REPORT OF THE
VIRGINIA DEPARTMENT OF HEALTH ON

Comprehensive and Cost-Effective Means of Eliminating Tuberculosis Development Strategic Plan

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

HOUSE DOCUMENT NO. 60

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January 11, 1994

TO: The Honorable Lawrence Douglas Wilder
Governor of the Commonwealth of Virginia

The Members of the General Assembly of Virginia

I am pleased to transmit this report which constitutes the response of the Virginia Department of Health to House Joint Resolution No. 531 of the 1993 Session of the General Assembly of Virginia.

This report offers the results of the Department's study and review of comprehensive and cost-effective means of eliinating tuberculosis (TB) and protecting the public from the disease until it is eliminated by ensuring that individuals receive appropriate treatment.

Robert B. Stroube, MD, MPH
State Health Commissioner

Enclosure

HOUSE JOINT RESOLUTION 531

adopted by the 1993 General Assembly

January 10, 1994

A study by the Virginia Department of Health about effective methods to arrest the spread of active tuberculosis (TB) and prevent the developement of multidrug-resistant TB.

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EXECUTIVE SUMMARY

This report was written pursuant to House Joint Resolution (HJR) 531, adopted by the 1993 General Assembly. The resolution calls for the study of effective methods to arrest the spread of active tuberculosis (TB) and prevent the development of multidrug-resistant tuberculosis (MDR-TB). The report describes the causes for the recent resurgence of TB, and the scope of the TB problem in the United States and Virginia. Strategies for prevention, detection, and treatment of TB, as well as increased funding requirements to carry out proposed recommendations, are presented.

Background

TB is caused by a bacterium called Mycobacterium tuberculosis (M.tb.) which spreads through the air from a person suffering from TB of the lung or larynx to susceptible persons who share the same air. The more frequently a susceptible person breathes air containing M.tb., the more likely will infection occur. TB is not highly communicable. Only 30 percent of household contacts to an active case of pulmonary TB become infected. The percentage can increase with overcrowding in poorly ventilated environments. For this reason, TB is most common among persons living in crowded conditions.

Recent Resurgence of TB

In the last century, TB was the leading cause of death in the United States and it remained so well into the 20th century. Improved housing and living conditions, aggressive public health interventions, and development of effective drug therapy in the late 1940s led to a steady decline in TB cases. However, TB cases in the United States are again reaching epidemic proportions; 26,673 cases were reported nationally in 1992. In Virginia the reported cases of TB remained fairly steady from 1986 to 1991; 415 were reported in 1986, and 379 in 1991. The number reported in 1992 was 456, and as of December 20, 1993, 464 cases have been reported. In Virginia in 1991, 8.4 percent of the TB cases reported had at least partial resistance to one drug; in 1992 it was 5.9 percent.

Basic TB Control Strategies

The majority of active TB cases could be averted if preventive therapy is administered to persons with TB infection; MDR-TB could be prevented if patients complete their course of treatment in accordance with their physicians' instructions. While there is a heightened national interest to look for innovative approaches to contain the problem, the federal Centers for Disease Control and Prevention (CDC) have reiterated that the single most important step for controlling the disease is the effective and appropriate treatment of TB. It is essential that physicians follow

the May 1993 treatment recommendations of the national Advisory Council for the Elimination of TB. These recommendations were published in the October 1993 issue of the Virginia Epidemiology Bulletin which is mailed to all licensed physicians in the Commonwealth. Treatment serves three public health purposes:

- Treatment is effective in preventing persons with TB infection (which is non-communicable) from progressing to clinically active disease.

- Treatment of active cases benefits individuals and can eliminate transmission of TB to others.

- Continuation of the full course of treatment can prevent the development of MDR-TB.

Because non-compliance with treatment recommendations has contributed significantly to the resurgence of TB and MDR-TB, the CDC strongly encourages the use of directly observed therapy (DOT) whenever there is concern about non-compliance. The utilization of public health outreach workers is crucial for the success of DOT.

Multidrug-Resistant TB (MDR-TB)

While the prevalence of MDR-TB in Virginia is still low, every case gives concern. The necessary course of treatment increases from approximately 6 months for non-MDR-TB to 18 to 24 months or longer for MDR-TB, and the cure rate decreases from nearly 100 percent to 60 percent, respectively. Major outbreaks of MDR-TB have occurred in other states within correctional institutions, shelters, residential facilities, and hospitals. Prompt diagnosis and rigid adherence to the CDC treatment guidelines can greatly minimize outbreaks.

The current Regulations for Disease Reporting and Control require the directors of laboratories to report TB cases identified by culture. However, commercial and hospital laboratories are not required to report the results of drug susceptibility testing. If all laboratories were required by regulations to submit TB isolates to the Division of Consolidated Laboratory Services for drug susceptibility testing, delays in initiating treatment of MDR-TB could be minimized.

Containing Outbreaks in Institutions

Recent reports of the increased transmission of TB in institutional settings such as hospitals, nursing homes, homeless shelters, and jails and prisons in other states indicate that priority should be given to:

- Early identification and treatment of patients with suspected or confirmed TB disease,

- Strict adherence to isolation procedures for such patients,

- Adequate environmental control of TB, i.e., the use of ultraviolet lights and negative pressure ventilation in rooms occupied by TB patients,

- Rapid reporting of cases of TB to the appropriate local health department, and

- Coordination of treatment and follow-up of all cases with the appropriate local health department and the Virginia Department of Health (VDH) Bureau of TB Control.

Populations Especially at Risk for TB

The TB epidemic is occurring primarily among the urban poor, minorities, immigrants and refugees from countries with high TB rates, homeless persons, migrant workers, injecting drug users, residents of correctional facilities, nursing home residents, and persons infected with HIV. The latter have a striking vulnerability to TB; once infected, they are much more likely to develop TB disease than those not HIV-infected. As is currently being done in Virginia, HIV-infected persons should be closely monitored for TB symptoms and screened for TB as part of their routine health care. Another important measure is outreach into medically underserved low-income populations to screen for TB.

The VDH initiated a special incentive program in 1992 to address the problem of treating homeless persons with TB. Such persons, especially those also infected with HIV, need immediate access to housing and services for two primary reasons:

- They are at the greatest risk of continued homelessness, illness, and even death due to their dual diagnoses, and

- They have the greatest likelihood of transmitting TB because they tend to congregate in poorly ventilated settings.

The VDH has made it a priority to identify hospitalized homeless persons with TB who are at risk of treatment non-compliance and to provide for their living needs in a supervised environment before they are discharged from the hospital.

Legal Measures for Controlling TB

On occasion, there is a need to deal with persons who refuse to take medications despite

repeated counseling. Such persons are a potential risk to the public and may need to be isolated. An amendment to the Code enacted by the 1993 General Assembly makes rapid isolation possible after all other measures to convince patients to take medications have been exhausted and a significant risk exists that the patient may be lost to treatment. The law provides an appropriate balance between public health needs and the protection of human rights. An order for isolation may be sought by the Commissioner only after an array of incentives, counseling, and support have been provided to the person and DOT has not been successful. A procedure for court review follows within three days.

Last, but not least, the past decade has shown that policies for the prevention of TB must be developed in concert with those for HIV infection. The VDH has been doing this for several years and will continue.

Conclusion/ Recommendations

While cases of TB are increasing in Virginia, the situation is not yet "out of control." Since TB is a major public health concern, individual health care clinics/facilities and health care providers in the private sector must also fully participate to decrease the spread of this disease. The following should be done to prevent the problem from getting worse:

- Screen more persons for TB, especially those at high risk for TB, such as persons with HIV infection and foreign-born persons. Use licensing regulations to require screening of health-care-facility personnel for TB;

- Ensure that the Division of Consolidated Laboratory Services is well equipped to provide rapid diagnostic services;

- Employ 22 more outreach workers to conduct directly observed therapy (DOT); $209,030 in funding, and FTE's have been included in the Governor's budget of December 20, 1993;

- Inform health care providers about the latest recommendations of the Advisory Council for the Elimination of TB;

- Reinforce the Homeless Incentive Program (HIP), including additional incentives and enablers. The cost will be $147,000;

- Urge medical schools to give greater emphasis to courses on TB;

- Reinforce infection control measures in hospitals and other institutions housing TB patients;

- Provide for environmental adaptations in local health departments at a one time cost of $187,000;

- Establish appropriate facilities for isolating persons with, or suspected of having, infectious TB, and treating cases of MDR-TB. The cost will be $276,000;

- Provide for acute care hospitalization and second line anti-TB drugs at a cost of $128,000;

- Reinforce program management and evaluation at the VDH at a cost of $80,000. This is necessary because of the reduction in funding and resources that occurred for several years before the resurgence of TB;

- Provide seven additional public health nurses for local health departments at a cost of $210,000;

- Investigate and control outbreaks of TB promptly, involving both public health and individual health care service systems; and

- Solicit the support of the Medical Society of Virginia for the implementation of these recommendations.

The total cost for implementing the portion of these recommendations that will be the direct responsibility of VDH is $1,237,030 in general funds for the first year. Since the cost for environmental adaptations is a one time expenditure of $187,000, the continuation budget request is $1,050,030 per annum after the first year.

Chapter 1

INTRODUCTION AND BACKGROUND

This report was written pursuant to House Joint Resolution (HJR) 531 (Appendix 1), adopted by the 1993 General Assembly. The Resolution calls for the study of effective methods to arrest the spread of active tuberculosis (TB) - also referred to as TB disease - and prevent the development of multidrug-resistant tuberculosis (MDR-TB). The Committee members who helped with the study are listed in Appendix 2.

Virginia's TB cases declined by 44 percent during the years 1982 through 1991. However, from 1987 to 1991, the number of TB cases dropped by only 17 percent, compared to 38 percent during the previous five year period. Figure 1 depicts graphically the cases and Figure 2 (overleaf) the case rates of TB in Virginia for the period 1982 through 1992; Figure 3 (overleaf) the case rates of TB in Virginia as compared to those in the nation for the period 1982 through 1992. The decline in case rate per 100,000 population in the nation from 1987 to 1991 had slowed to one half of the rate of decline in the previous five year period.

