmink and Garner (1999) also evaluated this study, and found that the proportion of patients with active TB who completed treatment did not differ significantly between the intervention and control groups. Volmink and Garner were critical of the study, stating that the results did not lend support to claims for the benefit of health education as the results are confounded by the effects of a monetary incentive used in tandem with the educational intervention.

In a randomized control study by Seetha et al. (1981) the incentive component was evaluated in an urban setting in Bangalore, India. In this study, the incentives were strategies intended to motivate TB patients and their families to influence the drug-collection practices of these patients. For this study incentives consisted of home visits coupled with health education sessions. In this study, the educational nature of the incentive led to a confounding effect. It was impossible to examine the specific contribution of home visits on the outcomes, since health education was simultaneously provided as part of the incentive.

During the first three months of TB treatment, four home visits were conducted by health visitors. The health visitors were existing field staff of primary health centres who
received short training in educating TB patients. At each home visit, health visitors met with TB patients and at least half the patients' household members. Using a flip chart, they provided health education related to TB causes, spread of disease, and the need for uninterrupted treatment. Health visitors also assessed TB patients' drug-collection practices. The researchers concluded that incentives such as home visits and health education sessions were effective in increasing adherence to and completion of TB treatment. The researchers recommended that more studies are needed to find out the optimum number of home visits required to influence patients to complete their TB treatment. Since this study population was from an urban setting, the researchers also recommended that future studies should include patients from rural settings. Volmink and Garner (1999) did not review this study.

Since the overall findings of this meta-analysis indicated that all program components produced the desired effect, there is limited ability for comparison and discovery in relation to the effects of factors on program components.

**Effects of Factors on Program Components**

**Research Question Two**

*What are the effects of skills of interveners, cultural experience, setting, and program length on the program components and effectiveness in reducing the incidence of TB or in increasing adherence to and completion of TB treatment?*

**Skills of interveners.** In this meta-analysis, of all studies that provided data on skills of interveners, all TB program components were effective in producing the desired patient or community outcomes. Most studies used health professionals, and RNs were the most frequently reported professionals. In studies that used health professionals, the DOT and incentives components, the assessment services and incentives, the education and incentives,
and the assessment services and education services components were assessed to determine their influence on adherence to and completion of TB treatment (Diez et al., 1996; Miles & Maat, 1984; Morisky et al., 1990; and Warhane et al., 1989). All components influenced adherence to and completion of TB treatment.

This finding provides support for using health professionals to deliver TB programs. The contribution from different types of health professionals to adherence to and completion of TB treatment is not clear, and should be examined. This is important since there are no specific guidelines on program staff for TB programs. Knowledge that using health professionals is effective in producing the desired outcomes is valuable for program planners and clinicians.

It was impossible to compare these findings to Volmink and Garner's (1999) report, since data on this aspect of their sample were not provided. However, Volmink and Garner contended that it would be important to determine the effects of supervision by professionals and lay workers. The researchers cautioned against the wide-scale implementation of programs using health professionals.

To increase the probability of treatment completion, Chaulk and Kazandjian (1998) advocated for wide-scale implementation of DOT for TB patients. Since one single case of TB can generate clusters of new cases, the researchers proposed universal DOT. However, the researchers did not examine the effects of using different interveners. The implications of these findings are important since, they provide support for conducting studies on the cost-effectiveness of using different categories of interveners to provide directly observed therapy.
**Cultural experience.** In this meta-analysis, of all studies that provided data on cultural experience, all TB program components were effective in producing the desired patient or community outcomes. In the programs reporting on cultural experience, the assessment services and incentives components were most frequently evaluated and found to be effective in influencing adherence to and completion of TB treatment. This finding provides support for hiring staff that have cultural experience, that is the staff received cultural training or the staff have backgrounds similar to program participants. This is important, since in North America most TB patients are refugees, immigrants and First Nation’s people. Knowledge that using staff with cultural experience is effective in producing the desired outcomes is valuable for program planners and clinicians.

