

Special Article

THE USE OF LEGAL ACTION IN NEW YORK CITY TO ENSURE TREATMENT OF TUBERCULOSIS

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ABSTRACT

Background and Methods After an increase in the number of cases of tuberculosis, New York City passed regulations to address the problem of nonadherence to treatment regimens. The commissioner of health can issue orders compelling a person to be examined for tuberculosis, to complete treatment, to receive treatment under direct observation, or to be detained for treatment. On the basis of a review of patients' records, we evaluated the use of these legal actions between April 1993 and April 1995.

Results Among more than 8000 patients with tuberculosis, regulatory orders were issued for less than 4 percent. Among patients with a variety of social problems, only a minority required regulatory intervention: 10 percent of those with injection-drug use, 16 percent of those with alcohol abuse, 17 percent of those who were homeless, 29 percent of those who used "crack" cocaine, and 38 percent of those with a history of incarceration. A total of 150 patients were ordered to undergo directly observed therapy, 139 patients to be detained during therapy, 12 patients to be examined for tuberculosis, and 3 patients to complete treatment. These 304 patients had a median of three prior hospitalizations related to tuberculosis and one episode of leaving the hospital against medical advice. Repeatedly noncompliant patients and those who left the hospital against medical advice were more likely than others to be detained. The median length of detention was 3 weeks for infectious patients and 28 weeks for noninfectious patients. As compared with patients ordered to receive directly observed therapy, the patients who were detained remained infectious longer, had left hospitals against medical advice more often, and were less likely to accept directly observed therapy voluntarily. Altogether, excluding those who died or moved, 96 percent of the patients completed treatment, and 2 percent continued to receive treatment for multidrug-resistant tuberculosis.

Conclusions For most patients with tuberculosis, even those with severe social problems, completion of treatment can usually be achieved without regulatory intervention. Patients were detained on the basis of their history of tuberculosis, rather than on the basis of their social characteristics, and the less restrictive measure of mandatory directly observed therapy was often effective. (N Engl J Med 1999;340:359-66.)

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IN 1992, New York City reported 3811 cases of tuberculosis, nearly three times the number of cases reported 15 years before.¹ As part of a comprehensive response, the New York City Department of Health expanded services for patients with tuberculosis and in 1993 updated the Health Code to permit compulsory actions to protect the public health. The commissioner of health could issue orders compelling a person to be examined for suspected tuberculosis, to complete treatment, to receive treatment under direct observation, or to be detained for treatment.²

Although there was widespread support for these changes,³ there was concern that the department would use its new powers as a means of social control,⁴ and some believed it was unfair to detain patients when their ability to comply voluntarily with treatment was affected by lack of adequate housing, primary health care, and services for substance abusers.^{5,6} The fear was that patients with a history of drug or alcohol abuse or homelessness would be singled out for legal action. In fact, some groups, including civil liberties organizations and organizations advocating for patients with the acquired immunodeficiency syndrome (AIDS), unsuccessfully supported a challenge to the regulations in court, seeking to require the department to exhaust every less restrictive option before ordering detention,⁷ rather than allowing it the discretion to skip steps.

New York City's tuberculosis-control program has been highly successful; new cases decreased by 54.6 percent and cases of multidrug-resistant disease by 87.3 percent between 1992 and 1997.⁸ We evaluated the first two years of the regulatory program, focusing on the use of detention and less restrictive measures to ensure the completion of treatment and the risk factors for detention.

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METHODS

The Regulatory Framework

The revised Health Code went into effect on April 29, 1993. During the period we studied, voluntary directly observed therapy was the standard of care in New York City and was provided in hospitals, clinics, patients' homes, work sites, and locations in the community such as park benches and abandoned buildings. Housing was available for homeless patients with tuberculosis and human immunodeficiency virus (HIV) infection; later during the study period, it was also available for homeless patients who were not infected with HIV. Most programs of directly observed therapy offered patients who complied with therapy incentive payments of \$5 to \$25 a week in fast-food coupons, tokens for transportation, or both.⁹ The department also provided assistance and referrals to patients who had problems with housing and substance abuse. Before any regulatory intervention was undertaken, the department attempted to remove any barriers to adherence to therapy. Department policy was to use the least restrictive measure possible, although it had the discretion to order detention before other measures. For example, voluntary directly observed therapy might never be offered to a patient with a history of leaving hospitals against medical advice. Instead, an order for treatment under direct observation would be issued, or even an order for detention, if the patient had repeatedly become lost to follow-up and infectious between admissions. Similarly, if a patient refused to accept the diagnosis of tuberculosis, an order for outpatient therapy would be considered futile and detention would be pursued. Since orders were issued only for patients whose tuberculosis might pose a threat to the public health, all patients covered by the regulatory program had suspected or confirmed active pulmonary tuberculosis.

