ADHERENCE TO TREATMENT FOR LATENT TUBERCULOSIS INFECTION:

A MANUAL FOR HEALTHCARE PROVIDERS

CHARLES P. FELTON
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ABBREVIATIONS

AIDS	acquired immune deficiency syndrome
CBO	community-based organization
CDC	Centers for Disease Control and Prevention
DOT	directly observed therapy
EMD	electronic monitoring device
HIV	human immunodeficiency virus
IMG	international medical graduate
INH	isoniazid
LTBI	latent tuberculosis infection
TB	tuberculosis
TST	tuberculin skin test
U.S.	United States

I. INTRODUCTION

Patient adherence to the advice and directives of health care providers has received increasing attention over the past several years. This is largely due to a growing realization that the promise of efficacious, new therapies to treat long-term and chronic disease conditions cannot be realized unless patients consistently adhere to therapy.[1] Adherence can influence the emergence of new disease strains, individual health outcomes, and the overall cost of health care. For example, multi-drug resistant tuberculosis (TB) emerged largely because of widespread nonadherence to treatment for TB disease. A 12 month course of treatment for latent TB infection (LTBI) was found to be 93% effective among adherent patients, as compared to 75% effective among the overall population prescribed the treatment.[2] HIV-infected patients who take less than 90% of prescribed doses of antiretroviral medications are unlikely to achieve viral suppression and corresponding health improvements.[3,4] High blood pressure can be controlled with daily medication, but uncontrolled hypertension in non-adherent patients leads to highly increased risk of heart disease, complications of which represent a significant proportion of health care costs in developed countries.[5]

In the treatment of active TB disease, adherence has been addressed aggressively, resulting in markedly improved treatment completion rates and patient outcomes. Adherence to and completion of LTBI treatment is receiving increased attention with the inclusion of targeted treatment for LTBI as a component of tuberculosis control strategy in the United States.

Treatment adherence may be best understood as a set of interrelated behaviors that includes cognitive formulation of a personal understanding of why pharmacotherapy is prescribed; interpersonal skills to communicate effectively with health care providers; and practical skills related to medication-taking.[6] Meeting the challenge of improving adherence requires that clinicians, pharmacists, and nurses enter into areas of social and behavioral sciences that may be unfamiliar to them.

"Adherence to Treatment for Latent Tuberculosis Infection: A Manual for Health Care Providers" attempts to map out these areas in enough detail to be useful in routine clinical practice. The manual begins with an overview of adherence to pharmacological therapy in general, with particular emphasis on LTBI treatment adherence. It then presents established and innovative approaches to improving adherence to treatment of LTBI. According to need and available resources, one or more of these evidence-based strategies may be implemented by individual providers or incorporated into comprehensive TB programs. Finally, the manual gives an overview of the program evaluation process through which the implementation and impact of adherence support interventions may be evaluated.

II. ADHERENCE

In the health care context, 'adherence' refers to the extent to which patient behavior coincides with medical advice.[7] Beyond taking prescribed medication doses at prescribed intervals, adherence entails keeping medical appointments and following advice related to behaviors other than medication taking, such as diet restrictions and exercise.[8,9] Partial adherence is common in treatment of all types of diseases and among all populations. Estimates of adherence to therapeutic regimens range worldwide from 18% to 80%, with patients in developed countries achieving approximately 50% adherence to therapy for chronic or long-term illnesses.[10-12]

As a 2003 World Health Organization report on the topic emphasizes, "adherence is simultaneously influenced by several factors (page xiv)".[1] Individual patient characteristics are only one factor that impacts on adherence, albeit the one most often studied. Other important influences include socio-economic factors, the structure and nature of health care services offered, the quality of patient-provider communication, and the nature of social support that patients receive.

A. FACTORS ASSOCIATED WITH ADHERENCE TO TREATMENT

Patient related factors The evidence linking demographic characteristics such as age, race, gender, educational level, and socioeconomic status is inconsistent.[13-15] However, certain other patient-related variables have been associated with adherence behavior. These include:

- Knowledge about treatment regimens[16-18]
- Patient perception of benefits derived from therapy and barriers to treatment[19-21]
- Socio-demographic factors, including homelessness, mental illness, lack of social support, and higher number of life stressors[22-24]
- Specific cultural beliefs about medication taking, disease transmission, and disease progression which can also influence medication-taking behavior.[25-27]

Provider characteristics may influence the quality of patient-provider relationships and thus have an impact on patient behavior. In particular:

- The quality of physicians' interpersonal skills has been shown to affect adherence[28,29]
- Positive outcomes may be more likely when physicians make efforts to explain treatment regimens and address patient concerns[30-33]
- Increased nonadherence has been noted in situations where doctors appear insensitive, use medical jargon, view patients as complainers, or do not provide clear messages about the cause of the illness or reasons for treatment[34,35]

Clinic facilities affect patients' access to care and therefore can impact on adherence. Important factors that may hinder adherence are:

- Long waiting times before appointments
- Inconvenient clinic hours
- Lengthy delays between initial contact and follow up appointments
- Substantial travel costs[9,36,37]

Characteristics of treatment regimens can also affect patients' ability and willingness to adhere to them. Adherence has been shown to decrease with an increase in:

- Number of medications, frequency of dosing, and complexity of regimen[38-42]
- Duration of regimen[14]
- Side effects[43]
- Special instructions, such as dietary change[44]

Disease characteristics have also been shown to influence adherence. Nonadherence may be more common among patients with:

- Chronic rather than acute illness[10,37]
- Greater disability produced by the disease[14]
- Resolution of disease symptoms, because patients who are no longer symptomatic feel they have no further need for medications[45,46]

Children and adolescents face specific adherence challenges. Pediatric and adolescent treatment adherence tends to be low, with several studies suggesting that adolescents are less adherent than younger children.[47] Pediatric adherence to treatment is largely determined by the ability of the parent/guardian to understand and follow through with administration of the recommended treatment. As they grow older, children have the cognitive ability to carry out treatment-related tasks but continue to need parental supervision. In addition, older adolescents are influenced to a larger extent by peers and their social environment. Assigning too much responsibility to the child for treatment management can lead to poor adherence. Most studies indicate that children and adolescents who assume sole responsibility for their treatment regimen early on are less adherent and less in control of their disease management. Studies of LTBI and other illnesses show that a child's adherence to medications is associated with the degree of parental involvement and understanding about the disease and the complexity of the treatment regimen.[48]

Given the range of factors impacting on patient adherence, there is no test or single variable to discriminate between people who will adhere to therapy and those who will not. Therefore, an appropriate strategy to assess patients' actual behavior is essential to any efforts to improve adherence. Existing methods to measure adherence are discussed below in section II.C.

B. ADHERENCE TO TREATMENT OF LTBI

Targeted treatment of LTBI is an important part of the national strategy for eliminating tuberculosis in the United States. The CDC's Healthy People 2010 objectives for TB include increasing to 85% the proportion of high-risk persons with LTBI who complete a course of treatment.[49] High-risk groups include those with recent infection (within 2 years); recent immigrants from countries with high rates of TB; people with HIV infection or other immunosuppressive conditions; children under the age of five, people who are homeless or living in shelters; and injection drug users.[50] Rates of LTBI treatment completion in the US have consistently fallen below the 85% target. Greater attention to the assessment of adherence and strategies to improve it can make an important contribution to improving LTBI treatment completion rates, thus furthering the larger goal of TB control and elimination.

Differences between Adherence to Treatment for TB Disease and for LTBI

Both TB disease and LTBI require regimens of many months duration. However, treatment of each condition is associated with its own specific challenges.

In the case of TB disease, challenges include fear of stigmatization, which can discourage patients from presenting for treatment and follow-up care and from taking medication in front of others. Certain characteristics of TB treatment make adherence difficult, including regimens of multiple medications, medication-associated side effects, and the need to take medication beyond the symptomatic phase of the disease. Several factors contribute to the high profile of adherence to treatment for TB disease: 1) TB is a contagious disease with risk of transmission to others; 2) nonadherence is associated with prolongation of the disease's infectious phase; 3) nonadherence is also associated with risk of developing drug-resistant organisms that may be spread throughout the community; and 4) the human and fiscal costs of treating resistant organisms are substantial. The attention directed to the role of adherence in treatment of TB disease has prompted in-depth assessments of diverse adherence support interventions.

Directly observed therapy (DOT) has been recommended as the preferred method for ensuring completion of treatment for TB disease and has been incorporated into the World Health Organization's primary strategy for the global control of TB.[51] DOT refers to supervision of the ingestion of every treatment dose. A review of articles published from 1966 through 1996 on DOT programs for TB treatment found that treatment completion rates were greater than 90% when therapy was supervised.[52] Programs that used partial supervision of therapy or self-administered treatment achieved lower rates. However, high rates of TB completion have been achieved in some communities without the use of universal DOT.[53] Alternatives to DOT include various strategies to monitor adherence, such as the use of electronic monitoring devices that record when a medication container is opened.[54] Another approach is the use of fixed-dose combination pills, which reduce pill burden and prevent the development of resistant organisms in case of nonadherence.[55]

In contrast to TB disease, the greatest challenges in treating LTBI are often behavioral. Effective treatment of LTBI entails convincing the patient of the need for prolonged treatment of a non-contagious infection that may never develop into TB disease, using medications with potential side effects. Patients with LTBI are completely asymptomatic, often unaware or doubtful of having the infection, and uninformed about the availability of effective preventive treatment. Many people express an 'unrealistic optimism' regarding LTBI and underestimate their personal risk of developing

TB disease. In addition, they often do not appreciate the efficacy of LTBI treatment, but may overestimate the potential adverse events associated with it. Patients may also have many competing priorities in their lives and few support networks to draw on when undergoing a long course of preventive treatment. Finally, they may not identify role models in their own lives who have adopted this preventive behavior.

Comparison of Disease- and Treatment-Related Factors Affecting Treatment Adherence in TB Disease and LTBI

Factors Affecting Adherence	In TB disease	In LTBI	Effect on LTBI adherence
Perceived severity	strong	weak	hinders
Perceived susceptibility	strong	weak	hinders
Duration of therapy	usually 6 months	usually 9 months	equal to TB disease
Intensity of therapy	multiple medications	usually monotherapy	facilitates
Directly observed therapy	standard of care	not standard of care	hinders
Symptoms	symptomatic	asymptomatic	hinders
Infectiousness	infectious	non-infectious	hinders
Public health threat	threat	indirect threat	hinders

While adherence to treatment of TB disease has received substantial attention in the literature, relatively less data have accumulated on adherence to LTBI treatment. Existing information on measurement of LTBI treatment completion and adherence rates suggests that they are low across LTBI patient populations.[56] In New York City Department of Health and Mental Hygiene chest centers, the most recent data show that the completion rate for all patients started on LTBI treatment is 51%, based on attendance at clinic visits. The treatment completion rate among people identified as contacts to active TB patients is 64%.[57] In Seattle and Kings County, WA, the completion rate for refugees starting treatment for LTBI between 1996 and 1998 was 41%.[58]

There is a relatively small but growing body of research on completion of and/or adherence to treatment for LTBI. As is true in the literature on adherence to other treatment regimens, demographic characteristics such as age, race, gender, educational level, and socioeconomic status have not been consistently associated with adherence. However, several other variables have been shown to impact on adherence.