It was impossible to compare these findings to Volmink and Garner’s (1999) report, since data on this aspect of their sample were not provided. However, Chaulk and Kazandjian (1998) found that DOT coupled with incentives such as, culturally appropriate staff produced the highest treatment completion rates. The implications of ensuring that program staff has cultural experience are complex. First, programs in urban centres may not be able to find staff that represents all the cultural groups served by the program; and second, cultural training may be costly. These findings provide support to examine the cost-effectiveness of using staff with cultural experience, and to identify the content of an effective cultural training model for TB staff.

**Setting.** In this meta-analysis, of all studies that provided data on program settings, all TB program components were effective in producing the desired patient or community outcomes. Most studies contained one or two program components that were delivered in TB clinics. In the programs that used TB clinics, five different components were delivered
to improve the patient outcome. The assessment services component, the DOT and incentives, assessment services and incentives, education services and incentives, and assessment services components were evaluated and found to be effective in influencing adherence to and completion of TB treatment. This finding provides support for using clinics to provide TB care. This is important, since after decades of decline of TB rates in North America, the infrastructure for TB care was dismantled. Between 1985 and 1992, the annual number of TB cases nationwide increased or failed to decline (Chaulk et al., 1995).

Knowledge that programs delivered in clinics are effective in producing the desired outcomes is valuable for program planners and clinicians. These findings provide support for examining the specific characteristics of TB clinics to assess their influence on program effectiveness.

It was impossible to compare these findings to Volmink and Garner’s (1999) and Chaulk and Kazandjian’s (1998) reports, since data on this aspect of their sample were not provided.

**Program length.** In this meta-analysis, of all studies that provided data on program length, all TB program components were effective in producing the desired patient or community outcomes. Most studies contained one or two program components and lasted longer than six months. In the programs lasting more than six months, the assessment services component was most frequently evaluated and found to be effective in influencing adherence to and completion of TB treatment. This finding provides support for developing programs that last more than six months. This is important, since TB drugs must often be given for longer than six months for patients to be cured. Knowledge that programs lasting longer than six months are effective in producing the desired outcomes is valuable for
program planners and clinicians.

It was impossible to compare these findings to Volmink and Garner’s (1999) report, since data on this aspect of their sample were not provided. However, Chaulk and Kazandjian (1998) found that adherence to most medical regimens is inversely proportional to the length of therapy, the number of drugs administered, the frequency of drug administration, and the overall complexity of the treatment regimen. The researchers supported their findings with theoretical and empirical evidence (Haynes, Taylor and Sacket, 1979; Sbarbaro, 1981; Sbarbaro, 1985). Chaulk and Kazandjian recognized the implications of these findings on TB drug regimens, which typically include three or four antibiotics, have potential adverse effects, and last for at least six consecutive months. To increase the probability of treatment completion, the researchers proposed DOT recommended by the Centre for Disease Control (CDC) and the American Thoracic Society (ATS) as the standard of care for pulmonary TB (CDC, 1994; CDC, 1993; ATS, 1994).

**Research Question Three**

*What are the effects of patients' age, gender, and homelessness on the program components' effectiveness in reducing the incidence of TB or in increasing adherence to and completion of TB treatment, and why?*

In this meta-analysis, of all studies that provided data on patients' age, all TB program components were effective in producing the desired patient or community outcomes. The studies that provided data on age of participants mostly evaluated programs in which mean age values were between 30 and 39 interval. In studies in which patients were between 30 and 39, three different types of component combinations were evaluated. The three types of program components were: 1) assessment services; 2) assessment services
and incentives; and 3) education services and incentive. In these three programs, all components were effective in producing the desired patient outcome. Therefore, for patients between 30 and 39, the assessment services component, assessment services and incentives, and education services and incentives components were effective in increasing adherence to and completion of TB treatment.

