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National Action Plan to Combat Multidrug-Resistant Tuberculosis

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List of Abbreviations

AAP American Academy of Pediatrics ACET Advisory Council for the Elimination of Tuberculosis ADAMHA Alcohol, Drug Abuse, and Mental Health Administration AHCPR Agency for Health Care Policy and Research AIDS Acquired immunodeficiency syndrome ALA American Lung Association AMA American Medical Association ASD Adult/Adolescent spectrum of disease surveillance system ASTHO Association of State and Territorial Health Officials ASTPHLD Association of State and Territorial Public Health Laboratory

Directors ATS American Thoracic Society BCG Bacille Calmette-Guerin BHCDA Bureau of Health Care Delivery and Assistance, HRSA BOP Bureau of Prisons CBO Community-based organization CDC Centers for Disease Control CDER Center for Drug Evaluation and Research, FDA CDRH Center for Devices and Radiological Health, FDA CPCRA Community Program for Clinical Research on AIDS CSTE Council of State and Territorial Epidemiologists DATC Drug abuse treatment centers DAVDP Division of Anti-Viral Drug Products, FDA DOT Directly observed therapy EPO Epidemiology Program Office, CDC FDA Food and Drug Administration HCFA Health Care Financing Administration HEPA High-efficiency particulate air (filter) HICPAC Hospital Infection Control Practices Advisory Committee HIV Human immunodeficiency virus HRSA Health Resources and Services Administration HUD Housing and Urban Development IDSA Infectious Disease Society of America IND Investigational New Drug IRMO Information Resources Management Office, CDC LHD Local health department MDR-TB Multidrug-resistant tuberculosis NACHO National Association of County Health Officials NASADAD National Association of State Alcohol and Drug Abuse Directors NCET National Coalition for the Elimination of Tuberculosis NCHS National Center for Health Statistics, CDC NCID National Center for Infectious Diseases, CDC NCPS National Center for Prevention Services, CDC NETSS National Electronic Telecommunication Surveillance System NIAID National Institute for Allergy and Infectious Diseases, NIH NIDA National Institute on Drug Abuse, ADAMHA NIH National Institutes of Health NIOSH National Institute for Occupational Safety and Health, CDC NJCIRD National Jewish Center for Immunology and Respiratory Diseases NPHHI National Public Health and Hospital Institutes OGC Office of General Counsel, CDC and HCFA OGD Office of Generic Drugs, FDA OHA Office of Health Affairs, FDA OOC Office of the Commissioner, FDA OOP Office of Orphan Products, FDA OPPE Office of Program Planning and Evaluation, CDC ORA Office of Regulatory Affairs OSHA Occupational Safety and Health Administration, U.S. Department

of Labor OTI Office for Treatment Improvement, ADAMHA PAS Para-aminosalicylic acid, an antituberculosis drug PHLIS Public Health Laboratory Information System PHPPO Public Health Practice Program Office, CDC POE Port of entry PSD Pediatric spectrum of disease surveillance system RFA Request for assistance RVCT Report of verified case of tuberculosis SBIR Small Business Innovation Research program TBDS Tuberculosis Database System TIPS Treatment Improvement Protocol Statements USCLHO United States Conference of Local Health Officers USPHS United States Public Health Service UVGI Ultraviolet germicidal irradiation

Summary

At no time in recent history has tuberculosis (TB) been as great a concern as it is today. TB cases are on the increase, and the most serious aspect of the problem is the recent occurrence of outbreaks of multidrug-resistant (MDR) TB, which pose an urgent public health problem and require rapid intervention. A Task Force composed of representatives of many federal agencies has developed a National Action Plan for addressing this problem. The Task Force identified a number of objectives to be met if MDR-TB is to be successfully combatted. These objectives fail under the categories of a) surveillance and epidemiology -- determining the magnitude and nature of the problem; b) laboratory diagnosis -- improving the rapidity, sensitivity, and reliability of diagnostic methods for MDR-TB; c) patient management -- effectively managing patients who have MDR-TB and preventing patients with drug-susceptible TB from developing drug- resistant disease; d) screening and preventive therapy -- identifying persons who are infected with or at risk of developing MDR-TB and preventing them from developing clinically active TB; e) infection control -- minimizing the risk of transmission of MDR-TB to patients, workers, and others in institutional settings; f) outbreak control; g) program evaluation -- ensuring that TB programs are effective in managing patients and preventing MDR-TB; h) information dissemination/ training and education; and i) research to provide new, more effective tools with which to combat MDR-TB.

The Action Plan lays out a series of activities to be undertaken at the national level. For each category, the Plan presents statements of problems to be overcome, followed by a summary of the objective to be achieved and steps to be carried out. For each implementation step, responsibility is assigned to the appropriate organization and start- up dates are listed.

INTRODUCTION

Tuberculosis (TB) is an infectious disease caused by the bacterium Mycobacterium tuberculosis, which is spread almost exclusively by airborne transmission. Although the disease can affect any site in the body, it most often affects the lungs. When persons with pulmonary TB cough, they produce tiny droplet nuclei that contain TB bacteria, which can remain suspended in the air for prolonged periods of time. Anyone who breathes air that contains these droplet nuclei can become infected with TB.

A person who becomes infected with the TB bacillus remains infected for years. Usually a person with a healthy immune system does not become ill, but is usually not able to eliminate the infection without taking an antituberculosis drug. This condition is referred to as "latent tuberculous infection." Persons with latent tuberculous infection are asymptomatic and cannot spread TB to others. Generally, a positive TB skin test is the only evidence of infection. About 10-15 million persons in this country are infected with M. tuberculosis. About 10% of

otherwise healthy persons who have latent tuberculous infection will become ill with active TB at some time during their lives.

TB Control Programs

Our programs for controlling TB have two major arms. The first and highest priority is to detect persons with active TB and treat them with effective antituberculosis drugs. Effective treatment keeps the patients from dying of TB and stops the transmission of infection to other persons in the household, at the work site, or in the community. Treatment of active TB involves taking multiple antituberculosis drugs daily (or two or three times weekly) for at least 6 months. If the patient does not take the medications for the full treatment period, the disease may not be cured and may recur. If medications are not prescribed properly or taken regularly, the TB organisms can become resistant to the drugs, and drug-resistant TB may then be transmitted to other persons. Drug-resistant disease is difficult and expensive to treat. Thus, the most important step to prevent drug-resistant disease is to ensure that patients take all their medication. Directly observed therapy is the best way of ensuring patient compliance.

The second major control intervention is to detect and preventively treat persons who do not have active TB, but who have latent tuberculous infection and may be at high risk of developing active TB. With drug-susceptible TB, preventive therapy with isoniazid greatly reduces the risk of developing active TB. Preventive therapy requires treatment daily or twice weekly for a minimum of 6 months, and many patients do not complete a full course of therapy without direct observation.

Increase in TB Cases

The United States had a significant decline in the number of TB cases over the past several decades -- from >84,000 cases in 1953 to a nadir of approximately 22,000 cases in 1984. In 1987, the Department of Health and Human Services established an Advisory Committee (now Council) for the Elimination of Tuberculosis (ACET). In 1989, the ACET published the Strategic Plan for the Elimination of Tuberculosis in the United States. The Plan established a national goal of TB elimination (i.e., an incidence of <1 case per 1 million population) by the year 2010. An interim goal for the year 2000 is an incidence of 3.5 cases per 100,000 population.

Since the Strategic Plan was published, dramatic changes in the incidence and epidemiology of TB have jeopardized the goal of TB elimination. In 1984, the long-standing annual decline in TB cases abruptly ended, and from 1985 through 1991, approximately 39,000 more cases were reported than would have been expected had the previous downward trend continued.

