ABSTRACT

As the recent increase in cases of tuberculosis is addressed, there is a danger that the need for increased protection of the public health will create a climate in which the rights of individuals with tuberculosis and human immunodeficiency virus (HIV) infection may be disregarded. This paper considers ethical and policy issues in the control of tuberculosis. The authors conclude that mandatory HIV testing is not critical to effective tuberculosis control, and that although individuals infected with HIV are at increased risk for developing tuberculosis, exclusionary employment practices are not justified. Because failure to complete the course of tuberculosis treatment increases the prospect that drug-resistant strains will develop, it is crucial to require all those who commence treatment to complete their therapy. To ensure the completion of treatment, special attention must be paid to the needs of the homeless, drug users, and those with psychiatric impairments. In addition, all tuberculosis patients should begin their posthospital care under direct observation. Patients who fail to complete treatment despite efforts to encourage and facilitate their cooperation should be subject to confinement after a hearing with full due process protections. (Am J Public Health. 1993:83:649-654)

The Dual Epidemics of Tuberculosis and AIDS: Ethical and Policy Issues in Screening and Treatment

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Introduction

The 20th century has witnessed a dramatic decline in tuberculosis, a scourge of the 19th century. Improved living conditions for the mass of Americans and, in the 1950s, the achievements of medicine contributed to this epidemiological triumph. What remained by the late 1970s were low levels of the disease, with foci in minority groups accounting for 70% of reported cases. The lingering problem of tuberculosis was largely the consequence of poverty, overcrowded living conditions, inadequate access to health care, continued immigration from countries where tuberculosis was endemic, and failing programs of public health.

Despite an upsurge of cases of tuberculosis as early as 1979 in New York City,^{1,2} the incidence of disease in the United States did not begin to register a marked increase until 1985.3 In the ensuing 6 years, 28 000 tuberculosis cases in excess of expectations based on previous trends were reported.4 The dramatic reversal in the course of tuberculosis in the United States has been largely confined to urban centers where human immunodeficiency virus (HIV) infection rates are high.^{2,5,6} The reservoir of latent tuberculosis infection, itself the product of failed social and public health policy,^{2,6-8} has thus been transformed into a critical public health challenge. The upsurge in reactivation tuberculosis is largely rooted in the 30- to 40-fold increase in the risk of disease in those dually infected with HIV and microbacterium tuberculosis.3,5,9

Aggravating the upsurge in tuberculosis has been the sharp increase in multidrug-resistant strains of microbacterium tuberculosis, the treatment of which involves toxic drugs and is costly, long-term (up to 2 years), and often ineffective. This new public health threat, most clearly in evidence in New York City,^{9–12} has also been reflected in outbreaks in Texas,¹³ Miami,¹⁴ and San Francisco.⁹ If the resurgence of reactivation tuberculosis can largely be traced to the concurrent epidemic of HIV infection and the social conditions that give rise to the spread of tuberculosis infection, the emergence of resistant strains fundamentally reflects a failure of social policy.1-4,6-8,15 Nationally, only 75% of tuberculosis cases complete therapy within 12 months, a figure described by Centers for Disease Control and Prevention officials as "markedly below" the national objective of 95%. More striking are the low levels of completion in a number of American cities: in Washington, DC, Chicago, and New York, the rates are 60%, 58%, and 54%, respectively. In some inner-city communities the rates are even lower.16 At Harlem Hospital, which serves an impoverished and largely African-American community, 89% of tuberculosis patients are lost to follow-up.17

Uncompleted treatment generates drug-resistant strains of microbacterium tuberculosis. The congregate sheltering of large numbers of homeless individuals and hyperincarceration in jails and prisons have exacerbated the problem: the microbacterium spreads most efficiently in confined environments where there are large numbers of highly susceptible persons with compromised immune systems, including those with HIV infection.6-9,15-17 Inadequate infection control procedures, the absence of properly ventilated spaces, the lack of an appropriate number of isolation areas, and the scarcity of negative pressure rooms have accelerated the spread of disease.9,11,12,14,18,19

Given the epidemiology of the tuberculosis epidemic, its relationship to HIV infection, and the fact that it is the most socially marginalized who are typically

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sick with or at risk for tuberculosis and HIV, there is a danger that the demands by the public for increased health protections will create a climate within which the rights and interests of those with tuberculosis and HIV are disregarded. Additionally, there is the potential that the policies created during the first decade of the acquired immunodeficiency syndrome (AIDS) epidemic that promoted and protected individual choice and confidentiality and that sought to prevent unwarranted acts of discrimination could be subverted in the name of tuberculosis control.18 Finally, the resurgence of tuberculosis compels us to confront the question of whether the voluntarist strategy for dealing with the HIV epidemic is compatible with the compulsory tradition of dealing with tuberculosis.