Volmink and Garner (1999) evaluated programs for adult patients. Of these programs, most were successful in producing the desired patient outcomes. However, one study reported that DOT provided to adult patients by RNs (as compared to self-administered therapy) was not effective in influencing treatment completion rates (Zwarenstein et al., 1998). Zwarenstein et al. contended that surveillance of pill swallowing could be alienating and authoritarian. Furthermore, surveillance could detract the carer from providing patient support, could decrease the patient’s responsibility for self-care, and could increase stress on the carer by transferring from patient to carer the responsibility for successful treatment completion. These researchers supported their findings with empirical and theoretical evidence (Dick and Pekeur, 1995; & Steyn, Van der Merwe, Dick, Borcherds, and Wilding, 1997). Chaulk and Kazandjian’s review (1998), the researchers did not provide data on this aspect of their sample.

In this meta-analysis, of all studies that provided data on patients’ gender, all TB program components were effective in producing the desired patient or community outcomes. The studies that provided data on gender of participants mostly evaluated programs in which participants were male. In these studies, the assessment services component was most frequently evaluated and found to be effective in influencing treatment completion rates. Current data on TB suggest that prevalence of the infection is higher in
men than in women, consequently there is a higher annual risk of infection in men than in woman (Hudelson, 1996). In a paper that reviewed gender differentials in tuberculosis, Hudelson claimed that gender differences existed in rates of compliance with treatment. For example, Cassels et al., (1982) found that older women in TB treatment programs were more likely to default than older men. In Hudelson’s review, the increased presence of men in TB programs is explained using empirical evidence, which demonstrated that women are sometimes less likely than men to seek care unless their illnesses become very serious. A study by Reuben (1993) examined women and malaria, and found that underprivileged women are generally loaded with household chores and the care of young children, and so are less likely to seek healthcare services. Hudelson argued that because the health and welfare of children is closely linked to that of mothers, TB in women can have serious repercussions for families and households. Hudelson concluded that responses to illness differ in women and men, and that barriers to treatment completion of TB are different for women and men. Hudelson implied that increased efforts to identify and address gender differences in the control of TB would address the difficulties that women face in accessing health care services. Although no intervention studies have been conducted to address gender differentials in TB control, Hudelson suggested that control programs responsive to constraints faced by women will have greater success in enabling women to complete treatment. It was not possible to compare these findings to Volmink and Garner’s (1999) review, since data on these aspects of their sample were not provided.

In this meta-analysis, only one study revealed whether patients were homeless. In this study, conducted in Barcelona Spain, the DOT and incentives components were effective in influencing treatment completion rates (Diez et al., 1996). This program enrolled the
unemployed, alcoholics, injection drug users, and persons with structural family problems and lack of stable housing and was designed to complement follow-up care for these TB patients. The goal was to provide treatment, nourishment, and lodgings for marginal or poor TB patients willing to comply with treatment (Diez et al.). The program was staffed with a full-time social worker and was given an annual budget ($145 000 USD/year) to cover nutritional needs and housing for twenty homeless patients per day. A smaller allowance ($7400 USD/year) was also available to cover incidental patient needs. Diez et al., concluded that during the entire period of anti-tuberculosis treatment, the admission of homeless persons to a modest residential facility with minimal health supervision and incentives (room, board, and DOT) influenced higher degrees of treatment completion rates. Volmink and Garner's (1999) review included some studies in which patients were homeless. However, these studies did not include active TB patients and focused on evaluating the effects of an educational strategy on whether homeless patients returned to clinic for TB skin testing.

According to Chaulk and Kazandjian (1998), no demographic variables (occupation, level of income, level of education) reliably and consistently predict adherence to therapy. This finding is consistent with this meta-analysis, which determined that most TB programs that enrolled various patients were successful in achieving the desired outcomes.

Similarly, Wobeser et al., (1999) found that factors such as birth outside Canada, homelessness, alcohol abuse, standard initial drug regimen, being in hospital at treatment initiation, and multi-drug resistance could not predict failure to complete TB treatment.

This section concludes the discussion chapter. The following chapter will present the summary, implications, and conclusions.
CHAPTER V
SUMMARY, IMPLICATIONS AND CONCLUSIONS

Summary

The purposes of this meta-analysis were to identify components of TB programs, and to determine to what extent these components affected the outcomes of interest. This study also examined factors that may enhance or impede effectiveness of TB programs.

