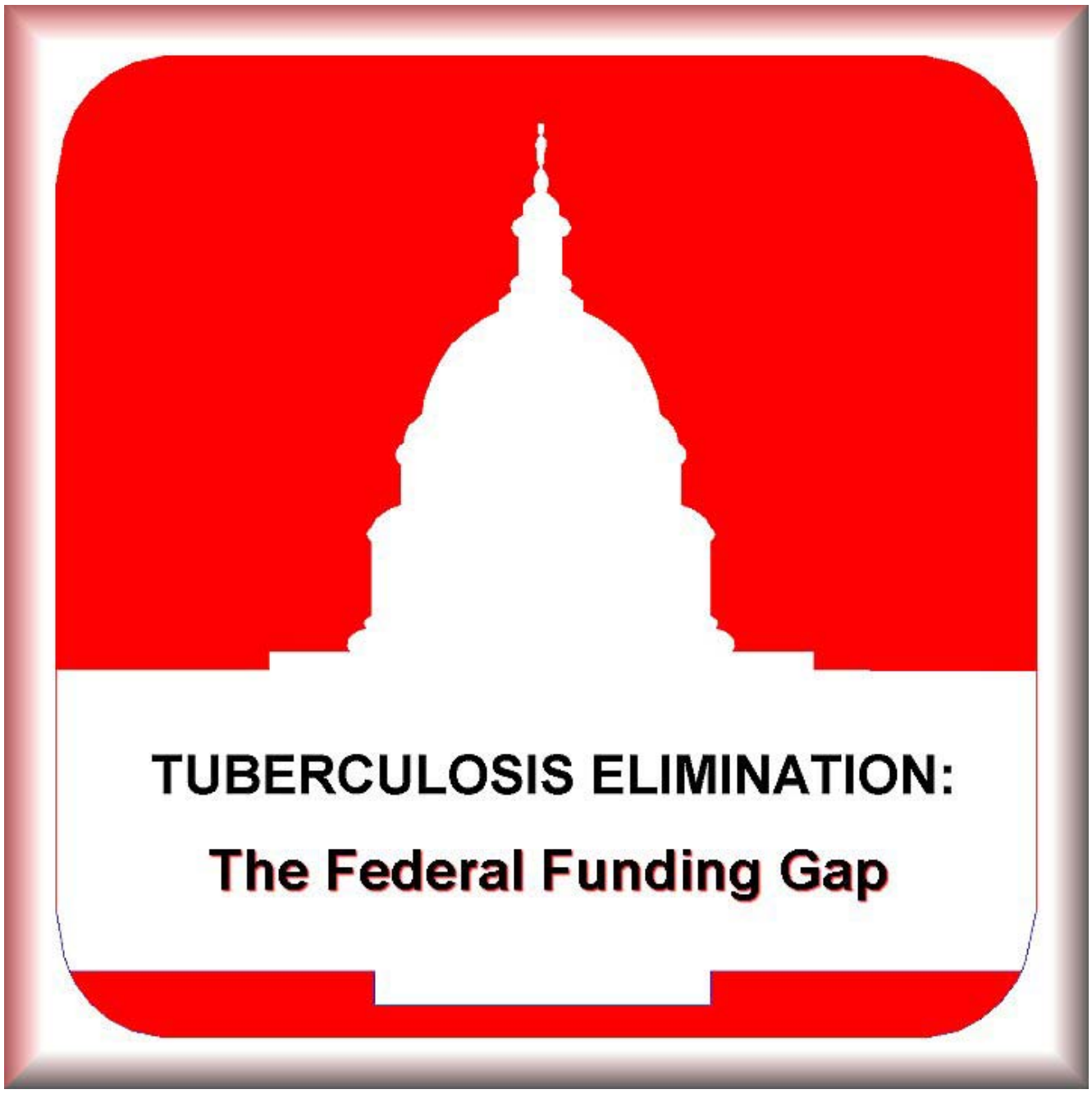


The National Coalition for Elimination of Tuberculosis
2004

NATIONAL COALITION FOR ELIMINATION OF TUBERCULOSIS

Founded in 1991, the National Coalition for the Elimination of Tuberculosis (NCET) is a coalition of national, state and local public health, medical professional, health care and service organizations. Members include:

AIDS Action Council
AIDS-SidAlert International
American Academy of Family Physicians
American Academy of Pediatrics
American Association for Continuity of Care
American Association for Respiratory Care
American Association for World Health
American College of Chest Physicians
American College of International Physicians, Inc.
American College of Physicians
American College of Preventive Medicine
American Correctional Health Services Association
American Federation of State, County and Municipal Employees
American Health Care Association
American Hospital Association
American Jail Association
American Lung Association
American Medical Association
American Nurses Association
American Public Health Association
American Society for Microbiology
American Thoracic Society
Asian American and Pacific Islander Health Forum
Association for Professionals in Infection Control and Epidemiology
Association of Asian Pacific Community Health Organizations
Association of Community Health Nursing Educators
Association of State and Territorial Directors of Nursing
Association of State and Territorial Health Officials
Charles P. Felton Model Tuberculosis Center
College of American Pathologists
Congress of National Black Churches
East Coast Migrant Health Project
Francis J. Curry National Tuberculosis Center
Infectious Diseases Society of America
Migrant Clinicians Network
National Association of Community Health Centers, Inc
National Association of County Health Officials
National Black Nurses' Association
National Coalition for the Homeless
National Commission on Correctional Health Care
National Council of La Raza
National Foundation for Infectious Diseases
National Health Care for the Homeless Council
National Leadership Coalition on AIDS
National Minority AIDS Council
National Public Health Information Coalition
National Rural Health Association
National Tuberculosis Controllers Association
National Tuberculosis Nurse Consultant Coalition
Pan American Health Organization
Project HOPE
Society for Hospital Epidemiology of America, Inc.

TB ELIMINATION: THE FEDERAL FUNDING GAP

A Report to Congress from the National Coalition For Elimination of Tuberculosis

"We are at a critical juncture. On the one hand, control of tuberculosis in the United States has been regained and we are at an all time low in the number of cases. On the other hand, we are now particularly vulnerable to complacency and neglect that comes with the declining numbers of cases." Institute of Medicine

EXECUTIVE SUMMARY

If you think tuberculosis is under control in the United States today, you would be wrong. Upon review of the provisional 2003 data from the National TB Surveillance System, many have concluded that a cycle of neglect of tuberculosis has begun, reminiscent of the devastating and costly resurgence between 1985 and 1992. The cycle of neglect is defined by the lack of political commitment to TB elimination and declining federal support for elimination activities. In 2003, the 14,871 cases reported represented a decline of only 1.4 percent in cases reported in 2002. This is the smallest annual decrease reported since 1992, the year the incidence of tuberculosis peaked during the previous resurgence. Likewise, the $135.7 million in project funding for the Center for Disease Control and Prevention's Division of Tuberculosis Elimination in FY 2003 represented a decrease of 27 percent in the last decade, when adjusted for inflation.