Various types of order were issued (Table 1). Patients had a right to an attorney and could challenge an order for detention in court. Even if a patient did not contest the detention, judicial authorization for the detention was required after 60 days. Thereafter, the department had to justify continued detention to the court every 90 days.

Infectious patients were generally admitted to Bellevue Hospital, where they were confined in a standard isolation room on a

guarded ward where non-detained patients with pulmonary disease were also cared for. Noninfectious patients were detained at Goldwater Memorial Hospital, where they stayed on a 29-bed ward, mostly in 4-bed rooms. Each patient had cable television and a phone for incoming calls. The ward had a balcony and a day room, and there were escorted off-ward activities within the hospital grounds, as well as programs addressing substance abuse, education, and recreational therapy. Once at Goldwater Memorial Hospital, patients were considered for discharge before the completion of treatment at monthly, interdisciplinary meetings. Comprehensive medical care, including treatment for AIDS, was available at both facilities.

Study Design and Definitions

The records of the New York City Bureau of Tuberculosis Control were reviewed retrospectively to identify patients who were subject to regulatory action in the first two years of the program (between April 29, 1993, and April 29, 1995). Some patients were served with more than one type of order. Records of directly observed therapy, legal records, clinic records, and information from a centralized tuberculosis registry were reviewed. For patients who were detained, records of tuberculosis-related hospitalizations were also reviewed. Follow-up information available through December 31, 1997, was included.

In order to compare characteristics of patients in the regulatory program with other patients with tuberculosis, data on patients in the regulatory program in whom tuberculosis was diagnosed in 1993 or 1994 were compared with information from the tuberculosis registry on all other patients in New York City in whom tuberculosis was diagnosed during the same period but who were not subject to regulatory action. The comparative analysis was limited to cases diagnosed in 1993 and 1994 so that only patients given a diagnosis during the same period were included in the comparison.

Compliance was defined as taking at least 80 percent of prescribed medications and was calculated on a weekly basis. Homelessness was defined as documentation of a stay in a shelter or of homelessness in the record; not all patients characterized as homeless were homeless at the time the regulatory action was taken. Multidrug resistance was defined as resistance to at least isoniazid and rifampin.

TABLE 1. TYPES OF REGULATORY ACTION.*

DESCRIPTION	EVIDENCE REQUIRED	BASIS FOR RESCINDING ORDER
Order for examination for suspected tuberculosis as outpatient or in detention	Clinical symptoms or history of tuberculosis and refusal by patient to come to clinic or submit to examination in hospital	After minimal time required, tuberculosis can be either diagnosed or ruled out. No forcible examination allowed.
Order to complete treatment	History of leaving hospital against medical advice or noncompliance early in course of treatment	Patient completes treatment or is given another order.
Order for directly observed therapy	Noncompliance with voluntary directly observed therapy or history of leaving hospital against medical advice or previous order for detention while infectious	Patient completes treatment, self-administration of medication is allowed, or patient is detained.
Written warning of possible detention	Failure to adhere to order for directly observed therapy without plausible excuse or <80 percent compliance for more than 2 wk	Patient completes treatment or is detained.
Order for detention while infectious	Proof of suspected infectiousness, either by smears or clinical symptoms, plus failure to abide by infection-control guidelines or inability to be separated from others as outpatient	Patient has three negative smears or clinical evidence of noninfectiousness.
Order for detention while noninfectious	Proof of substantial likelihood that patient cannot complete treatment as outpatient (e.g., documented noncompliance with directly observed therapy, denial of diagnosis of tuberculosis, history of inability to be located)	Patient is discharged early to court-ordered directly observed therapy or patient completes therapy. Order must be periodically reviewed by court.
Discharge from detention before cure (for noninfectious patient)	Change in circumstances so that compliance with outpatient, directly observed therapy is likely (e.g., new insight, substance-abuse treatment, new home environment, or family support)	Patient completes treatment or is detained again if patient fails to comply with outpatient treatment.