For determining the sample of this study, a literature search was conducted, and reports that addressed TB program components and their effectiveness in producing the desired patient or community outcomes were collected. Study data were collected from 27 published reports. Most studies were published in the nineties and were conducted in North America. The most reported design was case control (retrospective comparison), with sample sizes consisting of one patient to 200 patients.

The substantive and methodological variables of studies were abstracted from each report and coded in a data collection form. These variables were critically examined, and were used to address the research questions. Of the 27 studies, 13 were given quality scores greater or equal to five, making them adequate to address the three research questions. Three studies comprised a sub-sample, and additional quantitative analysis was performed on these studies to compute an effect size.

The meta-analysis synthesized empirical knowledge of TB program components that helped to decrease incidence of TB or increase adherence to and completion of TB treatment. This study determined what TB program components were effective in increasing adherence to and completion of TB treatment or in reducing the incidence of TB using the vote-counting method. The results of this study indicated that the DOT and incentives
components were most frequently evaluated and found to be effective in reducing the incidence of TB. However, all studies that evaluated TB program components also demonstrated that the components had significant effects on all outcomes in the hypothesized direction.

Using the Mantel-Haenszel method, it was possible to compute an effect size for four studies. However, one of the effect sizes was considered an outlier and could not be included in further analysis, since it would skew the analysis. The effect size was calculated for only one of the two outcomes of interest, that is adherence to and completion of TB treatment. The average effect size across all components for TB programs was 2.2. This average was calculated using data from three different studies that evaluated the influence of assessment services, educational services and incentives combination, and incentives on adherence to and completion of TB treatment. The variance of the mean effect size was 0.01, and the 95% CI was 1.8 to 2.7. The results of this study indicated that assessment services, the education services and incentives combination, and incentives were effective in improving adherence to and completion of TB treatment. Treatment completion is considered the cornerstone of successful TB control, since it is the only way to determine patient outcomes (Wobeser, Yuan, and Naus, 1999).

This meta-analysis also tried to determine the effects of factors such as skills of intervener, cultural experience, setting, program length, age, gender, and homelessness on the effectiveness of program components in increasing adherence to and completion of treatment or in reducing the incidence of TB. The most frequently reported interveners were RNs. However, there is evidence that health professionals may not always be the best people to deliver TB program components (Volmink and Garner, 1999). Most studies reported that
interveners were of similar cultural background to the study participants or had received some cultural training. TB care lasts for six to twelve months and is mostly delivered in TB clinics. Researchers are not fully reporting on demographic characteristics of their samples. In this meta-analysis, most studies did not report on age, gender, and homeless status.

**Limitations.** Since the overall results of this meta-analysis indicated that all program components produced the desired effect, there was limited ability for comparison and discovery in relation to the effects of factors on program components.

Data were collected from published reports, and the absence of unpublished reports in the sample of this meta-analysis represents a limitation of this study. The two reviews used to discuss the results of this meta-analysis did not include unpublished reports in their sample. The small sample for this meta-analysis also represents a limitation of this study. The two reviews used to discuss the results of this study had small sample sizes.

The lack of statistical data needed to calculate an effect size further reduced the number of studies included in the quantitative analysis to address the research questions. This led to using the same group of studies to conduct the analysis, which may introduce bias and limit the generalizability of the results.

**Implications**

The literature regarding TB programs is vast. Meta-analysis pertaining to TB program effectiveness can clarify and improve our knowledge of TB program planning and evaluation.

**Policy and Practice.** This meta-analysis found that DOT coupled with incentives was effective in reducing the incidence of TB. Cautioning that DOT alone may be ineffective in the fight against TB, Chaulk and Kazandjian (1998) recommended that DOT
should include appropriate incentives and enablers based on the needs of individual patients. It would be important for clinicians to incorporate DOT and incentives, but these components require that health professionals be frequently available for observing patients taking their TB drugs.