In the summer of 2000, the Institute of Medicine (IOM) of the National Academy of Sciences issued a report, *Ending Neglect: The Elimination of Tuberculosis in the United States*. The report states that the resurgence of tuberculosis in the United States was the price of neglect reflected in earlier funding reductions and concludes that, with proper funding, organization of prevention and control activities, and research for development of new tools, tuberculosis can be eliminated as a public health problem in the United States.

The small decrease in the incidence of tuberculosis in 2003 should be considered a sentinel event. The United States must heed this warning and once again provide the necessary resources for TB control and prevention. The National Coalition for Elimination of Tuberculosis recommends undertaking an unprecedented initiative--***Intensified Support and Activities to Accelerate Control (ISAAC)***--to enhance, maximize and target resources to sustain the momentum of the past 10 years and accelerate the control and elimination of tuberculosis in the United States.

Intensified Support and Activities to Accelerate Control--ISAAC

The National Coalition for Elimination of Tuberculosis recommends an increase of **$105 million** in project funding for the CDC's Division of Tuberculosis Elimination in FY 2005 to support the initiative of ***Intensified Support and Activities to Accelerate Control--ISAAC*.** This initiative has four components of critical program activity:

- **Tuberculosis in African Americans** **$10 million**

Intensify efforts to prevent, detect and treat tuberculosis among African-Americans and thus reduce/eliminate the racial disparity in the incidence of tuberculosis in this population.

- **Tuberculosis and the U.S.-Mexico Border** **$70 million**
  Intensify efforts to prevent, detect and treat tuberculosis among foreign-born persons in the United States.
  - Intensify TB control activities among persons who regularly cross the U.S.-Mexico border.
  - Intensify efforts to prevent, detect and treat tuberculosis among foreign-born persons in the United States.
  - Intensify international technical assistance activities.

- **Universal Genotyping** **$17 million**
  Intensify utilization of universal genotyping (DNA fingerprinting) for all culture positive TB cases in the United States.

- **Research to Improve Diagnosis and Treatment** **$8 million**
  Intensify applied research that will lead to new tools for the diagnosis and treatment of tuberculosis.

INTRODUCTION

"Tuberculosis can be extinguished as a public health problem...If the opportunity to end tuberculosis is not seized now, it may be lost indefinitely."

These words appeared more than 40 years ago in a report from the 1959 Arden conference organized by the Public Health Service (PHS) and the National Tuberculosis Association (now the American Lung Association). The conference was organized to advise the PHS on how to use available resources to accelerate the decline of tuberculosis in the United States. The conferees had every reason to forecast the demise of the disease in this country. They were buoyed by the evident success of the (then) new combination drug therapy, rapidly declining TB morbidity and mortality, and categorical funding for TB prevention and control activity.

What the conferees could not foresee were events that would make their forecast appear, in hindsight, to be very optimistic indeed. They did not anticipate the elimination of categorical funding for TB control. Nor did they foresee the emergence of HIV/AIDS and a host of socioeconomic problems, including increases in homelessness, injection drug use and increasing rates of incarceration. These events created fertile ground for the re-emergence of tuberculosis as a serious public health threat in the United States. In the mid-1980s, the trend toward elimination was reversed and the nation experienced a resurgence of tuberculosis for several years, with a 20 percent increase in reported cases between 1985 and 1992.

The federal response to this emergency was seriously hampered because the public health infrastructure was allowed to crumble during the nearly 10-year period when categorical funding for TB control was zero. The United States lacked the trained professionals, laboratories and organizational capacity needed to respond swiftly. By the late 1980s, what had been complacency was clearly neglect. Significant federal resources were necessary to regain control of tuberculosis--more than $1 billion in New York City alone.

A renewed emphasis on TB control and a major commitment of resources in the early- to late 1990s resulted in a substantial decline in the disease. After 1992, with control re-established, rates began to decline at approximately 6 percent to 7 percent each year. Since then, the decline has been 44 percent, from 26,673 cases in 1992 to 14,871 cases in 2003. However, the rate of decline has slowed significantly in recent years and the 14,871 cases reported in 2003 represents the smallest annual decrease reported since 1992.

> *We have two choices in the United States. We can continue the path toward neglect and experience another unnecessary, expensive resurgence of tuberculosis. Or we can take the necessary steps to continue progress toward tuberculosis elimination. Choosing the path of elimination—ending neglect—represents not only sound public health policy but good fiscal policy as well.*
>
> *–David Satcher, M.D.,* Former U.S. Surgeon General

THE NATIONAL TUBERCULOSIS CONTROL PROGRAM

If you think tuberculosis is under control in the United States today, you would be wrong. Upon review of the provisional 2003 data from the National TB Surveillance System, many have concluded that a cycle of neglect of tuberculosis has begun, reminiscent of the devastating and costly resurgence between 1985 and 1992. In 2003, the 14,871 cases reported represented a decline of only 1.4 percent over cases reported in 2002. This is the smallest annual decrease reported since 1992, the year the incidence of tuberculosis peaked during the previous resurgence.

Beyond this, there are more troubling signs. Nineteen states reported more cases in 2003 than in 2002. Twelve states--Alabama, Alaska, Arizona, Delaware, Indiana, Iowa, Louisiana, Nevada, South Dakota, Utah, Vermont and Wyoming--saw increases of more than 10 percent. Seven of the latter states are "low incidence states" and the increase in tuberculosis in such low-incidence states underscores the importance of controlling and maintaining the public health infrastructure to control tuberculosis in all states.

The 14,871 reported cases of tuberculosis in 2003 represent only the tip of the iceberg. Ten million to 15 million people in the United States have latent TB infection. These people have been infected with the TB germ but have no symptoms and cannot spread the disease to others. However, a substantial proportion of them eventually will develop active tuberculosis unless they are treated. If left untreated, the people with latent TB infection represent more than one million future cases of tuberculosis.