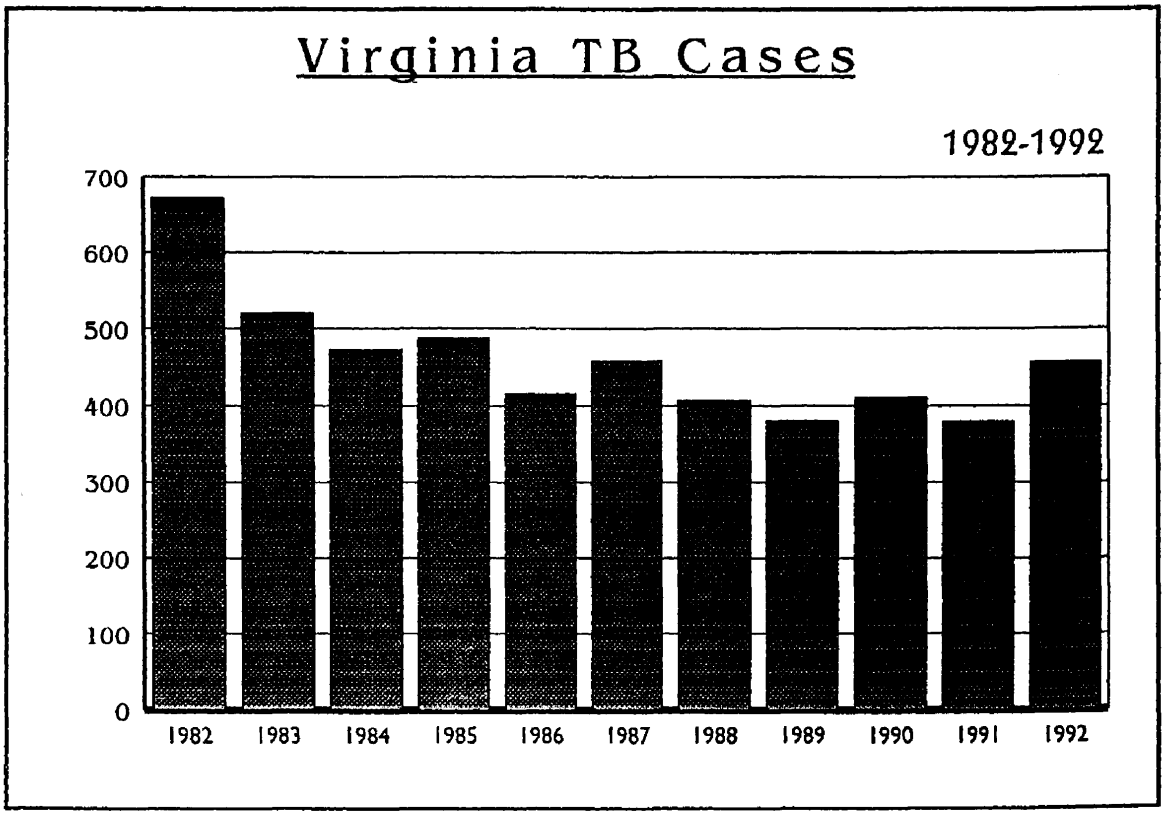

Figure 1

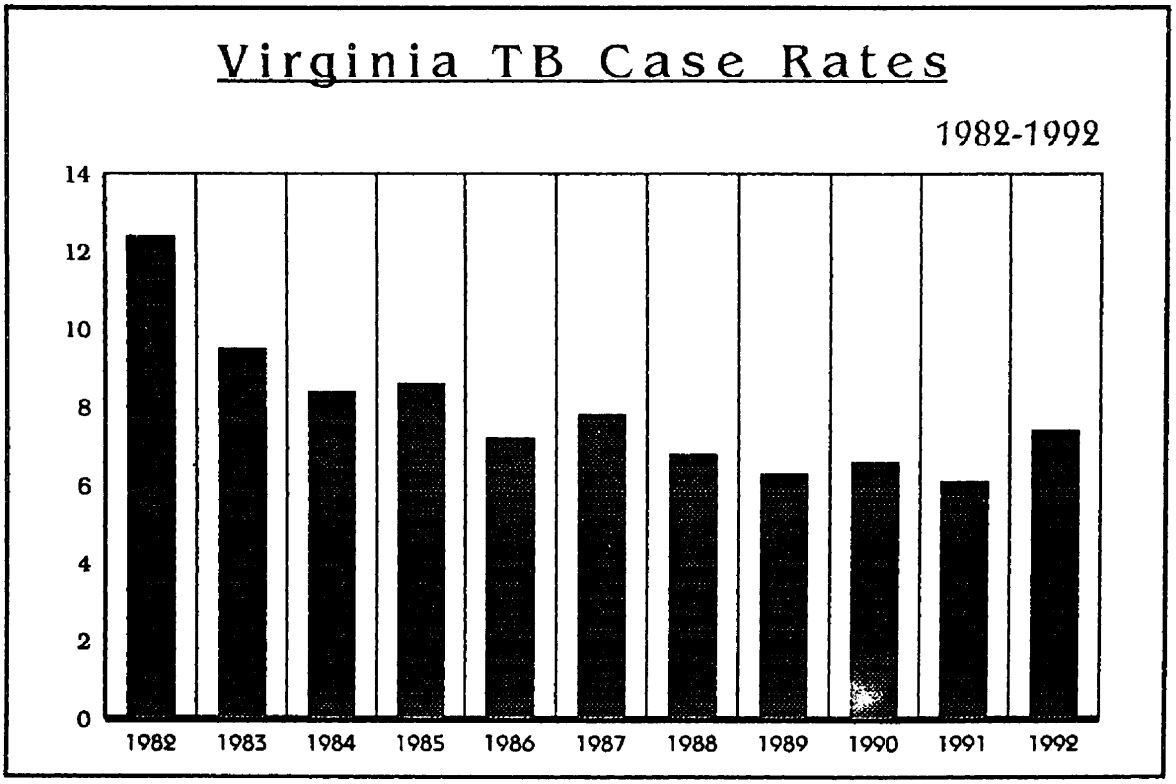

Figure 2

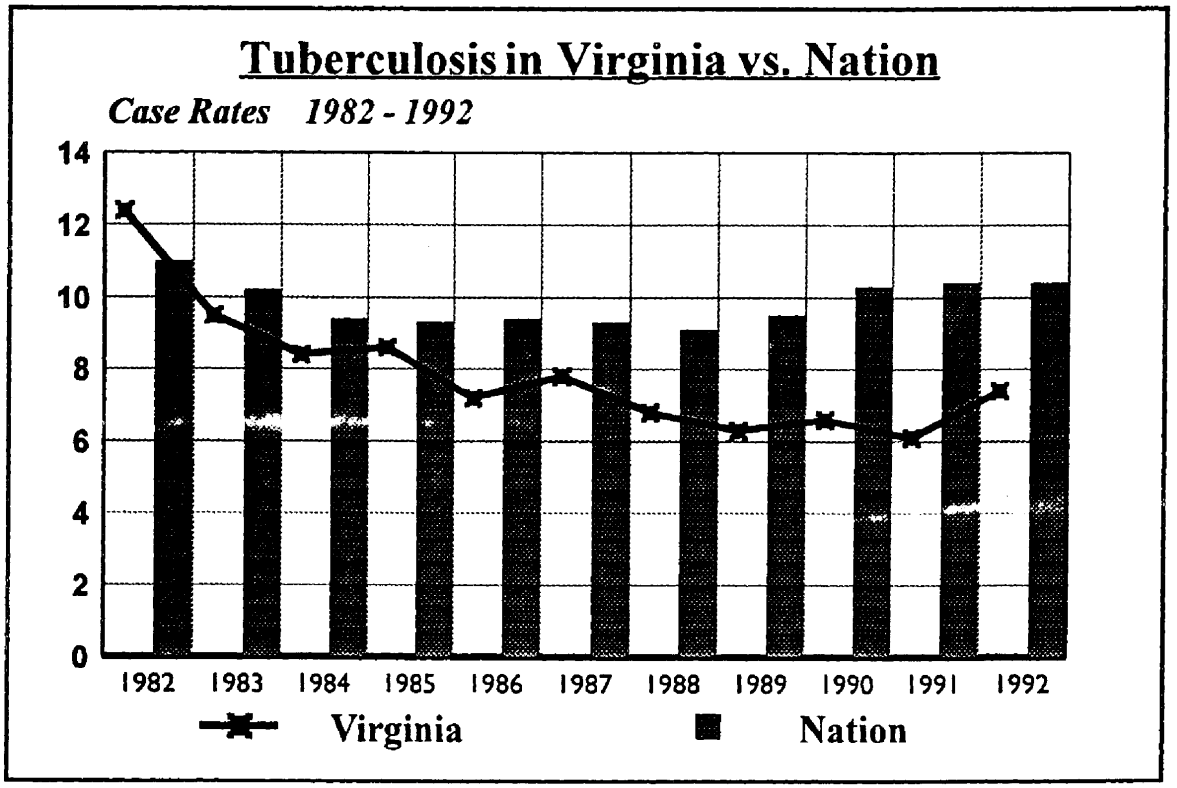

Figure 3

In 1991, 379 cases of TB were reported in Virginia, a nearly 8 percent decline from the 410 reported in 1990. However, in 1992 the number increased to 456. This is the largest single year increase over the last ten years, and only two cases less than the number reported in 1987. As of December 20, 1993, 464 cases have been reported.

Historical Origins of Tuberculosis

In the 19th century, TB was the leading cause of death in the United States. Death by "consumption" (so called because of the wasting experienced by patients) remained one of the leading causes of death well into the 20th century. At that time, there was little treatment for TB. Because TB is contagious, patients were housed in isolation facilities called sanatoriums. Improvements in housing, living, and sanitary conditions ultimately helped to reduce the U.S. incidence of TB disease and its associated mortality. The introduction in the 1940s of effective drug therapy and the closing of sanatoria over the next three decades led to the perception that TB had been eliminated.

Although the overall U.S. rate of TB disease was declining until the mid-1980s, urban areas with deteriorating social conditions were still disproportionately affected by TB. Transmission among persons in crowded living conditions (e.g., homeless shelters, correctional facilities, hospitals, and nursing homes) contributed to an increase in TB cases in certain communities, as well as to disease outbreaks. Increased immigration from countries with high TB prevalences also played a significant role. Since 1985, the incidence of TB disease in the nation has increased 18 percent and is reaching epidemic proportions in some urban areas.