Most people who receive DOT are patients who represent an increased risk for non-adherence to treatment, or patients who cannot complete TB treatment. For example, the Canadian Tuberculosis Standards recognized that patients are best treated with DOT since it has been shown that predicting compliance is impossible (the Canadian Lung Association, 1996). But the standards do not recommend universal DOT for managing TB patients, they particularly indicate DOT for the following groups:

1) patients who miss appointments frequently
2) patients who disappear from supervision
3) patients who admit to not taking medication
4) substance abusers
5) psychologically disturbed patients
6) patients for whom such a regimen is recommended by a supervising health care worker
7) patients who relapse

Universal DOT is standard in various regions, for example, in outpost communities of the Northwest Territories. To provide universal DOT, funding for incentives must be secured. The human resources required to deliver DOT and incentives to all TB patients would need to be found, since these components will require many health professionals to reach large numbers of TB patients.

In this meta-analysis, an average effect size of 2.2 was calculated for the outcome of
adherence to and completion of TB treatment. Based on the results of this meta-analysis, assessment services, educational services and incentives, and incentives were effective in increasing the rates of adherence to and completion of TB treatment. However, the current CDC treatment goals calling for 90% of all TB cases to complete the recommended TB treatment was not achieved in most programs. Volmink and Garner (1999), and Chaulk and Kazandjian also determined that in most programs the treatment completion rates fell below the 90% criterion. These findings lead to two questions: Are programs aiming to meet the CDC treatment goal of 90%? Is the CDC treatment goal perhaps too high, since world-wide there is a lack of resources allocated for TB care?

**Research.** Based on the results of this meta-analysis, all components of TB programs influenced all outcomes in the hypothesized direction. The evidence for TB programs is largely evaluative. This suggests that only a minority of TB interventions for improving patient or community outcomes have been tested. It is imperative that we examine the components delivered in TB programs so that their effects on program outcomes can be measured. Some of the studies included in this meta-analysis did not provide in-depth descriptions of program components. It would be difficult to replicate the exact conditions of the program. For example, some studies that evaluated more than one program component failed to distinguish between the effects of their component of interest and other components also present within the program. The specific contributions of each component are hard to distinguish. There is a need for studies designed so that the specific contribution of each program component is clearly identified.

These findings lead to another question: is anything else in TB programs influencing the desired outcomes? It is imperative for researchers to clearly describe, evaluate, and
report on the particular variables under study.

In this meta-analysis, when health professionals were used programs were successful. This study did not examine the differences between types of health professionals. It would be important to examine the effects of different health professionals (RNs, physicians, and social workers) on the effectiveness of program components in producing the desired patient or community outcomes.

Further study on cultural training are needed to determine the characteristics of training models that can be used to improve the cultural experience of TB staff.

Conclusions

This meta-analytic study identified TB program components that were effective, and discussed the effects of factors on the success of TB programs in achieving the desired outcomes. The results of this meta-analysis, which synthesized valid empirical knowledge, will inform health care professionals of evidence-based interventions that improve program outcomes. In addition to providing evidence-based knowledge for clinicians, the results of this meta-analysis will inform public policy on TB program design. The evidence supports the effectiveness of interventions such as DOT in influencing better TB program outcomes. However, based on existing policy, DOT is mostly a selective intervention implemented only in special cases.

The evidence suggests that it is impossible to predict patient compliance. Thus DOT coupled with incentives provided by professional or supportive staff may influence better treatment completion rates. However, this meta-analysis demonstrated that the present CDC 90% target for patients completing treatment is far from a reality. Increased efforts should focus on developing and testing patient interventions or staff interventions to improve
adherence to and completion of TB treatment or to decrease the incidence of TB.
References

References marked with an asterisk indicate studies included in the meta-analysis.


Tubercle & Lung Disease, 77, 420-424.


Lung Disease, 76, (5), 441-449.


American Medical Association. 275, (7), 554-558.