Much of the recent increase in cases is believed to be due to TB among persons infected with human immunodeficiency virus (HIV). For HIV-infected persons who have latent tuberculous infection, the risk of developing active TB is 7%-10% per year. Even more dramatic is the effect seen when persons who are already infected with HIV become newly infected with M. tuberculosis. In two outbreaks in which HIV- infected persons were exposed to cases of infectious TB, 40% of the exposed persons developed active TB within a few months; thus, among such persons, active TB develops soon after infection and progresses rapidly, often resulting in death. Other groups at high risk for TB include persons in group or institutional settings, such as correctional facilities, shelters for the homeless, residential care facilities,

nursing homes, and hospitals, where the environments may be conducive to airborne transmission of TB.

Drug-Resistant TB

Recently, drug-resistant TB has become a serious concern. In a recent survey in New York City, 33% of cases had organisms resistant to at least one drug, and 19% had organisms resistant to both isoniazid and rifampin, the two most effective drugs available for treating TB. When organisms are resistant to both isoniazid and rifampin, the course of treatment increases from 6 months to 18-24 months, and the cure rate decreases from nearly 100% to less than or equal to 60%.

Drug-resistant TB is not limited to New York. CDC recently conducted a nationwide survey of drug resistance among all TB cases provisionally reported during the first 3 months of 1991. Overall, 14.4% of these cases tested had organisms resistant to at least one antituberculosis drug, and 3.3% had organisms resistant to both isoniazid and rifampin. Furthermore, the drug resistance problem appears to be worsening. For example, from 1982 to 1986, only 0.5% of new cases were resistant to both isoniazid and rifampin; by 1991, this proportion had increased to about 3.1%. Among recurrent cases, 3.0% were resistant to both drugs during 1982-1986, but in 1991 this proportion had more than doubled, to 6.9%.

Against this background of increasing numbers of TB cases and increasing numbers of drug-resistant cases, a serious new phenomenon has appeared: out-breaks of multidrug-resistant (MDR) TB in institutional settings. From 1990 through early 1992, CDC, in collaboration with state and local health departments, investigated seven outbreaks of MDR-TB in hospitals and correctional facilities in Florida and New York. To date, these outbreaks have included >200 MDR cases. Virtually all these cases had organisms resistant to both isoniazid and rifampin, and some had organisms resistant to seven antituberculosis drugs. Most of the patients in these outbreaks were infected with HIV. Mortality among patients with MDR-TB in these outbreaks was high, ranging from 72% to 89%, and the median interval between TB diagnosis and death was short, from 4 to 16 weeks. In addition to hospitalized patients and inmates, transmission of MDR-TB to health-care workers and prison guards has also been documented; at least nine of these workers have developed active MDR-TB, and five of them have died.

The rise in drug-resistant TB and the outbreaks of MDR-TB are a manifestation of serious underlying problems in the health-care infrastructure in the United States. An increasing proportion of TB cases is occurring among persons who were born in another country or who are homeless, who have substance abuse problems or mental illness, or who have other socioeconomic or medical problems, such as HIV infection, that make compliance with therapy difficult. Yet, at the same time that the number and complexity of TB cases have been increasing, fiscal constraints in government at all levels have led to cutbacks in many TB control programs. As a result, health departments have not had adequate resources to place all potentially noncompliant patients on directly observed therapy or to bring outbreaks under control. There have been shortages of antituberculosis drugs and significant increases in their costs. Screening and preventive therapy have not been offered consistently to many groups at high risk of TB (e.g., HIV-infected persons) because of limited resources.

Several other factors have contributed to the outbreaks. The increasing incidence of TB in many areas is bringing more persons with active, infectious TB into institutional settings, such as health-care and correctional facilities, many of which serve populations in which there is

also a high proportion of HIV-infected persons. This convergence creates an opportunity for transmission of TB, and many areas lack adequate facilities and practices for controlling the transmission of airborne disease or for adequately treating and managing TB patients. In addition, recognition of drug-resistant TB has often been delayed because current methods for diagnosing TB and performing drug susceptibility tests require weeks to months to complete. Furthermore, the selection of drugs available for treating TB is limited, which makes the treatment of drug-resistant cases particularly difficult.

In response to the emergence of MDR-TB, a federal Task Force was convened in December 1991 to develop a national plan to combat the problem. This document summarizes that plan by identifying the problems that need to be addressed, outlining the objectives for addressing each problem, and listing the implementation steps needed to attain each objective. Attached to each implementation step is a time frame for initiating the step. Many activities that are indicated as beginning in 1992 and 1993 will continue in subsequent years.

The National Action Plan does not replace the Strategic Plan for Elimination of Tuberculosis; rather, it identifies steps that need to be taken quickly to address the MDR-TB problem specifically. This plan is a blueprint for action by federal agencies. However, many of the implementation steps will depend on the cooperation of many sectors of society.

SURVEILLANCE AND EPIDEMIOLOGY

Determine the magnitude and nature of the problem.

To combat MDR-TB, it is first necessary to determine the magnitude of the problem and the factors that are associated with its spread. Surveillance involves collecting information about a condition, such as TB, that allows us to see trends in the disease over time and in specific geographic areas and provides an estimate of morbidity and mortality and a basis for allocation of resources. Although surveillance for TB has been ongoing for decades, it should be expanded to capture information necessary to track the emergence of multidrug resistance. Epidemiology includes studies that define the factors that promote or retard the development of a given disease, such as MDR-TB. Epidemiologic studies will help identify where MDR-TB is being spread, what activities are associated with increases or decreases in transmission, and which preventive strategies are effective.

Problem 1

National surveillance systems are inadequate to accurately determine the frequency and patterns of drug-resistant TB.

Objective:

Develop nationwide surveillance systems for determining the drug susceptibility patterns of persons with active TB.

	Responsible organization	Start date
1.	Develop a resolution to promote routine drug-susceptibility testing of M. tuberculosis isolates.	CDC CSTE/ASTPHLD	1992

2. Add reporting of drug-suscepti- CDC 1993 bility results to the CDC Report CSTE of Verified Case of TB (RVCT) TB control programs System, which collects data on persons with TB.

3. Increase CDC support to states CDC 1992-93 for expansion of the RVCT surveil- lance system to collect additional information, such as results of drug-susceptibility testing.

4. Develop the capacity to transmit CDC 1992-93 RVCT data electronically between state health departments and CDC to enable more rapid collection and dissemination of data on drug susceptibility.

5. Develop a module to facilitate CDC Under way reporting of M. tuberculosis drug- ASTPHLD susceptibility patterns by using the Public Health Laboratory Infor- mation System (PHLIS), which collects nationwide data on M. tuberculosis isolates processed in state public health laboratories.

6. Develop a software package that CDC 1992-93 links TB management and surveil- CSTE lance systems, including the Tuber- ASTPHLD culosis Database System (TBDS), RVCT, National Electronic Telecom- munication Surveillance System (NETSS), and PHLIS datasets at the state level.

7. Provide on-site support in computer CDC 1992-93 programming and use as needed to support TB data collection and analysis.

Problem 2

Hospitals, correctional facilities, and other institutional settings have been the focus of outbreaks of MDR-TB. The extent of MDR-TB transmission in the community has not been well studied. Epidemiologic studies and surveillance data are needed to assess the risk of infection and disease and factors promoting TB transmission in institutional settings, as well as the extent of community transmission.

Objective:

Conduct epidemiologic investigations and studies to better define the scope and magnitude of the problem, to identify risk factors for transmission of TB in special settings, and to define the extent of MDR-TB transmission in the community.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Draft a coordinated approach to CDC Under way outbreak investigation, and define specific issues to be addressed in outbreak investigations (e.g., quantitate disease attack rates among exposed persons).

2. Investigate MDR-TB outbreaks in CDC Ongoing hospitals, other health-care TB control programs facilities, prisons, other insti- tutional settings, and the community, as indicated.

3. Enhance MDR-TB-related health CDC Ongoing hazard investigations and technical assistance.

4. Consider collecting additional CDC 1992-93 information to identify exposures TB control programs in high-risk settings (e.g., correctional facilities).

5. Conduct epidemiologic studies to CDC Ongoing identify risk factors for transmis- BOP sion of MDR-TB in health-care faci- lities, correctional facilities, and other settings where there is risk of TB transmission.