Factors Associated with Adherence to and Completion of Treatment for LTBI

Patient-related factors

Positive associations with adherence or treatment completion have been found for:

- Recent exposure to TB[59]
- High perceived benefits of treatment, or expectations of positive outcomes of treatment[47]
- Social norms and values that uphold treatment for LTBI[47]
- Knowledge and treatment of TB and LTBI[17]

Negative associations with adherence or treatment completion have been found for:

- Substance dependency[60]
- Concurrent illnesses and additional treatment regimens[61]
- Low perception of susceptibility to TB disease[62]
- Low intention to complete treatment[63]
- Lack of social support[64]
- Among immigrant adolescents, greater acculturation and more years in the United States[62]

Clinic facilities may influence treatment completion and adherence to the extent that they adequately address patient needs:

- Inaccessible or inconvenient care locations may discourage treatment completion[65]
- Lack of translators and language appropriate patient information may also be a barrier to care[66]
- Conversely, the use of tangible incentives and enablers and reminders have been shown to increase treatment completion[63]

Characteristics of the treatment regimen may discourage adherence and treatment completion. These include:

- Concerns about the toxicity of LTBI medications[64]
- Fear of side effects[60]

Prior versus Currently Recommended Method of Assessing Completion of LTBI Treatment

Literature on LTBI treatment has reflected routine health care practice in its tendency to focus attention on completion rates, with relatively less focus on actual medication adherence. More recent research does assess adherence in addition to treatment completion, and offers several adherence assessment strategies that may be adapted in clinical settings.

Determination of completion of LTBI treatment was previously based on patient adherence to monthly duration of treatment alone (according to attendance at monthly clinic visits), without an assessment of whether the patient actually took their medication and without estimation of doses taken. This focus has generally resulted in the overestimation of LTBI treatment completion rates. Furthermore, it encouraged both patients and providers to disregard how adherence to medications contributes to the effectiveness of treatment and anticipated health outcomes.

Completion of LTBI treatment is currently based on total number of doses actually ingested within a pre-defined period.[67] For example, the 9-month regimen of daily isoniazid consists of a minimum of 270 doses administered within 12 months, allowing for minor interruptions in therapy. Thus, all efforts to monitor adherence should be directed towards adherence with doses in addition to attendance at clinic visits.

C. MEASURING ADHERENCE

Adherence measurement is important for several reasons. Accurate assessment of adherence behavior can contribute to effective and efficient treatment planning. In addition, precise adherence measurement is necessary to ensure that changes in health outcomes can be attributed to the recommended regimen. Finally, decisions to change recommendations, medications, and/or communication style in order to enhance patient participation depend on valid, reliable measurement of adherence.[1]

While no gold standard exists for measuring medication adherence, several different direct and indirect indicators have been utilized with varying success.[68] **Direct measures** include direct observation of medication taking, measuring levels of the drug or tracer compounds in body fluids, biologic markers, and monitoring clinic attendance. Frequently used **indirect measures** are self-report of medication taking, physician assessment, electronic monitoring devices, pill count, medication refill rate, and monitoring for an expected therapeutic outcome. This last option is not helpful in the setting of asymptomatic conditions like LTBI. In general, direct measures are more objective and yield more reliable assessments of adherence, though each method has limitations.[41]

Direct Measures

Directly Observe Patients

Trained health care providers observe and record a patient's adherence.

Advantages	Limitations
• Adherence is verified and recorded by a health care provider	• Expensive and resource intensive
• Ensures that parents/caregivers are administering the medications as prescribed	• Inconvenient for patients and caregivers
• Health care providers can administer medications and teach techniques for administering medications	• Some programs do not have the infrastructure to provide DOT in-home or on-site visits
• Can be effectively combined with DOT visit of a TB case	• DOT is required for biweekly regimens

Measure Biological Markers

Levels of TB medications can be measured in a patient's urine to assess adherence.

Advantages	Limitations
• Providers can verify self-reported adherence of medications within the last 72 hours	• Expensive and inconvenient
	• No information available about levels of the medications before the 72-hour period
	• Reason for non-adherence is not available

Indirect Measures

Ask the Patient (self-report)

A health care provider or health educator can assess a patient's adherence to LTBI treatment.

Advantages	Limitations
• Quick and inexpensive	• Patients may be reluctant to admit non-adherence
• Easy to use	• Poor recall can result in inaccurate reporting
• Self-reported *non-adherence* is usually reliable	
• Can reveal reason(s) for missed doses	

Educating patients and caregivers about the importance of accurate reporting of adherence should be done at the initial visit. The following suggestions can help lessen inaccurate reporting of adherence by patients and their caregivers.

Use a standardized adherence questionnaire	Limits charting time for providers and increases consistency with which adherence is monitored**.**
Question patients carefully	Patients are more likely to respond accurately when asked in a non-judgmental manner. Give the patient "permission" to admit missed doses. Rephrasing and repeating a question can confirm if correct information was obtained.
Ask patients about doses missed during the last week	Asking patients to recall a recent period of time, such as number of doses missed in last 3 days and/or last 7 days, has shown to enhance the accuracy of self-reported adherence.
Give patients the option to individually enter self-reported adherence into a computer	Computer-assisted self-administered interviews (CASI) have been shown to improve disclosure of undesirable behavior and provide more accurate information than face-to-face interviews. Even populations with limited computer skills and education have felt comfortable with the technology.
Use an adherence calendar	Calendars are not only helpful for patients, serving as a daily reminder, but also for providers, as they are a record of medications taken.

See Appendix A for an example of a self-report questionnaire.

Monitor Clinic Attendance

Monitoring and recording clinic visits allows health care providers to identify patients who are adherent or delinquent in terms of attendance.[70]

Advantages	Limitations
• Poor clinic attendance can be a good indication of non-adherence to LTBI medications	• Good clinic attendance does not always correlate with adequate medication adherence
	• Adherence to medications is not assessed
	• Reason for non-adherence is not available

Monitor Pills

Patients can be asked to bring in their medication bottles and remaining doses can be counted at clinic visits.

Advantages	Limitations
• Inexpensive	• Cannot determine whether pills were ingested or discarded, when they were ingested, or whether the appropriate number of pills was taken at the correct intervals
• Easy for staff to conduct	• Pill counts have been shown to overestimate adherence [71,72]
	• Not widely used in clinical practice because of difficulty of ensuring that medication bottles are brought back to clinic

Calculate Medication Refill Rate

Pharmacy databases can be used to check when prescriptions are filled initially, re-filled over time, and prematurely discontinued.

Advantages	Limitations
• Inexpensive	• Provides no information on pill ingestion
• Non-obtrusive for patient	• Pattern of non-adherence with this technique remains undefined
	• Not practical in clinical settings where patients use several pharmacies

Use Electronic Monitoring Devices

Prescription bottles equipped with Electronic Monitoring Devices (EMDs) can be distributed and collected at monthly visits and used to measure adherence.[73] The EMD utilizes an electronic device located in the cap of the prescription bottle which records the date and time that the cap is removed. One example is the Micro Electronic Monitoring System (MEMS®, Aardex Corp., Palo Alto, CA).

Advantages	Limitations
• Provides detailed information including actual dosing interval	• Expensive
• Can be used to provide feedback on adherence to patients	• Complex to use
	• Doesn't track number of pills removed or ingested
	• Not practical for large patient populations
	• Inaccuracies due to improper use or technical problems

Issues Specific to Children and Adolescents

Studies indicate that children inflate their adherence behaviors in self-report, much as adults do. Parents or caregivers may not provide precise information about children's medication taking, as they may be reluctant to admit their inability to have their children adhere with medical advice. Therefore, families should receive individualized education on adherence and the importance of accurately assessing adherence.[48]

Summary

Adherence measurement plays an important role in patient treatment. While there is no single universally preferred measure of adherence, several measures provide valuable, if partial, information. A combination of indirect assessment (e.g. self-report) with a direct measure (e.g. record of clinic attendance) is considered the current "state-of-the-art" in measurement of adherence behavior. The selection of an appropriate combination of direct and indirect measures depends on the degree of precision required, the resources available, preferences of the patient population, and specific characteristics of the therapy being assessed.

III. IMPROVING TREATMENT ADHERENCE

Diverse factors coalesce to impact on patient adherence, and thus efforts to improve adherence may be more effective when they address multiple aspects of adherence and are tailored to patient needs and preferences. One straightforward way to become familiar with issues affecting the population is to conduct a needs and resources assessment specific to treatment adherence and completion. Strategies for needs assessment are discussed below. However, even before assessing the needs of a particular patient population, LTBI providers and programs should be aware of the cultural dimensions of health care provision in the United States, and of how cultural factors can impact on efforts to improve adherence and treatment completion.

A. INTEGRATING CULTURAL COMPETENCY

Recent immigrants account for an increasingly large proportion of persons with LTBI in the United States. Degrees of acculturation, culturally specific beliefs related to health and illness, and perceptions of the U.S. medical and public health care systems all impact on the success of health promotion and prevention interventions. Therefore, health care providers should interact with patients in culturally appropriate ways that maximize the effectiveness of the adherence support they offer.

Get to Know the Patient Population
• Determine primary languages spoken and which cultural groups predominant among those accessing program services.
• Learn the values, beliefs, and traditional concepts particular to these groups.
• Explore perceptions held about health, illness, and health care systems, especially in relationship to TB and LTBI.

A culturally-competent approach to care can help build trust and credibility with patients. This is especially important among populations that stigmatize TB and LTBI patients and who are unfamiliar with the U.S. medical and public health systems. Focus group discussions with community members and leaders, international medical graduates (IMGs), and former and current patients can provide insight into the beliefs and practices of a particular population, as can online resources. Collaborations with community-based organizations (CBOs) can yield information and insight, and bring LTBI treatment programs into community networks.

Staff members should be educated about relevant cultural beliefs and practices of the communities they serve, and should practice techniques for good communication with patients, described in Section III C. It is crucial to understand the patient population and identify and address socio-cultural differences, as misinterpretation of certain behaviors or intentions can adversely affect the patient-provider relationship. Patients who are uncomfortable or do not understand providers or program staff may be less likely to initiate or complete treatment.

Develop Cultural Competency among Program Staff
• Educate staff members about common patient beliefs related to TB/LTBI.
• Emphasize confidentiality for patients from cultures that stigmatize TB/LTBI patients.
• Invite community leaders and/or IMGs to discuss communication styles used by different cultures and teach staff how to appropriately address patients.
• Coach staff to rephrase questions for individuals from cultures not comfortable discussing health issues or who fear disclosure of their health information to others.
• Train staff on how to work effectively with translators.
• Offer fact sheets, courses, or workshops that cover cultural competency issues.
• Participate in monthly meetings to discuss cases and learn from experiences working with diverse patient populations.

Employing individuals from the community and with a diversity of backgrounds also helps to create a culturally competent environment. However, incorporating small changes, such as ensuring that patient forms and educational materials are available in multiple languages, can have a big impact on the comfort level of foreign-born patients.

Integrate Cultural Competency
• Utilize translators, preferably the same gender as the patient or parent/caregiver.
• Ensure that educational materials are available in multiple languages.
• Provide medical history and consent forms in multiple languages.
• Identify common misconceptions about TB and LTBI and address these issues with patients and parents/caregivers.
• Work with CBOs and community leaders to build partnerships to establish trust and credibility with community members.
• Involve community members as volunteers and/or employees for the program.

Resources on cultural competency are widely available, including manuals, training materials, and courses. Local health departments and medical associations may also offer workshops for health care providers, some of which are free of charge and/or offer continuing education units. Some resources for developing cultural competency are listed in Appendix B.

Listening to and learning from patients is the first step towards creating a culturally competent atmosphere. Improved understanding and communication make it easier to identify and minimize barriers that patients and their families face. As a result, patients may be more willing to initiate LTBI treatment, and better able to adhere to the regimen until it is completed.

B. NEEDS AND RESOURCE ASSESSMENT

The first step of an assessment of adherence support needs may be to evaluate completion rates among the targeted patient population.[74,75] Where rates of treatment completion are below target levels, a comprehensive needs assessment can offer insight into barriers to adherence and program gaps or inadequacies. The detailed information obtained about patient satisfaction and preferences helps LTBI programs to better understand their patient population and make informed decisions about where resources should be allocated. The resulting information allows a program to modify and/or design interventions to overcome significant barriers and improve adherence and completion rates.

Conduct Patient Surveys

A staff member can conduct patient survey interviews in person or over the telephone. If possible, a staff member who is not directly involved in patient medical care and who has established relationships with patients should administer the questionnaire. Depending on the number of patients involved and the time dedicated to the needs assessment, a program may elect to use open-ended, short answer questions or multiple-choice questions.