### APPENDIX A

**Coding Scheme**

<table>
<thead>
<tr>
<th>Study Characteristics</th>
<th>Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Study identification number</td>
<td>Each study reviewed were assigned a code number sequentially starting with a value of 1</td>
</tr>
<tr>
<td>Author of study</td>
<td>Name of the first author</td>
</tr>
<tr>
<td>Year of publication</td>
<td>Actual year (e.g.: 1996)</td>
</tr>
</tbody>
</table>

**Substantive Variables**

1. Components of TB programs:
   a) DOT
   b) Assessment services
   c) Education services
   d) Incentives
   e) Multi-components

2. Program outcomes
   - Community (i.e. incidence of TB) or
   - Patient (i.e. adherence to and completion of TB treatment)

3. Skills of intervener
   a) health professional
   b) health care worker
   c) community worker

4. Cultural experience
   - 0 = no
   - 1 = yes

5. Mode of delivery
   - One to one
   - Community wide

6. Setting
   a) patient home
   b) clinic
   c) other community location

   Country
   - Actual name of country of program

7. Length of program
   - Actual number of weeks or months

8. Participant involvement
   - Voluntary
   - Referral
   - Committed without choice
   - Recruited by researcher

9. Demographic data
   a) Age
   b) Gender
   c) Homelessness

   - Actual age of participants
   - Actual sex of participants
   - Actual number or percentage of homeless participants
### Methodological Variables

1. **Design**  
   Actual design of study

2. **Sample size**  
   Actual number of participants in study

3. **Response Rate**  
   Actual percentage obtained from final sample divided by participants approached

4. **Publication status**  
   - 0 = unpublished
   - P = published

5. **Measurement time**  
   Time at which outcomes of interest were measured

6. **Quality of study**  
   - 0 = threatened
   - 5 = threats well managed
   - 8 = threats managed successfully

   Overall quality of study  
   Actual value between 0 to 8
APPENDIX B

Characteristics of Studies Examining the Effectiveness of TB Programs

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Sample size</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Quality score</th>
<th>Reported relationship &amp; effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brudney &amp; Dobkin 1991</td>
<td>CC</td>
<td>182</td>
<td>AS DOT I</td>
<td>Patient</td>
<td>4</td>
<td>+</td>
</tr>
<tr>
<td>Caminero et al. 1996</td>
<td>D</td>
<td>102</td>
<td>DOT I ES</td>
<td>Patient</td>
<td>4</td>
<td>+</td>
</tr>
<tr>
<td>Chaulk et al. 1995</td>
<td>CC</td>
<td>20 US cities</td>
<td>DOT I</td>
<td>Patient</td>
<td>4</td>
<td>+</td>
</tr>
<tr>
<td>Chaulk &amp; Spies-Pope 1997</td>
<td>CC</td>
<td>N/S</td>
<td>DOT I</td>
<td>Community</td>
<td>5</td>
<td>+</td>
</tr>
<tr>
<td>Concato &amp; Rom 1994</td>
<td>D</td>
<td>104</td>
<td>DOT I</td>
<td>Patient</td>
<td>4</td>
<td>-</td>
</tr>
<tr>
<td>Curry 1968</td>
<td>CC</td>
<td>6345</td>
<td>AS I</td>
<td>Patient</td>
<td>5</td>
<td>+</td>
</tr>
</tbody>
</table>

Notes: CC= case control. AS= assessment services. DOT= directly observed therapy. I= incentives.
"+" = indicates a significant relationship between the independent and dependent variables in the hypothesized direction. D= descriptive without comparison. ES= educational services. N/S= authors reported percentages. "-" = indicates a significant relationship between the independent and dependent variables opposite to the hypothesized direction.
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Sample size</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Quality score</th>
<th>Reported relationship &amp; effect size</th>
</tr>
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<tr>
<td>Dick et al. 1996</td>
<td>D</td>
<td>351</td>
<td>DOT</td>
<td>Patient</td>
<td>3</td>
<td>-</td>
</tr>
<tr>
<td>Diez et al. 1996</td>
<td>CC</td>
<td>210</td>
<td>DOT I</td>
<td>Patient</td>
<td>6</td>
<td>+</td>
</tr>
<tr>
<td>El-Sadr et al. 1996</td>
<td>D</td>
<td>95</td>
<td>DOT I ES</td>
<td>Patient</td>
<td>3</td>
<td>+</td>
</tr>
<tr>
<td>Farmer et al. 1991</td>
<td>CA</td>
<td>54</td>
<td>AS I</td>
<td>Patient</td>
<td>7</td>
<td>+</td>
</tr>
<tr>
<td>Fujivara et al. 1997</td>
<td>CC</td>
<td>3811</td>
<td>DOT I</td>
<td>Community</td>
<td>5</td>
<td>+</td>
</tr>
<tr>
<td>Goourevitch et al. 1996</td>
<td>D</td>
<td>12</td>
<td>DOT AS</td>
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<td>4</td>
<td>+</td>
</tr>
<tr>
<td>Jin et al. 1993</td>
<td>RCT</td>
<td>1300</td>
<td>AS</td>
<td>Patient</td>
<td>8</td>
<td>+</td>
</tr>
</tbody>
</table>