6. Collect information on contacts of CDC 1992-93 reported MDR-TB patients who have been identified, examined, and found infected, so that the inci- dence of MDR-TB infection can be monitored.

7. Conduct epidemiologic studies to CDC 1993 define the extent of MDR-TB trans- mission in communities affected by MDR-TB outbreaks.

8. Develop a model to forecast the CDC 1992-93 effect of MDR-TB on trends in TB morbidity.

9. Create a subcommittee of the Task CDC 1992-93 Force to assess and forecast the HCFA economic impact of TB and MDR-TB AHCPR and the costs of implementing this OSHA Action Plan.

Problem 3

Certain subgroups of the population, including workers and clients of some service occupations, are at increased risk of TB. Data are needed to assess the risks and patterns of M. tuberculosis infection and active TB (both MDR-TB and drug-sensitive TB) among workers and others in settings where there is a risk of TB transmission.

Objective:

Determine the patterns of TB disease and infection among workers and others in settings where there is a risk of TB transmission, and characterize current programs for TB infection screening and infection control in these settings.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Explore the feasibility of CDC 1992-93 collecting and coding data on personal risk factors, including occupation, to allow determination of high-risk settings for MDR-TB.

2. Perform a survey of hospital-based CDC 1992 TB-related activities, including skin-testing programs for workers, infection control standards, and laboratory capabilities.

3. Develop a sentinel surveillance CDC 1992 program for TB infection among health-care workers to assess their risk of TB infection and the risk of active TB for those whose skin tests convert to positive.

4. Perform a survey of TB-related acti- CDC 1992 vities (worker skin-testing programs, BOP infection control standards, and ADAMHA laboratory capabilities) in other high-risk occupational settings, including correctional facilities and drug-abuse treatment centers.

5. Develop a TB infection sentinel sur- CDC 1993 veillance program to assess the risk BOP of TB infection and active TB among ADAMHA workers in other high-risk occupa- tional settings, including correc- tional facilities and drug-abuse treatment centers.

6. Perform studies on risk factors for CDC 1993-95 TB infection among workers in ADAMHA settings where surveillance programs document an excess risk of TB infection and active TB.

Problem 4

Persons with HIV infection have been the focus of recent MDR-TB outbreaks; however, the impact of HIV infection on TB trends has not been well characterized. Information is needed to assess the impact of HIV infection on recent trends in TB disease and infection, including MDR-TB, in the United States.

Objective A:

Characterize the HIV infection status of persons with TB and forecast the effect of HIV on future TB trends.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Obtain assurance of confidentiality CDC 1992 protection under Section 308(d) and 301 (d) of the Public Health Service Act for CDC surveillance activities that include information on the HIV status of persons with TB.

2. Work with state and local health CDC 1992-93 departments to assure confiden- State TB and tiality of TB/HIV information at HIV control programs all levels. Such measures would include providing training to state and local health department staff on maintenance of confidentiality.

3. Collect data on the HIV infection CDC 1992-93 status of TB patients reported State TB and through the RVCT, in accordance HIV control programs with state laws. HIV/AIDS surveil-

   lance coordinators

   CSTE

4. Continue HIV serosurveys in sen- CDC Ongoing tinel TB clinics.

5. Collect data on the HIV infection CDC 1993 status of TB patients through unlinked seroprevalence surveys in TB clinics.

6. Collect data on TB exposure and CDC 1993 disease in cohorts of women and children in ongoing perinatal HIV transmission studies.

7. Develop a model of TB/HIV co-infec- CDC 1992 tion to forecast the effect of HIV on TB morbidity trends.

Objective B:

Study drug-susceptibility patterns, treatment, and risk factors for TB among HIV-infected persons and perform surveillance of skin- test reactivity, anergy testing, and use of preventive therapy for persons with HIV infection.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Perform surveillance of TB testing CDC 1992-93 practices, TB disease, drug suscep- NIH tibility, and use of preventive therapy among HIV-infected persons through modification of the existing Adult/Adolescent Spectrum of Disease (ASD) and Pediatric Spectrum of Disease (PSD) surveillance systems, and the Community Program for Clinical Research on AIDS (CPCRA) and its Observational Data Base. These systems monitor diseases occurring among persons with HIV infection.

2. Expand cooperative agreement with the CDC 1993 National Public Health and Hospital NPHHI Institutes (NPHHI).

3. Enhance the HIV and AIDS reporting CDC 1992-93 system to collect supplemental TB State HIV and data, including the drug-suscep- TB programs tibility patterns of persons HIV/AIDS surveillance reported to have TB. coordinators

4. Add TB skin testing to the battery NIH 1992-93 of routine tests carried out in CDC existing national and international AIDS epidemiology cohort studies to determine the relationship between diminished reactivity to the TB skin test and immunologic status and to analyze the incidence and prevalence of TB among HIV-infected women.

LABORATORY DIAGNOSIS

Make the laboratory diagnosis of MDR-TB more rapid, sensitive, and reliable.

Many laboratory techniques for the diagnosis of TB and for identification of drug resistance were developed in the 1950s and 1960s. Although more accurate, rapid, and sophisticated methods are now available, these techniques have not been widely implemented, as TB was thought to be a declining disease and resources were shifted away from mycobacteriology laboratories. Now that both TB and drug resistance are increasing, the most current technologies need to be applied to their fullest capacity.

Problem 5

The most rapid currently available laboratory technologies to identify MDR-TB are not in widespread use in state and local health department laboratories.

Objective:

Increase the awareness and understanding of MDR-TB in the laboratory community, and upgrade the mycobacteriology capacity of state and local public health laboratories.

Responsible organization	Start date	Implementation steps
ASTPHLD	Completed	1. Conduct a survey of current laboratory practices and capabilities in state and territorial mycobacteriology laboratories.
CDC	1992	2. Develop cooperative agreements with state and local health departments to provide equipment and personnel to upgrade mycobacteriology laboratories.
CDC	1993	3. Develop state and regional laboratory centers that can rapidly identify and determine drug susceptibilities of M. tuberculosis isolates.
CDC	Ongoing	4. Develop a national specimen bank of MDR-TB isolates for use in proficiency testing and research.
ASTPHLD	1993	5. Explore upgrading the drug-susceptibility proficiency testing program, in collaboration with the College of American Pathologists.
CDC	1993	6. Develop self-assessment tools for laboratories to evaluate their practices.
CDC	1993	7. Develop a proficiency testing module to evaluate ability to use new technologies.
CDC	1993-98	8. Expand Laboratory Performance Information Exchange Systems for laboratories to share information on new technologies.

Problem 6

As the outbreak spreads to more geographic areas, current laboratory capacity to track and characterize the epidemic of MDR-TB may not be adequate.

Objective:

Enhance laboratory capacity to support outbreak investigations and special studies of MDR-TB.

Responsible organization	Start date	Implementation steps
CDC	Ongoing	1. Continue to support outbreak investigations through subtype characterization of isolates via DNA fingerprinting and enhanced drug-susceptibility testing.
CDC	Ongoing	2. Promulgate the use and transfer of proven, developed rapid diagnostic tests to clinical laboratories (e.g., radiometric culture and susceptibility testing, high-performance liquid chromatography, nucleic acid probes).
CDC	Ongoing	3. Develop strategies to transfer technologies for subtype characterization of isolates via DNA fingerprinting to state and city health departments, as appropriate.

Problem 7

Approximately 700,000 aliens * apply for permanent resident status annually in the United States. Under provisions of the Immigration and Nationality Act, each of these persons must receive a medical examination that includes an examination for TB. The quality of laboratories used by examining physicians abroad may not be adequate to perform sputum smear examinations to identify infectious TB or to perform drug-susceptibility tests.

Objective:

Evaluate the ability of these overseas screening laboratories to detect acid-fast bacilli, identify M. tuberculosis, and carry out drug-susceptibility tests; enhance their capability as needed.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Identify the top 20 immigrant visa- CDC 1992 processing posts abroad (in terms of the number of visas issued) with a high incidence of TB in the indi- genous population.