The Goal To Eliminate TB in the United States

The number of TB cases in the U.S. declined from more than 84,000 cases in 1953 to a low 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, and established a national goal of TB elimination (an incidence of less than 1 case per 1 million) by the year 2010. An interim goal for the year 2000 is an incidence of 3.5 cases per 100,000.

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 ended, and from 1985 through 1991, approximately 39,000 more cases were reported in the nation than would have been expected had the previous downward trend continued.

Factors Hindering Achievement of the Goal

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 TB infection, the risk of developing active TB is 7 to 10 percent per year; it is considerably lower for persons who are not HIV-infected. When HIV-infected persons become newly infected with TB, the effect is even more dramatic; active TB develops soon after infection and progresses rapidly, often resulting in death. Also, HIV-infected persons with active TB are a greater risk to those around them because the immunosuppression caused by HIV infection makes it more difficult to control their TB.

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.

Basic Clinical Information and Epidemiology

TB is caused by the bacterium Mycobacterium tuberculosis (M. tb.), 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. Anyone who breathes air that contains these droplet nuclei can become infected with TB.

Persons sharing the same air with a person suffering from active pulmonary TB may or may not become infected with TB. In general, the more frequently a susceptible person shares the air with someone with active TB the more likely the susceptible person will become infected. TB is not highly communicable. Only 30 percent of household contacts to an active case of pulmonary TB become infected. This percentage can increase significantly with overcrowding in poorly ventilated environments.

Persons with TB infection do not necessarily develop TB disease - that is, people can get infected by the bacteria, and not become ill from it. Ninety percent of those infected never develop active disease. Of the remaining 10 percent, half will develop TB disease within 2 years of infection and half develop active disease sometime later. Individuals with TB infection, but without disease are not ill and are not a threat to others. Generally, a positive TB skin test is the only evidence of infection. About 10 to 15 million persons in this country are infected with M.tb. Because TB infection may progress to TB disease, infected persons should usually receive 6 months of preventive treatment with isoniazid (INH).

When taken correctly, medications used to treat active TB disease are very effective. However, symptoms often subside within 2 to 3 weeks of beginning treatment, leading to a false perception of cure by the patient. The time required to adequately treat TB disease varies from 6 to 9 months, or longer, depending upon whether the individual is also infected with HIV. If the drugs are not taken as prescribed for the correct amount of time, drug resistant disease may result and other persons may become infected with drug resistant bacteria.

Although TB case rates have progressively declined over the past two decades, the decrease has been much less among nonwhites. Nearly two-thirds of cases now occur among African Americans, Hispanics, Asians, and Native Americans. Although specific data are not available, the higher risk in minority populations may be related primarily to poor socioeconomic conditions that result in overcrowding. Thus, prevention and control strategies should be targeted especially to high-risk minority populations.

Chapter 2

REINFORCING CURRENT TUBERCULOSIS CONTROL PROGRAMS

Existing Prevention and Control Methods

Much can be achieved by reinforcing TB control programs currently in place in the Commonwealth, such as identification of high-risk population groups, testing these persons for TB infection, the use of preventive treatment in persons infected with TB, and adequate and appropriate treatment of all persons with TB disease.

Improving Surveillance

The identification and reporting of TB cases, suspected cases, and contacts is at times slow or incomplete, thus delaying treatment. Some cases are not diagnosed or reported. This is more likely to occur among the poor, the elderly, the homeless, drug users, and prisoners. It is important to ensure that:

- All persons with signs and symptoms suggestive of TB receive an appropriate diagnostic evaluation within 2 weeks of initial contact with a health-care provider.
- Suspected or diagnosed cases are reported to health departments within 3 days of the time the diagnosis is made or suspected, or a positive laboratory result is obtained, so that contacts can be identified and examined.
- Active population-specific case finding, screening, and preventive intervention programs are carried out by health departments.
- Achievement of the above objectives is measured and assessed.

Action Steps

- Health departments, medical and nursing schools, schools of public health, volunteer agencies, professional societies, and minority advocacy groups should aggressively educate health-care providers and high-risk groups about the signs and symptoms of TB and the methods of diagnosis, treatment, and prevention.
- Health departments in highest risk areas should install a telephone answering machine for the convenience of health care providers who wish to report cases of TB outside of regular business hours.
- Health department staff should routinely monitor the time between the diagnosis of TB and the date the case is reported. Delays of more than 3 days should be investigated and action taken to prevent similar delays.
- Health department staff should conduct periodic reviews of selected record systems (e.g., laboratory reports, pharmacy reports, AIDS/HIV registries, and death certificates) to validate the surveillance system and detect failures to report cases.

- Public health officials should identify high-risk populations and areas in which active case finding and preventive intervention programs should be reinforced.

Improving Case Prevention

Preventable TB cases continue to occur. To prevent such occurrences, the following measures must be aggressively implemented:

- As far as possible, all persons should have the results of at least one tuberculin skin test documented in their medical record; those who test positive should be evaluated and counseled regarding their risk of developing TB.

- Tuberculin skin-testing programs should be conducted annually among the staff of TB clinics, mycobacteriology laboratories, shelters for the homeless, nursing homes, substance-abuse treatment centers, dialysis units, and correctional institutions. The staffs of hospitals, mental institutions, and home health-care agencies should be tested annually if the prevalence of TB infection exceeds five percent.

- Consideration should be given to installing and properly maintaining ultraviolet lights in high-risk facilities for the transmission of TB, such as jails, prisons, and shelters for the homeless.

- Hospitals that admit untreated TB patients or persons suspected of having TB should have proper facilities and procedures for instituting TB isolation.

- Consideration should be given to routinely obtaining sputum for mycobacterial smear and culture from symptomatic nursing home residents and HIV positive persons thought to have a lower respiratory infection.

- Close contacts should be examined within 7 days after a case of TB is reported to the health department.

- Infected contacts should be placed on preventive therapy if there is no evidence of clinical disease.

- Children through 14 years of age whose skin tests show no evidence of infection and who are close contacts of someone with infectious TB should be placed on preventive therapy until repeat skin testing (3 months after contact is broken) confirms the absence of infection.

- All persons identified as TB infected should be offered confidential HIV counseling and testing. Likewise, all persons identified with HIV infection should be tuberculin tested.

Improving Disease Containment

Many TB patients do not complete a recommended course of therapy. Nationally, more than 25 percent of sputum-positive patients are not known to have converted from positive to negative sputum culture within 6 months. In addition, almost 12 percent of patients are not known to be currently receiving therapy, and more than 17 percent of TB patients do not take their medication continuously. The following action steps are necessary to correct the situation:

- For each new infectious case, a specific treatment and monitoring plan should be developed within 4 days of diagnosis. This plan should include medications to be used (doses, duration, and frequency of administration), assessment of toxicity, and methods to be used to assess and ensure compliance.

- Lack of funds should not be a barrier to the provision of medications, laboratory services, and ancillary services to TB patients. While local health departments can take care of indigent patients, primary care providers have the obligation and responsibility to ensure treatment of other TB patients.

- Incentives may be necessary to enhance compliance with medications. It may be as simple as offering a cup of coffee and talking with a patient in the clinic, or as complex as providing food and housing for a homeless patient. Particular attention must be given to ensuring that patients have transportation to the clinic.

- Twice-weekly, directly observed therapy (DOT) (discussed in Chapter 11) should be used whenever needed.

- Treatment and isolation orders as authorized by the Code should be used in those instances when an infectious patient refuses to comply with self-administered therapy or DOT.

- Health departments should review each new TB case and each death from TB to determine if the case or death could have been prevented had the American Thoracic Society/Centers for Disease Control and Prevention (CDC) recommendations been followed. Based on these reviews, new policies should be developed and implemented to reduce the number of preventable cases.

- Expert assessment should be conducted of local health department TB control activities, such as through the VDH Program for Excellence review.

Improving Methods for Treating Disease

Current drug regimens are effective, well tolerated, and can be given with minimal effects on the patient's mode of living. A minimum of 6 months of multi-drug therapy is necessary to achieve a high probability of cure. There are at least four obstacles to achieving a cure:

- the failure of patients to comply with regimens of long duration, most often due to alcoholism or other substance abuse

- drug-resistant organisms

- adverse reactions that require interruption and modification of the original, and usually optimal, drug regimen

- the cost of the most effective regimens for treating MDR-TB

To ensure that patients are given the best care, the following are necessary:

- Strict adherence to the most recent recommendations for the treatment of TB by the Advisory Council for the Elimination of Tuberculosis (ACET), described in Chapter 3.

- Greater use of DOT.
- Greater use of the homeless incentive program (HIP) discussed in Chapter 10.

Improving Methods for Diagnosing Disease

Current techniques for diagnosing TB are beset by a number of limitations and problems. Available techniques are slow, resource intensive, and not ideally sensitive and specific. The following action steps are necessary:

- The Division of Consolidated Laboratory Services (DCLS) must be adequately equipped to provide complete laboratory diagnostic services for TB, as and when better methods for the diagnosis of TB emerge.
- The VDH should continue to disseminate information about new diagnostic methods to health care providers through the Virginia Epidemiology Bulletin which is published monthly. Important audiences to reach with education messages are infection control practitioners, medical and nursing educators, nurses, medical and nursing students, and physicians. The Commonwealth's three academic health centers and area health education centers also need to play an important role in these continuing medical education efforts.
- The American Lung Association's efforts to promote public health programs to deal with TB must be encouraged.
- Input should be sought from advocacy groups representing populations with high rates of TB to improve the education of their constituents and health care providers who serve them.

Chapter 3

TREATMENT OF TUBERCULOSIS

General Principals

Because administration of a single drug often leads to the development of a bacterial population resistant to that drug, effective regimens for the treatment of TB must contain multiple drugs to which the organisms are susceptible. When two or more drugs are used simultaneously, each helps prevent the emergence of tubercle bacilli resistant to the other(s). However, when the in vitro susceptibility of a patient's isolate is not known - which is generally the case at the beginning of therapy - selecting two agents to which the patient's isolate is likely to be susceptible can be difficult. Improper selection of drugs for the treatment of drug-resistant TB (i.e., providing only one drug to which most organisms are susceptible) may result in the development of additional drug-resistant organisms.