The purpose of this article is to articulate the ethical and policy issues that should be considered, as options for the control of tuberculosis are confronted. We address three specific questions:

- Will effective tuberculosis control programs necessitate mandatory HIV screening?
- Will efforts to protect those with HIV infection from tuberculosis require the adoption of restrictive employment practices?
- What public health policies will be necessitated by the challenge of the dual epidemics of tuberculosis and HIV to ensure that individuals with tuberculosis are identified and provided with treatment until cure?

Screening for Tuberculosis

Respect for autonomy and privacy dictate that most medical interventions be preceded by a process of informed consent.19 In the case of tuberculosis, however, clinical and public health practice has been to screen persons routinely on admission to hospitals, prisons, jails, shelters, and other congregate living facilities, as well as those who work in such settings. A combination of purified protein derivative (PPD) tests and, if needed, chest x-rays have been used in such screenings when it has been deemed epidemiologically justified. Informed consent is rarely sought for tuberculin screening. In the absence of an explicit objection, consent is presumed to exist. Divergence from the standard of informed consent in the case of tuberculosis may be justified by the medically benign nature of the routine screening process; the benefit that identification provides to the individual, who can be offered prophylactic treatment or therapy if active tuberculosis is present; and the public health benefit that results from identifying those who may be infectious. The harm principle, which permits restrictions on autonomy for the protection of others, and the principle of beneficence, which requires the adoption of policies that will, on balance, benefit others, provide the ethical justifications for such screening.

State statutes, regulations, and court decisions permit routine tuberculosis screening and in some cases provide authority for mandatory testing.²⁰ In the past, some persons may have sought to avoid identification because of the stigma associated with tuberculosis. Nevertheless, in institutional settings, it is unusual at this time for anyone to object to screening. The individual's interest in discovering a life-threatening but generally treatable disease provides the basis for compliance.

Although apparently healthy individuals are rarely compelled to undergo tuberculosis screening after explicitly refusing testing, administrators of prisons, jails, and shelters have reported that such refusals may result in exclusions from certain settings. Medical staff of such facilities must weigh the threat to others posed by undiagnosed disease, especially in facilities where the prevalence of HIV infection is high. The rights of privacy must be balanced against the need to prevent the spread of tuberculosis. Where the risk of tuberculosis transmission is demonstrable, the harm principle provides a justification for overriding the principle of autonomy.

Screening for Tuberculosis in the Context of HIV Infection

The protections surrounding HIV testing stand in sharp contrast to the common provisions for tuberculosis screening. In the first years after the development of the HIV antibody test, a broad consensus developed in favor of voluntary testing, with extensive requirements for counseling and specific consent. In recent years this consensus has been challenged.21,22 Nevertheless, the formal requirement for individual consent for HIV testing has remained largely intact.23 It is within the context of this shifting perspective that the issue of HIV testing in tuberculosis control programs must be considered.

Individuals who are immunocompromised, whether because of HIV infection or other causes, may be an rgic and thus unable to mount the immunological response that is crucial for the accurate reading of a PPD test. Thus, PPD screening may not accurately reflect the presence of tuberculosis infection in some HIV-positive persons. This has led some to argue that knowledge of HIV status is necessary for effective tuberculosis screening programs.^{24–26} The ethical, legal, and public policy considerations that provide a justification for routine or, in some cases, mandatory tuberculosis screening would, according to such reasoning, justify mandatory HIV screening.