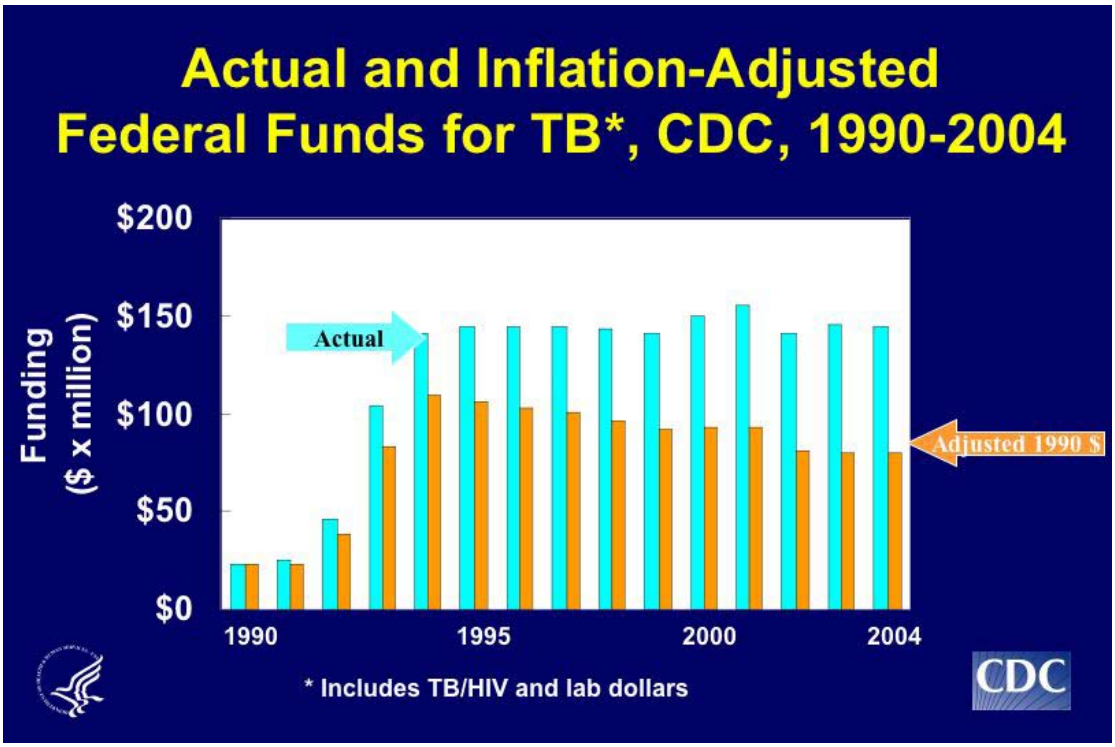
The federal responsibility for TB control resides within the Division of Tuberculosis Elimination (DTBE), a division of the National Center for HIV, STD and TB Prevention within the Centers for Disease Control and Prevention. The Division of Tuberculosis Elimination, in collaboration with the National Center for Infectious Diseases, the Public Health Practice Program Office, and the National Institute of Occupational Safety and Health is, in effect, the U.S. national TB program. It is charged with providing leadership and resources to control, prevent and eventually eliminate tuberculosis in the United States.

While TB control is a shared federal, state and local responsibility, federal dollars are an integral part of TB control in every state and local government. The funds for this effort are provided through the Division of Tuberculosis Elimination. These funds are provided to 68 jurisdictions through cooperative agreements and include all 50 states, the District of Columbia, nine large cities (such as New York City), Puerto Rico, and seven other jurisdictions such as Guam and the Virgin Islands (Figure 1). These funds support the core activities for local TB control programs and include identifying and treating cases of active tuberculosis and performing investigations to identify, evaluate and treat individuals who may have been infected by a new case, a network of public health laboratories, and three Model Tuberculosis Centers in New York City, Newark and San Francisco. These funds also support applied research and clinical trials projects at sites throughout the country.

The Division of Tuberculosis Elimination also supports the core activities of TB control at the federal level including the National TB Surveillance System, technical assistance and personnel

for outbreak investigations, human resource development and training, applied research and clinical trials, and international technical assistance.

At a time when the United States should be redoubling its efforts to maintain control of tuberculosis, the Division of Tuberculosis Elimination is facing its most severe budget crisis in years. Federal funding for TB control activities, in adjusted dollars, has not kept pace with inflation for the past 10 years. While there are multiple factors involved, the most significant factor is the lack of political commitment to adequately fund TB control in the United States. The current level of funding--$135.7 million--represents a 27 percent decrease in the last decade, when adjusted for inflation.



State and local TB control programs disproportionately carry the burden of this funding crisis because, in the aggregate, they are the single largest component of the Division's budget. TB control programs face collapse in most jurisdictions and would be severely damaged in the remainder if federal funding is not increased. Current reductions in federal support of local TB control programs have been particularly devastating in states with ongoing budget crises including Alaska, California, Colorado, Massachusetts, South Carolina and Texas.

INTENSIFIED SUPPORT AND ACTIVITIES TO ACCELERATE CONTROL—ISAAC

In 1989, the CDC and the Advisory Council for the Elimination of Tuberculosis (ACET) developed a strategic national plan to reduce the incidence of tuberculosis to 3.5 cases per 100,000 persons by the year 2000 and an elimination target of less than 1 case per 1 million population by 2010. At the rate of decline occurring then, it would take more than 60 years, well

beyond the target of 2010, to reach the goal unless the recommendations in the plan were implemented.

This plan was seriously hampered by the resurgence of tuberculosis previously described. The Institute of Medicine report, *Ending Neglect: The Elimination of Tuberculosis in the United States,* reviewed the lessons learned from the neglect of tuberculosis between the late 1960s and the early 1990s. It reaffirmed the goal of eliminating tuberculosis in the United States as defined by a case rate of less than 1 case per 1 million population and recommended a series of aggressive actions required to once again meet the goal:

- **Maintaining Control** of tuberculosis while adjusting control measures to declining incidence of disease and changing systems of health care management.
- **Accelerating the Rate of Decline** of tuberculosis (aimed at elimination) by increasing efforts at target tuberculin testing and treatment of latent infection.
- **Developing New Tools** necessary for the ultimate elimination of tuberculosis, including new diagnostic tests for latent infection, new treatments and an effective vaccine.
- **Increasing Involvement of the United States in Global TB Control,** recognizing the fact that tuberculosis is not constrained by national boundaries and that increasing proportions of new cases in this country are developing in individuals born in countries with high incidences of tuberculosis.
- **Mobilizing and Sustaining Public Support** and commitment for elimination of tuberculosis and regularly measuring progress toward that goal.

The Institute of Medicine recommendations have not been fully implemented due to declining federal resources. Moreover, the slowing of the decline in 2003 to 1.4 percent is a warning the United States must heed and once again provide the necessary resources for TB control and prevention. To regain momentum and accelerate control, aggressive and decisive actions are required**. The National Coalition for Elimination of Tuberculosis recommends an increase of $105 million to the Division of Tuberculosis Elimination to undertake an unprecedented initiative--*Intensified Support and Activities to Accelerate Control (ISAAC)*--to enhance, maximize and target resources to key areas of activity recommended by the Institute of Medicine, including:**

- **Maintaining Control** of tuberculosis while adapting to a declining incidence of disease and a changing system of health care financing and management.
  - ***ISAAC*: Tuberculosis and the U.S.-Mexico Border $70 million**
    - Intensify tuberculosis control activities among persons who regularly cross the U.S.-Mexico Border.
    - Intensify efforts to prevent, detect and treat tuberculosis among foreign-born persons in the United States.
    - Intensify international technical assistance activities.