A four-drug regimen with isoniazid (INH), rifampin (RIF), pyrazinamide (PZA), and streptomycin (SM) or ethambutol (EMB) is preferred for the initial treatment of TB. When adherence with the regimen is assured, such as with directly observed therapy (DOT), the four-drug regimen is highly effective even for INH-resistant organisms. Based on the prevalence and characteristics of drug-resistant organisms, at least 95 percent of patients will receive an adequate regimen (at least two drugs to which their organisms are susceptible) if this four-drug regimen is used at the beginning of therapy. Even with susceptible organisms, sputum conversion is accomplished more rapidly from positive to negative with a four-drug regimen than with a three-drug regimen of INH, RIF, and PZA. DOT is more easily managed with the four-drug regimen since it can be administered intermittently 3 times/week from the beginning of therapy. The four-drug regimen also can be administered 2 times/week following a 2-week initial phase of daily therapy. Finally, a patient who is treated with the four-drug regimen, but who defaults therapy is more likely to be cured and not relapse when compared with a patient treated for the same length of time with the three-drug regimen. The Advisory Council for the Elimination of Tuberculosis (ACET) recently issued guidelines for the treatment of TB (published in the Morbidity and Mortality Weekly Report, No. RR-7, May 21, 1993).

The Virginia Department of Health (VDH) provides medical care to about 50 percent of persons with TB infection or disease. The rest are cared for by private physicians, but local health departments are responsible for determining the contacts of these patients and ensuring that they receive follow-up. This is accomplished through experienced public health professionals in local health districts and a network of regional chest clinics.

Susceptibility Testing

All persons from whom Mycobacterium tuberculosis (M.tb.) is isolated should have drug-susceptibility testing performed on their first isolate; these results should be reported promptly to the health-care provider and to the health department.

Such testing will provide the basis for clinical therapeutic decisions. In addition, surveillance of drug-susceptibility reports will help identify emerging drug resistance and help monitor control efforts in areas where resistance is already established. Drug-susceptibility testing should be performed on additional isolates from patients whose cultures fail to convert to negative within 3 months of beginning therapy, or if there is clinical evidence of failure to respond to therapy. The mycobacteriology section of Division of Consolidated Laboratory Services (DCLS) routinely tests all initial M.tb. cultures for sensitivity to all first line drugs, and retests any M.tb. cultures collected three months

after the initial culture to determine if drug resistance has emerged. The problem in Virginia is with private and hospital labs that do not submit cultures to DCLS and do not provide sensitivity testing unless ordered by the attending physician.

Initial Regimen for TB Disease

During the first 2 months, the drug regimen should include INH, RIF, PZA, and EMB or SM. When drug susceptibility results are available, the regimen should be altered as appropriate. This regimen should be administered to all patients unless the likelihood of INH or RIF resistance is low.

Analysis of local rates of drug resistance provides the best basis for determining when the four-drug regimen might not be necessary. Local data may indicate that the population in general is at low risk for drug resistance or that specific and definable subgroups in the population are at low risk for drug resistance. In the past, when national INH-resistance rates were about 4 percent and declining, two- and three-drug regimens were considered adequate. Community rates of INH resistance less than 4 percent may be an indication that an initial regimen with fewer than four drugs may be acceptable. However, continued surveillance of drug susceptibility patterns is necessary to ensure that low rates of drug resistance continue. The rate of INH and/or RIF resistance statewide in 1992 was 3.5 percent, and in excess of 4 percent in northern Virginia and the Richmond metropolitan area.

Institutions (e.g., health-care and correctional facilities) that are experiencing outbreaks of TB resistant to INH and RIF or that are resuming treatment for a patient with a prior history of anti-tuberculosis therapy may need to begin five-drug or six-drug regimens as initial therapy. These regimens should include the four-drug regimen and at least three drugs to which the suspected multidrug-resistant (MDR) strain may be susceptible.

When the results of drug susceptibility tests become available, regimens should be specifically defined on the basis of those results. For example, patients whose TB organisms are susceptible to INH and RIF should receive a regimen of INH and RIF for a full 6 months, supplemented with PZA during the first 2 months. The treatment regimen of patients with drug-resistant organisms should be determined in consultation with physicians experienced in the treatment of drug-resistant TB.

Immunosuppressed Patients

HIV infection and other factors that compromise a patient's immune system are important considerations when clinicians select the most effective regimen for the treatment of TB. These factors are particularly important with drug-resistant TB because of the potential for rapid disease progression and death when patients receive inadequate treatment. The ACET recommends that such patients be treated for a total of 9 months and for at least 6 months after sputum conversion. No evidence suggests that intermittent therapy - twice a week or 3 times per week - will not be as effective for the treatment of TB among HIV-infected persons. If drug susceptibility results are not available, EMB or SM should be continued for the entire course of therapy because of the risk of rapid disease progression while the patient is on inadequate therapy.

Preventive Therapy for Persons with TB Infection

Isoniazid (INH) preventive therapy has an efficacy of up to 93 percent for persons with TB infection who complete treatment. Such therapy is critical for preventing TB infection (which is not communicable) from progressing to TB disease.

The usual preventive therapy regimen is INH (10 mg/kg daily for children, up to a maximum adult dose of 300 mg daily) for 6 to 12 months. Twelve months of therapy is recommended for persons with HIV infection and persons with stable abnormal chest x-ray films consistent with past tuberculosis. The other groups should receive a minimum of 6 continuous months of therapy. Isoniazid can be given twice weekly in a dose of 15 mg/kg (up to 900 mg) when therapy must be directly observed and resources are inadequate for daily therapy. Persons for whom preventive therapy is indicated can be categorized into two groups as follows:

High-Risk Groups

- Persons with HIV infection and TB skin test reactions $\geq$ 5 mm, and persons with risk factors for HIV infection whose HIV infection status is unknown, but who are suspected of having HIV infection.
- Close contacts of persons with newly diagnosed infectious tuberculosis and TB skin test reactions $\geq$ 5 mm. In addition, TB skin test-negative children and adolescents who have been close contacts of infectious persons within the past 3 months are candidates for preventive therapy until a repeat tuberculin skin test is done 12 weeks after contact with the infectious source.
- Recent converters (i.e., persons whose TB skin test reactions have increased) by $\geq$ 10 mm within a 2-year period if less than 35 years old; $\geq$ 15 mm increase if more than 35 years of age.
- Persons with abnormal chest x-ray films that show findings likely to represent old healed TB and skin test reactions $\geq$ 5 mm.
- Intravenous drug users known to be HIV-seronegative and skin test reactions $\geq$ 10 mm.
- Persons with medical conditions that have been reported to increase the risk of tuberculosis and skin test reactions $\geq$ 10 mm.

Other Groups

In addition, in the absence of any of the above risk factors, persons less than 35 years of age in the following high-incidence groups are appropriate candidates for preventive therapy if their reaction to a tuberculin skin test is $\geq$ 10 mm:

- Foreign-born persons from high-prevalence countries.
- Medically underserved low-income populations, including high-risk racial or ethnic minority populations, especially African Americans, Hispanics, and Native Americans.

- Residents of facilities for long-term care (e.g., correctional institutions, nursing homes, and mental institutions).

Impediments to the Treatment and Control of TB

During the past few years, several impediments to the treatment and control of TB have arisen. The more important of these (not listed in any special order) are:

- The occurrence of TB in migrant farm workers and the practical difficulties in dealing with this transient population.
- The increase of TB in immigrants to the United States from countries with a high prevalence of TB.
- The recent increase in multidrug-resistant TB.
- The greater susceptibility of HIV-infected patients to TB.
- Patient's non-compliance with treatment orders.
- The potential for outbreaks of TB in institutions such as correctional facilities and nursing homes.

These issues are discussed in the subsequent chapters.

Chapter 4

TUBERCULOSIS AND MIGRANT FARM WORKERS

The nation experiences an influx of migrant farm workers annually. While they primarily congregate in California, Texas, Puerto Rico, and Florida, some come to Virginia. They begin arriving in early May, peak in mid-July, and leave in early November. The influx to Virginia has declined in recent years.

Scope of Problem in the United States

There are an estimated 2.7 to 4.0 million migrant and seasonal farm workers. Only about 12 percent are served by federally supported migrant health centers. As part of a study, 310 persons were screened for TB, HIV infection, and syphilis in 14 migrant camps in Florida in early 1993. The findings were as follows:

- 5 percent were HIV positive
- 44 percent of the 267 TB skin tests that were read were positive
- 47 percent of persons with positive skin tests returned to be evaluated for TB disease
- Of the 47 percent, 18 were diagnosed with TB infection and one had TB disease

The relatively high prevalence of TB and HIV infection compared to the general population underscores the need for more aggressive TB control measures for migrant workers.

Scope of Problem in Virginia

Migrants congregate mainly on the Eastern Shore and in the northwestern region of Virginia. This results in the introduction to Virginia of undiagnosed TB and old, inadequately treated TB. The transiency of migrant workers hinders the successful treatment of TB. They often have difficulty coming to the local health department. Therefore, the ideal way to deliver services to them is via outreach, i.e., having public health workers go to their homes, places of work or migrant health care centers.

No tracking system exists to ensure continuity of TB treatment, and implementing a reliable one would be very problematic. From 1984 to 1988, the Virginia Department of Health (VDH) Bureau of TB Control, and the Thomas Jefferson and Eastern Shore health districts conducted a study of TB among migrants in Virginia. Forty three percent of the persons tested were positive for TB infection compared to only 5 to 6 percent in the general population.

Twenty eight cases of active pulmonary TB were diagnosed through this screening program from 1984 to 1988; 4 cases among migrants were reported in 1989, none in 1990, and 4 in 1991. Of the persons identified as TB infected, 66 percent were started on preventive therapy, but only 12 percent of these patients completed the treatment course.

Tuberculin skin testing of migrants by the Eastern Shore Health District was discontinued in 1989; however, Delmarva Rural Ministries (a federally funded migrant health center) continues to provide TB skin testing and refers migrants with positive skin tests to health department clinics on

the Eastern Shore. The cost of chest x-rays and medications are absorbed by the district. The Nelson County and Charlottesville health departments continue to screen migrants and hold annual evening clinics for their migrant population which is substantially smaller than that on the Eastern Shore.

Current levels of infection among migrants are not known, but due to the national resurgence of TB and the epidemic of HIV infection it is probably higher than in the 1980s. If resources will allow the VDH intends tuberculin skin testing of this population on the Eastern Shore next year. Virginia is fortunate in that the magnitude of the TB problem in migrants is less than that in states such as California, Texas and Florida.

