

SOCIAL AND BEHAVIORAL SCIENCES EXERCISE 4: Ethical  
Concerns In Delivering Public Health Services Debate:  
Arguments For and Against Universal Directly Observed  
Therapy (DOT) for Tuberculosis (TB)  
**STUDENT VERSION 1.0**

**SBS Exercise 4: Ethical Concerns in Delivering Public Health Services Debate: Arguments For  
and Against Universal Directly Observed Therapy (DOT) for Tuberculosis (TB)**

**Estimated Time to Complete Exercise: 2 hours for preparation and 1 hour for the debate,  
over 2 class sessions**

**LEARNING OBJECTIVES**

At the completion of this exercise, participants should be able to:

- Describe the role of public health programs in meeting individual & community needs
- Argue for or against required public health services
- Describe the role of public health in protecting the public good while upholding individual autonomy

**ASPH SOCIAL AND BEHAVIORAL SCIENCES COMPETENCIES ADDRESSED**

E.9. Apply ethical principles to public health program planning, implementation, and evaluation

**ASPH INTERDISCIPLINARY/CROSS-CUTTING COMPETENCIES ADDRESSED**

H.8. [Leadership] Apply social justice and human rights principles when addressing community needs

J.2. [Professionalism] Apply basic principles of ethical analysis (e.g., the Public Health Code of Ethics, human rights framework, other moral theories) to issues of public health practice and policy

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## **Introduction**

Public health issues often reveal a tension between protecting the community and upholding individual autonomy. This tension is evident in controversies surrounding policies about childhood immunizations and smoking in public places, and also influences public health approaches to control of communicable diseases.

The Code of Ethics of the Society for Public Health Education elucidates several principles that demonstrate this conflict. The Preamble lists “respect for autonomy” as a fundamental ethical principle. In Article I: Responsibility to the Public, Section 6 supports “the privacy and dignity of individuals.” However, Section 1 supports “the right of individuals to make informed decisions regarding health, as long as such decisions pose no threat to the health of others” (emphasis added). Section 2 states that public health educators should “encourage actions and social policies that support and facilitate the best balance of benefits over harm for all affected parties.” Section 9 reinforces the idea that services must be provided equitably; that is, certain groups should not be singled out for special treatment.

The facts surrounding the transmission and treatment of TB make it a prime example of the tension between private rights and public good. The need to ensure treatment completion for TB cases, along with physicians’ inability to accurately identify non-adherent patients in advance, led to the recommendation of universal DOT.

## **Background Information on Tuberculosis Rates in the 1980s**

In the mid to late-1980s, large cities in the United States witnessed a dramatic resurgence of TB with reversals of downward trends and rates of new cases doubling. New York City was particularly hard hit, with cases tripling from 1979 to 1992. The de-funding of public TB control programs coincided with long-term upward trends in urban poverty, increased immigration from countries where TB is endemic, and in some cities, housing shortages. Rising homelessness was particularly acute in New York City, where families excluded from low-income housing joined newly deinstitutionalized mental health patients in overcrowded shelters. Outbreaks of TB in shelters, hospitals, and prisons revealed that infection-control systems for congregate facilities were inadequate. The 1980s also saw a rise in substance use in major US cities, and injection drug and crack cocaine users were disproportionately affected by the new surge in TB. Such individuals were often incarcerated; jails and prisons served as a nexus for further transmission. Additionally, upon release ex-offenders often became homeless and homeless shelters thus served to further spread TB infection. Finally, the emergent epidemic of HIV/AIDS created a national pool of immuno-compromised individuals uniquely vulnerable to TB disease.

In the midst of the resurgence of TB was a frightening sub-epidemic of multi-drug resistant (MDR) TB, stemming in large part from widespread non-completion of treatment (inadequate prescribing practices by physicians also played a role). MDR-TB required a more complex, longer course of treatment and, in immuno-compromised patients, led to extremely high fatality rates if not adequately treated. Many of these causative factors intersected, so that for instance, the population within an urban shelter system included high numbers of substance users who tended to be malnourished and spent time together, often engaging in behaviors that put them at high risk for HIV infection, and who had no regular access to health care or were reluctant to access services for fear that their drug use would be investigated. Such a group would be at high risk for TB infection and for progression to TB disease in the absence of appropriate treatment.

In response, federal, state, county, and local resources were invested in rebuilding TB surveillance and treatment programs, and in strategies to help ensure completion of TB treatment while providing alternatives to mandatory detention. The most important of these strategies has been DOT for outpatients, in which patients receive daily or twice-weekly doses of TB medications from a health care worker who witnesses that each dose is ingested. DOT may be done in a clinical setting, patient residences, schools, workplaces, or other agreed-upon settings. DOT is often combined with other outpatient services, including substance use treatment programs, and includes access to social service providers.