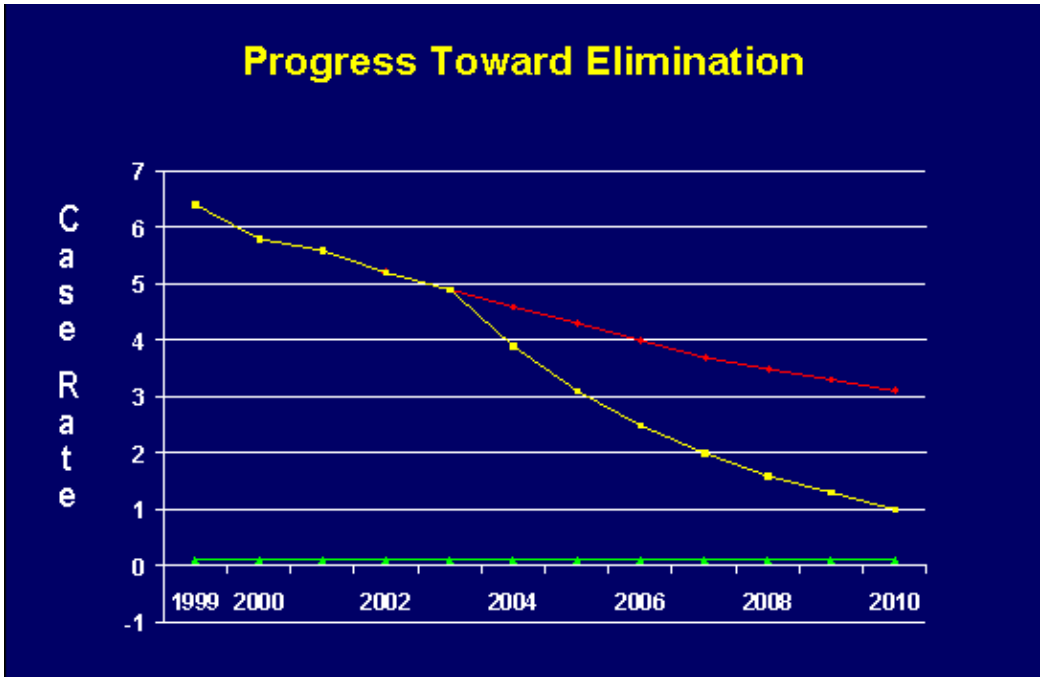
- **Speeding the Decline** of tuberculosis and advancing toward the elimination of tuberculosis through increased efforts for targeted tuberculin skin testing and treatment of latent TB infection.

- ***ISAAC:* Tuberculosis in African Americans $10 million**
  - Intensify efforts to prevent, detect, and treat tuberculosis among African Americans and reduce/eliminate the racial disparity in the incidence of tuberculosis in this population.
- ***ISAAC:* Universal Genotyping $17 million**
  - Intensify utilization of universal genotyping (DNA fingerprinting) on all reported TB cases in the United States.

➢ **Developing the Tools** needed for ultimate elimination of tuberculosis—new diagnostic tests, particularly for diagnosis of infection, new treatments and an effective vaccine.

- ***ISAAC:* Research to Improve Diagnosis and Treatment $8 million**
  - Intensify applied research activity to lead to new tools for the diagnosis and treatment of tuberculosis.

Even with the ***ISAAC*** initiative in place, it will still take many decades beyond 2010 to reach the target of TB elimination in the United States. Shown below is the target rate of decline (--Δ--), the current rate of decline (--♦--) and an accelerated rate of decline (--□--) achieved only with increased resources to fully implement activities such as those in ***ISAAC***.



➢ ***ENDING NEGLECT BY MAINTAINING CONTROL***

What does this mean? To maintain control of tuberculosis, a successful program must identify and treat individuals with active tuberculosis. It must find and test individuals who may have had contact with TB patients to determine whether they, too, are infected. If so, they must be provided appropriate treatment.

To meet these goals, TB controllers must first determine whether a person who has symptoms of tuberculosis actually has the disease. This requires a tuberculin skin test, a chest X-ray,

collection of sputum for microscopic analysis, culturing of sputum to determine whether the TB germ is present and, where appropriate, culturing the bacteria to determine whether they are drug-resistant. Genotyping (DNA fingerprinting) is often performed to identify the particular strain of the TB germ growing in the patient.

When a diagnosis of tuberculosis is confirmed, a patient-centered treatment plan must be developed that ensures the completion of therapy. This approach typically involves six to nine months of directly observed therapy (DOT) in which an outreach worker actually watches as the patient takes each and every dose of medication. If medication is not taken properly, the patient is at risk of developing multidrug-resistant tuberculosis (MDR-TB).

To identify persons who might have had contact with TB patients, a contact investigation is completed. It begins with an interview of the patient to identify other people the patient may have exposed to the disease, such as family members and co-workers. All contacts are then tuberculin skin tested. Individuals who have a positive skin test are candidates for follow-up tests--chest X-ray, etc.--to determine whether they, too, have active tuberculosis. All individuals with a positive skin test are further evaluated for appropriate therapy, whether for latent infection or active disease.

This scenario played out more than 14,871 times in the United States in 2003. It requires a robust infrastructure that has:

- Healthcare workers with appropriate technical training and, increasingly, with cross-cultural training to work with foreign-born patients;
- A network of laboratories with the technical staff and equipment needed to deliver timely, accurate results;
- An information management system that enables timely reporting of cases, the management of individual cases and contact investigations, and the evaluation of program performance; and
- Education and training materials for healthcare providers, patients and their communities.

- ***ISAAC Component:*** **Tuberculosis and the U.S.-Mexico Border $70 million**
  - **Intensify tuberculosis control activities among persons who regularly cross the U.S.-Mexico Border**

The incidence of tuberculosis along the U.S.-Mexico border is more than 50 percent higher than national rates in either Mexico or the United States. The 2,000-mile border region includes four states in the United States, six states in Mexico, 14 pairs of sister cities and 12 million inhabitants. More than 264 million persons legally cross the border northbound each year.

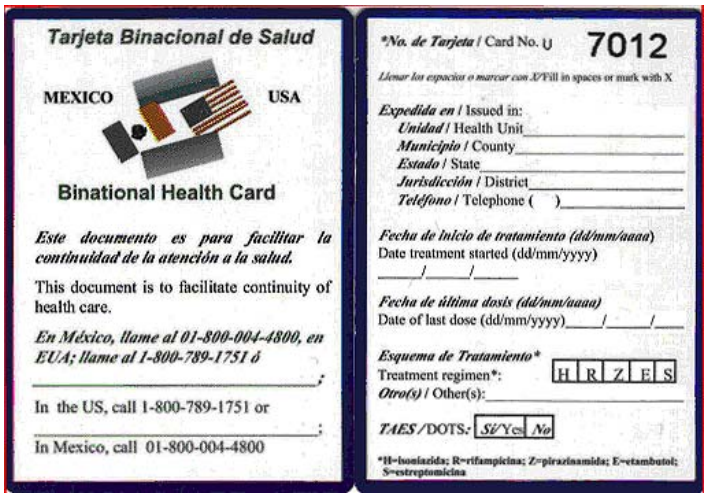
Immigrants from Mexico contribute substantially to TB morbidity in the United States. In 2002, 25 percent of all reported cases were from Mexico. The majority (70%) occurred in the four states that border Mexico--Arizona, California, New Mexico and Texas. Although these four border-states account for a significant proportion of the Mexico-born cases, the number of Mexico-born cases reported by other states appear to be increasing. For example, for the five-year period of 1998–2002, seven other states reported that at least 15 percent of their cases were Mexico-born including Colorado, Idaho, Kansas, Nebraska, Nevada, Oregon and Wyoming.

There are several factors that make TB control along the U.S.-Mexico border difficult and expensive. The counties along the border are among the poorest economically in the United States. About one-third of the U.S. border families live at or below the poverty line, compared with national average of 11 percent. Further, 10 of 24 counties evaluated along the border are medically underserved and of low socioeconomic status. Mexico-born TB patients are about twice as likely to move or become lost to follow-up than U.S.-born patients.