Chapter 5

TUBERCULOSIS AND FOREIGN-BORN PERSONS

Approximately 700,000 aliens (defined in the United States Immigration and Naturalization Act as any person not a citizen or national of the United States) apply for permanent resident status annually in the United States. The Act requires each of these persons, 15 years of age or older to receive a medical examination that includes an examination for TB. However, students, tourists, World War II veterans from the Philippines, and illegal aliens are not subject to these provisions. The quality of laboratories used by examining physicians abroad may not be adequate to perform sputum smear examinations to identify TB disease or to perform drug-susceptibility tests. It is the general consensus among public health officials that:

- Foreign-born persons residing in the U.S. have higher rates of TB than persons born in the U.S. In 1991, the TB case rate in the foreign-born was 40.1 per 100,000 population compared to 4.3 for U.S. born persons residing in Virginia.

- Many foreign-born residents are infected upon arrival in the U.S. because they emigrated from countries where TB disease is epidemic.

- In Virginia in 1991, foreign-born individuals were greater than nine times more likely to develop TB disease than their U.S.-born counterparts. Most develop disease within five years of entering the U.S.

- Successful treatment of TB infection and disease is hindered by language barriers and cultural differences.

Screening of prospective refugees, immigrants, and entrants from high-incidence countries should be intensified and persons with communicable TB excluded until they become noninfectious. Unless contraindicated, those with infection (without disease) should be started on preventive therapy either before, or within 2 months after entry into the U.S.

The Situation In Virginia

- Foreign-born individuals accounted for 33 percent of the 379 cases of TB reported in Virginia in 1991 and 30 percent of the 456 cases reported in 1992. Further details are found in Figures 4 and 5 (overleaf).

- In 1992, 71 percent of the 136 cases of TB reported in Northern Virginia occurred among the foreign-born. The same percentage of the state's entire 1992 foreign-born TB case load resided in northern Virginia. The remaining 29 percent resided in 11 different counties and cities throughout the Commonwealth making this a statewide problem.

U.S. And Foreign Born Cases 1988-1992

Year	1988	1989	1990	1991	1992	TOTAL
Total Cases	406	380	410	379	456	2031
U.S. Born Cases	323 79.6%	286 75.3%	294 71.7%	254 67.0%	320 70.2%	1477 72.7%
Foreign Born Cases	83 20.4%	94 24.7%	116 28.3%	125 33.0%	136 29.8%	554 27.3%

Figure 4

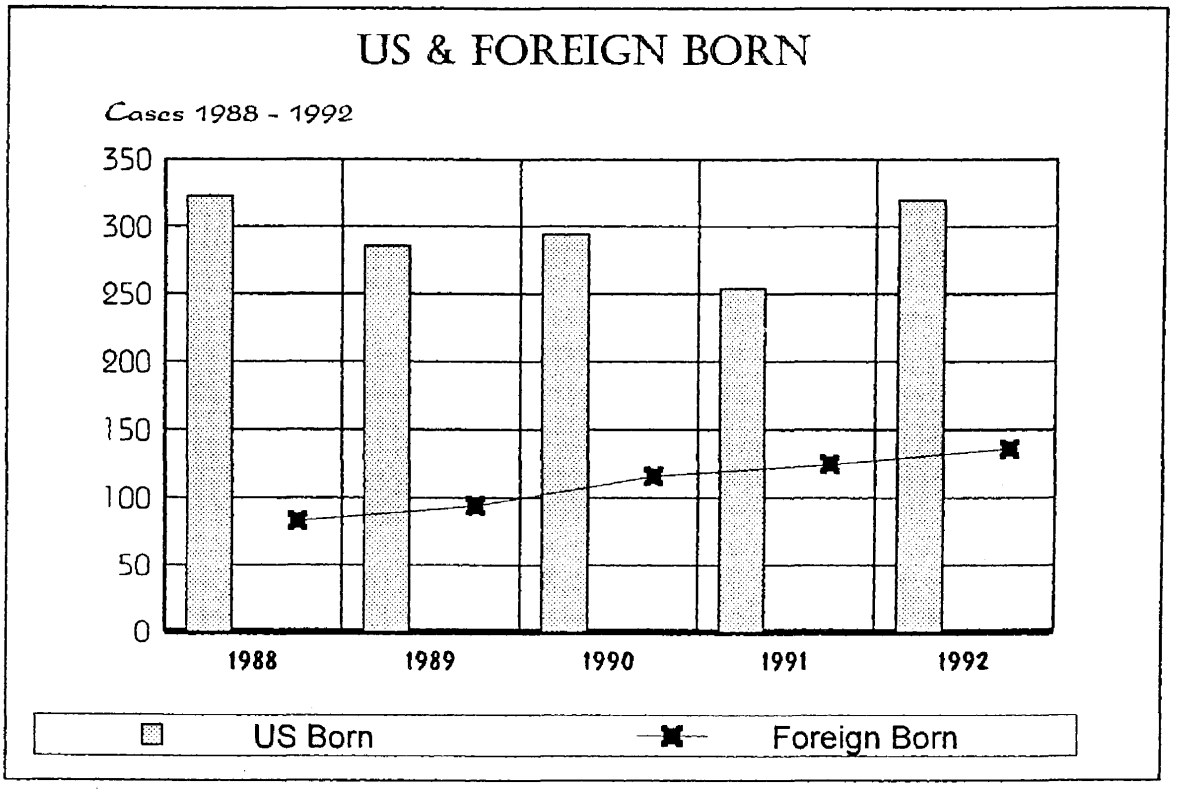

Figure 5

- At least 27 countries were represented among foreign-born cases of TB, with immigrants from Vietnam and the Philippines accounting for 41 percent of the cases in 1991. Thirty-five foreign countries were represented in Virginia's TB morbidity in 1992. Vietnam, the Philippines, El Salvador and India accounted for 57 percent of these cases.

Virginia's Approach To The Problem

- No foreign-born person, regardless of immigration status, is denied services by the VDH. All local health districts actively pursue the screening and evaluation of these high risk population groups and provide treatment.

- Districts with a significant percentage of foreign-born persons have public health outreach workers who are culturally and linguistically compatible with the populations they serve. They cultivate understanding and trust, and directly observe the therapy for TB cases who are at risk for or have a history of non-compliance. All 13 TB outreach workers currently employed in the Commonwealth are federally funded, but only three are full time classified employees. Turnover in these positions has been a recurring problem because the positions have not been full time and provide no benefits.

- In 1989, the American Lung Association of Virginia produced a four part videotape in 11 languages to educate foreign-born persons with TB. These tapes are used by local health districts. In addition, some districts have developed written materials specifically for the foreign-born.

Chapter 6

TUBERCULOSIS AND HIV INFECTION

Persons who have TB infection and subsequently acquire HIV infection are more likely to progress to TB disease than those who are HIV negative. Furthermore, persons who are HIV-infected and subsequently are exposed to TB are more likely to progress from infection to disease than those who are HIV negative, and have a rapid, severe progression of illness. Approximately 10 percent of the 1 million persons in the U.S. infected with HIV are also infected with TB. The prevalence of HIV infection among patients with TB disease varies around the country, but may exceed 40 percent in some areas. A person with a healthy immune system who is infected with TB will have a 10 percent lifetime chance of developing TB disease; it is 8 percent each year in a person with HIV infection.

HIV-infected people with active TB may be harder to diagnose because TB symptoms (e.g., fever and cough) are also symptoms or complications of HIV infection. Fever, night sweats, and wasting occur commonly with HIV infection, and cough is very common in opportunistic lung infections such as Pneumocystis carinii pneumonia, the most common infection in HIV patients. Diagnosis is made even more difficult because those with HIV infection may test falsely negative on the standard TB skin test. This is especially true later in the course of HIV infection, as immunity wanes.

The Situation in Virginia

- Since 1987, 81 TB cases are known to have had HIV infection. This is 3.3 percent of all the TB cases diagnosed over this time period. The percentage of TB cases with HIV has increased steadily each year, from 0.7 percent in 1987 to 5 percent in 1992.

- Over 25 percent of all TB cases with HIV have resided in Richmond City, but the rest have resided in 30 other counties and cities throughout the Commonwealth.

Chapter 7

MULTIDRUG-RESISTANT TUBERCULOSIS (MDR-TB)

MDR-TB occurs when patients do not take prescribed TB medications for the full treatment period. MDR-TB can usually be prevented by initially treating TB patients with four drugs and by administering TB medications on a directly observed basis.

Recently, drug-resistant TB has become a serious concern. In a recent survey in New York City, 33 percent of TB cases had organisms resistant to at least one drug, and 19 percent had organisms resistant to both isoniazid (INH) and rifampin (RIF). When organisms are resistant to both INH and RIF, the course of treatment increases from 6 months to 18 to 24 months, and the cure rate decreases from nearly 100 percent to less than 60 percent.

The Centers for Disease Control and Prevention (CDC) have conducted a nationwide survey of drug resistance among all TB cases provisionally reported during the first 3 months of 1991. Overall, 14.4 percent of the cases tested had organisms resistant to at least one anti-tuberculosis drug, and 3.3 percent had organisms resistant to both INH and RIF. Furthermore, the drug resistance problem appears to be worsening. For example, from 1982 to 1986, only 0.5 percent of new cases were resistant to both INH and RIF; by 1991, this had increased to 3.1 percent. Among recurrent cases, 3.0 percent were resistant to both drugs during 1982 to 1986, but in 1991 this proportion had more than doubled, to 6.9 percent. For the years 1990 through 1992, 6.3 percent of Virginia's 1,245 reported TB cases had resistance to at least one drug.

The increasing numbers of both TB cases and drug-resistant cases has resulted in outbreaks of MDR-TB in institutional settings in other states. From 1990 through early 1992, the CDC investigated seven outbreaks of MDR-TB in hospitals and correctional facilities in Florida and New York, involving more than 200 cases. Virtually all these cases had organisms resistant to both INH and RIF, and some had organisms resistant to seven anti-tuberculosis drugs. Most patients in these outbreaks were infected with HIV. Mortality was high, ranging from 72 percent to 89 percent, and the median interval between TB diagnosis and death was short, from 4 to 16 weeks. Transmission of MDR-TB to health-care workers (HCWs) and prison guards has also been documented.