There is no basis for such a conclusion. Although HIV-infected individuals may be anergic, knowledge of their HIV status is of little help in determining whether they are infected with tuberculosis.27,28 In settings where HIV prevalence is high and where coinfection with tuberculosis is common, PPD screening can be augmented with chest x-rays. Anergic persons with HIV infection can reside in a congregate environment after chest x-rays give reasonable clinical assurance that they do not have active infectious tuberculosis. Those who are not anergic but who are dually infected can be identified and treated prophylactically with isoniazid. Those with active disease can be identified through chest x-rays, isolated, and treated. To go beyond these recommendations and mandate HIV testing would not provide additional protection to the individual or to those with whom he or she lives or works. Absent a public health justification for mandatory HIV screening, no ethical grounds exist for overriding the privacy and autonomy of the subject of tuberculosis screening.

Testing of Workers

Individuals with HIV infection are at a substantially increased risk of developing active tuberculosis if they have tuberculosis infection.3,27 They are also at significant risk of developing fulminant, often fatal, active tuberculosis should they acquire infection with a multidrug-resistant strain of microbacterium tuberculosis.12,14 The question naturally arises as to whether there is a reasonable justification for HIV screening of persons whose work places them in contact with tuberculosis patients. Possible justifications are several. First, screening could serve to identify individuals at increased risk for developing infectious tuberculosis that could be spread to others, especially to those with HIV infection, who would be especially vulnerable were they to become infected. Hence HIV screening would be justified by the harm principle. Alternatively, HIV screening might be justified on paternalistic grounds as a way of protecting the HIV-infected worker. Neither argument is sufficiently strong, however, to overcome the ethical objections to invasions of privacy and overriding of autonomy.

An ethical analysis of whether health care and other workers should be subject to mandatory HIV screening to protect others from tuberculosis must begin with the question of whether such screening would provide protection above and beyond that provided by routine tuberculosis screening programs that should be in place. Periodic PPD screening, chest x-rays for anergic persons, prophylaxis against tuberculosis for those who are PPD-positive, and education of workers about the signs and symptoms of tuberculosis should reduce the risk of workertransmitted tuberculosis to an exceedingly low level. The theoretical possibility of some continued risk to others is too small to warrant mandatory HIV screening. Absent a significant public health threat, such screening would represent an invasion of privacy that could set the stage for unjustifiable employment discrimination.

If the risk to others is remote, what of the risk to such individuals themselves? Does such danger warrant the exclusion of those with HIV infection from employment settings in which they may be exposed to tuberculosis? From a legal perspective, the Americans With Disabilities Act²⁹ would appear to have settled the issue. The act states that those who are otherwise qualified cannot be barred from employment, public services, or accommodations because of disability,30 and tuberculosis is considered a disability under the act.³¹ Employers and service providers are required to make "reasonable accommodations" to ensure access to employment and services.32 However, the Equal Employment Opportunity Commission's implementing regulations declared that employers may exclude disabled workers placed at "significant risk" by certain jobs.^{33*} It is too soon to know how this interpretation of the Disabilities Act will fare in the courts.^{34**} Even if exclusions are determined to be permissible, that will not necessarily resolve the question of whether they would provide sufficient legal justification for mandatory HIV screening as a way of discovering those at risk.

How the courts ultimately interpret the Disabilities Act need not be dispositive from an ethical and policy perspective. It is crucial to emphasize that those responsible for the management of prisons, hospitals, and shelters are both legally and morally obligated to reduce the level of risk to their employees from infection with tuberculosis. They are legally obligated to do so under the General Duty clause of the Occupational Safety and Health Act³⁵ and under relevant state occupational health regulations covering employment by state institutions. They are morally obligated to do so by the principle of justice, because workers have a right to expect that their work will not expose them to hazards that can be eliminated or significantly reduced.36 Recent outbreaks of tuberculosis in hospitals, prisons, and shelters make it clear that these obligations have not been met and that federal and state regulatory authorities need to enforce standards that would protect exposed workers.

Regardless of whether practices and structural reforms protective of employees have been instituted—and in the short run it may be beyond the capacity of some institutions to meet relevant Centers for Disease Control and Prevention guidelines designed to prevent the spread of tuberculosis³⁷—it is the obligation of the employer to inform current and prospective workers of the risks associated with their work and to encourage those who believe they are at risk to undergo voluntary HIV testing, so that they may fully appreciate the significance of the choices they will make.