Elements of a Patient Needs Assessment Survey
• Demographic characteristics of patients and parents/caregivers
• Satisfaction with clinic environment and physical space
• Satisfaction with clinic hours, wait time, and other aspects of patient flow
• Perceptions about clinic staff
• Preferred enablers, incentives, and gifts
• Preferred educational materials and formats
• Suggestions for improving services

See Appendix C for a sample patient needs assessment questionnaire.

Seek Input from Clinic Staff

Clinical and support staff can provide a wealth of information about the organizational aspects of an LTBI program. Staff members who work directly with patients are aware of common complaints and concerns of patients, and can provide insight into issues that affect patient flow. Needs assessments with staff should be in an interview format. Preferably, a non-managerial staff member should conduct the interviews to create an environment where program staff feels comfortable being fully honest and frank. If an outside interviewer is not feasible, anonymous questionnaires may also be used to give honest feedback.

Assess Available Resources for Program Development

Decisions to implement adherence support strategies should take into account the available resources, both staffing and financial. Priority should be given to strategies that facilitate care for the majority of patients, while minimizing the strain on program resources.

Factors Affecting Availability of Resources for Program Development
• Total program funding
• Cost of intervention, staffing, and facilities
• Length and security of funding
• Population served
• Potential sources of alternative or additional resources

C. INTERVENTIONS TO IMPROVE ADHERENCE

Just as a needs assessment may reveal multiple barriers to successful treatment adherence and completion, interventions that include several strategies addressing multiple dimensions of adherence behavior have been shown to be more effective than single-target interventions.[76]

1. Health Care Provider-Centered Strategies

Studies across a variety of disease conditions and populations show that various dimensions of the patient-provider relationship impact on health outcomes.[30-32,48,77] Translation of these research findings into practical steps to improve the patient-provider relationship is challenging, in part because the relationship is multidimensional and may be operationalized in disparate ways.[33,78,79] Because studies demonstrating effective provider-based interventions to improve adherence to medications are sparse, provider-based adherence support should be combined with strategies that address other dimensions of adherence as well.

Communicate Effectively with Patients

Providers can do much to increase their ability to engage patients in open dialogue about adherence. A useful guideline may be found in the recent "Kalamazoo Consensus Statement."[80,81] The document identifies the following "essential elements of physician-patient communication:"

- Establish rapport
- Initiate full discussion of illness and treatment
- Ask for relevant information using open-ended questions
- Summarize and clarify information as necessary
- Elicit patient's perspective on illness and treatment
- Offer information
- Negotiate the treatment plan
- Bring the visit to a close

Applied to improving adherence to LTBI treatment, these communication elements highlight several important areas of the patient-provider encounter. Given that there is no simple test to identify those who will adhere poorly, and because clinical providers and particularly physicians have been found to be poor at predicting adherence in their patients,[3] every patient on LTBI treatment should be engaged in adherence discussions.

Communication about LTBI Adherence
Rapport: Acknowledge the challenge of adhering to treatment and affirm that the final decision to take medications rests with the patient.
Discussion: Encourage patients to fully express concerns and to personalize diagnosis and treatment.
Seek patient input: Ask about acceptance of treatment and adherence behavior in a non-judgmental way, and encourage patients to reflect on circumstances surrounding instances of nonadherence.
Explore patient perspectives: Ask about health beliefs, normative factors, and priorities that may impact negatively or positively on adherence.
Offer information: Respond to expressed concerns and doubts in terms that patients understand, and confirm that they have absorbed it.
Negotiate: Collaborate with patients to develop strategies to fit treatment and clinic visits into their daily routines and to identify appropriate adherence tools.
Conclude visit: Ask if any issues remain to be addressed, summarize discussion, and make arrangements for follow-up.

2. Clinic-Centered Strategies

An assessment of patient needs and preferences may reveal specific clinic setting-related factors that can discourage LTBI treatment completion and that can lead to nonadherence with medical care and treatment. While individual problems may be simple to rectify, any steps taken to improve adherence support will be more effective when they are coordinated so as to ensure that patients have easy access to services at appropriate times.[74,82]

Designate an Adherence Team Leader

One way to ensure continuity of services is to designate a team leader with primary responsibility for patient adherence. The adherence team leader has the responsibility to organize adherence support efforts, develop adherence support strategies and tools, monitor the implementation of program efforts, and work as a liaison between medical staff, support staff, and patients in the LTBI program. The background and experience of a team leader can vary. Health educators, nurses, caseworkers, social workers, and/or other program staff members can all serve as a team leader. A team leader should be selected based on motivation, interest in working with the patient population, willingness to build relationships with patients, strong communication skills, resourcefulness, and creativity.

A team leader may assume a variety of patient care and organizational roles depending on the resources of the program. Once adherence support interventions are in place, the time commitment required of an adherence team leader need not be substantial.

Roles of an Adherence Team Leader
Organizational Roles
• Serve as a liaison between staff, patients, and relevant family members
• Establish close, collaborative relationships with clinical and support staff
• Provide activities and snacks to ease long wait times in the clinic
• Help clinical staff streamline services and minimize wait times
• Develop strategies to minimize barriers and tools to improve adherence
• Ensure accurate contact information is maintained for each patient
• Call and/or send out appointment reminder letters
• Maintain a record of all appointments missed and follow-up with patients
• Coordinate meetings to inform staff about successes and deficiencies in the program
Patient-Related Roles
• Make introductions to new patients and relevant family members
• Educate patients on adherence to and completion of LTBI treatment
• Elicit and address patient concerns
• Serve as a case manager and refer patients for additional medical care or social services
• Facilitate communication with providers

For programs that serve a large patient population, the team leader may choose to delegate some roles to other members of staff.

Develop a Multidisciplinary Approach

A multidisciplinary team of providers can provide adherence support that is both comprehensive and consistent in its message. Adherence support teams may consist only of an adherence-dedicated nurse, a primary care physician, and the patient. Or, they may provide a full spectrum of services including pharmacy, social work, health education, case management, system navigation, outreach, mental health counseling, and social support for individuals and groups. Teams also vary in degree of integration: a team may share office space and exchange information several times a day, or they may meet to exchange information once a month. In any case, smooth, consistent communication between team members and clients is essential.

3. Patient-Centered Strategies

As noted above, a variety of factors influence patients' desire and ability to be adherent. Interventions may target one or several of these patient-related factors.

Patient Education

Patients' understanding of their diagnosis and treatment regimen can influence their adherence behavior, as can their perception of benefits of and barriers to treatment adherence and completion. Therefore, patient education can be a very effective response to many of the difficulties in getting patients to adhere to a complete course of LTBI therapy. Patient education should include some individual sessions that are tailored to the patient's needs and level of understanding about LTBI and its treatment, including potential side effects of TB medications. All staff members that deliver health-related information should be trained in effective communication techniques, recognizing that *how* information is communicated can have a greater impact on patients than *what* is communicated.

Trained health educators use a wide repertoire of educational models and strategies. As an example, the informational-motivational-behavioral (IMB) model is outlined here. The IMB has been shown to be effective in experimental interventions to reduce the risk of HIV infection delivered by clinical and non-clinical health care workers. It has also been applied to other protective health behaviors, and preliminary work towards its application to medication adherence has been done.[1,83-87]

The IMB model posits three fundamental prerequisites for behavior change. The first is **information**, which includes basic knowledge concerning the target behavior and patients' beliefs about the behavior, which may diverge from information that health care providers convey. **Motivation** to practice the behavior includes perceptions of individual vulnerability, perceived costs and anticipated benefits of the target behavior, and perceived social support or social norms for engaging in the behavior. Specific **behavioral skills**, including appropriate strategies and tools, are necessary to execute the target behavior. In the IMB model, providing information and strengthening motivation precede teaching the behavioral skills that are ultimately needed to initiate and maintain a desired behavior.

Educational sessions that aim to improve adherence to LTBI treatment should explore patient attitudes towards their diagnosis and recommended treatment, in addition to providing basic TB and LTBI information. Possible drawbacks of accepting treatment and any perceived barriers should be addressed.

Information: Techniques for Effective Communication
• Engage patients in dialogue.
• Explore patient perceptions and beliefs.
• Use clear, non-medical language.
• Identify specific examples that are relevant to patient experience.
• Cover essential points first and reiterate them at the end of the session.
• Ask patients to articulate important points in their own words.

Educational sessions should also devote time to the individual patient's motivation to adhere to treatment. Motivation, as conceptualized in the IMB model, includes personal risk and possible risks to others. For example, parents with LTBI may be concerned about their children's exposure to TB if their infection should become active disease. In the same way, the anticipated benefits to others and social approval or approbation may be more powerful motivations than expected individual health outcomes.

Motivation: Help Patients Personalize Medical Advice
• Coach patients to articulate risk of disease in personal terms.
• Identify personalized short- and long-term goals that are coherent with adherence.
• Help patients articulate adherence-promoting social norms that are relevant to their lives and goals.

Another crucial function of health education is to help patients develop adherence-promoting behavioral skills that are tailored to fit individual lifestyles.

Behavior: Teach Skills to Improve Adherence
• Identify personalized 'cues' to remember dose times.
• Assess need for pill boxes, pill crushers, timers, and other adherence tools.
• Demonstrate and practice use of adherence tools.
• Review potential side effects and devise a plan for managing them.

Group Education

Patient education that integrates needed information, motivational support, and behavioral skill-building may also be conducted through group educational sessions. For instance, an interactive group setting can be an effective space for discussion of potential side effects and how to manage them. Activities designed to strengthen motivation may be particularly appropriate for groups. For instance, a former TB patient may offer testimony about the difficulty of treating TB disease as compared to LTBI, and then ask group members to share their reactions and similar stories.

Effective Use of Written Materials

Patient educational materials and approaches should be culturally relevant, suitable for low literacy levels, and available in multiple languages. They should be prominently displayed in the clinic. Providers and other clinic staff should not simply hand these materials to patients, but rather, should take time to look at the materials with patients, highlight important points, and confirm that the patient understands the material. As mentioned above, the best communication combines verbal information with written materials, such as brochures, pamphlets, and photo-novelas or comic book style narratives.[88]

Enablers and Incentives

In recent years, health officials have come to agree on the importance of enablers and incentives to help TB patients complete treatment.[89] They are equally useful to retain LTBI patients in treatment and encourage them to adhere. Enablers and incentives are most effective when they are tailored to the particular population being served, and for pediatric patients should be offered to parents/caregivers as well as patients. A brief survey of preferences or a needs assessment can be conducted to determine appropriate enablers and incentives.

TB treatment programs regularly provide enablers, i.e. items or services that facilitate clinic attendance. Examples are food, food coupons, bus tokens, and child care facilities. For LTBI treatment, tools that facilitate adherence, such as pillboxes, pill splitters and crushers, utensils to administer liquid forms of medications, and calendars to mark off doses taken, are also important enablers.[90]

Incentives are small rewards given to patients to encourage them to take their medications and/or keep their appointments. They may be offered at intervals during the course of treatment or reserved for treatment completion. Incentives can help motivate patients to complete a long treatment regimen, and can serve as rewards for good adherence. Examples of incentives include coupons for restaurants, movie theaters, or department stores, games and toys for children, and commemorative plaques or certificates marking the completion of treatment.

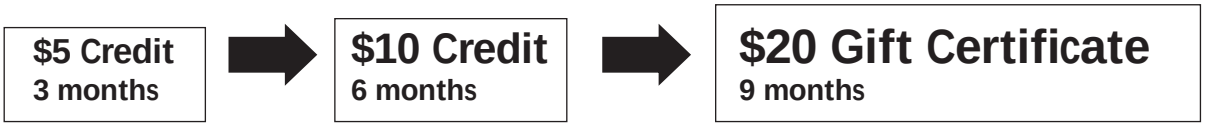
Incentives in a Goal-Oriented Approach

The duration of LTBI treatment is a deterrent for patients to initiate treatment as well as a barrier to completion of LTBI treatment. Using a goal-oriented approach may be an effective method for overcoming these issues. Breaking the 9 month treatment regimen into three different steps or target goals can help patients set practical short-term goals that will lead to completion. As patients progress towards completion of LTBI treatment, the rewards for reaching each 3 month, 6 month, and 9 month goal improves. This helps keep patients and their parents/caregivers motivated and focused on moving forward toward completion of treatment. A goal-oriented approach to LTBI treatment can benefit programs that have limited resources to offer monthly incentives. Distribution of incentives can be limited to when patients reach a target date, such as at the 3 month, 6 month, and 9 month marks of their treatment regimen.