**Notes:**  
D= descriptive without comparison. DOT= directly observed therapy. “-” = indicates a significant relationship between the independent and dependent variables opposite to the hypothesized direction. CC= case control. I= incentives. “+” = indicates a significant relationship between the independent and dependent variables in the hypothesized direction. ES= educational services. CA= cohort analytic. AS= assessment services. RCT= randomized controlled trial.

Table continues
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Sample size</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Quality score</th>
<th>Reported relationship &amp; effect size</th>
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<tbody>
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<td>Klein &amp; Naizby 1995</td>
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<td>DOT</td>
<td>Patient</td>
<td>3</td>
<td>+</td>
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<tr>
<td>McDonald et al. 1982</td>
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<td>21</td>
<td>AS I</td>
<td>Patient</td>
<td>4</td>
<td>+</td>
</tr>
<tr>
<td>Miles &amp; Maat 1984</td>
<td>CC</td>
<td>58</td>
<td>AS I</td>
<td>Patient</td>
<td>5</td>
<td>+</td>
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<tr>
<td>Morisky et al. 1990</td>
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<td>205</td>
<td>ES I</td>
<td>Patient</td>
<td>8</td>
<td>+</td>
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<tr>
<td>Mushtaque et al. 1997</td>
<td>CC</td>
<td>9597 households 44505 individuals</td>
<td>ES AS I</td>
<td>Community</td>
<td>3</td>
<td>+</td>
</tr>
<tr>
<td>Neher et al. 1996</td>
<td>D</td>
<td>771</td>
<td>DOT AS ES</td>
<td>Patient</td>
<td>4</td>
<td>+</td>
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</tbody>
</table>

Notes:  
D = descriptive without comparison.  
DOT = directly observed therapy.  
"+" = indicates a significant relationship between the independent and dependent variables in the hypothesized direction.  
AS = assessment services.  
I = incentives.  
CC = case control.  
RCT = randomized controlled trial.  
ES = educational services.

Table continues
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Sample size</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Quality score</th>
<th>Reported relationship &amp; effect size</th>
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<tbody>
<tr>
<td>Onozaki &amp; Shakya 1995</td>
<td>CC</td>
<td>428</td>
<td>AS</td>
<td>Patient</td>
<td>5</td>
<td>+</td>
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<td>Saunderson 1995</td>
<td>D</td>
<td>34</td>
<td>AS</td>
<td>Community</td>
<td>4</td>
<td>+</td>
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<tr>
<td>Schecter 1997</td>
<td>D</td>
<td>N/S</td>
<td>AS DOT I</td>
<td>Patient</td>
<td>3</td>
<td>+</td>
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<tr>
<td>Schluger et al. 1995</td>
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<td>113</td>
<td>DOT I</td>
<td>Patient</td>
<td>4</td>
<td>+</td>
</tr>
<tr>
<td>Seetha et al. 1981</td>
<td>RCT</td>
<td>235</td>
<td>I</td>
<td>Patient</td>
<td>8</td>
<td>+</td>
</tr>
<tr>
<td>Wilkinson et al. 1996</td>
<td>CC</td>
<td>184</td>
<td>AS ES</td>
<td>Patient</td>
<td>6</td>
<td>+</td>
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<tr>
<td></td>
<td>CC</td>
<td>2426</td>
<td>DOT</td>
<td>Patient</td>
<td>6</td>
<td>+</td>
</tr>
</tbody>
</table>