But beyond such warnings, should employers be permitted to exclude those infected with HIV and to undertake testing to identify such individuals? On the one hand, the moral principle of respect for autonomy would dictate a willingness to permit fully informed workers to take such risks. On the other hand, the principle of beneficence could lead to a policy of paternalistic exclusion.

Employers have a moral obligation, and perhaps a legal one as well under the Americans with Disabilities Act, to make every reasonable accommodation to ensure that those who have identified themselves as having HIV infection may be given work assignments that will reduce their exposure to tuberculosis. This is especially the case with nonprofessional employees, whose economic circumstances may limit their ability to choose their conditions of employment. But where such accommodations are not possible or where employees do not ask for them, should employers be permitted to exclude those with HIV infection from certain jobs or settings?

We conclude that they should not. A policy of exclusion would not only represent a restriction on individual autonomy but would ineluctably lead to mandatory HIV screening. Such screening would not only entail a burden on employees but, given the political realities of institutional life, would inevitably lead to the reciprocal mandatory HIV testing of patients and inmates. Such an outcome would be wholly disproportionate to the legitimate goal of preventing tuberculosis in those informed about the risks.

Perhaps most critically, the decision on the part of HIV-infected workers to work in settings where they may be exposed to tuberculosis should be viewed not as recklessness but rather as socially laudable. This is especially true in the case of HIV-infected health care workers. At a time when many health care workers seek to avoid contact with patients with HIV infection,³⁸⁻⁴⁰ where the risks of nosocomial infection are low, HIV-infected workers demonstrate by their behavior a commitment to the traditions of medicine that have held patient welfare to be the highest value.

Treating Tuberculosis: State Responsibility and Individual Obligations

The public health threat posed by tuberculosis requires the development of programs that can secure the cooperation of those who have tuberculosis and the elimination of the social, medical, and psychological barriers to compliance with treatment. It also provides the ethical, constitutional, and legal justification for requiring individuals to undergo such treatment.⁴¹ The harm principle, as well as long-recognized constitutional standards, provides the ethical and legal foundations for the compulsory hospitalization of tuberculosis patients during the acute infectious stage of their illness.^{20,42-44} Nevertheless, legal orders to hold patients with

^{*}Note that the Americans with Disabilities Act explicitly states only that employers may require that the employee "not pose a direct threat to the health or safety of other individuals in the workplace" Pub L No. 101-336, §103(b). "Direct threat" is defined as "significant risk ... that cannot be eliminated by reasonable accommodation" Pub L No. 101-336, §101(3).

^{**}Although the decision was not dispositive because it was decided under a different statute, in the recent decision of *International Union, United Auto Workers v Johnson Controls, Inc,* the Supreme Court refused to recognize danger to the woman employee herself as a justification for discrimination.

active disease in the hospital are uncommon; most such patients feel ill and desire treatment. At least during the period of initial hospitalization, the immediate interests and preferences of patients usually coincide with the demands of the public health.

But treatment during the infectious phase is not sufficient. A failure to complete therapy until cure renders the initial therapeutic intervention ineffective, often results in the recurrence of infectiousness, and increases the probability that drugresistant strains of tuberculosis will emerge.^{2,3,15,45-47} Indeed, from the public health perspective, uncompleted treatment poses a greater threat than nontreatment. In New York City, for example, where the problem is most serious, the possibility exists that, if the development of drug-resistant strains of tuberculosis goes unchecked, isoniazid and rifampinwhich have served so well in the past in the clinical and public health response to tuberculosis-will lose their effectiveness.

Achieving compliance with tuberculosis treatment in the postacute phase of disease is difficult. The patient no longer feels ill and thus may lack the motivation to continue a prescribed medical regimen. A range of social factors including homelessness, drug and alcohol addiction, and psychiatric disease decrease the willingness or ability of many patients to comply with treatment protocols. Therefore it is necessary to adopt public policies that will ensure the completion of therapy until cure.^{2,15,20,42-47}

The constitutional and ethical principles that provide the justification for requiring treatment during the infectious period also provide the justification for requiring treatment until cure. Extension of the practice of compulsory treatment will, in many jurisdictions, require additional legislation.^{20,45,46} Such legislation should respect the rights of those with tuberculosis, to the extent compatible with the protection of the public health, and should mandate policies that facilitate the cooperation of patients in their care.