A variation of this goal-oriented approach involves accumulating credits or points toward an incentive that is redeemed upon completion. Each month that a patient successfully adheres to LTBI medications, the program team leader or clinician distributes credits to patients. The credits earned can be used towards the reward given at the end of treatment. Patients can earn credit toward a gift certificate at a music or clothing store, or can select an item corresponding to the amount of credit they have earned.

Instructions should be given at the beginning of a patient's treatment regimen. Patients who do not complete the regimen may return to receive the gift certificate in the value earned at the time they stopped the regimen. The hope is that if patients return to collect their credit, they can be persuaded to resume their treatment.

A patient who completes 3 months of treatment earns a $5 credit towards the certificate. After 6 months of treatment a $10 credit towards the certificate is recorded, and when the patient completes 9 months of treatment a $20 gift certificate is awarded. The bigger increase in reward between the 6 months and 9 months will help reinforce the importance of completion.



LTBI programs can also give these credits in conjunction with monthly enablers. This method may be useful for programs that do not have the resources to provide incentives on a monthly basis.

Social Reinforcement for Adherence

Rather than rewarding individual adherence to treatment, incentives can be formulated so as to provide social reinforcement for adherence. Social incentives include refreshments or more substantial fare offered in clinic waiting rooms, organized so as to encourage interaction among patients. If clinic staff members create a warm, welcoming environment along with refreshments, the waiting time can become a positive social experience. Staff and patients can engage in such activities as trips to amusement parks and local cultural events. In addition, on-site social activities such as celebrations of patient birthdays and holiday parties at holiday times help cultivate a sense of connectedness among patients and between patients and staff.[91] One very effective method is to host a celebration for those who complete treatment, with completers receiving completion cards to commemorate the event. See Appendix D for an example of an LTBI treatment completion card.

Adherence-Specific Case Management

Case management can be used to improve adherence by ensuring that patient services related to treatment are adequate, appropriate, well-coordinated, and uninterrupted.[92] Case management is often provided by nurses, social workers, and paraprofessional staff. Designated staff members assess patient needs, facilitate access to needed services, make necessary referrals, and ensure the coordination of patient care. While the activities subsumed by a particular case management program may be narrow or broad in conformance with the program's resources and mission, case managers should begin with a structured intake process that identifies individual barriers to adherence and appropriate steps to overcome them. The case manager attends to patients' barriers internally where possible, and refers them to outside agencies as needed. Case management can effectively address common barriers in underprivileged communities, including homelessness and marginal housing, lack of food, lack of access to employment opportunities, substance abuse, undiagnosed or untreated mental illness, and low literacy levels, following up on referrals and acting as a liaison for the patient and social service providers when necessary. Case managers can also facilitate access to immigrant services.

Adherence-specific case managers can employ the same IMB framework suggested as an educational strategy. They should provide **information** about available services and how to access those services; generate **motivation** to build the material supports necessary for adherence by resolving concrete barriers; and promote constructive **behavioral skills** by coaching patients in problem-solving techniques that will be useful through the course of their treatment.

Case managers can serve as a program's link to local community resources. Even relatively disadvantaged communities may be rich in resources that can be accessed to secure housing, substance abuse treatment, access to entitlements, and other services. The more familiar with the community and its specific populations case managers are, the better they can mobilize local resources in response to individual patient needs.[58]

Effective case managers do not work in isolation but rather need a mechanism to engage the collaboration of all providers involved in patient care. Multidisciplinary case management meetings provide such a mechanism. In each meeting a member of the case management team gives a summary of a case: medical background, relevant social and cultural issues, and treatment regimen. Professionals from diverse backgrounds provide insight and advice about the progress of an individual patient. Topics may range from helping a patient with obtaining employment, food, housing, or referrals to securing additional medical care or psycho/social interventions.

Topics for Review in Case Management Meetings
• Patients initiating LTBI treatment
• Significant medical and/or social situations confronting individual patients
• Change of treatment regimen
• Resolution of barriers and administration of necessary referrals for individual patients
• Issues pertaining to cultural competency
• Adherence and completion rates in the jurisdiction

Directly Observed Therapy (DOT) for LTBI

LTBI treatment lends itself well to DOT because the therapy is limited to 9 months and can be administered daily or twice weekly. It has been shown to be very successful in the management of both active TB and LTBI.[93,94] DOT has been recommended as the standard of care for TB disease in the US[95] and adopted by the World Health Organization as a keystone of its recommended strategy for global control of TB.[51] In the strictest sense, DOT involves simply supervising the ingestion of every dose of treatment. "Enhanced DOT" programs are enriched by additional social and adherence support services plus incentives and enablers, and have been shown to be more effective than DOT programs without such features.[96-98] DOT for LTBI has significant drawbacks, including its expense, infrastructural requirements, labor-intensity, and the potential for patients to perceive it as intrusive and inconvenient.[99,100] Nevertheless, DOT may be the most effective way to ensure completion of treatment for patients at elevated risk for progressing from LTBI to TB disease, including patients with HIV infection and very young children.

Pharmacist-Based Coaching

Some programs have the resources to offer an on-site pharmacist. In addition to facilitating medication pick-up for patients, an on-site pharmacist can address many treatment related factors associated with non-adherence. Pharmacists can educate patients in advance about possible side effects and how to respond to them.

Pharmacists who combine their detailed knowledge of medications with an effective approach to patient education are uniquely qualified to:

- Answer questions about dosage frequencies and length of treatment
- Advise patients on possible side effects and how to respond to them
- Help patients integrate LTBI treatment into their existing pharmacotherapeutic regimens and identify possible drug-drug interactions

Additionally, the pharmacist can be a valuable member of the adherence support team, reinforcing messages from the physician and health educator about the importance of adherence. Pharmacist records may also provide feedback on whether the patients have picked up their medications.

Behavior-Specific Coaching

Another approach to improving adherence focuses exclusively on pill taking and provides very specific feedback on patients' pill-taking behavior, as measured by one of the methods described above in section I C. A well-articulated version of this approach is 'cue-dose training'.[101] Cue-dose training entails an accurate assessment of patients' adherence for a specific period of time, which is then reviewed with a provider experienced in cue-dose training. The provider works with the patient to examine circumstances that lead to missed doses, and identify cues to remember doses that are appropriate for the particular patient. Cues may be as simple setting out medication bottles where they can be seen at meal times or after brushing one's teeth, or they may be involve recruiting family members to remind a patient of the dose time.

Nearly all adherence measures may be used to provide patients with feedback on their adherence. However, some measures may be seen as intrusive or punitive and thus do not lend themselves to use in an intervention. For example, because urine testing may be used in a punitive fashion in substance abuse and other treatment programs, its use in TB control programs may be tainted by these associations. Patients may perceive urine testing as a lack of trust from the provider and may, in some cases, withdraw from treatment.

Cue-Dosing Using Electronic Monitoring Devices

Electronic monitoring devices (EMD), such as the Micro Electronic Monitoring System (MEMS®, Aardex Corp., Palo Alto, CA), are described in section I.C. on Measuring Adherence. One version of the MEMS®, the Smart Caps®, is particularly amenable to use as an adherence tool because it contains an alarm that can be set to beep at dose times, and it displays the length of time that has passed between doses. Additionally, the company that markets MEMS® cap also offers an adherence service in which, following electronic downloading of daily data, a nurse will review the output and call the patient to ask questions or make suggestions. Thus, the information recorded in the MEMS® cap can be used in a patient-centered, pro-active manner.[102]

Cue-Dosing Using Pill Counts

As with EMDs, pill counts can be used to measure and affect adherence. Patients may be instructed to bring their pill bottles to the clinic, not only to count the pills, but also to discuss why the anticipated number of doses does not match the actual number of doses. Health care personnel who adopt this method of cue dosing should develop an effective protocol for reminding patients to come to clinic appointments with their pill bottle, since it is essential to the intervention. In addition, health care personnel should administer an adherence self-report survey to all patients, since an empty bottle does not mean that all medications were taken appropriately.

Social Support

The positive impact of social networks and social support on adherence has been demonstrated in studies of health issues including stress reduction, control of alcohol use, smoking cessation, weight loss, breast cancer screening, reduction of myocardial infarction risk, blood pressure monitoring, and enhanced prenatal care. Recent studies have specifically demonstrated the importance of social support for preventing the progression from LTBI to active TB disease, improving adherence to TB and LTBI treatment, and improving coping and quality of life.[103,104]

Social support is a complex phenomenon that is conceptualized as having specific components.[105,106] These are:

- **Emotional support:** affection, trust, and empathy, as well as specific encouragement for behavioral change
- **Instrumental support:** tangible aid and services, such as connection to welfare benefits or counselors, or helping with timing of medications
- **Informational support:** answering questions about medication adherence, substance use programs, etc.
- **Appraisal support:** helping the individual discuss the pros and cons of adherence, evaluate adherence from a personal perspective, and move towards adherence; and
- **Access to resources:** assistance in obtaining housing, medical benefits, and other needed services.

Social Support Provided by Peer Health Workers

Also known as community health workers or lay health advisors, peer workers come from the same community and/or background as patients. Peer workers have been matched to patients on the basis of ethnicity, gender, sexual orientation, substance abuse history, or past homelessness. Peers utilize shared experiences as a resource for helping their patient-clients, and they have credibility with patients because they share reference groups and have faced the same issues and constraints in terms of treatment. Peer workers who themselves have completed treatment have proven particularly effective in TB studies.[25,26,104] Peer workers for LTBI programs may have been treated for active TB disease or for LTBI. Capacities in which peers can effectively promote adherence to LTBI treatment include: health education, case management, patient navigation or liaison, and outreach. Studies of peer support for various disease treatments have demonstrated their effectiveness in improving medication adherence and appointment keeping.[91,107,108]

Roles of Peer Workers
• Help patients navigate the health care system
• Facilitate access to social and community services needed for successful treatment completion
• Improve patient-provider communication by relaying medical information in terms that patients understand
• Make health care providers aware of specific barriers to communication
• Assist patients in accomplishing treatment-related tasks
• Cultivate "helping relationships" that bond patient and peer in a uniquely personal alliance for health-promoting behaviors

Peer workers are especially valuable members of an interdisciplinary adherence support team. Peers come to the team with a sense of how patients experience LTBI treatment and adherence, and may be better able than professionals to perceive misunderstandings and barriers to provider-client communication. Because their interactions with clients are based on empathy and shared experiences and because they frequently have more open access to clients, peer workers may glean more information about actual and potential challenges to adherence than do professional team members. For the same reasons, peer team members may also communicate the team's messages to clients most effectively.

Social Support for Patient Families

When appropriate, education on TB/LTBI, LTBI treatment, and adherence should be offered to patient family members, so that they may understand the treatment and assist the patient in being adherent.

Social Support Provided in Group Settings

Group activities provide an opportunity for patients to receive social support from other patients and also generate social reinforcement for treatment adherence. The use of groups, therefore, can extend beyond a specific purpose such as health education. Patients can discuss the difficulties of LTBI treatment and sustaining adherence to treatment. By discussing any frustrations, doubts, and fears openly, they can receive support and advice from other patients who have overcome similar problems. Group activities are more likely to generate social support and reinforcement when they are freely offered to patients on treatment – but not required. Enablers, such as carfare, refreshments, and child support should accompany group activities to the extent possible. Groups are also a good setting in which to publicly recognize when patients have met certain goals. Gifts and citations can be presented each month to patients with improved adherence. All patients who complete LTBI treatment should be offered an opportunity to celebrate their achievement.