The routinization of DOT has led to a decline in the incidence of detention of TB patients, and much improved rates of treatment completion. This improvement, along with increased funding and interagency collaboration, improved surveillance, diagnostic techniques, and changes in recommended drug regimens, enabled TB control programs to regain the ground lost in the 1980s and early 1990s, so that in the early 21<sup>st</sup> century, TB disease incidence in the United States is at historic lows.

## References

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Society for Public Health Education. Code of Ethics <http://www.sophe.org/about/ethics.html> accessed 2/23/09.

[The following is an excerpt from Bayer R, Dupuis L. Tuberculosis, public health, and civil liberties. *Ann Rev Public Health*. 1993; 16:307-26. pp. 317-319

## **DIRECTLY OBSERVED THERAPY**

Among the strategies designed to enhance patient compliance is directly observed therapy (DOT), a practice that involves having the patient take his or her medications in the presence of a health care provider or other responsible third party. First proposed for individuals with poor records of treatment adherence and for those whose demographic or psychological profile suggested a high risk of treatment failure, directly observed therapy has emerged as a standard of care (18). Recently, the Centers for Disease Control and Prevention, a number of prominent physicians, and others have recommended that all tuberculosis patients be placed on a regime of directly observed therapy, at least in localities where rates of completion fall below an acceptable level (18, 22, 34). Indeed, the Advisory Council for the Elimination of Tuberculosis calls for DOT in areas where treatment completion falls below 90% (18).

The primary rationale for the administration of medications under direct supervision is the recognition that non-adherence is common among patients who must take medication over an extended time period (22, 55). In the case of tuberculosis, such non-compliance has the grave consequence of leading to drug resistance and reactivation of clinical disease. The CDC recommends that DOT "be considered for all patients because of the difficulty in predicting which patients will adhere to a prescribed treatment regimen" (18). In addition, the recommendation for universal, rather than selective, DOT is motivated by a desire to avoid discrimination based on race, social class, and other factors that providers may perceive to have an effect on compliance (22).

The practice of directly observed therapy has been efficacious from a public health perspective. It has contributed to increasing rates of treatment completion (17, 18). In addition, a recent study in Texas found substantial declines in the rates of drug resistance and relapse after the institution of a county-wide program of universal directly observed therapy (55). The rate of primary drug resistance (i.e. the patient contracted a drug-resistant strain from another person) decreased from 13.0 percent to 6.7 percent, while the rate of acquired resistance (i.e. a patient's initially drug-

sensitive strain became resistant, probably due to a treatment failure) declined from 14.0% to 2.1%. The relapse rate declined from 20.9% to 5.5% (55).

From an ethical, legal, and constitutional perspective, the important question is not who should be offered the support of DOT, but rather, when may DOT be imposed by the state.

Faced with the dramatic rise of multidrug-resistant tuberculosis and data that suggested very high rates of treatment failure, Iseman, Cohn & Sbarbaro put forth a public health argument for universal directly observed therapy.

We believe it is time for entirely intermittent [2 – 3 times per week] directly observed treatment programs... to be used for all patients. Some will argue that it will be impossible to treat every patient with directly observed therapy and that many people with tuberculosis do comply with treatment and would be offended by having to submit to direct observation while they swallow medications. Unfortunately, the literature is replete with studies demonstrating... that professionals are not able to distinguish the compliant from the noncompliant in advance (34).

Given the price of failure, in morbidity, mortality, and the cost of treating resistant strains of TB, [Iseman and colleagues] conclude, "We cannot afford not to try it." The case for universal directly observed therapy, at least at the outset of treatment, has also been made by the United Hospital Fund Working Group on Tuberculosis and HIV. It too was concerned by the failure of other approaches to achieve high rates of treatment completion and by the inability of professionals to predict treatment adherence. Though fully aware of the burdens that DOT would entail for some individuals, the working group concluded that, on ethical and legal grounds, universal DOT was desirable:

The fact that all start their post-hospitalization treatment under a common program of supervision should help to reduce the stigma of treatment and create an effective public health plan for the control of TB. Such an approach will also limit the extent to which initial treatment decisions violate the principle of justice, which seeks to preclude acts of invidious discrimination (22).