*None of the orders permit the forcible administration of medication.

Statistical Analysis

Epi Info version 6.03 was used for bivariate and stratified analyses.¹⁰ Chi-square tests were used for the comparison of proportions. Odds ratios and 95 percent confidence intervals were used to compare risk factors for detention, and the Wilcoxon rank-sum test was used for nonparametric testing. SAS statistical software was used to perform logistic-regression analyses, with use of forward conditional selection.¹¹ Two multivariate models were used. In the first, demographic, social, and selected disease-related characteristics for all patients with tuberculosis reported in 1993 and 1994 were included, and the risk of any regulatory action was determined. In the second model, demographic, social, and disease-related variables and adherence to treatment for all patients in the regulatory program during the study period were included, and the risk of detention was determined with patients receiving mandatory directly observed therapy serving as the reference group. All P values were two-tailed, and P values of less than 0.05 were considered to indicate statistical significance.

RESULTS

A median of 31 patients (range, 1 to 49) were detained at any one time. The percentage of patients detained never rose above 2 percent of the overall population of patients with tuberculosis, which numbered at least 8000. Of 328 patients for whom regulatory orders were issued during this period, 24 patients did not have tuberculosis (9 were ordered to be examined for suspected tuberculosis, 4 were ordered to undergo observed therapy pending the completion of the diagnostic evaluation, and 11 were detained until tuberculosis was ruled out). Our analyses were restricted to the remaining 304 patients with confirmed tuberculosis.

Social and Demographic Characteristics

From April 29, 1993, through April 29, 1995, regulatory action was taken to ensure treatment of 304 patients (Fig. 1), with a median age of 35 years (range, 16 to 73). A total of 170 (56 percent) were male; 211 (69 percent) were black, 21 (7 percent) were white, 68 (22 percent) were Hispanic, and 4 (1 percent) were Asian. Of the 304 patients, 273 (90 percent) were born in the United States or Puerto Rico. HIV infection was documented in 147 (48 percent), 103 (34 percent) had negative HIV tests, and HIV status was unknown for 54 patients (18 percent).

Among the patients for whom orders were issued, 152 (50 percent) had a history of homelessness, 128 (42 percent) had used injection drugs, 183 (60 percent) had used “crack” cocaine, 191 (63 percent) had a history of alcohol abuse, and 145 (48 percent) had a history of incarceration. Approximately half the detained patients with a history of homelessness were homeless at the time of detention. Among patients given a diagnosis of tuberculosis in 1993 or 1994, the highest rates of both regulatory intervention and detention were consistently among patients with a history of crack use and those who had been incarcerated for criminal activities. Nonetheless, the majority of patients with tuberculosis who had severe social problems never required any regulatory intervention, and very few required detention (Table 2).