In addition, providing opportunities for patients to give recognition to program staff, such as a certificate for the 'staff member of the month' elected by patients, can highlight the principle that adherence results from a therapeutic alliance between patients and health care providers.

Support Groups

Support groups provide a venue for addressing psycho/social issues surrounding the LTBI diagnosis and treatment and for cultivating social support for adherence. Participation in support groups has the potential to mitigate the stigma associated with TB and LTBI common among certain populations, as it brings people together with a shared diagnosis in a respectful, nurturing environment. The group provides a safe forum for discussion of individual problems, and can help to reduce isolation, promote socialization, and increase problem-solving abilities. Depending on the age of patient, it may be more appropriate to involve both patients and their families in group sessions. Support groups can serve as a forum for patients and patient families to voice frustrations and concerns about TB/LTBI treatment, and to cultivate a shared commitment to completion of treatment.

Support groups can also be an effective setting for TB education, as long as the goal is to elicit wide participation and open discussion, rather than to cover a predetermined curriculum. Important topics for discussion include the difference between TB/LTBI, how TB is transmitted, and patient perspectives on diagnosis and treatment. The table below outlines key considerations for establishing a support group.[109]

Starting a Support Group
Criteria for membership
• Diagnosis with TB or LTBI
• Willing to perform group tasks and follow group guidelines
Exclusion Criteria
• Behavioral problems incompatible with group norms
• Inability to tolerate group setting
• Unwillingness to disclose TB or LTBI diagnosis
• Friction with one or more group members
Tasks of Group Facilitator
• Determine setting and group size
• Obtain permission of program staff
• Select, if needed, a co-facilitator
• Formulate guidelines and goals
• Identify and invite appropriate group members
• Meet with potential group members to prepare them for group work
• Build a group's "culture", i.e. a safe place for members to speak
• Identify common problems and barriers
• Direct problem-solving mechanisms
• Schedule specific activities and guest speakers
• Determine the use of enablers/incentives
• Maintain group confidentiality

In TB/LTBI support groups, certain potentially sensitive issues will arise. The group leader must create a safe environment and use his/her skills to focus the group on its supportive nature, and to redirect group dynamics if one or more participants make judgmental or confrontational statements.

4. Improving Adherence among Children and Adolescents

Treatment for LTBI is recommended for pediatric patients because their infection is more likely to have been recent and thus more likely to progress to active TB disease. Because their immune systems are not fully developed, children under 5 years of age with LTBI are particularly vulnerable to developing TB disease, as compared to healthy adults and school-aged children.[110] Adolescents are at an increased risk for progression to active disease because of physiologic changes that accompany adolescent development.[111]

Parental supervision and guidance of children in the performance of health behaviors is crucial. Shared family responsibility of treatment tasks and continuous reinforcement appear to be important factors in the enhancement of adherence to treatment in pediatric patients. In addition to parental supervision, behavioral techniques designed for children, such as goal setting, cueing, and rewards or tokens, have been found to improve adherence in the school-age population.

Involvement of multiple individuals in a child or adolescent's treatment regimen can create additional challenges to their adherence and completion of treatment. Children and adolescents should not be solely responsible for adherence. A parent, caregiver, or older sibling could assume this supportive role. Even with adolescents, parental involvement has been recognized as an important factor in adherence. Parents/caregivers can take on vital roles by providing support for children, observing and mandating adherence, and monitoring adverse health outcomes. However the reverse is also true: negative attitudes or beliefs held by parents/caregivers about LTBI treatment, and lack of understanding of the importance and proper administration of LTBI treatment can result in poor adherence to the medications by their children. Studies on LTBI and other illnesses show that a child's adherence to medications is associated with the degree of parental involvement and understanding about the disease and the complexity of the treatment regimen.[112-115]

Giving parents/caregivers the proper tools and techniques to administer medications can also improve LTBI adherence. Many parents/caregivers experience difficulty in administering medications to young children.[90] Parents may become frustrated with the duration of treatment and the daily struggle of administering medications to their child. Recognizing this issue as a potential barrier to adherence and completion, program staff and clinicians can educate parents/caregivers and demonstrate or recommend successful techniques to give medications to young children. Program staff can also provide encouragement and support to help parents/caregivers ensure that children continue and complete the entire treatment regimen.

Although adolescents are able to administer their own medications, active involvement of parents/caregivers in adolescents' medical treatment is still important and has been associated with better outcomes.[48] One effective strategy is to have parents/caregivers and children agree on a particular incentive for adherence, such as a family outing or a gift, awarded in the first few months of treatment and again upon completion. Because adolescents are sensitive to peer influences, they may benefit from peer support for adherence to treatment.[116] One recent study of adolescents prescribed treatment for LTBI found that peer counseling was associated with higher self-esteem and sense of mastery, characteristics which in turn were associated with treatment completion.[117]

IV. PROGRAM EVALUATION

Systematic program evaluation is increasingly recognized as an important component of all health care activities. Incorporating evaluation strategies into planning for programs serves three valuable purposes. Evaluation helps to ensure that the program is implemented according to design. It can also be used to determine the effect of a program on targeted outcomes, such as adherence and completion rates. Finally, an evaluation can assess program acceptability among patients and parents/caregivers. Each of these three dimensions of evaluation generates unique information.

- **Process evaluation** is systematic tracking of program activities and all aspects of service delivery. Monitoring and assessment of program implementation can inform strategies for quality assurance and improvement, and also provide evidence to explain the outcomes achieved.
- **Outcome evaluation**, or assessment of a program's adherence and completion rate-related effects, provides justification for funding, technical assistance, and community and organizational support.
- **Assessment of patient satisfaction** can be conducted in a variety of ways, from a brief anonymous survey completed by patients to a longer questionnaire completed with an interviewer or by computer. As part of continuous quality improvement initiatives, feedback from patients can be incorporated into program modifications and helps to ensure that patient needs are met.

A comprehensive evaluation plan of a program to enhance adherence and completion of LTBI treatment would incorporate these three dimensions into a comprehensive evaluation plan. The following overview covers all three, although time and financial constraints may dictate a focus on only one dimension or two.

A. EVALUATION CRITERIA

Several guides to effective program evaluation exist, including handbooks for U.S. HIV/AIDS programs and international initiatives, and the Centers for Disease Control and Prevention's (CDC) 'Framework for Program Evaluation in Public Health'.[118,119] These resources identify criteria for program evaluation that is at once useful, cost-conscious, scientifically and ethically sound, and practical within existing program constraints.

Criteria for Designing a Program Evaluation
• **Utility:** The evaluation addresses the needs of its targeted audience in terms of its actual content, the timeliness of its findings, and follow-up steps.
• **Feasibility:** Design is realistic within the financial, political, and practical constraints of its setting, and represents an efficient use of resources.
• **Propriety:** Applicable legal and ethical guidelines are followed to safeguard the welfare of all those directly or indirectly involved.
• **Accuracy:** Design, conduct, analysis, and conclusions of the evaluation adequately address the program features that impact on the outcomes being evaluated.

These criteria should inform each step of a program evaluation, from defining its objectives to incorporating its results. Ideally, the evaluation steps will progress in conjunction with program planning and implementation, although each program must adjust its evaluation to its own constraints and opportunities.

B. EVALUATION STEPS

Define Evaluation Goals

The first step in evaluation is discussion among representatives of interested parties, including those who will carry out the evaluation as well as those affected by its results. Full discussion among providers and program staff, a patient's family members, community representatives, and others will lead to a common understanding of the evaluation's purpose and goals.

Objectives	Considerations
• Review reasons for evaluation	• Utilize information from preliminary needs assessment, if done
• Clarify expected utility of evaluation	• Obtain input from all interested parties (providers, staff, parents/caregivers, community groups)
• Specify results to be obtained	
• Identify target audience for evaluation results	

Assess Evaluation Readiness

Becoming familiar with the basics of evaluation and assessing available resources will help to design a feasible evaluation that does not overtax program resources.

Objectives	Considerations
• Identify individual(s) responsible for overseeing the evaluation	• All groups affected by evaluation should have a voice in its design
• Become familiar with evaluation concepts and terminology	• Utilize available evaluation-related technical assistance and trainings
• Assess resources for collecting patient-level data and tracking service delivery	• Plan for database to track key indicators, e.g. adherence, completion of treatment, and use of program services

Design an Evaluation Plan

The next step is to formulate evaluation questions, variables, and indicators based on the defined evaluation goals. For process evaluation, the United Way of America's Logic Model presents one easily adapted framework for distinguishing among key variables to be monitored.[120]

These key variables are:

- **Inputs**, including staff and other resources dedicated to the program.
- **Activities** related to program services, ranging from medical evaluations for LTBI to case management meetings to record keeping.
- **Outputs** or results of program activities, such as follow-up visits completed or missed, prescriptions of medication to treat LTBI, adherence tools provided, or medication calendars filled in at home and reviewed during clinic visits.

For an evaluation of outcomes, appropriate outcome indicators include those that are **immediate**, such as patient flow during clinic hours; **intermediate**, such as adherence as measured at monthly clinic visits; and **long-term**, such as completion of treatment. Process indicators, as well as outcome indicators, should be included in an assessment of patient and parent/caregiver satisfaction upon exiting the program. Sample constructions of logic models can be found on the United Way website's Outcome Measurement Resource Network page at www.unitedway.org. See Appendix E for an example of a program acceptability survey to be administered to patients.

Objectives	Considerations
• Formulate evaluation questions related to program implementation, outcomes, and/or acceptance	• Link questions to testable hypotheses about program operations (process) or impact (outcome)
• Identify study design, variables, and related indicators	• A sample of patients and parents/caregivers and/or a limited time period may be selected for evaluation
• Select data collection methods; create forms to document program implementation as necessary	• Define data collection protocol, personnel, and timeline
	• In some cases, open-ended interviews may be preferable to structured instruments

Collect and Analyze Data

Even standardized instruments and data collection forms should be pre-tested for clarity, respondent acceptability, and ease of use. Evaluation experts may be approached for feedback on instruments and tools. Evaluation staff should carefully review the protocol and guidelines for the ethical conduct of research on human subjects, including minors. Regular monitoring of data collection and entry is essential to detect missing data and errors in time to correct them.

Objectives	Considerations
• Pilot the evaluation instruments prior to beginning evaluation	• Select a sample of subjects or similar population to pre-test instruments; practice using forms to document program services
• Monitor process to ensure quality control	• Qualitative data can be analyzed using appropriate software and coding techniques that rely on inter-rater concordance to establish reliability
• Enter data in database	
• Periodically check entered data for accuracy and correct errors promptly	
• Analyze data to answer evaluation questions and test hypotheses	

Develop and Disseminate Conclusions

Evaluation findings can have implications for program management, planning, and funding. Even when evaluation results appear to be straightforward, evaluators may want to engage service providers, patients and parents/caregivers in discussions about the significance of the findings, possible explanations for the results, and what conclusions should be drawn from them.

Objectives	Considerations
• Highlight implications for program improvement and planning	• Conclusions should explain the limitations of the evaluation
• Disseminate to audiences targeted in first step of evaluation	• Share results with interested parties who helped to formulate original evaluation goals
• Develop criteria for next steps based on evaluation findings	

V. CONCLUSION

More effective and culturally competent LTBI programs need to be developed to meet the Healthy People 2010 objective for 85% treatment completion rates for LTBI, and to improve the sub-optimal completion rates reported nationwide. LTBI programs are better equipped to develop effective, culturally competent interventions to improve adherence to treatment and completion rates to the extent that staff members understand their patient population and can identify relevant barriers to adherence and treatment completion. Conducting a needs assessment, routinely measuring adherence, consistently employing tools for improving adherence and completion rates, and systematically evaluating a program are also crucial in the development of effective LTBI programs. Innovative approaches can inspire future interventions and provide responses to the challenges facing many programs and their patients. The effective treatment of LTBI is an essential step toward realizing the goal of TB elimination.