Most TB control experts believe that it is essential to integrate TB program activities into institutional and other health-care settings with the first priority being to provide preventive and curative services for TB in correctional facilities. The Virginia Department of Health (VDH) Bureau of TB Control has a close working relationship with correctional facilities.

Epidemiology and Surveillance to Contain MDR-TB

Systematic surveillance of M.tb. isolates for drug susceptibility is critical and could:

- identify where drug resistance is already a problem;
- monitor the epidemiology of drug resistance as to place, person, and time;
- detect outbreaks of MDR-TB.

Infection Control to Prevent MDR-TB

To reduce the risk of nosocomial/institutional transmission, HCWs must be educated to have a high index of suspicion for TB and to be aware of atypical patterns of the disease among HIV-infected persons. Rapid laboratory support is critical; acid-fast bacillus (AFB) smear results must be available within 24 hours. HCWs must also be educated about the need for early and appropriate therapy.

Efforts to Prevent MDR-TB in Virginia

Several efforts are underway to contain MDR-TB.

- The Division of Consolidated Laboratory Services (DCLS) utilizes the most specific, sensitive and rapid methods available for the isolation, identification and drug sensitivity testing of MDR-TB isolates. Sensitivity to INH, RIF, PZA, EMB and SM are tested routinely on all initial isolates of M.tb. Isolates identified as resistant are forwarded to the CDC for susceptibility testing to second line drugs.

- The Department of Corrections (DOC) currently screens all new inmates to rule out active TB before they are placed in the general prison population. If TB is suspected, the inmate is isolated at Greensville Correctional Center (GCC) until active TB can be ruled out or the inmate is rendered non-infectious. The isolation rooms at GCC were recently renovated to ensure their efficiency. In 1993, the DOC began annual testing of its staff and inmates for TB infection. Results are submitted to the VDH Bureau of TB Control.

- The Department of Mental Health, Mental Retardation, and Substance Abuse Services' (DMHMRSAS) 15 facilities were evaluated by VDH in the past year to determine their suitability for isolation of TB patients. Twenty rooms were identified that meet current CDC guidelines and an additional 20 that could be properly equipped for a relatively low cost. Recommendations including the use of ultraviolet lights and changes in admission procedures were made to reduce the likelihood of TB transmission in these facilities. The DMHMRSAS and VDH are currently drafting a TB screening and treatment protocol for new entrants into these facilities. Plans to assess selected facilities for environmental measures to prevent the spread of TB are scheduled to be completed by January 1995. TB education of staff in these facilities is scheduled to begin in October 1993. A similar program in the Commonwealth's five methadone maintenance centers has been implemented since 1988.

- In January 1993, DCLS and VDH staff began presenting educational seminars to health department personnel, infection control practitioners, correctional facility staff and commercial and hospital laboratory staff in six locations throughout the Commonwealth. MDR-TB is one of the major topics covered.

- The Bureau of TB Control's current surveillance system, designed along the same lines as the one adopted by CDC in 1993, allows the Bureau to record the initial drug sensitivities of all confirmed TB cases and identify the patterns and location of drug resistant disease. It also allows for the identification and recording of drug resistance that emerges after the initiation of therapy. The Bureau is currently developing a computer network linking the VDH Central Office with its Epidemiology Consultants in the field and the 12 health districts with the highest incidence of TB. When in place, this network will allow electronic transfer of information to speed case reporting, end the need for duplicate data entry, and facilitate local epidemiological analysis.

- The development and implementation of the homeless incentive program (HIP), the extensive use of directly observed therapy (DOT) and the amendment and reenactment of Section 32.1 - 48.02 of the Code of Virginia are all important steps in preventing TB outbreaks and the emergence of MDR-TB. These approaches are outlined in the next three chapters.

- The VDH has a contract with the University of Virginia (UVa) Medical Center for the availability of two beds frequently utilized by patients with MDR-TB.

Other Actions for Preventing MDR-TB

Several additional steps will be necessary to contain MDR-TB.

- The current Regulations for Disease Reporting and Control require the directors of laboratories to report Mycobacterial diseases identified by culture. Exemptions are made for laboratories operating in medical care facilities when the facility assumes the reporting responsibility, and laboratories that submit a positive culture for identification and/or confirmation to DCLS. If all laboratories were required by regulations to submit M.tb. isolates to DCLS, drug susceptibility testing could be better assured. At present, commercial and hospital labs only do susceptibility testing if ordered by the physician and are not required to report the results, even if the tests are done.

- The Commonwealth should use its licensure authority to ensure that facilities such as hospitals, hospices, nursing homes, adult care residences and day care centers for adults and children require the thorough screening of their staff to rule out communicable TB within one month of employment, and annually thereafter. Their prospective patients or clients should be required to be thoroughly screened to rule out communicable TB within one month before admission to the facility or program and annually thereafter.

- The administrators of facilities run by or under contract to DMHMRSAS, DOC and the VDH have expressed willingness to comply with the recommendations of the CDC and VDH to require the initial and periodic screening of their staff to rule out communicable TB. The Commonwealth should consider making compliance with these recommendations a condition of employment or contract renewal. This has been done in the correctional systems of other states.

Chapter 8

TUBERCULOSIS IN NURSING HOME PATIENTS

Background

Tuberculosis case rates are higher for persons 65 years of age and older than for any other age group. In 1992, the 6,025 tuberculosis cases reported in the U.S. for persons 65 years of age and older accounted for more than 22 percent of the U.S. total, even though this age group represents only 12 percent of the U.S. population. The corresponding figures for Virginia were 151 or 33 percent.

In the U.S., approximately 5 percent of all elderly persons live in a nursing home and represent 88 percent of the nation's approximately 1.7 million nursing home residents. Such concentrations of elderly persons, many of whom are infected with tubercle bacilli and some of whom are immunosuppressed, create high-risk situations for tuberculosis transmission. In 1984-1985, a CDC-sponsored study of 15,379 tuberculosis cases from 29 states indicated that the incidence of tuberculosis among nursing home residents was 39 cases per 100,000 population; the incidence among elderly persons living in the community was 21 cases per 100,000 population.

General Guidelines for Nursing Homes

Each nursing home should assure that appropriate TB prevention and control measures are undertaken to protect residents and staff. These are:

- Report all cases of TB among residents and staff to the local health department.
- Ensure that persons for whom treatment of disease or preventive treatment is indicated complete the appropriate course of treatment under direct supervision by a staff member.
- Make arrangements to educate patients, families, visitors, and employees about TB.
- Skin-test all new residents and employees as soon as their residency or employment begins unless they have documentation of a previous positive reaction. All persons with a reaction of 10 mm or more should receive a chest radiograph to identify current or past disease. Each tuberculin-positive resident should be evaluated annually. Skin-test-negative employees having contact (of 10 or more hours per week) with elderly residents should periodically have repeat skin tests.
- Excuse from work staff members who are considered to have infectious TB, until the diagnosis is excluded or until they become noninfectious as a result of effective chemotherapy.

Investigation for Contacts and Their Management

Contacts who have documented skin-test conversions and whose chest radiographs do not reveal TB should be given at least 6 months of preventive therapy unless medically contraindicated. Other residents and staff with positive tuberculin reactions should be given preventive therapy and monitored according to the guidelines described earlier.

The most important step in a contact investigation is to allocate contacts into higher- and lower-risk groups. A higher-risk contact is defined as any person who shared the air with a source patient for a relatively longer time and who has other risk factors relatively higher than those of other known contacts. Nursing home/facility residents sharing the same wing or ventilation circuit should usually be considered close contacts.

By initially evaluating the higher-risk contacts for evidence of TB infection and/or disease, the actual infectiousness of the source patient can be inferred. If there is no evidence of recent transmission of infection in this group, extending the investigation is not appropriate. If data indicate recent infection in the higher-risk group, the investigation should be extended to include lower-risk contacts until the levels of infection detected approximate that in the local community.

Chapter 9

LONG TERM CARE FOR CERTAIN TB PATIENTS

No inpatient facilities have currently been identified for long term treatment of patients with complicated TB, multidrug-resistant tuberculosis (MDR-TB), and those requiring legal isolation. Persons who need such facilities are often not acutely ill, but remain a threat to the public due to the long periods of time required to render them non-infectious. Funding is necessary for securing such facilities. Several options are available:

- Establish "TB Centers of Excellence" at Virginia's state funded teaching hospitals. This may require some renovation and additional staffing, but such Centers would be of great benefit to interns and residents.

- Utilize private facilities (Directly Observed Therapy Centers or Mini-Sanatoria) as housing for appropriate TB patients. This option would require purchase or lease of the facility, some renovation, and staffing.

- Utilize existing state owned buildings such as unused facilities of the Department of MHMRSAS. This option would require renovations and staffing and hence would be costly.

- Contract with private hospitals with the capability and willingness to house infectious TB patients for prolonged periods of time. Payment would be required only when these beds are occupied, at the rate of about $300 per diem.

- Contract with existing state programs (such as existing facilities in the Department of MHMRSAS) with the capabilities and willingness to house infectious TB patients for prolonged periods of time. These contracts would pay only when these beds are occupied, and only cost about $300 per diem.

Estimates of cost for the first three options are not detailed at this time. The last two options do not require capital outlay, but only the $300 per diem rate.

Because of the threat that the number of cases of TB will continue to increase, the VDH is more aggressive with some of the special measures (homeless incentive program and directly observed therapy) that it has begun to adopt during the past few years. These are described in the subsequent chapters.

Chapter 10

HOMELESS INCENTIVE PROGRAM (HIP)

The homeless have traditionally been an extremely difficult group to manage throughout the course of 6 to 12 months of TB treatment. Intensive follow-up by outreach workers is not typically an advantage in dealing with this population. Homeless persons with TB usually do not seek medical attention until their disease is advanced, generally require initial hospitalization, and are often lost to follow-up. This often leads to the development of drug resistant disease and sometimes death. The goal of HIP is to provide incentives for homeless TB patients to comply with treatment. The HIP provides housing (at the expense of the Virginia Department of Health (VDH) Bureau of TB Control) and access to social services such as food stamps and general relief. The patient is required to be available at a prearranged time, either daily or twice weekly, so a public health nurse or outreach worker can administer directly observed therapy (DOT) or transport the patient to clinic.