2. Evaluate the TB diagnostic capabilities CDC 1992 of laboratories used by examining physicians and identify those that require upgrading.

3. Provide any training necessary to CDC 1993 upgrade laboratory proficiency in collecting sputum, identifying positive sputum smears, identifying the TB bacillus, and performing drug-susceptibility tests.

4. Provide oversight, proficiency CDC Ongoing testing, and consultation to ensure adequate TB diagnostic and drug- susceptibility testing capability.

PATIENT MANAGEMENT

Prevent patients with drug-susceptible TB from developing drug- resistant disease. Effectively manage patients who have developed drug-resistant disease.

A generation ago, TB was a common problem that most physicians had experience in treating. With the decline of TB, this expertise was lost. In addition, the lack of health-care coverage for a large segment of our society has led to inadequate resources for treatment of many patients with TB, including MDR-TB. Moreover, drug resistance has made treatment much more complicated and expensive. Thus, we need to upgrade our national ability to provide optimal treatment for all patients.

Problem 8

TB treatment must be given for a minimum of 6-9 months. If TB patients do not complete therapy, they may not be cured, and if they take medications incorrectly, the organisms may become drug resistant. Therefore, TB patients need some degree of supervision to ensure compliance with and completion of therapy.

Objective:

Provide guidance regarding a step-wise approach to assure completion of therapy for all TB patients, with particular emphasis on implementation of directly observed therapy (DOT).

Responsible Start Implementation steps organization date ---------- ---------- --

1. Increase CDC grant-supported DOT. CDC 1992-95
2. Encourage state- and locally CDC 1992-95 supported DOT.
3. Expand use of the CDC Outreach CDC Ongoing Training Course that promotes enhanced compliance/DOT.
4. Recommend DOT policies for TB ACET 1992-95 programs, with emphasis on areas with a high prevalence of drug- resistant disease.
5. Foster Medicaid and other third- HCFA 1993 party funding for DOT. Encourage DOT HRSA in primary care facilities, drug ADAMHA treatment centers, HIV/AIDS residential facilities, HIV clinics, migrant clinics, and shelters.
6. Promote the use of DOT by health-care NCET Ongoing providers. CDC

   HRSA ADAMHA NASADAD
7. Issue new CDC/American Thoracic ATS 1992 Society/Infectious Disease Society of CDC America/American Academy of Pediat- IDSA rics Treatment Statement emphasizing AAP extensive use of DOT.
8. Provide ongoing technical assistance, CDC Ongoing both on-site and telephone, to promote expanded use of DOT in the field, as well as in clinics and other sites, by health departments and other health-care providers, e.g., community-based organizations (CBOs), Visiting Nurse Association, and correctional facilities.
9. Include DOT workshop at National TB CDC 1992 Conference. ADAMHA
10. Perform a survey of state and local CDC 1993 health departments to identify addi- ADAMHA tional approaches being used to en- hance patient compliance (including use of incentives and treatment in special settings, e.g., shelters for the homeless, long-term hospitali- zation, drug-abuse treatment sites, court-ordered DOT, and quarantine).
11. Contract to study effectiveness and CDC 1993 cost-effectiveness of various TB ADAMHA treatment strategies, including DOT in the field, DOT in clinics, DOT in special settings such as drug-abuse treatment sites, and use of incentives.

Problem 9

Approximately 700,000 aliens apply for immigrant visas abroad annually. Many of these applicants live in countries that have a high incidence of MDR-TB because of inadequate programs for managing and treating persons with TB.

Objective:

To decrease the likelihood of introduction of MDR-TB to the United States, evaluate the feasibility of establishing DOT programs in four or five of the countries from which a high volume of immigration originates and which have a high incidence of TB.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Study feasibility of establishing DOT CDC 1993 programs in four or five countries with high incidence of TB from which a high volume of immigrants originate.

2. Work with the Departments of State and CDC 1993 Justice to develop and implement DOT programs overseas.

3. Work with clinics and physicians who CDC 1994 examine a high volume of immigrants to implement pilot DOT programs for visa applicants.

4. Evaluate the efficacy of pilot DOT CDC 1994 programs.

5. Continue providing oversight, consul- CDC Ongoing tation, and evaluation for successful DOT programs overseas.

Problem 10

Few inpatient facilities are available for long-term treatment of patients with complicated TB cases, particularly those with MDR-TB, and many areas do not have a method of paying for these services.

Objective:

Explore varying options for long-term institutionalization of TB patients, including patients with MDR-TB, and assist health depart- ments in securing Medicare, Medicaid, and other funds for financing institutional care.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Respond to requests from states for CDC Ongoing possible solutions when problem cases arise.

2. Prepare an options paper for handling CDC 1992 persons in need of long-term hospi- HCFA talization, addressing cost issues. ADAMHA

   HRSA

3. Survey state health departments for CDC 1992 information on available facilities HCFA and current state practices regarding ASTHO Medicare or Medicaid payment for TB hospitalization.

4. Review findings of the survey and CDC 1992 examine possibility of expanding HCFA Medicare or Medicaid coverage to ADAMHA include all TB or MDR-TB patients in HRSA need of institutionalization.

5. Determine need for revised rules, CDC 1993 regulations, and policy for paying HCFA for long-term treatment of patients with complicated TB cases. Develop and implement a strategy.

6. Disseminate findings from the survey, CDC 1993 recommend options for long-term HCFA institutionalization, and provide information to states on how to secure financing.

7. Review HCFA policies relevant to HCFA Under way inpatient treatment of patients with CDC TB. Identify need for modifications.

Problem 11

Many TB patients do not have health insurance. Local health department budgets have difficulty providing adequate services to all who need them. Resultant breaks in the continuity of care may lead to the development of drug-resistant disease.

Objective:

Find means to pay for outpatient services to persons who do not have third-party coverage.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Identify types of patients who could HCFA 1992 qualify for Medicaid/Medicare coverage for preventive or curative services.

2. Identify types of curative or preven- HCFA 1992 tive services that could qualify for Medicaid/Medicare coverage.

3. Distribute memorandum to regional and HCFA 1992 state Medicaid/Medicare offices outlin- ing HCFA policy concerning payment of claims for TB preventive or curative services.

4. Explore means for reimbursement of TB CDC 1993 preventive services that are not HRSA currently covered by Medicaid/Medicare. HCFA

5. Notify regions, states, large cities, CDC 1992 and territories about federal policy concerning Medicaid and Medicare coverage for preventive and curative TB services.

6. Seek advice from the Social Security CDC 1992 Administration on the possibility of HCFA modifying the Disability Definitions to include TB.

7. Initiate discussions with private CDC 1992 insurers to explore options for funding TB treatment and prevention.

Problem 12

TB patients, particularly those with MDR-TB, often require specialized services that are difficult to provide in all acute-care hospitals and outpatient clinics.

Objective:

Evaluate the feasibility of developing specialized inpatient and outpatient TB treatment units and regional inpatient treatment centers.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Work with selected health depart- CDC 1993 ments to explore the advantages and disadvantages of specialized TB treatment units.

2. Work with selected health depart- CDC 1992-93 ments to explore third-party reim- HCFA bursement mechanisms for care in specialized TB treatment units.

3. Work with selected health depart- CDC 1993-95 ments, acute-care institutions, and medical schools to establish a number of regional centers of excellence for treating difficult-to-manage TB cases, especially patients with MDR-TB.

Problem 13

Drugs needed to treat TB, particularly MDR-TB, are often unavail- able, and some of them are expensive, which may be an obstacle to effective treatment.

Objective:

CDC, Food and Drug Administration (FDA), pharmaceutical manufac- turers, and others will work together to assure an ongoing supply of currently licensed antituberculosis drugs at an acceptable cost.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Develop and maintain a list of all FDA Ongoing current manufacturers of bulk and finished TB drugs.