REFERENCES

1. World Health Organization, *Adherence to Long-term Therapies: Evidence for Action*. 2003, World Health Organization: Geneva, Switzerland.
2. Comstock, G.W., *How much isoniazid is needed for prevention of tuberculosis among immunocompetent adults?* Int J Tuberc Lung Dis, 1999. **3**(10): p. 847-50.
3. Paterson, D.L., et al., *Adherence to protease inhibitor therapy and outcomes in patients with HIV infection.* Ann Intern Med, 2000. **133**(1): p. 21-30.
4. Bangsberg, D.R., et al., *Non-adherence to highly active antiretroviral therapy predicts progression to AIDS.* Aids, 2001. **15**(9): p. 1181-3.
5. Krousel-Wood, M., et al., *Medication adherence: a key factor in achieving blood pressure control and good clinical outcomes in hypertensive patients.* Curr Opin Cardiol, 2004. **19**(4): p. 357-62.
6. Haynes, R.B., et al., *Interventions for helping patients to follow prescriptions for medications.* Cochrane Database Syst Rev, 2002(2): p. CD000011.
7. Haynes, R., *Introduction*, in *Compliance in Health Care*, R. Haynes, D. Taylor, and D. Sackett, Editors. 1979, Johns Hopkins University Press: Baltimore.
8. O'Brien, M.K., K. Petrie, and J. Raeburn, *Adherence to medication regimens: updating a complex medical issue.* Med Care Rev, 1992. **49**(4): p. 435-54.
9. Besch, C.L., *Compliance in clinical trials.* Aids, 1995. **9**(1): p. 1-10.
10. Sackett, D.L., et al., *Patient compliance with antihypertensive regimens.* Patient Couns Health Educ, 1978. **1**(1): p. 18-21.
11. Besch, C., et al. *Preliminary results of a compliance study with CPCRA 007 combination nucleoside study (NuCombo)*. in *4th Conference on Retroviruses and Opportunistic Infections*. 1997. Washington.
12. Stewart, R.B. and L.E. Cluff, *A review of medication errors and compliance in ambulant patients.* Clin Pharmacol Ther, 1972. **13**(4): p. 463-8.
13. Dunbar, J., *Predictors of patient adherence: patient characteristics*, in *The Handbook of Health Behavior Change*, S. Shumaker, E. Schron, and J. Ockene, Editors. 1990, Springer: New York. p. 348-360.
14. Haynes, R., *Determinants of compliance: The disease and the mechanics of treatment*, in *Compliance in Health Care*, R. Haynes, D. Taylor, and D. Sackett, Editors. 1979, Johns Hopkins University Press: Baltimore.
15. Meichenbaum, D. and D. Turk, *Facilitating Treatment Adherence: A Practioner's Guidebook*. 1987, New York: Plenum Press.
16. Barnhoorn, F. and H. Adriaanse, *In search of factors responsible for noncompliance among tuberculosis patients in Wardha District, India [published erratum appears in Soc Sci Med 1992 Jun;34(11):ll].* Soc Sci Med, 1992. **34**(3): p. 291-306.
17. Alcabes, P., et al., *Compliance with isoniazid prophylaxis in jail.* Am Rev Respir Dis, 1989. **140**(5): p. 1194-7.
18. Menzies, R., I. Rocher, and B. Vissandjee, *Factors associated with compliance in treatment of tuberculosis.* Tuber Lung Dis, 1993. **74**(1): p. 32-7.
19. Janz, N.K. and M.H. Becker, *The Health Belief Model: a decade later.* Health Educ Q, 1984. **11**(1): p. 1-47.
20. Becker, M., *The health belief model and personal behavior.* Health Educ Monogr, 1974. **1**: p. 324-508.
21. McCallum R et. al., *Effects of previous medication experience and health beliefs on intended compliance to an imagined regimen.* Journal of Compliance in Health Care, 1988. **3**: p. 125-134.
22. Eraker, S.A., J.P. Kirscht, and M.H. Becker, *Understanding and improving patient compliance.* Ann Intern Med, 1984. **100**(2): p. 258-68.
23. Gordillo, V., et al., *Sociodemographic and psychological variables influencing adherence to antiretroviral therapy.* Aids, 1999. **13**(13): p. 1763-9.

24. Catz, S.L., et al., *Patterns, correlates, and barriers to medication adherence among persons prescribed new treatments for HIV disease.* Health Psychol, 2000. **19**(2): p. 124-33.

25. Rideout, M. and R. Menzies, *Factors affecting compliance with preventive treatment for tuberculosis at Mistassini Lake, Quebec, Canada.* Clin Invest Med, 1994. **17**(1): p. 31-6.

26. Rubel, A.J. and L.C. Garro, *Social and cultural factors in the successful control of tuberculosis.* Public Health Rep, 1992. **107**(6): p. 626-36.

27. Bailey, E.J., *An ethnomedical analysis of hypertension among Detroit Afro-Americans.* J Natl Med Assoc, 1988. **80**(10): p. 1105-12.

28. Bartlett, E.E., et al., *The effects of physician communications skills on patient satisfaction; recall, and adherence.* J Chronic Dis, 1984. **37**(9-10): p. 755-64.

29. Sbarbaro, J.A., *The patient-physician relationship: compliance revisited.* Ann Allergy, 1990. **64**(4): p. 325-31.

30. Clark, N.M., et al., *Impact of education for physicians on patient outcomes.* Pediatrics, 1998. **101**(5): p. 831-6.

31. Clark, N.M., et al., *Long-term effects of asthma education for physicians on patient satisfaction and use of health services.* Eur Respir J, 2000. **16**(1): p. 15-21.

32. Stewart, M.A., *Effective physician-patient communication and health outcomes: a review.* Canadian Medical Association Journal, 1995. **152**(9): p. 1423-33.

33. Mead, N. and P. Bower, *Patient-centred consultations and outcomes in primary care: a review of the literature.* Patient Educ Couns, 2002. **48**(1): p. 51-61.

34. Korsch, B.M. and V.F. Negrete, *Doctor-patient communication.* Sci Am, 1972. **227**(2): p. 66-74.

35. McIntosh, J., *Processes of communication, information seeking and control associated with cancer: A selective review of the literature.* Soc Sci Med, 1974. **8**(4): p. 167-87.

36. Orr, P.R., D.W. Blackhurst, and B.S. Hawkins, *Patient and clinic factors predictive of missed visits and inactive status in a multicenter clinical trial. The Macular Photocoagulation Study Group.* Control Clin Trials, 1992. **13**(1): p. 40-9.

37. Cramer, J., *Overview of methods to measure and enhance patient compliance*, in *Patient compliance in medical practice and clinical trials*, J. Cramer and B. Spiker, Editors. 1991, Raven Press: New York. p. 3-10.

38. Blackwell, B., *The drug regimen and treatment compliance*, in *Compliance in Health Care*, R. Haynes, D. Taylor, and D. Sackett, Editors. 1979, Johns Hopkins University Press: Baltimore.

39. Cramer, J.A., *Medication compliance in epilepsy.* Arch Intern Med, 1991. **151**(6): p. 1236-7.

40. Stone, V.E., et al., *Perspectives on Adherence and Simplicity for HIV-Infected Patients on Antiretroviral Therapy: Self-Report of the Relative Importance of Multiple Attributes of Highly Active Antiretroviral Therapy (HAART) Regimens in Predicting Adherence.* J Acquir Immune Defic Syndr, 2004. **36**(3): p. 808-816.

41. Bond, W.S. and D.A. Hussar, *Detection methods and strategies for improving medication compliance.* Am J Hosp Pharm, 1991. **48**(9): p. 1978-88.

42. Eisen, S.A., et al., *The effect of prescribed daily dose frequency on patient medication compliance.* Arch Intern Med, 1990. **150**(9): p. 1881-4.

43. Arnsten, J., et al. *Adherence and Viral Load in HIV-Infected Drug Users: Comparison of Self-Report and Medication Event Monitors (MEMS)*. in *7th Conference on Retroviruses and Opportunistic Infections*. February 2000. San Francisco, CA.

44. Norell, S.E., *Improving medication compliance: a randomised clinical trial.* Br Med J, 1979. **2**(6197): p. 1031-3.

45. Singh, N., et al., *Determinants of compliance with antiretroviral therapy in patients with human immunodeficiency virus: prospective assessment with implications for enhancing compliance.* AIDS Care, 1996. **8**(3): p. 261-9.

46. Caldwell, J.R., et al., *The dropout problem in antihypertensive treatment. A pilot study of social and emotional factors influencing a patient's ability to follow antihypertensive treatment.* J Chronic Dis, 1970. **22**(8): p. 579-92.

47. Hovell, M.F., et al., *Increasing Latino adolescents' adherence to treatment for latent tuberculosis infection: a controlled trial.* Am J Public Health, 2003. **93**(11): p. 1871-7.

48. DiMatteo, M.R., *The role of effective communication with children and their families in fostering adherence to pediatric regimens.* Patient Education and Counseling, 2004. **55**(3): p. 339.

49. Healthy People 2010 Objectives. *http://www.healthypeople.gove/documents/html/objectives/14-13.htm.* [cited 2005 June 13].

50. Horsburgh, C.R., Jr., *Priorities for the treatment of latent tuberculosis infection in the United States.* N Engl J Med, 2004. **350**(20): p. 2060-7.

51. World Health Organization, *Global Tuberculosis Control*. 1999, World Health Organization.

52. Chaulk, C.P. and V.A. Kazandjian, *Directly observed therapy for treatment completion of pulmonary tuberculosis: Consensus Statement of the Public Health Tuberculosis Guidelines Panel.* Jama, 1998. **279**(12): p. 943-8.

53. Bayer, R., et al., *Directly observed therapy and treatment completion for tuberculosis in the United States: Is universal supervised therapy necessary?* American Journal of Public Health, 1998. **88**(7): p. 1052-58.

54. Moulding, T., *Medication monitors to treat tuberculosis. A supplement to directly observed therapy.* American Journal of Respiratory and Critical Care, 1999. **159**(3): p. 989-91.

55. Moulding, T., A. Dutt, and L. Reichman, *Fixed-dose combinations of antituberculosis medications to prevent drug resistance.* Annals of Internal Medicine, 1995. **122**: p. 951-54.

56. Marks, S.M., et al., *Outcomes of contact investigations of infectious tuberculosis patients.* Am J Respir Crit Care Med, 2000. **162**(6): p. 2033-8.

57. Bureau of Tuberculosis Control, N.Y.C.D.o.H.a.M.H., *Tuberculosis in New York City, 2003: Information Summary*. 2004, New York City Department of Health.

58. Goldberg, S.V., et al., *Cultural case management of latent tuberculosis infection.* Int J Tuberc Lung Dis, 2004. **8**(1): p. 76-82.

59. Reichler, M.R., et al., *Treatment of latent tuberculosis infection in contacts of new tuberculosis cases in the United States.* South Med J, 2002. **95**(4): p. 414-20.

60. LoBue, P.A. and K.S. Moser, *Use of isoniazid for latent tuberculosis infection in a public health clinic.* Am J Respir Crit Care Med, 2003. **168**(4): p. 443-7.

61. Gilroy, S.A., M.A. Rogers, and D.C. Blair, *Treatment of latent tuberculosis infection in patients aged > or =35 years.* Clin Infect Dis, 2000. **31**(3): p. 826-9.

62. Coly, A. and D. Morisky, *Predicting completion of treatment among foreign-born adolescents treated for latent tuberculosis infection in Los Angeles.* Int J Tuberc Lung Dis, 2004. **8**(6): p. 703-10.

63. White, M.C., et al., *Randomized controlled trial of interventions to improve follow-up for latent tuberculosis infection after release from jail.* Arch Intern Med, 2002. **162**(9): p. 1044-50.

64. Ailinger, R.L. and M.R. Dear, *Adherence to tuberculosis preventive therapy among Latino immigrants.* Public Health Nurs, 1998. **15**(1): p. 19-24.

65. Salabarria-Pena, Y., et al., *Effects of acculturation and psychosocial factors in Latino adolescents' TB-related behaviors.* Ethn Dis, 2001. **11**(4): p. 661-75.