HIP is a cooperative effort among the VDH Bureau of TB Control, local health departments, social services and hospitals. Since April 17, 1992, when the program was initiated, it has housed 18 homeless TB patients and prevented an additional five from becoming homeless. The total cost through July 31, 1993, has been $48,135. Of the patients participating in this program, 13 are still on treatment, six have completed treatment, one has died, one has moved out of state without completing therapy, and only two have been lost to follow-up. This translates to a success rate of 90.5 percent for an average cost of less than $25 per patient per day. The success of the HIP indicates that consideration must be given to the patient's social condition because therein lies the reason for noncompliance leading to treatment failure.

DIRECTLY OBSERVED THERAPY (DOT)

A major cause of drug-resistant TB and treatment failure is patient nonadherence to prescribed treatment. Treatment failure and drug-resistant TB can be life-threatening and lead to prolonged infectiousness and increased transmission of TB in the community. DOT is one method of ensuring adherence; it requires that a health-care provider or other designated person observe while the patient ingests medications every time these medications are scheduled to be taken.

DOT should be considered for all patients, but is especially necessary for persons who:

- are homeless
- are substance abusers
- have HIV infection
- have disease reactivations
- have multidrug-resistant tuberculosis (MDR-TB)
- are mentally ill

Decisions regarding the use of expanded or universal DOT should be based on a quantitative evaluation of local treatment completion rates. The CDC recommends that if the percentage of patients who complete therapy within 12 months is less than 90 percent or unknown, the use of DOT should be expanded. If 90 percent or more complete a recommended course of therapy within 12 months, the expanded use of DOT may not be necessary, but should be considered. In 1991, only 58.9 percent of TB cases beginning treatment in Virginia completed treatment within 12 months.

DOT programs have been shown to increase adherence in both rural and urban settings. A hospital in New York City reported that only 11 percent of TB patients reported to an outpatient clinic for further treatment when discharged from the hospital. In contrast, a program in which DOT was routinely used for all patients had a completion rate of 98 percent. Although expanding the use of DOT may require additional resources, the CDC has reported that DOT is cost effective. One case of MDR-TB can cost $150,000 to $200,000 per year because of the extra cost of drugs. DOT can be provided to one person for $1,200 per year.

When DOT is administered, the method must be specifically defined for each patient and be based on a thorough assessment of each patient's medical needs, cultural influences, living/employment conditions, and preferences. The patient and the provider should agree on a method that ensures the best possible DOT routine and which preserves confidentiality. DOT can be conducted with regimens given daily, twice a week, or 3 times per week. Many patients who receive daily therapy can be

successfully managed with self-administered therapy. Public health officials responsible for TB treatment should be notified when patients not receiving DOT miss appointments or demonstrate behaviors suggestive of non-compliance. These patients should be placed on DOT, and all regimens administered twice a week or 3 times per week for the duration of therapy.

Effective use of DOT usually requires an outreach worker to go into the community to locate a patient and administer each dose of medication. However, DOT can be administered in various settings, including all clinics, community health centers, migrant centers, homeless shelters, prisons or jails, nursing homes, schools, drug treatment centers and hospitals. Persons administering DOT may include physicians, nurses, health care aides, family members, nursing home staff, correctional facility personnel, staff of community-based organizations, school nurses or teachers, reliable volunteers, drug treatment center employees, social and welfare caseworkers, and clergy or other community leaders.

The use of incentives or enablers may promote adherence to DOT. Incentives can vary from housing for homeless TB patients to a nutritional supplement. Enablers can range from an outreach worker delivering medications to offering bus fare to attend TB clinics. DOT can significantly reduce the need for more complex interventions such as legal isolation and achieve the same results.

Chapter 12

LEGAL ISOLATION OF TUBERCULOSIS PATIENTS

Occasionally, there is a need to isolate persons who refuse to take prescribed medications for TB despite repeated counseling and attempts at directly observed therapy (DOT). Isolation is always the method of last resort to ensure the adequate treatment of infectious TB disease and prevent transmission to others.

Until recently, the time required to obtain a court order for isolation often resulted in disappearance of the patient. The 1993 General Assembly amended and reenacted Section 32.1-48.02 of the Code (Appendix 3) authorizing the Commissioner to require treatment and/or temporary detention without a court order, for persons with airborne communicable diseases under certain specific circumstances. This amendment was prompted by several instances in which persons with infectious MDR-TB could not be detained for the time necessary to have their cases considered by the court.

Only the Commissioner can issue a temporary detention order (for a period not to exceed 48 hours unless inclusive of a weekend or holiday). The Commissioner will consider the temporary detention of any person with TB when notified by a district director that a person's medical record clearly reflects one of the following:

- The person has refused or failed to report to the local health department after having been ordered to do so for treatment and education concerning his/her disease;
- The person has a documented history of failure to adhere to a prescribed course of treatment for his/her disease; or
- The person indicates that he/she will not comply with the prescribed treatment for his/her disease.

When all else fails, a court order for isolation will be sought. The Code requires the Virginia Department of Health (VDH) to prove the following in any person for whom an isolation order is sought:

- The person is infected with a communicable disease.
- The person had engaged in at-risk behavior even though he was counseled not to do so.
- The person has demonstrated an intentional disregard for the health of the public by engaging in at-risk behavior despite counseling to the contrary.
- The person will continue to be a risk to the public unless isolated.

Chapter 13

RECOMMENDATIONS

While cases of TB are increasing in Virginia, the situation is not yet "out of control." The following interventions should prevent the problem from getting worse:

Screening and Diagnosis

- Screen more persons for TB, especially those at high risk for TB, such as persons with HIV infection and foreign-born persons. Most of the recent increase in TB has been among these two groups. Screening is also important for health-care-facility personnel. Licensing regulations should require screening of health-care-facility personnel for TB within one month of employment.

Laboratory Services

- Ensure that the Division of Consolidated Laboratory Services is well equipped to provide rapid diagnostic services commensurate with the state of the art.

Directly Observed Therapy (DOT)

- Employ more outreach workers to conduct directly observed therapy (DOT). There is a crucial need for approximately double the number of outreach workers currently employed by the VDH. They are most capable of ensuring that patients comply with prescribed therapy. MDR-TB could be prevented if patients complete their course of treatment.

Educating Health Care Providers

- Inform health care providers about the latest recommendations of the Advisory Council for the Elimination of TB. This is important because for several decades (due to the declining incidence of TB), many medical schools did not devote much attention to TB. The Commonwealth's three academic health centers must give greater emphasis to TB in medical school curricula.

Infection Control

- Reinforce infection control measures in hospitals and other institutions housing TB patients. Ultraviolet irradiation systems should be used to protect health care personnel from exposure

to the bacteria that causes TB. Rooms occupied by TB patients must have negative pressure ventilation.

Facilities for Isolating Presons

- Establish appropriate facilities for isolating persons with, or suspected of having, infectious TB. The need for this arises every now and then, but unfortunately there is a paucity of properly equipped facilities.

Community Health Centers

- Ensure that Community Health Centers take on the responsibility of caring for TB patients; it would be more economical and practical than having physicians from the VDH travel the Commonwealth to provide these services. VDH physicians can provide guidance and consultation.

Migrant Health Centers

- Ensure that Migrant Health Centers address the health care needs of migrants. TB is a significant problem among migrants.

Area Health Education Centers

- Encourage Area Health Education Centers to sponsor continuing education courses on TB, especially for physicians in localities far removed from major academic centers.

Outbreak Investigations

- Investigate and control outbreaks of TB promptly.

Support of Private Physicians

- Solicit the support of the Medical Society of Virginia to carry out the recommendations in this report.

Chapter 14

CONTINUING AND ONE TIME COSTS OF TUBERCULOSIS INTERVENTIONS

The following are estimated costs of selected tuberculosis (TB) interventions discussed in this report and designed to detect infection in high risk populations, provide therapy to prevent progression to active disease, treat active TB, and prevent the emergence of drug resistant disease.

CONTINUING COSTS

1. Directly Observed Therapy (DOT)

DOT is a useful means of insuring treatment, but is labor intensive and extremely time consuming. Utilizing outreach workers is the most cost effective method of providing DOT. The Virginia Department of Health (VDH) currently employs 13 outreach workers in 11 high morbidity health districts which account for over 75 percent of the Commonwealth's annual TB morbidity. These positions are 100 percent federally funded, but only three are full-time. Ten persons are employed for 1,500 hours per year or less, due to the unavailability of full time equivalents (FTEs). These positions are assigned to the counties of Fairfax (.75) and Arlington (.75), and the cities of Alexandria (.75), Petersburg (.5), Virginia Beach (1.25), Hampton (.75), Newport News (.75), Portsmouth (.75) and Richmond (.75).

Requirements

With an increasing number of TB cases in Virginia, state funds and FTEs are needed for ten additional outreach workers. The localities and the proposed number of new FTEs for each are: Fairfax (3), Arlington (1), Prince William (1), Accomack and Northampton (1), Henrico and Chesterfield (1) and the cities of Alexandria (1), Richmond (1) and Newport News (1). The funds requested include the costs of salary, benefits and travel, and the northern Virginia differential where appropriate. The required funding of $ 209,030 in general funds and FTEs was included in the Govenor's budget on December 20,1993.

2. Compliance Incentives and Enablers

A cost effective method of avoiding/minimizing drug resistant disease is offering patients incentives to comply with prescribed therapy and enablers to facilitate compliance. Homeless non-infectious TB cases can be housed for a cost of $20 to $55 per day, depending on their location. The alternatives are either a hospital at $300 to $900 per day or an infectious drug resistant patient lost to medical follow-up. The average number of TB cases participating in Virginia's homeless incentive program (HIP) since its creation has been 18 annually.

Requirements

An estimated $122,000 in general funds annually is needed to continue and expand the HIP and $25,000 in general funds annually is needed for compliance incentives and enablers for persons who are not homeless.

3. Hospitalization

For patients requiring acute care, there is a need for an additional $80,000 in general funds annually for two more beds at the University of Virginia (UVa) Medical Center. This will save money over the $300 per day UVa charges the Bureau of TB Control when additional beds are needed.

For infectious patients, not acutely ill, the rates for hospitalization range from $300 to $900 per day in Virginia. Unfortunately, most hospitals discharge TB cases or suspects within three to seven days of diagnosis rather than holding them until they are non-infectious (after about three weeks of therapy in most instances). For the homeless TB patient, the alternatives to continued hospitalization are discharge to the streets or to a shelter. The HIP program cannot place these persons while they are infectious.