A regional strategy to combat active TB disease along the border is essential to manage tuberculosis in the migratory population along the common border. Since 1991, the CDC has funded several projects that have improved the coordination of and communication about TB control activities in this region. For example, binational TB projects in several adjoining jurisdictions along the U.S.-Mexico border of Arizona, California and Texas are responsible for control activities on both sides of the border, including case management, contact investigations, and provision of laboratory services for diagnosis and case management. These projects focus on persons with tuberculosis who cross the border frequently.

Additional projects include CureTB and TB*Net*. CureTB, operated by the San Diego County TB control program, is a joint U.S.-Mexico referral system designed to improve the continuity of care for patients with active tuberculosis and their contacts who are at high risk. TB*Net*, operated by the Migrant Clinicians Network and based in Austin, TX, issues patients a portable medical record that helps them gain access to medical services for TB disease or infection.

In March 2003, the CDC and the Mexico National TB program established the *United States-Mexico Binational TB Referral and Case Management Project*. The goals of the project are to coordinate the referral of patients between the health systems of both countries and to ensure continuity of care and completion of TB treatment for patients who migrate between the United States and Mexico. This effort is intended to improve the understanding of migrating TB patients, ensure that patients receive continuous care and allow the completion of six-month treatment regimens necessary to cure tuberculosis. The centerpiece of the new program is the *Binational Health Card* shown below.

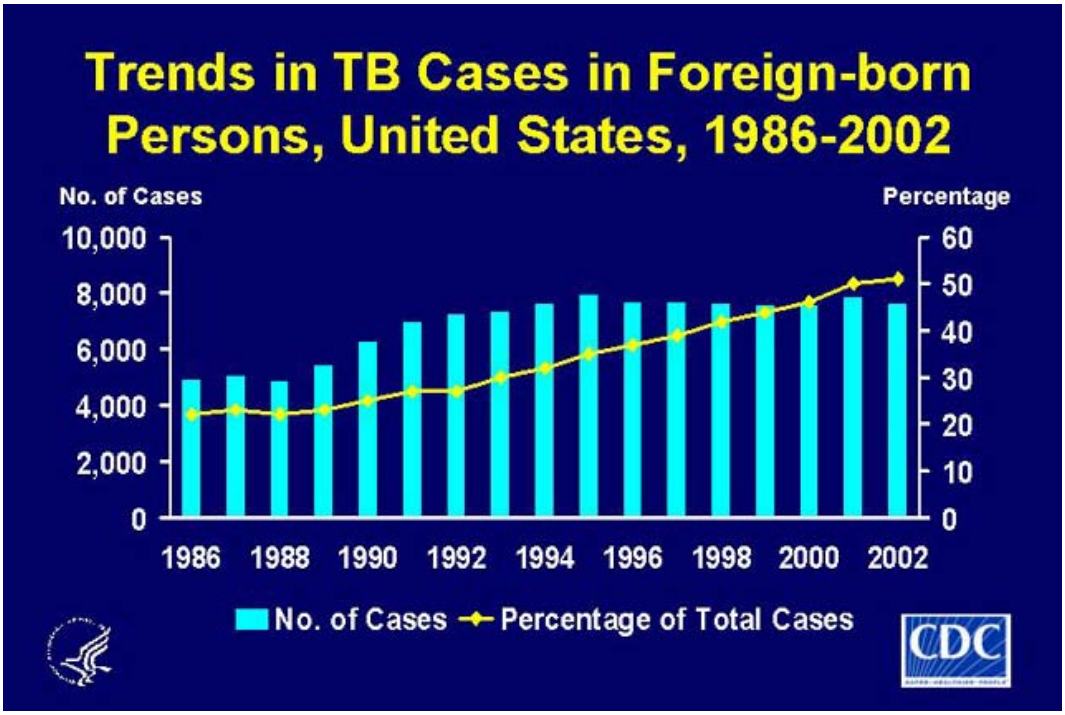


This card contains a unique identification number to monitor patients, the location where the card is issued, treatment initiation date, date of last dose of TB treatment, treatment regimen, DOT or non-DOT administration of treatment, and toll-free telephone numbers in Mexico and the United States. The card allows health care providers access to clinical information to manage a patient's care through links to secure databases in Mexico and the United States.

More than 900 binational health cards have been issued since March 2003. Cards have been issued in several sister cities, counties, and states along the border including San Diego, CA/Tijuana, Baja California; Arizona/Sonora; El Paso, TX/Las Cruces, NM/Ciudad Juarez, Chihuahua; Webb County, TX/Nuevo Laredo, Nuevo Leon; and Cameron County, TX/Matamoros, Tamaulipas. Three other pilot sites in Chicago, Tennessee and Washington State are utilizing this card system, but are not receiving supplemental funding.

- ***ISAAC Component:*** **Tuberculosis and the U.S.-Mexico Border**
  - **Intensify efforts to prevent, detect, and treat tuberculosis among foreign-born persons in the United States.**

The proportion of TB cases occurring in foreign-born persons in the United States has increased steadily in recent years, from 27 percent of all cases in 1992 to 53 percent of all cases in 2003.



In 2002, for the first time since information on birth country was added to the case report form in 1986, the proportion of total cases occurring in foreign-born persons exceeded 50 percent. In 22 states in 2002, more than half of reported TB cases were among the foreign-born. In seven states --California, Colorado, Hawaii, Idaho, Massachusetts, Minnesota and New Hampshire--more than 70 percent of the cases occurred among foreign-born persons. Moreover, the case rate among foreign-born persons is at least eight times higher than among U.S.-born persons.

Preventing and controlling tuberculosis in foreign-born people requires special resources. For example, in Minnesota, where 76 percent of the TB cases are in foreign-born persons, the current caseload of active TB cases includes people from 25 countries of origin, representing 20 different spoken languages. Serving such a diverse population poses formidable challenges to local health departments and clinicians, especially in rural areas of Minnesota, where more than 20 percent of Minnesota's TB cases occur. The challenges include providing not only interpreter services but also healthcare workers with cross-cultural training who can work effectively with patients and their families and with community-based organizations that address the medical and other needs of immigrant and refugees. Healthcare workers must also be able to address issues around homelessness, substance abuse and a variety of lifestyles that will allow them to interact effectively with high-risk groups.

To address the high rate of tuberculosis among foreign-born persons in the United States, CDC is collaborating with public health partners to strengthen TB programs in countries with a high incidence of TB disease and to implement TB control activities among recent international arrivals and along the U.S.-Mexico border.

- ***ENDING NEGLECT BY SPEEDING THE DECLINE***

Tuberculosis has begun to retreat into marginal, difficult-to-treat populations in the United States. These populations include the foreign born, persons in correctional institutions, persons who use drugs, drink alcohol excessively or are co-infected with HIV, and the foreign-born. They also include persons in racial/ethnic minorities who have inherited a legacy of poverty, racism, and poor access to care. These populations present stark challenges to TB control efforts. But if we take up this challenge, we can speed the decline of tuberculosis in the United States.