2. Contact manufacturers to inform them FDA Ongoing of the increase in TB and MDR-TB and ask them to notify FDA if they anti- cipate manufacturing and/or supply problems or if they contemplate leaving the market.

3. Develop active surveillance of FDA Ongoing pharmaceutical manufacturers to anti- cipate manufacturing and/or supply problems or if they contemplate leaving the market.

4. Restore stable supplies of isoniazid, FDA October streptomycin, and para-aminosalicylic 1992 acid (PAS) on a long-term basis.

5. In the interim, assure adequate FDA Ongoing supplies and distribution of strepto- CDC mycin and PAS through an Investiga- tional New Drug mechanism until relicensing occurs.

6. Provide information to the FDA Task CDC Ongoing Force on antituberculosis drug needs, trends in TB morbidity, and other related matters.

7. Establish surveillance of existing CDC Ongoing antituberculosis drug supplies, needs, and costs in a representative sample of state and local health departments.

8. Explore feasibility of a federal CDC 1992-95 contract to provide antituberculosis drugs to state and local health departments.

Problem 14

Laws, regulations, and/or procedures for the quarantine, detention, reporting, and treatment of patients may be out of date or inadequate as the epidemiology of TB continues to evolve.

Objective:

Develop guidelines and recommendations that address the legal issues of TB control.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Review current federal and state laws CDC 1992 and regulations on quarantine, FDA reporting, treatment, and court- ADAMHA ordered DOT of TB patients.

2. Develop draft recommendations or ACET 1992 guidelines for when and how to CDC report, treat, and obtain court ADAMHA orders for DOT and quarantine of noncompliant patients.

3. Seek comments on recommendations CDC 1992 and guidelines from state and local TB control officials, health depart- ment legal offices, ASTHO, ACET, and others as appropriate.

4. Publish recommendations and guide- ACET 1993 lines. CDC

Problem 15

Homeless TB patients are often not able to complete TB therapy because of lack of stable housing and need for other social services; as a result, drug-resistant disease may develop.

Objective:

TB patients who are homeless, have unstable living arrangements, or lack essential social services will have access to housing for the duration of their TB treatment and will receive assistance with social services.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Alert Housing and Urban Development CDC 1992 (HUD) and others who provide social HRSA services to the homeless about the problem.

2. Arrange a meeting involving represen- CDC 1992 tatives of CDC, HUD, HRSA, and consortia authorized under the Comprehensive AIDS Resources Emer- gency Act of 1990 (also called the Ryan White Act) to explore this issue.

3. Assist state and local TB control CDC Ongoing programs in identifying local solutions to lack of housing for TB patients. Collect and disseminate information on successful strategies used in different areas.

Problem 16

TB among migrant and seasonal farm workers may be undiagnosed and inadequately treated because of lack of stable housing, the unique work situation, and geographic mobility; as a result, drug-resistant disease may develop.

Objective:

Coordinate public health systems so that migrant and seasonal farmworkers have access to diagnosis and treatment.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Publish recommendations for ACET 1992 prevention and control of TB among migrant workers.

2. Assist state and local governments, HRSA 1992-93 along with constituency groups, to ASTHO develop better tracking systems Migrant Clinicians for migrant and seasonal workers. Network

   CDC

3. Coordinate services and ASTHO 1993-95 reimbursement -- statewide and Migrant Clinicians interstate -- among state health Network offices, local health offices, and USPHS Regional migrant health centers. Offices

   CDC HCFA

Problem 17

TB patients who have substance abuse problems are likely to be noncompliant with TB therapy and may develop drug-resistant disease as a result.

Objective A:

Improve patient compliance with antituberculosis regimens among substance abusers in drug-abuse treatment centers.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Alert ADAMHA grantees and others ADAMHA Ongoing who receive ADAMHA publications about the emerging MDR-TB problem.

2. Provide guidelines to drug-abuse ADAMHA September treatment providers on how to detect, HRSA 1992 prevent, treat, and report TB among their clients (Treatment Improvement Protocol Statements {TIPS} program).

3. Provide training to substance abuse CDC September treatment staff on TB detection and ADAMHA 1992 management. HRSA

4. Encourage cooperation between drug- ADAMHA ASAP abuse treatment centers (DATC) and CDC local health departments for timely HRSA notification when persons with active TB in drug-abuse treatment are lost to follow-up.

5. Develop a system to track patients ADAMHA 1993 who receive services at different LHD DATC sites to ensure that there is DATC no break in their TB treatment services.

6. Strongly encourage all ADAMHA grant- ADAMHA Ongoing ees to include TB screening and HRSA preventive services in grant appli- cations.

7. Develop a Request for Assistance ADAMHA 1993 (RFA) to assess the extent of TB infection and disease among substance abusers both in and out of DATC, assess the rates of compliance with antituberculosis medications, and study innovative methods to enhance compliance among substance abusers.

Objective B:

Improve patient compliance with antituberculosis regimens among substance abusers not in drug-abuse treatment programs.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Develop a system that encourages CDC 1993 persons at high risk (including sub- LHD stance abusers not in DATC) to come ADAMHA for TB prevention and treatment ser- DATC vices, provides such services, and ensures patient compliance.

Problem 18

Approximately 700,000 aliens apply for permanent resident status annually. A large percentage of these applicants come from countries where TB (including MDR-TB) is common. Under provisions of the Immi- gration and Nationality Act, many aliens with active TB are admitted to the United States with a waiver of excludability. When such persons arrive at a U.S. port of entry (POE), CDC staff notifies state and local health authorities at the final destination. However, CDC does not have staff at all major POEs and must rely on the Immigration and Naturalization Service staff to provide copies of the aliens' medical documentation so that health authorities can be notified. Conse- quently, notification on some aliens arriving with TB is missed, with resultant breaks in continuity of care and possible development of drug-resistant disease.

Objective:

Improve the process of notifying state and local health depart- ments about aliens arriving with TB.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Identify the top 10 immigrant- CDC 1992 processing POEs not currently staffed by CDC.

2. Assign part-time staff to the top 10 CDC 1993 POEs to coordinate TB medical documentation and notification.

SCREENING AND PREVENTIVE THERAPY

Identify persons who are infected with or at risk of developing MDR-TB and prevent them from developing clinically active TB.

In addition to treating patients with active TB, patients who are infected with the TB organism but are not yet sick must be treated. Because many persons remain in this latent stage for years and then develop active disease, treatment of such persons will prevent many future cases of TB. In the treatment of active TB, noncompliance with therapy leads to the development of drug-resistant disease; however, this problem can be reduced by preventing active disease from developing. In addition, the development of active disease among persons infected with MDR-TB can be reduced if a standard approach to the evaluation and management of persons exposed to MDR-TB can be developed.

Problem 19

A standard approach to the evaluation and management of persons exposed to MDR-TB is lacking.

Objective:

Develop and publish an approach to the evaluation and management of persons exposed to MDR-TB.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Develop and disseminate guidelines CDC 1992 for evaluating and managing persons exposed to MDR-TB.

Problem 20

Many persons in populations at high risk for TB may also be at risk for noncompliance with therapy if active TB develops; as a result, drug-resistant TB may develop.

Objective:

Implement screening and preventive therapy programs, including supervised preventive therapy, among populations at high risk for both TB and noncompliance.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Expand existing demonstration projects CDC 1993 for promoting skin testing and preven- BOP tive therapy for clients in drug ADAMHA treatment programs and inmates in correctional facilities.

2. Expand screening for TB and tubercu- CDC 1993 lous infection to include all immigrants and refugees. Consider adding tuberculin skin testing to the medical evaluation of aliens.

3. Develop recommendations for each local CDC 1993 area to maximize participation of ADAMHA drug abusers in drug-abuse treatment NASADAD services and TB diagnostic, preven- tive, and treatment services.

4. Initiate an RFA for TB outreach demon- ADAMHA 1993 stration projects to screen and place drug abusers on preventive therapy in several areas of the country.