Multidrug-resistant tuberculosis (MDR-TB) patients, especially those totally resistant to both INH and RIF, often remain infectious for up to six months after treatment begins. Their discharge places others, often children in their household, at risk for infection. To this date, the only willing institution with facilities equipped for proper isolation of TB patients is the Greensville Correctional Facility in Jarrett, Virginia. The VDH does not wish to incarcerate these individuals, but there are no funds available to use other options.

Requirements

There is a need for $276,000 in general funds annually to place these categories of TB patients in facilities equipped and willing to provide long term care (such as in unoccupied facilities of the Department of Mental Health, Mental Retardation and Substance Abuse Services) until they can be rendered non-infectious.

4. Second Line Drugs Used in Treating Multi-Drug Resistant (MDR) TB Cases

In each of the last three years, an average of four cases of MDR-TB, fully resistant to INH and RIF, have been identified and treated in Virginia. These cases require treatment with second line drugs, and local health departments have had to bear the cost.

Requirements

There is a critical need for $48,000 in general funds annually to defer the cost to local health departments for treating MDR-TB with second line drugs. TB morbidity among localities varies each year; with general funds the Bureau of TB Control will be able to distribute the funds to the localities most in need.

5. Program Management and Evaluation

The Bureau of TB Control is currently understaffed, because the steady decline of TB cases prior to the recent resurgence resulted in drastic cuts in personnel and funding. The Bureau is requesting FTEs and funding to support an epidemiologist and two support staff to properly administer and evaluate the effectiveness of the interventions proposed in this document.

Requirements

Three FTEs and $80,000 in general funds are requested annually to support an epidemiologist and two support staff in the Central Office.

6. District Health Department Needs

Seven public health nurses, one for each of the health districts of Arlington, Fairfax, Richmond, Hampton, Newport News, Piedmont and Roanoke, are needed to enable these districts to carry out the proposed recommendations contained in this report. The needs have been identified by the district directors. The primary responsibility of the nurses will be the screening and follow up of persons at high risk for TB.

Requirements

Seven FTEs and $210,000 in general funds annually are needed for these public health nurses.

ONE TIME COSTS

1. Environmental Adaptations

The Bureau of TB Control recently purchased ultraviolet lights (UV) to protect against the transmission of TB in 125 health department facilities. Although very effective in killing airborne contaminants such as TB, the need exists to supplement UV with negative pressure and ventilation directly to the outside in areas where certain high risk activities occur (sputum collection and

induction). No funds are currently available to aid local health districts with these adaptations.

Requirements

There is a critical need for $187,500 in one time general funds for these protections.

APPENDIX 1

1993 SESSION

LD9026443

HOUSE JOINT RESOLUTION NO. 531

Offered January 25, 1993

Requesting the Department of Health to study effective methods of arresting the spread of active tuberculosis and preventing the development of multidrug-resistant TB in Virginia.

Patrons—Scott, Callahan, Christian, Connally, Darner, Deeds, Dillard, Harris, Hull, Jones, Mayer, Puller, Van Landingham and Wood

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Referred to the Committee on Rules

WHEREAS, since 1990 Virginia has reported a 7.9 percent increase in the number of tuberculosis cases, where prior to 1990 the number of TB cases in Virginia had steadily decreased; and

WHEREAS, there are 32 cases in Virginia of a strain of TB that does not respond to conventional treatment; and

WHEREAS, there is a growing concern in Virginia regarding the impact of TB and multidrug-resistant TB on public health; and

WHEREAS, it is important to all Virginians that effective steps be taken to minimize the adverse public health effects of TB and multidrug-resistant TB; and

WHEREAS, the highest priority in TB control is to detect people with active TB and treat them with effective antituberculosis drugs via directly observed therapy (DOT), thus preventing the development of multidrug-resistant TB; and

WHEREAS, the General Assembly cannot be expected to make an informed judgment about TB control strategies without the benefit of extensive study; now, therefore, be it

RESOLVED by the House of Delegates, the Senate concurring, That the Department of Health study and review comprehensive and cost-effective means of eliminating TB and protecting the public from the disease until it is eliminated by ensuring that individuals receive appropriate treatment. The Department of Health shall consider the short-term and long-term costs and benefits of various tuberculosis-control strategies in Virginia including, but not limited to, directly observed therapy (DOT), compliance incentives and enablers, mandatory quarantine, commitment of the noncompliant patient to a hospital or facility for treatment, and environmental adaptions.

The Department shall complete its work in time to submit its findings and recommendations to the Joint Subcommittee Studying the Needs of Foreign-Born Individuals in the Commonwealth and the Joint Subcommittees Studying the Human Immunodeficiency Viruses and AIDS, the Governor, and the 1994 Session of the General Assembly as provided in the procedures of the Division of Legislative Automated Systems for processing legislative documents.

Official Use By Clerks	
Agreed to By The House of Delegates	**Agreed to By The Senate**
without amendment ☐	without amendment ☐
with amendment ☐	with amendment ☐
substitute ☐	substitute ☐
substitute w/amdt ☐	substitute w/amdt ☐
Date: _____	Date: _____
_____	_____
Clerk of the House of Delegates	Clerk of the Senate

APPENDIX 2

Members of the Tuberculosis Study Committee

Grayson B. Miller, Jr., MD, Director
Office of Epidemiology, Virginia Department of Health

Laura Wimmer
American Lung Association

Balvir Kapil, MD
Virginia Department of Corrections

Opal Bristow, RN
Virginia Department of Corrections

Ronald Forbes, MD
Virginia Department of Mental Health, Mental Retardation and Substance Abuse Services

Kathy Bailey
Association of Practitioners in Infection Control, Virginia

James Ghaphery, MD
Medical Society of Virginia

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Alexandria Health District, Virginia Department of Health

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Achana Ball, MD
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Sheila Spelman, RN, Nurse Manager
Eastern Shore Health District, Virginia Department of Health

Sandra Landry, RN
Thomas Jefferson Health District, Virginia Department of Health

Jane Moore, RN
Alexandria Health District, Virginia Department of Health

Deborah Staley, RN
Crater Health District, Virginia Department of Health

Pat Clausen, RN
Fairfax Health District, Virginia Department of Health

Gail Sutler, RN
Chesterfield Health District, Virginia Department of Health

Thomas Privett
Bureau of Tuberculosis Control, Virginia Department of Health

Angelos Iatridis, MD
Bureau of Tuberculosis Control, Virginia Department of Health

APPENDIX 3

1993 SESSION

LD8768196

HOUSE BILL NO. 2391
AMENDMENT IN THE NATURE OF A SUBSTITUTE
(Proposed by the Senate Committee on Education and Health
on February 18, 1993)
(Patron Prior to Substitute—Delegate Darner)

A BILL to amend and reenact § 32.1-48.02 of the Code of Virginia, relating to isolation of certain persons with communicable diseases.

Be it enacted by the General Assembly of Virginia:

1. That § 32.1-48.02 of the Code of Virginia is amended and reenacted as follows:

§ 32.1-48.02. Investigations of verified reports or medical evidence; counseling; outpatient and emergency treatment orders; custody upon emergency order.—A. Upon receiving at least two verified reports or upon receiving medical evidence that any person who is reputed to know that he is infected with a communicable disease is engaging in at-risk behavior, the Commissioner or his designee may conduct an investigation through an examination of the records of the Department and other medical records to determine the disease status of the individual and that there is cause to believe he is engaging in at-risk behavior.

B. If the investigation indicates that the person has a communicable disease *caused by a non-airborne microorganism* and that there is cause to believe he is engaging in at-risk behavior, the Commissioner or his designee may issue an order for such person to report to the local or district health department in the jurisdiction in which he resides to receive counseling on the etiology, effects and prevention of the specific disease. The person conducting the counseling shall prepare and submit a report to the Commissioner or his designee on the counseling session or sessions in which he shall document that the person so counseled has been informed about the acts that constitute at-risk behavior, appropriate precautions, and the need to use appropriate precautions. The counselor shall also report any statements indicating the intentions or understanding of the person so counseled.

C. If the investigation, described in subsection A, indicates that the person has a communicable disease caused by an airborne microorganism which causes serious disease and can result in death and that the person has refused or failed to adhere to a prescribed course of treatment and, despite counseling, is engaging in conduct that places uninfected persons at risk of contracting such airborne communicable disease, the Commissioner or his designee may issue an outpatient treatment order for such person to report to the local or district health department in the jurisdiction in which he resides to receive appropriate outpatient treatment and education concerning his disease.

D. If the investigation, described in subsection A, indicates that the person has a communicable disease caused by an airborne microorganism which causes serious disease and can result in death and, despite documented and appropriate counseling, is engaging in conduct that unreasonably places uninfected persons at risk of contracting such airborne communicable disease and medical data demonstrate that he poses an imminent threat to the health of others, the Commissioner may issue an emergency order requiring such person to be taken immediately into custody and placed, for a period, not to exceed forty-eight hours, in the least restrictive, willing facility providing protection of the health of others and appropriate treatment to the person upon finding that at least one of the following conditions is met:

1. The person has refused or failed to report to the local health department after having been ordered to do so pursuant to subsection C, for appropriate outpatient treatment and education concerning his disease;

2. The person has a documented history of failure to adhere to a prescribed course of treatment; or

3. Documentation exists that the person has indicated that he will not comply with the prescribed treatment.

If the specified forty-eight-hour period terminates on a Saturday, Sunday or legal holiday, such person may be detained until the next day which is not a Saturday, Sunday,

or legal holiday. In no event may the person be detained for longer than seventy-two hours or ninety-six hours when the specified forty-eight-hour period terminates on a Saturday, Sunday or legal holiday. For purposes of this subsection, a Saturday, Sunday, or legal holiday shall be deemed to include the time period up to 8:00 A.M. of the next day which is not a Saturday, Sunday, or legal holiday. During this period, the Commissioner shall proceed in accordance with § 32.1-48.03.

E. In order to implement an emergency order issued pursuant to subsection D of this section, all state and local law-enforcement officers are authorized to take custody of the subject of such emergency order immediately upon issuance of the emergency order by the Commissioner.

2. That an emergency exists and this act is in force from its passage.