66. Codecasa, L.R. and G. Besozzi, *Acceptance of isoniazid preventive treatment by close contacts of tuberculosis cases: a 692-subject Italian study.* Int J Tuberc Lung Dis, 1998. **2**(3): p. 208-12.

67. American Thoracic Society and Centers for Disease Control and Prevention, *Targeted tuberculin testing and treatment of latent tuberculosis infection.* Am J Respir Crit Care Med, 2000. **161**: p. S221-S247.

68. DiMatteo, M.R., *Enhancing patient adherence to medical recommendations.* Jama, 1994. **271**(1): p. 79, 83.

69. Bayer, R. and D. Wllkinson, *Directly observed therapy for tuberculosis: History of an idea.* Lancet, 1995. **345**: p. 1545-48.

70. Carrion, P.G., et al., *Compliance with clinic attendance by outpatients with schizophrenia.* Hosp Community Psychiatry, 1993. **44**(8): p. 764-7.

71. Fletcher, S., E. Pappius, and S. Harper, *Measurement of medication compliance in a clinical setting.* Arch Intern Med, 1979. **139**: p. 635-38.

72. Pullar, T., et al., *Time to stop counting tablets?* Clinical Pharmacological Therapeutics, 1989. **46**: p. 163-68.

73. Arnsten, J.H., et al., *Antiretroviral therapy adherence and viral suppression in HIV-infected drug users: comparison of self-report and electronic monitoring.* Clin Infect Dis, 2001. **33**(8): p. 1417-23.

74. Fos, P.J., et al., *The role of quality improvement in disease management: a statewide tuberculosis control success story.* J Public Health Manag Pract, 2005. **11**(3): p. 222-7.

75. Phillips, L., *Tuberculosis infection in Missouri.* Missouri Epidemiologist, 1997. **19**(4): p. 16-17.

76. Roter, D.L., et al., *Effectiveness of interventions to improve patient compliance: a meta- analysis.* Med Care, 1998. **36**(8): p. 1138-61.

77. Bakken, S., et al., *Relationships between perception of engagement with health care provider and demographic characteristics, health status, and adherence to therapeutic regimen in persons with HIV/AIDS.* AIDS Patient Care STDS, 2000. **14**(4): p. 189-97.

78. Roter, D.L., *Observations on methodological and measurement challenges in the assessment of communication during medical exchanges.* Patient Educ Couns, 2003. **50**(1): p. 17-21.

79. Ingersoll, K.S. and C.J. Heckman, *Patient-clinician relationships and treatment system effects on HIV medication adherence.* AIDS Behav, 2005. **9**(1): p. 89-101.

80. Makoul, G., *Essential elements of communication in medical encounters: the Kalamazoo consensus statement.* Acad Med, 2001. **76**(4): p. 390-3.

81. Schirmer, J.M., et al., *Assessing communication competence: a review of current tools.* Fam Med, 2005. **37**(3): p. 184-92.

82. Staker, L.V., *Changing clinical practice by improving systems: the pursuit of clinical excellence through practice-based measurement for learning and improvement.* Qual Manag Health Care, 2000. **9**(1): p. 1-13.

83. Fisher, J.D. and W.A. Fisher, *The Informational-Motivational-Behavioral Skills Model*, in *Emerging Theories in Health Promotion Practice and Research: Strategies for Improving Public Health*, R.J. DiClemente, R.A. Crosby, and M.C. Kegler, Editors. 2002, Jossey-Bass: San Francisco. p. 40-70.

84. Fisher, J.D., et al., *Changing AIDS risk behavior: effects of an intervention emphasizing AIDS risk reduction information, motivation, and behavioral skills in a college student population.* Health Psychol, 1996. **15**(2): p. 114-23.

85. Fisher, J.D., et al., *Empirical tests of an information-motivation-behavioral skills model of AIDS-preventive behavior with gay men and heterosexual university students.* Health Psychol, 1994. **13**(3): p. 238-50.

86. Kalichman, S.C., et al., *Experimental components analysis of brief theory-based HIV/AIDS risk-reduction counseling for sexually transmitted infection patients.* Health Psychol, 2005. **24**(2): p. 198-208.

87. Fisher, J.D., *The IMB model of adherence. Invited presentation at the First International Workshop on the Informational-Motivational-Behavioral Skills Model*. 2000: Naples, Italy.

88. Cabrera, D.M., D.E. Morisky, and S. Chin, *Development of a tuberculosis education booklet for Latino immigrant patients.* Patient Educ Couns, 2002. **46**(2): p. 117-24.

89. Buchanan, R., *Compliance with tuberculosis drug regimens: incentives and enablers offered by public health regimens.* Am Journal of Public Health, 1997. **87**: p. 2014-17.

90. Charles P. Felton National Tuberculosis Center, *Improving Completion Rates for Treatment of Latent TB Infection in Children and Adolescents*. 2004.

91. El-Sadr, W., F. Medard, and M. Dickerson, *The Harlem family model: a unique approach to the treatment of tuberculosis.* J Public Health Manag Pract, 1995. **1**(4): p. 48-51.

92. Vlasnik, J.J., S.L. Aliotta, and B. DeLor, *Evidence-based assessment and intervention strategies to increase adherence to prescribed medication plans.* The Case Manager, 2005. **16**(2): p. 55.

93. Chaisson, R., et al., *A Randomized, Controlled Trial of Interventions to Improve Adherence to Isoniazid Therapy to Prevent Tuberculosis in Injection Drug Users.* American Journal of Medicine, 2001. **110**: p. 610-615.

94. Moore, R.D., et al., *Cost-effectiveness of directly observed versus self-administered therapy for tuberculosis.* Am J Respir Crit Care Med, 1996. **154**(4 Pt 1): p. 1013-9.

95. Centers for Disease Control and Prevention, *Tuberculosis elimination revisited: obstacles, opportunities, and a renewed commitment.* 1999, Advisory Committe for the Elimination of Tuberculosis. MMWR.: Atlanta. p. 7-8.

96. El-Sadr, W., et al., *Directly observed therapy for tuberculosis: the Harlem Hospital experience, 1993 [published erratum appears in Am J Public Health 1997 Feb;87(2):168].* Am J Public Health, 1996. **86**(8 Pt 1): p. 1146-9.

97. Chaulk, C.P., et al., *Eleven years of community-based directly observed therapy for tuberculosis.* Jama, 1995. **274**(12): p. 945-51.

98. Schluger, N., et al., *Comprehensive tuberculosis control for patients at high risk for noncompliance.* Am J Respir Crit Care Med, 1995. **151**(5): p. 1486-90.

99. Bayer, R., N. Dubler, and S. Landesman, *The dual epidemics of tuberculosis and AIDS: ethical and policy issues in screening and treatment.* Am J of Public Health, 1993. **83**(5): p. 649-54.

100. Bayer, R. and L. Dupuis, *Tuberculosis, public health, and civil liberties.* Annual Review of Public Health, 1995. **16**: p. 307-26.

101. Cramer, J.A., *Optimizing long-term patient compliance.* Neurology, 1995. **45**(2 Suppl 1): p. S25-8.

102. Rosen, M.I., et al., *Electronic monitoring and counseling to improve medication adherence.* Behaviour Research and Therapy, 2004. **42**(4): p. 409.

103. Chaisson, R.E., et al., *A randomized, controlled trial of interventions to improve adherence to isoniazid therapy to prevent tuberculosis in injection drug users.* Am J Med, 2001. **110**(8): p. 610-5.

104. El-Sadr, W., et al. *Effectiveness Of Peer Workers In A Treatment Program For Latent TB Infection.* in *2001 International Conference of the American Thoracic Society*. 2001. San Francisco, CA.

105. DiMatteo, R., *Social support and patient adherence to medical treatment: A meta-analysis.* Health Psychology, 2004. **23**(2): p. 207-218.

106. Heaney, C.A. and B.A. Israel, *Social networks and social support*, in *Health Behavior and Health Education*, K. Glanz, F. Lewis, and B. Rimer, Editors. 2002, Jossey-Bass: San Francisco, CA.

107. Witmer, A., et al., *Community health workers: integral members of the health care work force.* Am J Public Health, 1995. **85**(8 Pt 1): p. 1055-8.

108. Broadhead, R., D. Heckathorn, and F. Altice, *Increasing drug users' adherence to HIV treatment. Results of a peer-driven intervention feasibility study.* Social Science & Medicine, 2002. **55**(2): p. 235-36.

109. Charles P. Felton National Tuberculosis Center, *Social Services for Tuberculosis Clients*. 1999.

110. Ampofo, K.K. and L. Saiman, *Pediatric tuberculosis.* Pediatr Ann, 2002. **31**(2): p. 98-108.

111. Smith, M.H., *Tuberculosis in adolescents: characteristics, recognition, management.* Clin Pediatr (Phila), 1967. **6**(1): p. 9-15.

112. Magyary, D. and P. Brandt, *A school-based self-management program for youth with chronic health conditions and their parents.* Can J Nurs Res, 1996. **28**(4): p. 57-77.

113. Lemanek, K.L., J. Kamps, and N.B. Chung, *Empirically supported treatments in pediatric psychology: regimen adherence.* J Pediatr Psychol, 2001. **26**(5): p. 253-75.

114. Farley, J., et al., *Assessment of adherence to antiviral therapy in HIV-infected children using the Medication Event Monitoring System, pharmacy refill, provider assessment, caregiver self-report, and appointment keeping.* J Acquir Immune Defic Syndr, 2003. **33**(2): p. 211-8.

115. Bender, B.G., *Overcoming barriers to nonadherence in asthma treatment.* J Allergy Clin Immunol, 2002. **109**(6 Suppl): p. S554-9.

116. La Greca, A.M., K.J. Bearman, and H. Moore, *Peer relations of youth with pediatric conditions and health risks: promoting social support and healthy lifestyles.* J Dev Behav Pediatr, 2002. **23**(4): p. 271-80.

117. Morisky, D.E., et al., *Behavioral interventions for the control of tuberculosis among adolescents.* Public Health Rep, 2001. **116**(6): p. 568-74.

118. Health Resources and Service Administration HIV/AIDS Bureau, *A Practical Guide to Evaluation and Evaluation Terms for Ryan White CARE Act Grantees*. 1999: Washington, DC.

119. Centers for Disease Control and Prevention, *Framework for program evaluation in public health.* Morbidity and Mortality Weekly, 1999. **48**(RR-11).

120. United Way of America, *Measuring Program Outcomes: A Practical Approach*. 1996.

APPENDICES

A. ADHERENCE QUESTIONNAIRE

I'd like to ask you some questions to help us understand your experience with the TB medications you are taking.

Most people with TB infection have a few medications to take every day for many months. They find it hard to always remember their medications:

- Some get busy and forget to carry their medications with them.
- Some have many other medications to take and they are tired of it.
- Some decide to skip medications because they don't like how it makes them feel.

We need to understand how people with TB infection take their medications. So please tell us what you are really doing. Do not worry about telling us that you do not take all your medications. We need to know what is really happening, not what you think we "want to hear."

1. Where do you keep your medications? _____

2. When do you take your medications?
   a. morning
   b. afternoon
   c. evening
   d. at bed time

3. How do you take your medications?
   a. with food
   b. without food
   c. what else?

4. How do you remember to take your medications?
   a. family member reminds you
   b. keep medications visible
   c. incorporate to a specific daily routine (e.g., dinner, brushing teeth, etc.)
   d. other _____

5. How many pills did you miss . . .

TB Medicine	Yesterday	(B) Day before yesterday	(C) Day before that
INH			
RIF			
B6			
Other (specify)			

6. In the last 7 days, did you miss any of your TB medications?
   1 No
   0 Yes

6a. If yes, how many doses did you miss? _____

7. Why did you miss taking your medications? _____
   _____

8. Some people find that they forget to take their pills on the weekend days. Did you miss any of your anti-TB medications last weekend – last Saturday and Sunday?
   1 Yes
   0 No

Ask 9 only if no missed doses were reported in questions 5-8. Otherwise skip to question 10.