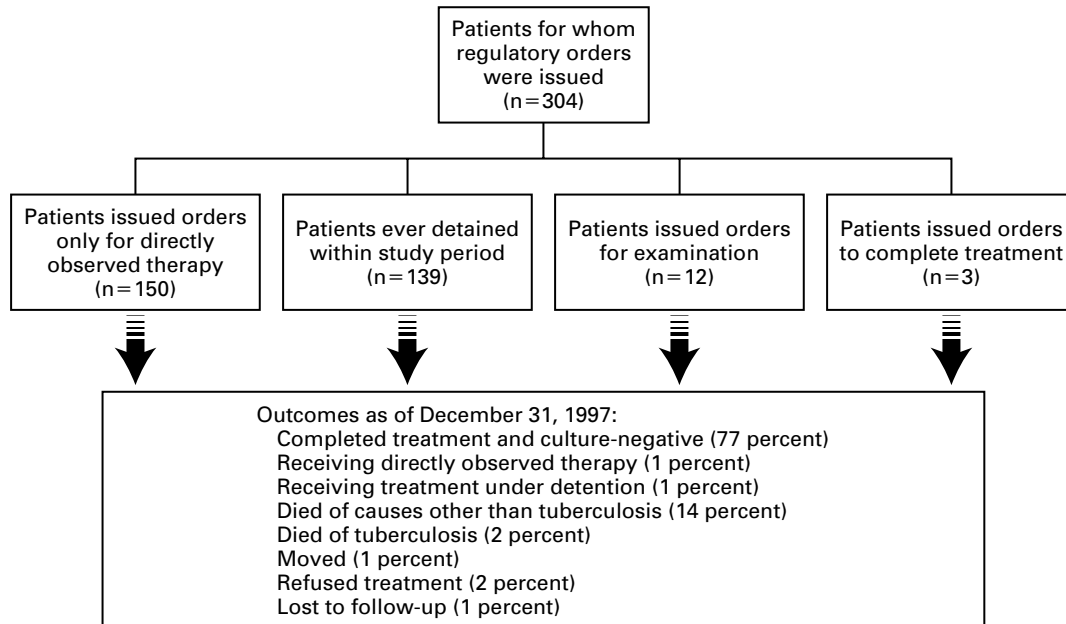


Figure 1. Outcomes of Patients with Tuberculosis for Whom Various Types of Regulatory Orders Were Issued in the First Two Years after Amendment of the New York City Health Code.

Because of rounding, percentages for outcomes do not total 100.

TABLE 2. SOCIAL PROBLEMS AMONG 6014 PATIENTS GIVEN A DIAGNOSIS OF TUBERCULOSIS IN 1993 OR 1994.

CHARACTERISTIC	PATIENTS WITH CHARACTERISTIC	PATIENTS REQUIRING REGULATORY INTERVENTION	PATIENTS ORDERED DETAINED
	no.	no. (%)	
Injection-drug use	921	93 (10)	46 (5)
Alcohol abuse	864	136 (16)	57 (7)
Homelessness	630	106 (17)	54 (9)
Crack use	462	133 (29)	62 (13)
Incarceration	280	107 (38)	51 (18)

History of Tuberculosis

A positive sputum smear for acid-fast bacilli was documented for 265 (87 percent) of the 304 patients, and cavitory tuberculosis was documented in 153 patients (50 percent). Drug resistance was documented in 124 patients (41 percent), and 78 (26 percent) had multidrug-resistant tuberculosis.

Before regulatory action was taken, patients had a median of 3 (range, 0 to 22) tuberculosis-related hospital admissions, and a median of 1 episode of leaving a hospital against medical advice (range, 0 to 16). When all tuberculosis-related admissions were combined, patients for whom orders were issued spent a median of 5 weeks (range, 0 to 100) in the hospital before an order was issued by the Department of Health.

Directly Observed Therapy

Before any regulatory orders were issued, 276 of the 304 patients (91 percent) were offered voluntary directly observed therapy; 155 (56 percent) accepted and received directly observed therapy voluntarily for a median of 28 weeks (range, 2 to 159), but they were compliant with therapy for less than a third of the time and could not be located for a median of 10 weeks (range, 1 to 116). None of the 28 patients (9 percent) who were never offered voluntary directly observed therapy were detained without first being ordered to undergo directly observed therapy.

Of 304 patients for whom orders were issued, 233 patients (77 percent) were required to receive therapy under direct observation; of this group, 174 (75 percent) were not subsequently detained. Warning letters were issued to 17 patients who remained non-compliant with treatment.

Detention

Of the 139 patients (46 percent) who were ever detained, 23 were detained only while they were infectious, for a median of 3 weeks (range, 1 to 18). Another 116 patients (38 percent) were placed under

long-term detention for a median of 28 weeks (range, 0 to 138); of these, 97 were detained at Goldwater Memorial Hospital for a median of 23 weeks (range, 2 to 138). Among detained patients who completed treatment at Goldwater Memorial Hospital, the median length of stay was 21 weeks (range, 6 to 34) for the 47 patients with drug-susceptible isolates and 50 weeks (range, 2 to 138) for the 21 with multidrug-resistant isolates. Of the 116 patients in long-term detention, 35 (30 percent) were discharged before completing treatment; they continued to receive treatment under court-ordered direct observation for a median of 19 weeks (range, 1 to 98).