Ensuring the Completion of Treatment

An effective approach to tuberculosis control must clearly spell out the responsibilities of the state and the individual patient. Ensuring the completion of therapy requires the development of an individualized assessment and care plan. Such a plan should include an educational component that explains to the patient the requirement of treatment during the acute phase and the necessity of continued treatment until cure. Although the focus of such efforts should be on eliciting patients' cooperation, it is vital that patients understand the threat to the public health from their condition and the possible future threat to their liberty if they fail to comply. This educational process should be reinforced by materials that are culturally appropriate.

Discharge from the hospital should depend on the existence of a reasonable discharge plan and a thorough evaluation of factors that may impede compliance with posthospitalization treatment. Patients who are homeless, who live in the threatening and chaotic environment of a shelter, or whose living arrangements are characterized by chronic emotional instability or substance abuse are unlikely to be compliant during the 3- to 18-month period required for the cure of tuberculosis. Individuals who are addicted to drugs or alcohol are unlikely to give precedence to their tuberculosis treatment, especially in the postacute phase when no symptoms prod them to continue treatment. Those who lives are characterized by social and psychological pathology are unlikely to comprehend or accept the necessity of prolonged tuberculosis treatment.2,45-48

An effective plan of treatment should include the provision of a secure residence with a range of social services and treatment options appropriate for each patient. Individuals with substance abuse problems must be encouraged to participate in and be guaranteed access to appropriate inpatient or outpatient treatment. Those with major psychiatric disorders must be offered appropriate clinical management. The resources necessary to ensure access to appropriate housing, social services, and drug and psychiatric treatment must be made available by the state.

The state's obligation to provide such resources is justified on both ethical and prudential grounds. From an ethical perspective, the imposition of an obligation to follow a course of therapy creates a corresponding obligation to facilitate the patient's cooperation. The public health threat posed by tuberculosis provides an additional moral justification for giving priority to such patients over others who may be equally in need. From a prudential perspective, the provision of these services is dictated by the importance of ensuring patient compliance in the most cost-effective manner. Absent appropriate supports, either the goal of treating each case of tuberculosis until cure will be compromised or it will be necessary to detain the noncompliant patient until cure. The cost of detention will far exceed the cost of the needed social services.

Incentives, including money, have been suggested as one route to induce poor, socially disorganized, and alienated patients to comply with treatment.46,48-51 Such proposals have been opposed on a number of grounds. Many find it morally objectionable to pay people for taking medication that is in their interest and will. in addition, protect others. Opponents argue further that financial incentives are likely to be used for continued drug and alcohol use, which is often integral to the inability of patients to comply with treatment plans. Finally, it has been asserted that the civic "lesson" that compliance with the law must be purchased by society might have negative long-term consequences; compliance might become an escalating fiscal burden and a constant subject for negotiation. These objections have merit. Nevertheless, in such an urgent situation, controlled studies of the effect of financial incentives on patient compliance must be undertaken.

It is doubtful whether the judicial doctrine of the least restrictive alternative⁵² would lead the courts to mandate social services, including adequate housing for homeless patients with tuberculosis.53 (The Supreme Court has refused to recognize a right to a basic state of welfare, holding only that, if benefits are provided, they must be provided nondiscriminatorily). Nevertheless, it is clear that public health departments and the state and city governments to which they are ultimately responsible should pursue a course that will most effectively ensure the protection of the public health at the lowest cost.

Directly Observed Therapy

Studies of patients under clinical care for a wide range of conditions have revealed widespread noncompliance.^{45–48,54–56} (Depending on the nature of the problem and the duration of treatment, from one fifth to more than three fourths of patients fail to comply.) Although the homeless and the psychiatrically impaired may evidence higher levels of noncompliance, failure to adhere to the course of prescribed therapy has characterized patients of all social classes and educational levels.^{54,55} In the case of noninfectious disease, the primary consequence of noncompliance is a possibly delayed cure and, in some cases, an exacerbation of illness for the individual. In the case of tuberculosis, however, noncompliance has profound public health implications.