**Notes:**  
- D = descriptive without comparison.  
- AS = assessment services.  
- "+" = indicates a significant relationship between the independent and dependent variables in the hypothesized direction.  
- N/S = one program was evaluated, number of subjects not specified.  
- DOT = directly observed therapy.  
- I = incentives.  
- RCT = randomized controlled trial.  
- CC = case control.  
- ES = educational services.
### Characteristics of Studies Examining the Effectiveness of TB Programs

<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Sample size</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Quality score</th>
<th>Reported relationship &amp; effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chaulk &amp; Spies-Pope 1997</td>
<td>CC</td>
<td>N/S</td>
<td>DOT I</td>
<td>Community</td>
<td>5</td>
<td>+</td>
</tr>
<tr>
<td>Curry 1968</td>
<td>CC</td>
<td>6345</td>
<td>AS I</td>
<td>Patient</td>
<td>5</td>
<td>+</td>
</tr>
<tr>
<td>Diez et al. 1996</td>
<td>CC</td>
<td>210</td>
<td>DOT I</td>
<td>Patient</td>
<td>6</td>
<td>+</td>
</tr>
<tr>
<td>Farmer et al. 1991</td>
<td>CA</td>
<td>54</td>
<td>AS I</td>
<td>Patient</td>
<td>7</td>
<td>+</td>
</tr>
<tr>
<td>Fujiwara et al. 1997</td>
<td>CC</td>
<td>3811</td>
<td>DOT I</td>
<td>Community</td>
<td>5</td>
<td>+</td>
</tr>
<tr>
<td>Jin et al. 1993</td>
<td>RCT</td>
<td>1300</td>
<td>AS I</td>
<td>Patient</td>
<td>8</td>
<td>1.99</td>
</tr>
</tbody>
</table>

**Notes:** CC = case control. N/S = sample size not specified. DOT = directly observed therapy. I = incentives. "+" = indicates a significant relationship between the independent and dependent variables in the hypothesized direction. AS = assessment services. CS = cohort analytic. RCT = randomized control trial.
<table>
<thead>
<tr>
<th>Study</th>
<th>Design</th>
<th>Sample size</th>
<th>Interventions</th>
<th>Outcomes</th>
<th>Quality score</th>
<th>Reported relationship &amp; effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>Klein &amp; Naidby 1995</td>
<td>CC</td>
<td>1769</td>
<td>DOT</td>
<td>Patient</td>
<td>6</td>
<td>+</td>
</tr>
<tr>
<td>Miles &amp; Maat 1984</td>
<td>CC</td>
<td>58</td>
<td>AS I</td>
<td>Patient</td>
<td>5</td>
<td>+</td>
</tr>
<tr>
<td>Morisky et al. 1990</td>
<td>RCT</td>
<td>205</td>
<td>ES I</td>
<td>Patient</td>
<td>8</td>
<td>+ 2</td>
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<tr>
<td>Onozaki &amp; Shakya 1995</td>
<td>CC</td>
<td>428</td>
<td>AS</td>
<td>Patient</td>
<td>5</td>
<td>+</td>
</tr>
<tr>
<td>Seetha et al. 1981</td>
<td>RCT</td>
<td>235</td>
<td>I</td>
<td>Patient</td>
<td>8</td>
<td>+ 3.7</td>
</tr>
<tr>
<td>Werhane et al. 1989</td>
<td>CC</td>
<td>184</td>
<td>AS ES</td>
<td>Patient</td>
<td>6</td>
<td>+ 48</td>
</tr>
<tr>
<td>Wilkinson et al. 1996</td>
<td>CC</td>
<td>2426</td>
<td>DOT</td>
<td>Patient</td>
<td>6</td>
<td>+</td>
</tr>
</tbody>
</table>

**Notes:** CC = case control. DOT = directly observed therapy. "+" = indicates a significant relationship between the independent and dependent variables in the hypothesized direction. D = descriptive without comparison. AS = assessment services, I = incentives, RCT = randomized controlled trial. ES = educational services.