Outcomes

Of the 304 patients we studied, 48 (16 percent) died during treatment, primarily from the complications of HIV infection; 12 died while in detention, and 5 died of tuberculosis. Excluding the patients who died, 5 who moved, and 6 patients with multidrug-resistant tuberculosis who were still receiving treatment in December 1997, 96 percent (235 of 245) completed treatment. Of the 10 patients who did not complete treatment, 4 were lost to follow-up despite extensive efforts to locate them, and 6 refused further treatment after having nearly completed treatment and having negative sputum cultures.

Of the 17 patients who received warning letters because of their noncompliance with mandatory directly observed therapy, 13 completed treatment without being detained, 1 was compliant while detained, 1 completed treatment after detention, 1 was lost to follow-up, and 1 refused further treatment after a nearly full course. Among the 35 patients who had been detained while noninfectious but were discharged before therapy was completed, 31 completed treatment, 1 continued to receive directly observed therapy for multidrug-resistant tuberculosis, 1 was detained again, 1 was lost to follow-up, and 1 died.

For the 153 patients with drug-susceptible tuberculosis who completed treatment, the median length of time from the diagnosis to the completion of treatment was 17 months (range, 5 to 130), and the median length of time from the issuance of the regulatory order to the completion of treatment was 9 months (range, 1 to 44). Among 48 patients with multidrug-resistant tuberculosis who completed treatment, the median length of time from diagnosis to the completion of treatment was 38 months (range, 12 to 157), and the median length of time from the issuance of the order to the completion of treatment was 18 months (range, 2.3 to 44). The remaining 34 patients had some drug resistance.

Patients with Regulatory Orders as Compared with Other Patients

There were 216 patients in whom tuberculosis was diagnosed in 1993 or 1994 for whom orders were

issued within the study period. Multivariate analysis showed that in these patients, as compared with the remaining 6014 patients with tuberculosis diagnosed in 1993 or 1994, factors significantly associated with intervention by the Department of Health were a history of alcohol abuse (odds ratio, 6.2; 95 percent confidence interval, 4.3 to 8.9; $P < 0.001$), a history of crack use (odds ratio, 4.8; 95 percent confidence interval, 3.3 to 6.8; $P < 0.001$), a history of homelessness (odds ratio, 3.5; 95 percent confidence interval, 2.4 to 5.1; $P < 0.001$), a history of injection-drug use (odds ratio, 1.8; 95 percent confidence interval, 1.2 to 2.6; $P = 0.004$), multidrug-resistant tuberculosis (odds ratio, 2.5; 95 percent confidence interval, 1.5 to 4.2; $P < 0.001$), a history of incarceration (odds ratio, 8.1; 95 percent confidence interval, 5.6 to 12.0; $P < 0.001$), and female sex (odds ratio, 3.4; 95 percent confidence interval, 2.3 to 4.9;

$P < 0.001$). A history of HIV infection was associated with a lower risk of regulatory action (odds ratio, 0.6; 95 percent confidence interval, 0.4 to 0.9; $P = 0.02$).

Patients Receiving Mandatory Directly Observed Therapy as Compared with Detained Patients

Patients who were detained were similar to patients who remained under orders to receive directly observed therapy; however, they were more likely to have cavitary disease, to have positive smears and cultures for a longer time, and to have a history of homelessness (Table 3). Patients who were detained also had significantly more previous hospital admissions related to tuberculosis and more episodes of leaving the hospital against medical advice; were less likely to be offered voluntary directly observed therapy; and when it was offered, were much less likely to accept it (Table 4). Multivariate analyses showed

TABLE 3. SOCIAL, DEMOGRAPHIC, AND DISEASE-RELATED RISK FACTORS FOR DETENTION AMONG PATIENTS FOR WHOM ORDERS WERE ISSUED.*