The call for universal directly observed therapy has provoked sharp opposition. First, it has been argued that such an effort would entail an enormous waste of scarce resources. Funds that could best be used to provide services to those most in need would be diverted to the supervision of those who would be compliant on their own (22, 31). But most critically, universal directly observed therapy has been challenged as an unethical intrusion upon autonomy, as "gratuitously annoying" (3); as a violation of the constitutional requirement that the least restrictive alternative be used; and as contrary to the requirements of the Americans With Disabilities Act that decisions involving restrictions on those with disabilities be based on an individualized assessment. The Policy Director for the Gay Men's Health Crisis, D Hansel, has written:

I cannot see how mandatory directly observed therapy can be reconciled with the principle of the least restrictive alternative in the exercise of governmental power, since it would require the imposition of a coercive treatment regimen in a class of people without any showing that they, as individuals will fail voluntarily to follow a course of medical treatment. Nor does it comport with basic Constitutional due process principles, which require an individualized determination before state sanctions are imposed (22).

Legal commentators too have generally rejected mandatory DOT as overly broad and thus violative of constitutional principles (6, 27, 46). However, this opposition to universal DOT should not be construed as a rejection of mandatory DOT in all cases. Even advocates for patients' civil liberties accept mandatory, court-ordered DOT in cases of clear noncompliance, especially when the alternative appears to be involuntary confinement (12). In its 1993 revision of the New York City Health Code, the City's Board of Health rejected universal mandatory DOT and instead authorized the Commissioner of Health to impose DOT on patients who were noncompliant with treatment during the noninfectious stage of their illness (41).

#### REFERENCES (from Bayer & Dupuis excerpt)

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## **EXERCISE:**

The class has been divided into 2 groups. Group 1 will examine arguments for the resolution (PRO) and Group 2 will examine arguments against (CON).

Be it resolved: “All persons who are diagnosed with pulmonary TB should be required to participate in directly observed therapy.”

Arguments should focus on the practical and ethical concerns about instituting universal DOT, including the following issues:

1. Identification/targeting of risk groups (including stigmatization)
2. The relationship between provider and patient
3. Emergence of drug resistance
4. Costs of health care
5. Access to health care
6. Preventing TB transmission

Each team will get:

- 2 minutes for opening statement
- 5 minutes to state its position
- 3 minutes for rebuttal

## **READINGS**

Society for Public Health Education. Code of Ethics

Arguments in favor of the resolution:

- Sbarbaro JA. All patients should receive directly observed therapy in Tuberculosis: PRO. Am Rev Resp Dis. 1988; 138:1075-1076.

Arguments opposed to the resolution:

- Bailey WC. All patients should receive directly observed therapy in Tuberculosis: CON. Am Rev Resp Dis. 1988; 138:1075-1076.



## **All Patients Should Receive Directly Observed Therapy in Tuberculosis**

### ***PRO: John A. Sbarbaro***

Public health officials are legally responsible for the control of tuberculosis. This responsibility is best met by assuring effective treatment of every contagious patient. Unfortunately, the Centers for Disease Control reported that as of December 1, 1986, 16% of known tuberculosis patients were not on treatment. Of those supposedly on treatment, 48% remained sputum positive at three months, and 27% were still positive at six months of therapy. Eighteen percent of those on treatment were known to not be taking their medication regularly and, therefore, were subject to developing resistant disease.

All of these problems could be corrected by the immediate implementation of supervised, directly administered treatment of *all* patients. At first, the expense of such programs might seem prohibitive, but upon cost-analysis, regimens in which 100% of the medication is directly administered prove to be less expensive than self-administered regimens.

For this cost-analysis, personnel costs (including fringe benefits of 30%) were taken from the State of Indiana and applied to the number of visits required by all nationally recommended regimens of 6 and 9 months duration. For example, a patient on a 9-month self-administered regimen would be expected to see a registered nurse for nine visits consuming at least 15 minutes per visit. The total personnel costs for the regimen would be \$37 (\$4.07 x 9 visits). If the care was provided by an LPN, the cost drops to \$29; a college graduate technician, to \$18; a community health worker, to \$12. For comparison purposes, the Arkansas regimen of daily treatment for one month followed by twice weekly treatment for 8 months would entail personnel costs of \$463 if each dose was administered by an RN, but only \$128 if given by a community worker.

Medication costs were obtained from the 1988 bid contracts of the State of South Carolina and then totaled for each regimen. As an example, 2 months of daily isoniazid, rifampin, and ethambutol followed by seven months of daily isoniazid and rifampin would cost \$368. The same drugs used in the 9-month Arkansas regimen would consume only \$64.

Finally, laboratory and roentgenogram costs were obtained from private competitive providers in the State of Colorado and then, assuming even better efficiency by the public sector, divided by two. Iseman and Sbarbaro have documented a minimum

reduction of two chest films and two cultures when directly administered regimens were utilized. Therefore, the savings associated with these tests was subtracted from the total personnel and medication costs of each directly administered regimen.