- ***ISAAC* Component: Tuberculosis in African Americans $10 million**
  - **Intensify efforts to prevent, detect, and treat tuberculosis among African Americans and reduce/eliminate the racial disparity in the incidence of tuberculosis in this population.**

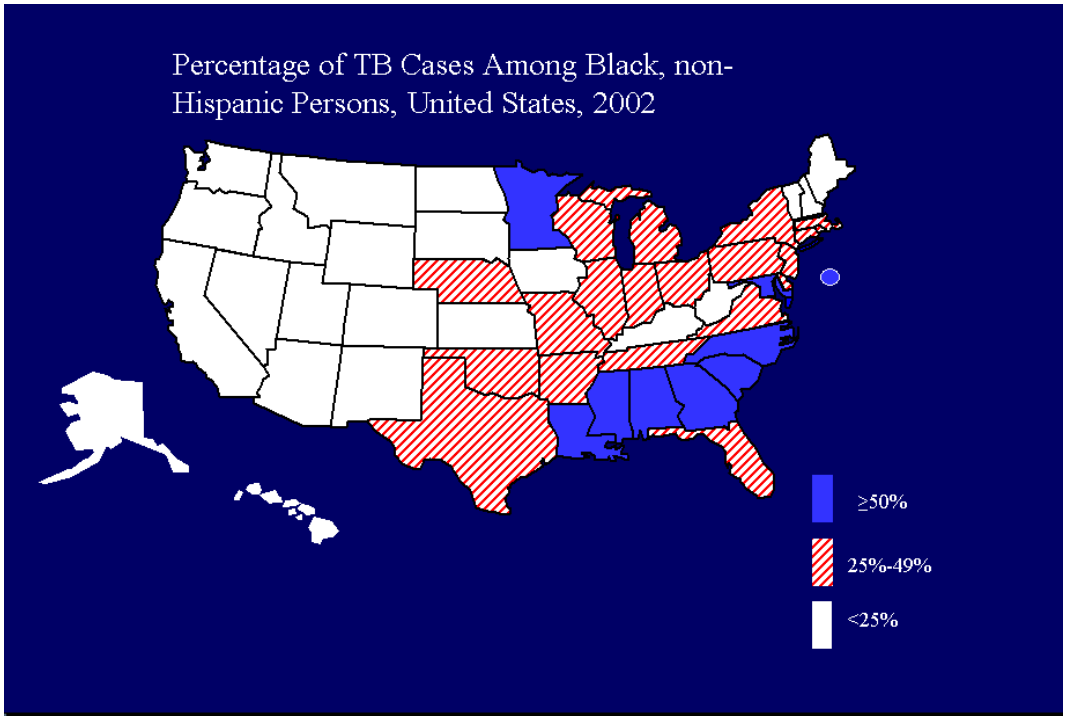
Black, non-Hispanic persons continue to have a disproportionate share of tuberculosis in the United States. In 2002, 4,439 cases of tuberculosis occurred in black, non-Hispanic persons, representing 30 percent of all cases. The rate of tuberculosis in blacks is 12.6 cases per 100,000 population, compared to 1.5 cases per 100,000 population in white, non-Hispanic persons.

The proportion of TB cases in African Americans is even greater if only TB cases occurring in U.S.-born persons are examined. In 2002, of the cases in U.S.-born persons, 3,387 occurred in black, non-Hispanic persons, representing 47 percent of all U.S.-born cases. Further, among African Americans, 62 percent of diagnosed cases occur in correctional facilities and 71 percent of those were HIV positive.

Although rates of tuberculosis in both blacks and whites have declined substantially over the past decade, the disparity remains. It is the legacy of poverty, racism and poor access to care. To close the gap, increased efforts must be made to eliminate tuberculosis in African Americans in

the United States. In the process of eliminating this disparity, we may be able to develop strategies we can use to address other racial and ethnic health disparities.

The efforts of the Division of Tuberculosis Elimination to address this disparity began with a focus on seven southeastern states: Alabama, Arkansas, Georgia, Louisiana, Mississippi, South Carolina and Tennessee. TB rates in these states have been consistently above the national average and more than half of the TB cases in these states occur in blacks.



Improved understanding of racial disparities for tuberculosis in these states will provide essential information that can guide efforts to reduce the disproportionate impact of tuberculosis on blacks. However, the disparity in TB rates in African Americans is a *national*, not a regional, problem. The Division of Tuberculosis Elimination is also supporting projects and working with partners in other parts of country to address the disparity.

In May 2003, the Advisory Council for the Elimination of Tuberculosis (ACET) consulted with representatives of 35 agencies and national, non-governmental African American organizations whose programs could have an impact on TB control efforts among African Americans. The participants comprised a diverse group that included academicians, health care providers, and religious leaders. Organizations attending the consultation included Alpha Kappa Alpha Sorority, AME Church, Howard University, Meharry Medical College and the NAACP. Discussion at the meeting developed two broad strategies to address the disparities. The strategies include identifying and working with new community partners and educating the public and health departments about the disparities and ways to address them.

Additional initiatives include a research and intervention study, "Addressing Tuberculosis Among African Americans in the Southeast," funded through the Tuberculosis

Epidemiological Studies Consortium. The project includes partners from Georgia, Mississippi, North Carolina, South Carolina and Tennessee. The objectives of the project are to determine barriers to health-seeking behavior and treatment adherence for African Americans with or at risk for tuberculosis and barriers to adherence to TB guidelines among providers who serve these populations, to develop and test interventions to overcome identified barriers, and to improve partnerships and collaboration among TB programs and providers/organizations serving these populations.

- ***ISAAC Component:*** **Universal Genotyping $17 million**
  - **Intensify utilization of universal genotyping (DNA fingerprinting) for all reported TB cases in the United States.**

When confronted with a new case of active tuberculosis, public health officials must identify other individuals who have had close contact with the infected person. Because tuberculosis is infectious, contacts must be tested to determine whether they, too, are infected. The goal is to identify all people at risk and to offer them treatment. In this way, an outbreak can be limited and prevented from spreading.

For decades, contact investigations have been based on a patient's response to a set of standard questions: Who do you live with? Work with? Socialize with? The answers to these questions provided TB controllers with the names of people who would then be tested. This approach has its limitations, however, primarily because individuals may not identify all their contacts. Contact tracing by this traditional "shoe-leather" approach is especially difficult when working with mobile populations such as the homeless, who move from shelter to shelter, county to county, or even state to state.

The tool of DNA fingerprinting is now helping TB controllers identify links between TB cases, even when they are widely separated in time and/or place. Just as the DNA molecules of individual humans differ from each other in slight but detectable ways, the DNA molecules in different strains of the TB germ can be distinguished through DNA fingerprinting. Thus, if two individuals are infected with TB germs that have identical DNA fingerprints, one can tentatively conclude that the two individuals are linked to each other in a chain of transmission. TB controllers can use molecular epidemiology to study the pattern of TB transmission within their communities.

The CDC launched the TB Genotyping Program to determine the genotype (DNA fingerprint) of every sample of TB germs in the United States. Laboratories in Lansing, MI, and Richmond, CA, were contracted with to perform genotyping as a service to state and city TB control programs beginning in January 2004.