CHARACTERISTIC	MANDATORY DIRECTLY OBSERVED THERAPY (N=150)	DETENTION DURING THERAPY (N=139)	ODDS RATIO (95% CI)†	P VALUE
Male sex — no. (%)	79 (52.7)	82 (59.0)	1.29 (0.79–2.12)	0.34
Age — yr				
Median	34	35		0.74
Range	17–69	16–70		
Race or ethnic group — no. (%)				
Black	109 (72.7)	94 (67.6)	0.79 (0.46–1.34)	0.42
Hispanic	31 (20.7)	33 (23.7)	1.20 (0.66–2.16)	0.67
Non-Hispanic white	10 (6.7)	10 (7.2)	1.09 (0.40–2.93)	0.96
Asian	0	2 (1.4)		0.23
Born in United States — no. (%)	136 (90.7)	125 (89.9)	0.92 (0.39–2.14)	0.99
HIV infection — no. (%)	80 (53.3)	63 (45.3)	0.73 (0.44–1.18)	0.21
Social history — no. (%)				
Homelessness	63 (42.0)	86 (61.9)	2.24 (1.36–3.69)	0.001
Injection-drug use	64 (42.7)	59 (42.4)	0.99 (0.60–1.62)	0.94
Crack use	84 (56.0)	93 (66.9)	1.59 (0.96–2.64)	0.07
Alcohol abuse	99 (66.0)	87 (62.6)	1.31 (0.80–2.17)	0.63
Incarceration	67 (44.7)	75 (54.0)	1.45 (0.89–2.37)	0.14
Type of tuberculosis — no. (%)				
Pulmonary only	119 (79.3)	124 (89.2)	2.1 (1.06–4.42)	0.02
Extrapulmonary only	2 (1.3)	0		
Both	29 (19.3)	15 (10.8)	0.5 (0.24–1.03)	0.04
Drug resistance — no. (%)	56 (37.3)	66 (47.5)	1.52 (0.92–2.50)	0.10
Multidrug resistance — no. (%)	34 (22.7)	44 (31.7)	1.58 (0.91–2.76)	0.11
Cavitary disease — no. (%)	63 (42.0)	85 (61.2)	2.17 (1.32–3.58)	0.001
Active tuberculosis				
Positive sputum smear — no. (%)	126 (84.0)	128 (92.1)	2.22 (0.99–5.05)	0.54
Duration of positive status (mo)				
Median	2	4		<0.001
Range	0–67	0–48		
Positive sputum culture — no. (%)	150 (100)	139 (100)		
Duration of positive status (mo)				
Median	4	7		<0.001
Range	1–100	0–89		

*Because of rounding, percentages may not total 100.

†The odds ratios compare the risk of detention for a patient with the characteristic in question with the risk for a patient without the characteristic. CI denotes confidence interval. The Wilcoxon rank-sum test was used for nonparametric testing (age, duration of positive status by sputum smear, and duration of positive status by sputum culture).

TABLE 4. HISTORY OF TREATMENT FOR TUBERCULOSIS AMONG PATIENTS FOR WHOM ORDERS WERE SUBSEQUENTLY ISSUED AND OUTCOME AFTER REGULATORY ACTION.*

VARIABLE	MANDATORY DIRECTLY OBSERVED THERAPY (N=150)	DETENTION DURING THERAPY (N=139)	ODDS RATIO (95% CI)†	P VALUE
No. of admissions for tuberculosis				
Median	2	3		0.001
Range	0–21	0–22		
No. of episodes of leaving hospital against medical advice				
Median	0	2		<0.001
Range	0–6	0–16		
Total length of hospitalization before detention (wk)				
Median	7	9		0.22
Range	0–64	0–106		
Voluntary directly observed therapy				
Offered — no. (%)	142 (94.7)	119 (85.6)	0.34 (0.13–0.84)	0.01
Accepted — no. (%)	93 (62.0)	53 (38.1)	0.38 (0.23–0.62)	<0.001
Complied with — %				
Median	30	30		0.25
Range	0–100	0–100		
Outcomes — no. (%)				
Completed treatment	109 (72.7)	114 (82.0)	1.72 (0.94–3.13)	0.08
Compliant while detained	0	3 (2.2)		
Compliant with mandatory directly observed therapy	2 (1.3)	1 (0.7)	0.54 (0.02–7.68)	1.00
Died	30 (20.0)	17 (12.2)	0.56 (0.28–1.11)	0.10
Lost to follow-up	3 (2.0)	1 (0.7)	0.36 (0.01–3.88)	0.62
Refused treatment	3 (2.0)	1 (0.7)	0.36 (0.01–3.88)	0.62
Moved	3 (2.0)	2 (1.4)	0.72 (0.08–5.35)	1.00

*Because of rounding, percentages may not total 100.