5. Develop a uniform database and track- CDC 1992 ing system for screening and preven- ADAMHA tive therapy in DATC and correctional BOP facilities.

INFECTION CONTROL

Minimize the risk of transmission of MDR-TB to patients, workers, and others in institutional settings.

TB is spread by an airborne route, and anyone who breathes air containing tubercle bacilli is at risk for acquiring infection. Because persons caring for and persons exposed to TB patients are at high risk of acquiring TB from their infectious patients, special precautions must be taken to prevent such spread while the best possible care for the patient is maintained.

Problem 21

Various infection control strategies are available to prevent TB transmission in institutional settings. These strategies are not consistently implemented, and their effectiveness and feasibility are not well characterized.

Objective:

Assess the effectiveness and feasibility of various infection control strategies in institutional settings (e.g., health-care facilities, substance abuse clinics, residential treatment centers, shelters for the homeless, correctional facilities) and ensure that appropriate procedures are implemented through educational and regulatory approaches.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Review the efficacy and cost- CDC 1992-93 effectiveness of isolation strategies.

2. Identify and prioritize TB infection CDC 1992-93 control procedures appropriate for hospitals and outpatient settings providing care to patients who are at high risk for TB or who are known or suspected to have active TB.

3. Update and revise the December 7, CDC 1993 1990, CDC infection control guide- HICPAC lines with new information and clari- fication as needed, including the roles of ventilation, ultraviolet germicidal irradiation (UVGI), and respiratory protection.

4. Develop a statement on issues related CDC 1992 to HIV-infected health-care workers HICPAC and TB.

5. Update statement on the role of BCG CDC 1992 vaccination in the control of TB, ACIP with focus on health-care workers. ACET

   HICPAC

6. Develop guidelines for selection and CDC 1992 use of respiratory protective devices HICPAC for protection against infection with M. tuberculosis.

7. Develop recommendations for design, CDC 1993 application, installation, monitoring, HICPAC and maintenance of UVGI fixtures.

8. Develop guidelines for effective envi- CDC 1993 ronmental TB prevention measures for BOP use in correctional facilities and ADAMHA drug-abuse treatment settings.

9. Inspect substance-abuse centers, shel- State 1993 ters for the homeless, and health-care and facilities on request to determine the local adequacy of ventilation, so that the HDs probability of TB transmission can be CDC minimized. OSHA

   HRSA HCFA ADAMHA

10. Perform cost analysis of modifying OSHA 1993 existing health-care, correctional, CDC and other high-risk institutional BOP facilities (including drug-abuse ADAMHA treatment settings) to achieve com- pliance with infection control requirements.

11. Review OSHA requirements for TB in- OSHA 1992 fection control in health-care facil- CDC ities, including drug-abuse treatment facilities, and other institutional settings, and suggest modifications and/or additions to the requirements.

12. Develop a Joint Advisory Notice be- OSHA 1992 tween the Department of Health and CDC Human Services and the Department of Labor on protection of workers against occupational TB transmission.

13. Develop a guidance document for OSHA 1992 OSHA compliance officers. CDC

14. Enforce compliance with the General OSHA Ongoing Duty Clause for worker protection against TB transmission.

Problem 22

Tuberculin skin testing of workers in settings where there is a risk of TB transmission is very important. Skin testing identifies workers who are infected with M. tuberculosis and need to be evaluated for active TB and for preventive therapy. It also serves as an indicator of the effectiveness of infection control practices. However, tuberculin skin-testing programs are not consistently imple- mented.

Objective:

Ensure that adequate tuberculin skin-testing programs for workers are in place in settings where there is a substantial risk of TB transmission.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Propose to the Joint Committee on CDC 1992 Accreditation for Health Organiza- tions the use of TB skin-test conver- sion rates among health-care workers as an outcome measure of the effec- tiveness of TB infection control programs in health-care facilities.

2. Develop recommendations for state CDC 1992 regulations requiring periodic TB skin testing of health-care workers (excepting only those with documented positive TB skin tests or histories of previous treatment for TB).

3. Develop recommendations for state CDC 1992 regulations requiring annual TB skin testing for corrections officers and other workers in high-risk institu- tional settings other than health care (e.g., shelters for the homeless).

4. Review state regulations regarding CDC 1992 certification for persons providing BOP TB screening at health-care or correc- tional facilities. Develop recommen- dations for state regulations.

5. Support health departments in CDC 1993 recruitment and assisting hospi- TB control programs tals, correctional facilities, and ADAMHA drug-abuse treatment settings to NASADAD develop, institute, and demonstrate the effectiveness of programs for systematic serial tuberculin skin testing of workers.

OUTBREAK CONTROL

Control outbreaks of MDR-TB.

Because transmission of TB may not be immediately recognized, common-source outbreaks can occur. Such outbreaks represent a challenge to public health efforts to control TB. Strategies for control of outbreaks include rapid identification, isolation, and treatment of infectious TB patients, evaluation of exposed persons for subclinical or latent disease, and preventive therapy for persons at high risk for infection. Such public health strategies have been complicated by the emergence of drug resistance, and some existing strategies may need to be modified.

Problem 23

The control of MDR-TB outbreaks is costly and complex, requiring close collaboration among local, state, and federal health officials and others (e.g., hospital officials, correctional facility officials, technical consultants).

Objective:

Facilitate collaboration of various officials and organizations in controlling MDR-TB outbreaks.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Develop more sensitive mechanisms to CDC Ongoing identify outbreaks (see page 10).

2. When MDR-TB outbreaks occur, estab- CDC Ongoing lish an outbreak control team to facilitate collaboration among various health officials, agencies, and tech- nical consultants.

3. Provide consultation to health depart- CDC Ongoing ments and institutions to facilitate control of outbreaks.

PROGRAM EVALUATION

Evaluate TB control programs to be sure they are effective in managing patients and preventing the development of MDR-TB.

An important part of the TB control effort is continuous evalua- tion of the effectiveness of existing control programs. Thus, methods to identify and correct problems in control programs must be developed before such problems result in the spread of disease, especially MDR- TB.

Problem 24

Some TB control programs may not be effective in managing TB patients, which may allow drug-resistant disease to develop. There is a need for assessing the quality of TB control (including health department infrastructure, facilities, and priorities).

Objective:

CDC, in conjunction with other agencies (e.g., the American Lung Association {ALA}, other members of the National Coalition for Elimin- ation of TB), will assist state and local health departments in assessing the adequacy of their TB control programs.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Enlist as many other organizations National TB Coalition 1993 (e.g., AMA, local or state medical societies, public health associa- tions, nursing associations, laboratory groups) as possible to encourage senior government officials (e.g., mayors, governors, legislators, health department directors) to request program reviews to assess the efficacy of TB control programs.

2. Encourage state TB control programs CDC 1993 work with ALA affiliates to arrange ALA and support these reviews.

3. Develop criteria for a model TB ACET 1992-93 control program. CDC

4. Develop an evaluation instrument, ACET 1992-93 based on the criteria for a model TB CDC control program, to be used as a framework for conducting program evaluation.

5. Conduct TB program reviews on 15-20 CDC 1993-94 TB control programs in areas with ALA the highest incidence of TB. ATS

6. Ensure that the results of these State and local Ongoing reviews are shared with senior TB control government officials (e.g., health programs department directors, mayors, State TB governors, legislators). elimination

   committees

7. Assure that all state and large CDC Ongoing metropolitan TB control programs prepare and submit program management reports to CDC. (These reports measure the efficacy of control efforts.)

8. Evaluate TB control programs (five CDC 1993 with the highest indices and five with the lowest indices of completion of curative therapy) to develop a composite of the elements included in a successful TB control program, and share this composite nationally.

Problem 25

Poor compliance with prescribed treatment promotes the development of drug-resistant strains of M. tuberculosis, which may lead to outbreaks of MDR-TB. Programs do not currently collect and analyze data on treatment outcomes that would identify populations at high risk for treatment failure.