The power of *universal* genotyping was shown recently in a TB outbreak in Kansas. Through the use of universal genotyping, Kansas identified clusters of cases that would have been hard to identify through standard contact investigations. They found the use of genotyping particularly useful in working with homeless communities, where contact investigations traditionally are difficult to pursue due to the anonymity of the population. Universal genotyping drew attention back to active cases that had no apparent epidemiological link with each other. Then, as a result

of more intensified investigations, further cases were not only linked but led to new cases being diagnosed early in the disease process. Even more significant was the fact that the genotyping results yielded indisputable evidence of case-to-case transmission. As a result, the shelters that house the homeless have become far more willing to partner with public health efforts to control and eliminate tuberculosis in their population.

Universal genotyping has several major benefits. It will enhance and expedite contact investigations as well as identify relationships between cases and new and unusual transmission settings. TB control in low-incidence areas will be also aided. TB transmission that occurs between patients who reside in different jurisdictions will be detected more readily and false-positive cultures will be identified more easily.

- ***ENDING NEGLECT BY DEVELOPING NEW TOOLS***

If the United States is to eliminate tuberculosis, it will need a coordinated strategy to end the cycle of neglect that has unnecessarily slowed progress toward achieving that goal. An important part of that strategy is a research agenda that will provide new tools for preventing and controlling the disease.

- ***ISAAC Component:*** **Research to Improve Diagnosis and Treatment $8 million**
  - **Intensify applied research that will lead to new tools for the diagnosis and treatment of tuberculosis.**

TB research nearly ground to a halt from 1970 to 1990. There was little interest in the disease and little funding available for basic or applied research. Few young scientists were trained to be TB researchers. The result was not only little progress in understanding this disease but also a crumbling of the scientific infrastructure needed to do TB research. In the past 12 years, increased funding to the CDC and National Institutes of Health has helped redevelop the relevant infrastructure and define new research strategies. The momentum must now be sustained.

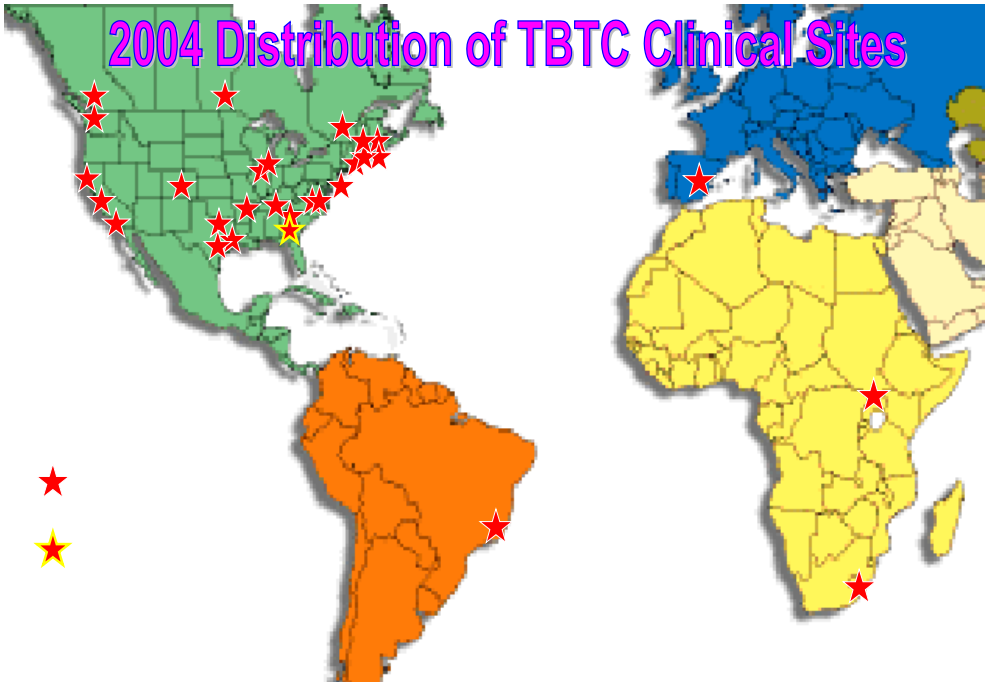
In *Ending Neglect*, the Institute of Medicine identified several key research areas and placed the highest priority on new diagnostic tools to identify people with latent tuberculosis. Scientists at the CDC, in collaboration with the private sector, have already reported progress on this highest priority. Their research describes a new diagnostic test for TB infection that has several advantages over the currently used, nearly century-old tuberculin skin test. The new test, the whole blood interferon-gamma assay, offers higher specificity and requires only one contact between a patient and a healthcare provider.

The Division of Tuberculosis Elimination supports several applied research programs that address the recommendations of the Institute of Medicine Report report. These include the Tuberculosis Trials Consortium (TBTC), the Tuberculosis Epidemiologic Studies Consortium (TBESC), and applied research done in the Tuberculosis/ Mycobacteriology Branch of the Division of AIDS, STD, and TB Laboratory Research. Additional applied research is done by CDC scientists, much of it in collaboration with scientists outside the CDC. All these efforts take advantage of the CDC's well-recognized expertise in doing population-based research.

Tuberculosis Trials Consortium

The CDC is mandated by the U.S. Public Health Service to conduct TB therapy trials. For more

than 35 years, the CDC has been responsible for conducting clinical trials to evaluate new drug regimens for preventing and treating tuberculosis. Ongoing clinical trials are currently being done by the Tuberculosis Trials Consortium, a consortium of 28 academic clinical centers and Veterans Administration Centers not only in the United States but also in Brazil, Canada, South Africa, Spain and Uganda.



Consortium members work closely with local public health departments to recruit and manage patients enrolled in the clinical trials. In a short period of time, the Tuberculosis Trials Consortium has become the world's premier research institution conducting such clinical trials. The recent addition of sites outside the United States and Canada will enable the Tuberculosis Trials Consortium to engage in global TB control efforts by broadening the applicability of its findings and by training foreign investigators in the highest caliber clinical research.

The new treatment guidelines for tuberculosis, published in 2003, incorporated the results of several studies done by the Tuberculosis Trials Consortium. These include shortened regimens for patients identified as being at low-risk for relapse or failure, and treatment in special situations such as HIV co-infection. Selected HIV-negative patients can now be effectively cured with a regimen consisting of only 56 direct observed therapy visits. This represents a 22 percent reduction in doses and a significant cost savings. The Tuberculosis Trials Consortium's newest project, Study 27, is evaluating the use of moxifloxacin (a fluoroquinolone) to decrease the infectious period and thus potentially shorten or simplify the treatment of disease.

One of the Tuberculosis Trials Consortium's other projects is Study 26, a Phase III clinical trial that will compare the effectiveness and tolerability of two regimens for treating latent TB infection. The pool of persons with latent TB infection is the largest source of new cases of active tuberculosis and is the biggest challenge to TB control. An intervention to curb the

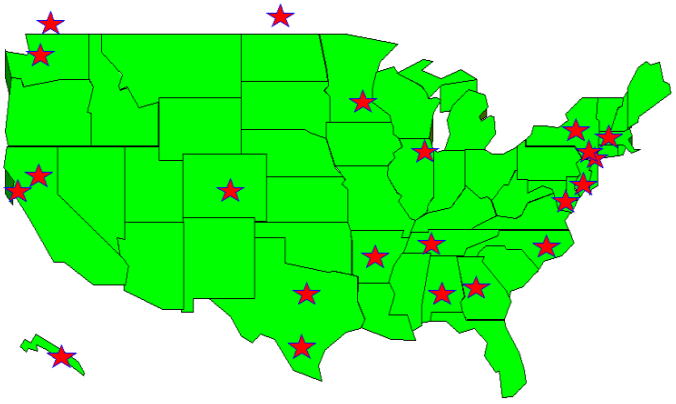
development of active disease in this population will have implications not only for the health of the person treated but also to the health of the community at large.