†The odds ratios compare the risk of detention for a patient with the characteristic in question with the risk for a patient without the characteristic. CI denotes confidence interval. The Wilcoxon rank-sum test was used for nonparametric testing (number of admissions, number of episodes of leaving the hospital against medical advice, and compliance with voluntary directly observed therapy).

that leaving the hospital against medical advice (odds ratio, 6.2; 95 percent confidence interval, 2.3 to 16.4; $P < 0.001$) and noncompliance with mandatory directly observed therapy (odds ratio, 4.3; 95 percent confidence interval, 1.4 to 13.3; $P = 0.01$) were significant predictors of detention.

DISCUSSION

Intervention by means of public health orders, including orders for detention, has become a small but integral part of New York City's successful efforts to control tuberculosis. In the first two years of the program, less than 2 percent of all patients with tuberculosis in New York City, and a minority of patients with substance abuse, homelessness, or a history of incarceration, required confinement for the completion of treatment. For 75 percent of patients ordered to receive directly observed therapy and 76 percent of patients who did not comply with such mandatory treatment who received a warning letter, detention was not necessary. The success of these interventions indicates that if detention is undertaken too quickly, patients' liberty may be limited un-

necessarily. Although the power of the Department of Health to omit steps that are less restrictive than detention to ensure treatment was upheld by the courts and was important for patients who might otherwise have eluded outreach efforts and continued to spread tuberculosis, this power was used sparingly. The success of mandatory directly observed therapy is based on the credible threat of detention; noncompliant patients are warned that failure to adhere to the treatment regimen could result in detention. New York City is fortunate to have two hospitals with secure wards in which to detain patients, thus avoiding the serious ethical problems raised by the prospect of having to jail patients with tuberculosis.¹²

Even though many patients had a history of noncompliance, advanced tuberculosis disease, and multidrug resistance, the use of orders for mandatory directly observed therapy or detention resulted in a completion rate of 96 percent. The concern that the power to detain patients would result in the discriminatory detention of patients who were homeless or who were substance abusers was not realized. Al-

though the proportion of patients who had a history of incarceration, substance abuse, or homelessness was high, the great majority of patients with both tuberculosis and social problems did not require any form of regulatory action. Since data collection was more complete for patients covered by regulatory orders than for other patients, the actual proportions of nondetained patients who had these characteristics may have been higher than indicated by the available data.

Detention was used only when it was judged necessary to protect the public health. Patients who were detained posed a serious risk to the public health. As compared with outpatients receiving mandatory observation of treatment, they were infectious for a longer period, left hospitals against medical advice more often, and were more likely to have cavitory disease. These were the patients the law was intended to reach — those with a history of repeated hospitalizations who did not accept directly observed therapy voluntarily, were not able to complete treatment without detention, and were likely to spread disease.

Because information on adherence for the entire group of patients with tuberculosis was not available, we cannot prove that every patient who was repeatedly noncompliant with therapy was subject to regulatory action and that there was no bias in issuing orders. However, careful monitoring of all patients, including those treated by private physicians, resulted in rates of completion of therapy among patients without multidrug-resistant tuberculosis of 89 percent in 1993 and 94 percent in 1994.^{13,14} Among the patients who received any regulatory order, the data indicate that there was no racial or social bias with regard to detention. We are confident that there was no serious bias and that virtually all patients who did not comply with treatment and who could be located were issued regulatory orders.

The costs of the detention program were substantial, but they were considerably below the expenses that were averted. The costs of hospitalization during detention for patients described in this study totaled nearly \$3 million (New York City Department of Health: unpublished data). In addition, the costs of staff to run the detention program included salaries for a program coordinator, a physician to review records and appear in court, and nine outreach workers to collect and review medical records of patients referred for regulatory action, prepare orders, monitor patients for whom orders had been issued, and respond to telephone inquiries. During this period, one Health Department lawyer reviewed all orders from a legal perspective, and additional legal staff represented New York City in the hearings for individual patients. Thus, at its height, the regulatory program probably cost nearly \$2 million per year, including the costs of hospital care.