9. When was the last time you missed any of your TB medications?
   a. Within the past week
   b. 1-2 weeks ago
   c. 2-4 weeks ago
   d. More than one month ago
   e. Never missed medication

10. For clinic staff only: Did patient keep monthly appointment (came within one week before or after scheduled appointment)?
   1 Kept appointment (END)
   0 Missed appointment (CONTINUE)

11. Why did you miss your monthly clinic appointment?

INTERVIEWER:
DO NOT READ THIS LIST, JUST USE IT TO CODE ANSWERS TO QUESTIONS 7-11
Check "P" column for patient responses; "C" column for caregiver or parent responses

	P	C		P	C
1. didn't fit in your daily routine			2. didn't feel like taking them/coming in		
3. simply forgot			4. busy with school work		
5. were too busy/had other priorities			6. were away from home		
7. felt sick or ill			8. were hospitalized		
9. felt depressed or overwhelmed			10. had legal issues such as court cases		
11. were experiencing abuse/domestic violence			12. were working		
13. were caring for relatives			14. fell asleep/slept through dose time		
15. ran out of pills			16. didn't understand regimen		
17. too hard to take so many pills			18. didn't think the medicine was helping		
19. wanted to avoid side effects			20. felt like the drug was toxic/harmful		
21. had other appointments			22. fear of interactions with other meds		
23. were drunk or high			99. other		

B. RESOURCES ON CULTURAL COMPETENCY

A Guide to Planning and Implementing Cultural Competence Organizational Self-Assessment

The Georgetown University National Center for Cultural Competence is an important resource for learning about and accessing resources to develop culturally competent public health campaigns and programs. **Available from:** Georgetown University Center for Child and Human Development, National Center for Cultural Competence; http://www.georgetown.edu/research/gucdc/nccc/ncccorgselfassess.pdf

Assuring Cultural Competence in Health Care: Recommendations for National Standards an Outcomes-Focused Research Agenda

The U.S. Department of Health and Human Services provides a comprehensive outline and guidance for assuring cultural competence in health care. **Available from:** U.S. Department of Health and Human Services, Office of Minority Health; http://www.omhrc.gov/clas/index.htm

Compendium of Cultural Competence Initiatives in Health Care

The compendium describes the activities in which public and private sector organizations are involved in an effort to reduce cultural and communication barriers to health care. **Available from:** Henry J. Kaiser Family Foundation; http://www.kff.org/content/2003/6067/

Cultural Competence in Health Care: Emerging Frameworks and Practical Approaches

This final report from the Commonwealth Fund summarizes the guidelines for developing culturally competence in various health care settings. **Available from:** The Commonwealth Fund, New York, NY, October 2002; www.cmwf.org

Six Steps Toward Cultural Competence

A practical guide to help health care providers and others become more culturally competent that includes detailed community profiles to help providers learn more about specific cultural groups. **Available from:** Center for Cross Cultural Health; http://www.crosshealth.com/

TB Education and Training Network, Subcommittee on Cultural Competency

The Subcommittee comprises TB trainers, educators, and health care workers who are passionate about cultural competency and its applications to TB control activities. **Available from:** CDC, National Center for HIV, STD, and TB Prevention, Division of TB Elimination; http://www.cdc.gov/nchstp/tb/TBETN/

Why is Cultural Competence Important for Health Professionals?

This article provides insight into culturally competent practices targeting the individual health care professional. **Available from:** Diversity RX; http://www.diversityrx.org/HTML/MOCPT1.htm

C. NEEDS ASSESSMENT QUESTIONNAIRE

My name is _____ and I'm from the _____ . I'd like to talk to you about the Chest Clinic at _____ . This may be your first visit to this clinic or you may have been coming for a while. To improve the services that we provide for patients who attend this clinic, we would like to ask you a few questions and get your suggestions about what things might be done differently.

Interviewer: Indicate whether respondent is

- ❑ Patient
- ❑ Caregiver

First I'd like to ask you a few general questions.

1. Where were you (and your child) born?

2. What language do you speak at home?

3. Why are you here today?
   a. TB skin test planting
   b. TB skin test reading
   c. Treatment of TB disease
   d. Treatment of TB infection
   e. Was told to come since had contact with TB

4. Is this your first visit to this clinic?
   - ❑ Yes (SKIP TO Q8)
   - ❑ No

5. How long have you been coming to this clinic?
   - ❑ Number of months _____
   - ❑ Number of visits _____

6. So far what do you think about the monthly clinic visits?

   _____

   _____

   _____

7. What do you like/don't like about your monthly clinic visits?

	Like	Don't like
a) Physical layout /attractiveness/cleanliness		
b) Video/Brochure		
c) Refreshments/food		
d) Doctor/PA		
e) Nursing staff		
f) Clerical staff		
g) Food coupons/metro cards		
h) Clinic organization		
i) Length of wait for doctor visit		
j) Other (specify)		

8. When patients complete treatment for TB disease or infection we'd like to celebrate their achievement. What do you think would be an appropriate reward?
   a. Movie tickets
   b. Gift certificates
   c. Restaurants certificates
   d. Party
   e. Other (describe)_____

9. We are considering offering more refreshments in the waiting room. What refreshments would you be interested in? _____

10. Are the clinic hours convenient for you?
    ❑ Yes
    ❑ No
    If no, what hours would be better? _____

11. Do you like the available reading materials and videos in the waiting room?
    ❑ Yes
    ❑ No

12. Are you interested in watching educational videos in the waiting room?
    ❑ Yes
    ❑ No

13. Another idea we are considering is adding a health educator who would be available to speak to you and address different issues and concerns that you may have regarding TB and its treatment. Do you feel that having such a person in the clinic would be beneficial to you?
    ❑ Yes
    ❑ No

14. Do you have any suggestions on how we can improve our services to better serve your needs?

    _____

D. LTBI TREATMENT COMPLETION CARD

LATENT TUBERCULOSIS INFECTION TREATMENT COMPLETION CARD

Name: _____

Date of Birth: _____

TST Date: _____ Result: _____mm

X-Ray Date: _____ Result: ❑ Normal
❑ Abnormal: _____

Start Date: _____ Regimen:
❑ INH-5 Months ❑ RIF-4 months
❑ INH-6 Months ❑ Other: _____

Stop Date: _____ Stop Reason:
❑ Completed Treatment
❑ Medical Advice
❑ Transferred Care

❑ I certify that the above information regarding treatment for latent tuberculosis infection is correct.

Signature _____

Clinic Address Clinic Telephone

E. PROGRAM EVALUATION MATERIALS

PROGRAM ACCEPTABILITY QUESTIONNAIRE

As you have now completed your participation in this program, we would like to ask you a few questions. Please keep in mind that the following information will be kept confidential and will not be shared with the staff in the clinic.

1. Did you attend your monthly clinic visits?
   0 No ***(If No go to 1d)***
   1 Yes

1a. How many of these scheduled clinic visits did you attend?
   1 All
   2 Most
   3 Some
   4 Few

1b. Overall, how much did you like or dislike your monthly clinic visits?
   1 Disliked a lot
   2 Disliked
   3 Liked
   4 Liked a lot

1c. I am going to read you a list of statements about your clinic visits. Please rate each statement on a scale of 1 through 4. Mark "1" if you strongly disagree and "4" if strongly agree.

	Strongly Disagree	Disagree	Agree	Strongly Agree
Clinic setting was unattractive or not clean	1	2	3	4
Doctor/PA/NP was very helpful	1	2	3	4
Short wait and well organized	1	2	3	4
Nursing staff was rushed	1	2	3	4
Clinic hours were inconvenient	1	2	3	4
Video/Brochure were informative	1	2	3	4
Clerical staff was rude	1	2	3	4
Travel costs were taken care of with car fare slip	1	2	3	4
The clinic staff really cares	1	2	3	4

Skip to 2.

1d. If you did not attend the monthly clinic visits, why not? Please rate each statement on a scale of 1 through 4. Mark "1" if you strongly disagree and "4" if strongly agree.

	Strongly Disagree	Disagree	Agree	Strongly Agree
Did not feel it was necessary	1	2	3	4
No one told me it was important	1	2	3	4
I forgot	1	2	3	4
Did not get any reminders	1	2	3	4
Felt too sick	1	2	3	4
Had no money for transportation	1	2	3	4
Was too busy	1	2	3	4
Too depressing to see sick people	1	2	3	4
Wait too long to be seen	1	2	3	4
Staff is rude/inconsiderate	1	2	3	4
Other - please specify	1	2	3	4

Now, I will ask you questions about our LTBI program services

2a. Did you find the program services helpful?

0 No

1 Yes ***(skip to 2c)***

2b. Was anything helpful about the program?

_____

_____

_____

(skip to 2d)

2c. What aspects of the program services did you find helpful?

_____

_____

_____

2d. Next I'd like to ask you about our LTBI program staff. Please rate each item on a scale of 1 through 4. Mark "1" if you strongly disagree and "4" if strongly agree.

The program staff...	Strongly Disagree	Disagree	Agree	Strongly Agree
• helped you remember to take your medication	1	2	3	4
• had a positive attitude about TB	1	2	3	4
• provided good information on treatment	1	2	3	4
• did not respond to your needs	1	2	3	4
• was supportive and caring	1	2	3	4
• wasn't always available to talk	1	2	3	4
• spent enough time with you	1	2	3	4
• provided good information about side effects	1	2	3	4
• prepared a helpful medication chart	1	2	3	4
• did not provide referrals when needed ***(circle N/A if no referrals were necessary)***	1	2	3	4
• pestered you too often	1	2	3	4

2e. What was the ***most*** helpful part of the LTBI program?

_____

_____

_____

2f. What was the ***least*** helpful part of the LTBI program?

_____

_____

_____

Now, I'd like to ask you questions about your doctor.

3. I am going to read you a list of statements about your doctor. Please rate each statement on a scale of 1 through 4. Mark "1" if you strongly disagree and "4" if strongly agree.

Do you feel that your doctor...	Strongly Disagree	Disagree	Agree	Strongly Agree
• was always available to talk you	1	2	3	4
• did not spend enough time with you	1	2	3	4
• did not always return your phone calls	1	2	3	4
• had a positive attitude about preventing TB	1	2	3	4
• is very knowledgeable	1	2	3	4
• used too many medical terms	1	2	3	4
• was not very attentive - did not listen to you	1	2	3	4
• explained everything in a way which helped you understand	1	2	3	4
• did not make you feel comfortable about asking questions	1	2	3	4
• can be trusted	1	2	3	4

Next I'm going to ask you questions about the staff in the TB clinic.

4. I will first read you a list of statements about the **nursing** staff in the clinic. Please rate each statement on a scale of 1 through 4. Mark "1" if you strongly disagree and "4" if strongly agree.

Do you feel that the nursing staff in the clinic...	Strongly Disagree	Disagree	Agree	Strongly Agree
• was courteous	1	2	3	4
• spent enough time with you	1	2	3	4
• did not review medication instructions with you	1	2	3	4
• had a positive attitude about preventing TB	1	2	3	4
• is very knowledgeable	1	2	3	4
• was not very attentive - did not listen to you	1	2	3	4
• explained everything in a way which helped you understand	1	2	3	4
• did not make you feel comfortable about asking questions	1	2	3	4
• can be trusted	1	2	3	4
• used too many medical terms	1	2	3	4

5. I will now read you a list of statements about the **administrative** staff in the clinic. Please rate each statement on a scale of 1 through 4. Mark "1" if you strongly disagree and "4" if strongly agree.

Do you feel that the administrative staff in the clinic . . .	Strongly Disagree	Disagree	Agree	Strongly Agree
• tried to accommodate you	1	2	3	4
• was not courteous	1	2	3	4
• was friendly	1	2	3	4
• was helpful when you called on the phone	1	2	3	4

6. Do you have any suggestions that can help patients take their medication more regularly?

_____

_____

_____

We have come to the end of this interview. We would like to thank you for your participation. Your assistance has helped us to help others in completing LTBI treatment. Please remember everything you have said will remain confidential.

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