Study 26 will enroll approximately 8,000 patients over the course of the trial. Enrollment has begun at several sites. Declining resources has limited the number of patients that can be enrolled annually and at current funding levels it will take many years to enroll the required number of patients. After nearly three years, only about 2,500 patients have been enrolled.

Tuberculosis Epidemiologic Studies Consortium

The Tuberculosis Epidemiologic Studies Consortium conducts epidemiologic, behavioral, economic, laboratory and operational research. The studies provide data for more effective and efficient TB control. The Tuberculosis Epidemiologic Studies Consortium was established in 2001 and consists of 22 sites-- 20 in the United States and 2 in Canada. Each site is a collaboration between a local and state health department, academic institution(s), or for-profit and non-profit organizations.

Tuberculosis Epidemiologic Studies Consortium (TBESC) sites



The work of the Tuberculosis Epidemiologic Studies Consortium addresses significant questions in TB control and prevention while building local capacities for epidemiologic research in participating state and metropolitan TB control programs and academic institutions.

The Consortium's research includes studies to:

- Identify and overcome barriers to treatment adherence for latent TB infection and TB disease among African Americans;
- Improve surveillance to identify missed opportunities for preventing tuberculosis in foreign-born persons;
- Assess the TB knowledge, attitudes, beliefs, and practices among private providers serving foreign-born populations at risk for tuberculosis;
- Develop culturally appropriate TB educational materials for leaders and staff of Hispanic service organizations;
- Develop a national genotyping registry for a molecular epidemiologic analysis of

multidrug-resistant strains of the TB germ; and
- Develop strategies for building capacity for TB control in low-incidence areas of the United States.

Additional resources are needed to develop the infrastructure and capacity for the efficient evaluation of TB diagnostics. This would permit studies of new diagnostic tests of latent TB infection and TB disease that are critical to the control and ultimate elimination of tuberculosis. The initiative would initially contribute to the evaluation of QuantiFERON-TB (QFT), a new test used to diagnose latent TB infection, by enrolling patients into an ongoing, approved protocol at selected sites.

ENDING NEGLECT BY ENGAGING IN GLOBAL TB CONTROL

The Institute of Medicine report recommended that the United States continue to play a significant role in global TB control. The report argued that the United States has a moral obligation to provide technical advice and other resources to help countries and organizations address the global epidemic. It also described the impact the global epidemic is having on the United States.

The global epidemic is enormous. About one-third of the world's population – two billion people – is infected with the TB germ. Each year here are about eight million new cases of active tuberculosis and two million deaths from the disease. Tuberculosis is the leading cause of death for people with AIDS and is the leading cause of maternal mortality.

Strengthening TB control programs in selected countries

Given its technical expertise, the Division of Tuberculosis Elimination plays a crucial role in the U.S. response to the global epidemic. However, given the enormity of the global epidemic, the Division must make difficult decisions about how best to use its limited resources outside the United States. Thus, the Division collaborates with other U.S. and international organizations to leverage international development resources to provide technical support for global TB control. The Division's partners include the U.S. Agency for International Development (USAID); the Tuberculosis Coalition for Technical Assistance; the Global AIDS Program; and the Global Fund for AIDS, Tuberculosis and Malaria.

Guided by a strategic plan, the Division provides technical support to many countries including Mexico, Brazil, Peru, the Philippines, Vietnam, India, Russia, the Baltic States and Botswana. By supporting TB control efforts in these countries, the CDC is also learning how to control and prevent tuberculosis in special situations. In Latvia, for example, in a project also supported in part by funds from USAID, the CDC and the Latvian government has established a training center to help other countries cope with MDR-TB. In Botswana, where about 80 percent of TB cases are also infected with the virus that causes AIDS, the CDC is not only helping local health officials cope with co-epidemics of tuberculosis and HIV but is also learning more about the dynamics of TB infection in a population with a high prevalence of HIV infection. Thus, the answers to questions being asked in countries like Latvia and Botswana will have important implications for TB control and prevention throughout the world, including the United States.

ENDING NEGLECT BY MOBILIZING SUPPORT FOR TUBERCULOSIS ELIMINATION

When Robert Koch, the physician/scientist who discovered the cause of tuberculosis, gave his Nobel Lecture in 1905, he underscored the importance of "instructing the people on the danger of tuberculosis." Many people today believe that tuberculosis, like smallpox, is a disease of the past. It is not. They are surprised to learn that tuberculosis still exists in the United States and that a TB epidemic is ravaging many countries around the world.

We must take steps to ensure that our success in reducing the incidence of tuberculosis in the United States will continue and not become another cycle of neglect. To take these steps, the country will need effective leadership to develop the political commitment required to eliminate tuberculosis here and to tackle the global epidemic.

Figure 1 FY 2003 CDC TB Grants Total: $108,014,964

Alabama	Idaho	Montana	Puerto Rico
$1,289,781	$149,012	$150,000	$888,100
Alaska	Illinois	North Marianas	Rhode Island
$462,925	$986,811	$320,849	$487,839
Arizona	Indiana	Nebraska	Samoa
$987,763	$722,993	$184,649	$61,405
Arkansas	Iowa	Nevada	San Diego
$802,189	$494,025	$432,641	$2,317,203
Baltimore	Kansas	New Hampshire	San Francisco
$869,887	$355,635	$335,425	$4,117,007
California	Kentucky	New Jersey	South Carolina
$7,632,145	$1,062,472	$5,405,986	$1,248,700
Chicago	Los Angeles	New Mexico	South Dakota
$2,688,787	$5,833,047	$406,641	$221,258
Colorado	Louisiana	New York City	Tennessee
$451,229	$1,378,204	$18,959,646	$1,525,666
Connecticut	Maine	New York State	Texas
$959,299	$171,053	$4,554,413	$5,848,674
D.C.	Marshall Islands	North Carolina	Utah
$979,956	$82,822	$1,888,662	$369,343
Delaware	Maryland	North Dakota	Vermont
$370,217	$1,425,161	$157,135	$101,840
Detroit	Massachusetts	Ohio	Virgin Islands
$607,328	$1,995,632	$1,114,191	$71,704
Florida	Michigan	Oklahoma	Virginia
$6,296,218	$741,675	$756,528	$1,344,095
Georgia	Micronesia	Oregon	Washington
$2,619,242	$156,856	$709,400	$1,532,298
Guam	Minnesota	Palau	West Virginia
$387,471	$770,542	$97,839	$334,536
Hawaii	Mississippi	Pennsylvania	Wisconsin
$1,295,202	$1,071,330	$766,712	$337,641
Houston	Missouri	Philadelphia	Wyoming
$2,728,904	$714,805	$1,260,927	$165,393