Although the costs of the program were high, the economic benefits appear to have been higher. Before the advent of regulatory intervention, ineffective and repeated hospitalization for the 304 patients ultimately ordered to receive treatment cost a total of more than \$25 million (New York City Department of Health: unpublished data). By curtailing such costs, as well as preventing the spread of tuberculosis, the regulatory interventions saved substantial direct costs.

Comparison with other programs is difficult because of the different criteria for detention, the different definitions of psychosocial variables, and the dissimilar detention facilities. Nevertheless, since New York City has more than twice as many cases of tuberculosis and many times as many cases of multidrug-resistant disease as any other city in the United States, its detention program has been the most active, detaining almost as many patients in two years as Massachusetts did in five years.¹⁵ However, the percentage of patients detained was lower in New York than in other jurisdictions.^{12,15,16}

As New York City's total number of cases of tuberculosis has declined, so has the number of patients detained. Only 44 patients were detained in 1997, once again representing approximately 2 percent of the total (New York City Department of Health: unpublished data). This decrease probably reflects both the program's success in identifying and completing the treatment of nearly all patients with existing disease and the decreased incidence of tuberculosis. In its implementation of the law, the Department of Health gave patients numerous less restrictive alternatives, reserving detention for the small number of patients who were truly unwilling or unable to adhere to treatment. Patients were evaluated on the basis of their histories with respect to tuberculosis, not on the basis of their social characteristics. Detention remained a last resort to cure patients, but, when applied, it was highly successful in ensuring complete treatment.

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REFERENCES

1. Frieden TR, Fujiwara PI, Washko RM, Hamburg MA. Tuberculosis in New York City — turning the tide. *N Engl J Med* 1995;333:229-33.
2. New York City Health Code §11.47(d) (1994).
3. Tuberculosis in the 1990s: ethical, legal, and public policy issues in screening, treatment, and the protection of those in congregate facilities — a report from the Working Group on TB and HIV. In: Dubler NN, Bayer R, Landesman S, White A. *The tuberculosis revival: individual rights and societal obligations in a time of AIDS*. New York: United Hospital Fund, 1992.
4. Lerner BH. Contagion and confinement: controlling tuberculosis along the skid road. Baltimore: Johns Hopkins University Press, 1998.
5. Developing a system for tuberculosis prevention and care in New York City. In: Dubler NN, Bayer R, Landesman S, White A. *The tuberculosis revival: individual rights and societal obligations in a time of AIDS*. New York: United Hospital Fund, 1992.
6. Annas GJ. Control of tuberculosis — the law and the public's health. *N Engl J Med* 1993;328:585-8.
7. Application of the City of New York v. Doc, 205 A.D.2d 469, 614 N.Y.S.2d 8 (1st Dept. 1994).
8. Bureau of Tuberculosis Control. Information summary, 1997. New York: New York City Department of Health, 1998.
9. Fujiwara PI, Larkin C, Frieden TR. Directly observed therapy in New York City: history, implementation, results, and challenges. *Clin Chest Med* 1997;18:135-48.
10. Dean AG, Dean JA, Coulombier D, et al. Epi Info, version 6.03: a word processing, database and statistics program for public health on IBM-compatible microcomputers. Atlanta: Centers for Disease Control and Prevention, 1995.
11. SAS/STAT software: syntax version 6. Cary, N.C.: SAS Institute, 1993.
12. Oscherwitz T, Tulskey JP, Roger S, et al. Detention of persistently nonadherent patients with tuberculosis. *JAMA* 1997;278:843-6.
13. Bureau of Tuberculosis Control. Information summary, 1994. New York: New York City Department of Health, 1995.
14. *Idem*. Information summary, 1995. New York: New York City Department of Health, 1996.
15. Singleton L, Turner M, Haskal R, Etkind S, Tricarico M, Nardell E. Long-term hospitalization for tuberculosis control: experience with a medical-psychosocial inpatient unit. *JAMA* 1997;278:838-42.
16. Burman WJ, Cohn DL, Rietmeijer CA, Judson FN, Sbarbaro JA, Reves RR. Short-term incarceration for the management of noncompliance with tuberculosis treatment. *Chest* 1997;112:57-62.

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