Because it is not now possible to determine which individuals will be compliant with tuberculosis treatment, sound public health practice dictates that all patients undergo directly observed therapy during the early phase of posthospitalization treatment. Such supervised therapy may take place in the home or in designated clinical settings. Every effort must be made to ensure that such treatment poses minimal interference with the patient's normal routine⁵⁷ and does not compromise confidentiality. Failure in this regard would impose additional burdens on patients and would inevitably compromise compliance. Careful and individualized assessment during the early course of directly observed therapy may make it possible to determine which patients can be permitted to continue their treatment without the supervision of a designee of the public health system. To limit the extent to which such decisions might represent invidiously discriminatory determinations, local and state health departments should develop clearly defined standards for making such judgments and should provide a mechanism for the review of such decisions.

Some have argued that requiring all patients to submit to directly observed therapy is an unacceptable intrusion on privacy and liberty.20 Why should those who have no prior record of failure to adhere to treatment be subjected to a regime that is appropriate only for those who cannot be trusted to take their medication? Wouldn't such a requirement be overbroad? Wouldn't it represent a violation of the constitutional principle that for each individual the least restrictive alternative should be relied on in pursuing the goals of public health? Opponents of such a requirement also argue that the cost of directly observed therapy in all instances represents a misallocation of scarce public health resources. We recognize that a requirement that all patients undergo directly observed therapy will entail imposing supervision on some patients who might otherwise complete the course of treatment without such oversight. Nevertheless, we believe that the marginal intrusions on privacy and restrictions on autonomy represented by supervised therapy are justified, on balance, by the public health benefits that could be achieved. Given the social costs of noncompliance, the expenditure of resources on mandated directly observed therapy, at least during the initial phase of treatment, clearly would represent a cost-effective approach to tuberculosis control.

Failure to Comply with Therapy: Confining the Noncompliant

The protection of the public health requires that those who fail to comply with therapy, even if they are currently noninfectious, be isolated to protect others from the recurrence of infectious tuberculosis and the emergence of drug-resistant organisms. Because confinement in the name of public health represents as serious a deprivation of liberty as does confinement by the criminal law,⁵⁸ it is crucial that the due process rights of the individual be protected at the time the determination of whether to detain is made.59 The provision of counsel, a hearing before an independent administrative or judicial tribunal, and the right to examine witnesses are essential. Issues of liberty and monetary costs dictate that the confinement of the patient be reviewed regularly and that ongoing efforts be made to engage such patients in programs that will prepare them for discharge.60

Conclusions

The measures we propose here will not be inexpensive. But they will be far less costly and far more equitable than efforts to confine many individuals for extended periods. The protection of the public health, a commitment to the least restrictive alternative, and the demands of fiscal responsibility dictate a common course in the face of the tuberculosis epidemic. The most prudent approach to tuberculosis will thus also be a response that poses the fewest threats to liberty.

Although such public health interventions may control tuberculosis, they will not eliminate it. The social conditions of poverty and overcrowding that facilitate the transmission of tuberculosis today are not so very different from those in the 19th and early 20th centuries, although they have been exacerbated by HIV. In many poor communities and in the overcrowded shelters, prisons, and jails, we have recreated the type of living conditions that existed in the slums of the early 20th century. These conditions are the predictable consequences of social and political neglect. The resurgence of tuberculosis is but one symptom of the failure to provide humane and adequate living conditions for all.

Four decades ago René and Jean Dubos brought *The White Plague*, their seminal study of tuberculosis, to a conclusion by stating:

Elucidation of the mechanisms of tuberculosis disease will long continue to require analysis by the methods of medical sciences. And the case of the stricken tuberculosis patient calls upon all the resources of medical practice. But the complete control of tuberculosis in society goes beyond medicine in its limited sense. It is a problem in social technology.⁶¹

That is a lesson we would do well to recall. \Box

Acknowledgments

Work on this article was supported by grants from the United Hospital Fund and the American Foundation for AIDS Research and by National Institute of Mental Health center grant 2-P50-MH43520 (Anke Ehrhardt, principal investigator). We wish to acknowledge the guidance, analysis, and criticism of the Task Force on HIV/TB, constituted with the support of these foundations.

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