Objective:

Assess program performance by collecting information on treatment outcomes of TB patients on an individual case basis, which will allow more effective targeting of resources.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Expand RVCT to collect information on CDC 1993 treatment outcome (e.g., continuity and completion of therapy).

INFORMATION DISSEMINATION/TRAINING AND EDUCATION

Effectively disseminate information about MDR-TB and its prevention and control.

Because the incidence of TB had been declining before its recent increase, many groups do not have adequate information on prevention, treatment, control, or laboratory procedures related to the disease. Information and communication systems need to be developed to deliver expanded training and education to health-care workers and labora- torians, and methods for disseminating educational information to populations most heavily affected and to the general public need to be developed or improved.

Problem 26

Expertise regarding treatment of TB, especially MDR-TB, is lacking in many parts of the United States.

Objective:

Develop a cadre of health-care professionals with expertise in the management of TB, including MDR-TB.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Increase knowledge about TB among NCET Ongoing health-care providers. Direct efforts CDC at all levels of training, including HRSA undergraduate and postgraduate levels. NJCIRD Address content of textbooks, medical and nursing school curricula, residency and fellowship training, and continuing medical education.

2. Provide supplemental training for CDC 1993 health-care providers in special HRSA settings (e.g., drug treatment ACET programs, migrant clinics, HIV treat- ADAMHA ment and prevention centers) regarding treatment and prevention of TB, with special emphasis on compliance and adverse reactions to therapy.

3. Work with medical schools and other CDC 1993 organizations to develop a cadre of NCET health professionals with expertise NJCIRD in management of MDR-TB to staff specialized TB units and regional centers of excellence.

Problem 27

Nosocomial transmission of TB to health-care workers and patients is occurring. Such transmission is preventable if recommended infection control practices are implemented.

Objective:

Disseminate information on the prevention of TB transmission to individuals and in facilities that provide services to persons who already have TB or who are at high risk for it.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Identify populations most heavily CDC 1992-93 affected for educational intervention HRSA (e.g., infection control practi- NCET tioners, infectious disease physicians, primary care practitioners, hospital epidemiologists, and TB nurse consul- tants and program managers in state and metropolitan health departments).

2. Develop curricula and materials on TB CDC 1992-93 infection control, principles of TB transmission, and techniques for improving communication between health departments and infection control prac- titioners in hospitals and correctional health settings.

3. Work with other professional and aca- CDC 1993-95 demic groups to provide TB infection control training.

4. Establish infection control training CDC 1993-95 programs.

5. Develop educational materials for CDC 1993-95 engineers and safety and health specialists about TB infection control practices.

6. Conduct regional workshops for training CDC 1993-96 consultants in infection control technology, design, installation, and maintenance.

Problem 28

A critical need exists for trained researchers to develop new diagnostic assays, therapeutic agents, and vaccines to meet present and future TB public health needs.

Objective:

Train adequate numbers of researchers to respond effectively to TB research needs.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Establish TB research training programs NIH 1993 for new investigators (postdoctoral fellowships and career development awards) and for senior investigators (senior fellowships and visiting fellowships at the National Institutes of Health {NIH}).

Problem 29

Mycobacteriology laboratory personnel may not be familiar with state-of-the-art TB diagnostic technologies and reporting practices.

Objective:

Provide training and evaluation of clinical mycobacteriology laboratory personnel in new diagnostic techniques for TB.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Utilize the National Laboratory CDC Ongoing Training Network to train mycobacter-iology laboratory personnel in new diagnostic techniques.

2. Develop appropriate training materials CDC Ongoing on TB for use in the laboratory setting, including new and emerging technologies.

Problem 30

Strategies for training and delivering TB information and education to health professionals and others have been inadequate.

Objective:

Develop an integrated system for professional information and communication on TB.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Educate policymakers, CBOs, and the NCET Ongoing public about MDR-TB.

2. Develop and pilot electronic "one-stop CDC 1992 shopping" for TB information and education.

3. Develop and pilot a responsive infor- CDC 1993 mation network for public health officials that provides timely elec- tronic data and information for action.

4. Develop a communication strategy for CDC 1993 TB information that will reach the NCET public, health-care providers, and high-risk populations.

5. Develop templates and models for CDC 1993 health departments to develop ASTHO relevant media-based information USCLHO campaigns. NACHO

   NCET

6. Consider creating a CDC TB hotline. CDC 1992

7. Evaluate effectiveness of training CDC 1993 and education efforts. NCET

RESEARCH

Perform research to identify better methods for combatting MDR-TB.

Many important questions about the biology of TB remain unanswered. However, for many years, research efforts and funding have not been focused on TB, and few researchers pursued careers in this area. As a result, such areas as the microbiology of the organism, vaccines, and treatment methods warrant immediate and extensive research. This need is highlighted by the concurrence of TB with HIV infection and the drug resistance of the organism.

Problem 31

Research on TB needs to be conducted and promoted by a variety of agencies, including CDC, NIH, FDA, and others. Coordination of research efforts among these agencies will be important in ensuring that critical knowledge gaps are addressed effectively.

Objective:

Develop a mechanism for coordinating TB research activities among the various agencies involved.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Form a research subcommittee to National MDR-TB Under way ensure interagency coordination of Task Force research programs.

Problem 32

There is a critical lack of knowledge about the basic character- istics of M. tuberculosis (e.g., growth, physiology, biochemistry, genetics, and molecular biology). This knowledge gap is a barrier to the development of new treatment and control modalities.

Objective:

Provide increased support for basic research on the biology of M. tuberculosis and the host responses to infection.

	Responsible organization	Start date	Implementation steps
1.	NIH CDC	Ongoing	Determine the basic mechanisms of acquisition of drug resistance in M. tuberculosis infection.
2.	NIH CDC	Ongoing	Expand basic research on the physiology, biochemistry, and structural biology of M. tuberculosis virulence factors and pathogenic mechanisms.
3.	NIH CDC	Ongoing	Determine the mechanisms of immunopathogenesis of M. tuberculosis infection, with special emphasis on the role of cytokines in disease progression.
4.	NIH CDC	Ongoing	Determine the immunologic and biologic factors associated with or responsible for latency and reactivation of M. tuberculosis infection.
5.	NIH CDC	Ongoing	Develop animal model systems to support basic and applied research on M. tuberculosis.
6.	NIH CDC	1992	Provide purified preparations of TB bacilli, purified antigens, and other purified components from M. tuberculosis to facilitate research.

Problem 33

Existing diagnostic methods to identify persons with drug-resistant TB are very slow, impeding treatment and control efforts.

Objective:

Develop and evaluate new technology to rapidly and reliably diagnose cases of TB and identify patterns of drug susceptibility.

	Responsible organization	Start date	Implementation steps
1.	NIH CDC	1992-93	Develop and evaluate rapid and simple methods for subtyping M. tuberculosis and identifying drug-resistant strains.
2.	NIH FDA	1992	Facilitate the development of improved diagnostic kits by systematically characterizing existing monoclonal antibodies against M. tuberculosis to determine the specificity and cross-reactivity of mycobacterial antigens.
3.	CDC	Ongoing	Develop and assess new methods for rapidly evaluating the susceptibility of tubercle bacilli in clinical isolates to antituberculosis drugs.

4. Develop and evaluate antigen detection NIH Ongoing assays and indirect serologic assays CDC for rapid diagnosis of active TB that FDA can be used in populations with either compromised or intact immune systems.

5. Evaluate the specificity and sensitivity CDC 1993 of candidate direct and indirect assays NIH for rapid diagnosis and identification of resistant strains in field situations.

6. Redirect a portion of the existing Small NIH 1992 Business Innovation Research (SBIR) program to encourage development of better tests.

7. Publish program announcements to en- NIH 1993 courage investigator-initiated (RO1) grant applications through NIH.

8. Implement an extramural research pro- CDC 1993 gram targeted toward development of HRSA diagnostic tests, rapid detection of drug resistance, and evaluation of candidate drugs.