When totaled, the direct costs (personnel and medication) of the self-administered regimens ranged from a high of \$405 when supervised by a registered nurse; to a low of \$311 if supervised by a community worker. The direct costs of the completely supervised regimens exceeded these amounts only when a nurse was directly administering all 96 doses of the 6-month regimen. Thus, in all but one directly administered regimen, the savings in medication and laboratory monitoring more than offset the increased cost of personnel.

Moreover, there is now overwhelming conclusive evidence that at least 35% of patients will not take their medication *and* physicians are unable to identify which patients will and will not take their treatment. Therefore, failures and relapses are inevitable among the self-medicated. When the costs associated with these excess relapses and failures are added to this analysis, all of the self-administered regimens become significantly more costly than any directly administered treatment program. And, if only one multiple resistant case is created by poor adherence to a self-administered regimen, the costs associated with self-administration become inordinately prohibitive.

**Sbarbaro JA. All patients should receive directly observed therapy in Tuberculosis: PRO. Am Rev Resp Dis. 1988; 138:1075-1076.**

## **All Patients Should Receive Directly Observed Therapy in Tuberculosis**

**CON: William C. Bailey**

Directly observed therapy is a very important principal in modern tuberculosis control. Without the appropriate use of such therapy, it would be impossible to achieve a high degree of success in the treatment of active disease. However, giving such therapy to all patients with tuberculosis is unnecessary, not cost-effective, and disruptive to good public health practices. This procedure, while it is essential to be used in selected patients, is very expensive, quite labor intensive, and would be impossible to carry out in most health departments throughout the United States if they attempted to provide this therapy for all of their tuberculosis patients. Fortunately it is not necessary to use this for all patients to achieve excellent results.

There are three reasons to give directly observed therapy: (1) when patients have failed to comply with regular therapy and have actually demonstrated treatment failure or relapse; (2) when patients are giving evidence of poor response to therapy before failure has occurred; (3) when predictors indicate the likelihood of failure to take self-administered therapy. While it is true that one cannot predict all the people in the third category, one can do reasonably well if you detect the alcoholics in the population with a simple measure such as the brief Michigan alcoholic screening test, which takes about five minutes to administer. One must then ensure that all of those individuals and any others with obvious social or emotional maladjustments are given directly observed therapy. Diligent observation and a close relationship with all others placed on self-administered therapy will allow one to fairly rapidly detect the others that are in the process of failure before failure occurs. Simply closely monitoring sputum conversion is an excellent means of detecting inadequate therapy.

The Alabama Department of Health and the Jefferson County Health Department, where Birmingham is located, both have excellent success in terms of all parameters that one could measure in assessing tuberculosis therapy. Approximately 30% of patients in Jefferson County are placed on directly observed therapy utilizing the criteria mentioned above. At the current time using this technique, 100% of patients on the tuberculosis register are under therapy, 96.2% convert within three months, 100% convert within six months, and 97.4% of the patients complete therapy on time. It would be impossible to achieve better results even if every patient was placed on directly observed therapy, and of course the cost would be prohibitive. Therefore, it is appropriate to use directly observed therapy in selected individuals, but because public health departments are stewards of the public money, it is inappropriate to use

this very expensive form of therapy other than in those who require it. The potential disadvantage of not directly observing tuberculosis therapy in all patients would be that in the process of watching for potential failure, one might allow a patient to go for a significant period of time on inadequate therapy and develop INH or other drug resistance. In fact, over the last five years in Birmingham, there have been three patients that have developed INH resistance on self-administered therapy. All have been successfully treated on directly observed alternative therapy. In most cases, the alternative therapy included directly observed rifampin and ethambutol, and in all cases the patients were successfully treated with no difficulties. There appears to be no disadvantage whatsoever to the program in Birmingham, Alabama, utilizing directly observed therapy in about 30% of the cases. In fact, it might be wise to attempt a reduction of this percentage if this could be accomplished without impairing the present excellent outcome. This would result in cost savings and a superior program, and is clearly preferable to the quite inappropriate approach of increasing directly observed therapy to include all patients.

I would like to emphasize in closing that I am not arguing against the use of directly observed therapy. It is very important to use this excellent form of therapy on selected patients, but by the same token it is vital to avoid the excessive costs associated with having all patients on this therapy.

**Bailey WC. All patients should receive directly observed therapy in Tuberculosis: CON. Am Rev Resp Dis. 1988; 138:1075-1076.**