Problem 34

Existing methods for identifying latent TB infection, especially among persons who are immunosuppressed, lack sensitivity and specificity.

Objective:

Develop and evaluate new technologies to rapidly and reliably identify latent tuberculous infection among both immunocompetent and immunosuppressed persons.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Develop and evaluate antigen detection CDC 1993-95 assays and indirect serologic assays NIH for rapid diagnosis of latent TB infection that can be used in popula- tions with either compromised or intact immune systems.

2. Determine sensitivity of different CDC 1993-95 diagnostic tests for TB for HIV- NIH infected patients at different levels of immune function.

3. Redirect a portion of the existing NIH 1992 SBIR program to encourage development of better tests.

4. Publish program announcements to en- NIH 1993 courage RO1 grant applications.

Problem 35

Currently available drugs are not sufficiently effective in treating MDR-TB. The duration of therapy required to treat TB with currently available drugs leads to noncompliance with therapy and development of drug-resistant disease.

Objective:

Encourage the development and evaluation of new drugs and modalities to treat and prevent MDR-TB, as well as to reduce the duration of therapy required to cure drug-susceptible TB.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Implement a protocol for a human trial CDC Ongoing of preventive therapy of MDR-TB with quinolone/pyrazinamide.
2. Initiate in vivo evaluation of quino- CDC 1992 lones. NIH

   HRSA
3. Evaluate depot preparations for CDC 1992 antituberculous chemotherapy. NIH

   HRSA
4. Establish clinical trials to evaluate NIH 1992 the potential antituberculosis effects CDC of drugs that have already been FDA approved for other indications.
5. Continue cooperative agreements with CDC Ongoing pharmaceutical manufacturers to screen compounds for antituberculosis activity.
6. Encourage pharmaceutical manufac- FDA Ongoing turers and academic researchers to NIH develop and screen new compounds for CDC antituberculosis activity. HRSA
7. Adapt new procedures for rapid, large- CDC Ongoing scale in vitro screening of potential HRSA antituberculous drugs.
8. Develop ability to test the in vivo CDC Ongoing antituberculosis activity in animal NIH models of experimental compounds found HRSA to be active in the rapid in vitro screening.
9. Design and evaluate clinical trials CDC Ongoing of TB treatment regimens by using new NIH compounds and modalities (including FDA depot preparations). HRSA
10. Design and evaluate clinical trials CDC Ongoing of TB preventive therapy regimens NIH that involve new compounds. FDA

    HRSA
11. Expand existing National Cooperative NIH Ongoing Drug Discovery Group- Opportunistic HRSA Infections Program.
12. Initiate new research to establish NIH Ongoing drug screening capability and develop CDC animal models. HRSA
13. Expand existing AIDS clinical research NIH 1993 efforts, including the AIDS Clinical Trials Group, CPCRA, and the Division of AIDS Treatment Research Initiative.

14. Fund meritorious grant proposals NIH 1992-93 received in response to RFAs for the development of new antituberculosis agents.

15. Evaluate the effect of therapy on the NIH 1993 infectiousness of TB patients to CDC determine the interval between the initiation of treatment and loss of infectivity.

Problem 36

Currently available vaccines against TB are not reliably effective in preventing acquisition of TB.

Objective:

Develop and evaluate new and improved vaccines to prevent infection and disease with M. tuberculosis.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Issue an RFA to address the following NIH 1992 objectives: identify and characterize immunogenic components of M. tuber- culosis; determine which immunogens elicit protective responses; charac- terize protective host responses; and develop animal models.

2. Evaluate candidate vaccines in phase NIH 1994-98 I, II, and III clinical trials. CDC

   FDA

Problem 37

The efficacy of various technologies for preventing TB trans- mission (e.g., general and local ventilation, UVGI, and personal protective equipment) has not been adequately evaluated.

Objective:

Conduct basic and applied research on the efficacy and role of various control methods for preventing transmission of TB.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Conduct research to develop and evalu- CDC 1993 ate the efficacy of various elements of ventilation (e.g., negative pressure, high-efficiency particulate air {HEPA} filters, laminar flow, UVGI, in-room HEPA filtration units) and to identify air disinfection techniques that do not require major facility modifications.

2. Design sampling and analytic methods CDC 1993 for measuring environmental contami- nation with TB bacilli.

3. Evaluate the efficacy of respiratory CDC 1993 protective devices against bioaer- osols, including particulate filter penetration, size characterization of droplet nuclei, and determination of respirator performance characteristics.

4. Fund extramural research to evaluate CDC 1992 the efficacy of UVGI, mycobacterial killing kinetics (including consider- ations of in-room aerosol distribution, effects of room air circulation, and interactions with ventilation and humidification).

5. Study the efficacy of the enclosed CDC 1993 floor model UVGI-fan unit.

Problem 38

Poor patient compliance leads to development of MDR-TB. Compliance is influenced by patient characteristics; characteristics of the health-care environment, including operational factors and compliance- enhancing intervention; and communication between patient and providers, including the quality of interpersonal communication and use of educational materials for transfer of information about the nature of the disease and treatment.

Objective:

Identify ways to improve compliance with therapy through behavioral research.

Responsible Start Implementation steps organization date ---------- ---------- --

1. Develop and test a predictor instru- CDC 1992-95 ment to identify the patient factors ADAMHA associated with poor compliance and development of MDR-TB, including personal, social, and cultural factors.

2. Expand research on cultural influences CDC 1992-96 on health-care utilization and adher- ADAMHA ence among foreign-born persons and minority groups at risk for MDR-TB.

3. Design and conduct operational CDC 1993-98 research on characteristics of TB ADAMHA health services, including case management, data management, staff selection and training, staff incen- tives, physician training, management and organizational structure, rela- tionships with community, community perceptions of services, community resistance to public health services, and clinic policies and practices.

4. Evaluate effectiveness of various CDC 1993-97 adherence interventions, including ADAMHA incentives, supports (enablers), and provision of social and additional health-care services to patients through TB programs.

5. Conduct a study of communication CDC 1993-96 styles of TB health-care providers; ADAMHA identify strengths and weaknesses and calculate the relationship between various styles and treatment outcomes.

6. By using research outcomes, develop CDC 1996-99 and evaluate innovative methods for ADAMHA training health-care providers in effective communication styles with patients.

7. Survey TB treatment practices of CDC 1993-94 health-care providers to determine ADAMHA discrepancies in practices that may lead to poor compliance and development of MDR-TB.

8. Utilize data from the survey of TB CDC 1992-95 treatment practices of health-care ADAMHA providers to design an in-depth study of barriers among providers most likely to treat patients at risk for MDR-TB.

9. Conduct formative communications CDC 1994-97 research to identify innovative and ADAMHA effective strategies to use persuasive educational messages to reach populations with high disease prevalence.

10. Evaluate educational strategies for CDC 1995-97 targeting the health-care providers ADAMHA of patients at risk for MDR-TB.

CONCLUSION

This National Action Plan to Combat Multidrug-Resistant Tuber- culosis lays out a series of activities that need to be undertaken at the national level. Priorities will vary from agency to agency, and activities should be undertaken within the time frames indicated, as resources permit. Many activities that are indicated as starting in 1992 and 1993 will continue in subsequent years. For state and local health agencies, the highest priority remains the detection and effective treatment of active cases. The Plan is a blueprint for action by federal agencies. However, many of the implementation steps will depend on the cooperation of many sectors of society. Indeed, the success of the plan will depend on a concerted effort and commitment at all levels and will involve collaboration between public health and other government agencies, professional societies, voluntary agencies, health-care providers, and many others.

Today the United States is at a critical point in history with respect to TB. Although a number of factors, including MDR-TB, are having an adverse effect on the TB problem, TB can be controlled and eventually eliminated if aggressive action is taken immediately. If such action is not taken, the TB problem will continue to grow in size and in complexity, and the costs of containing it will escalate.

- The term "alien" is defined in the U.S. Immigration and Nationality Act as any person not a citizen or national of the United States.

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