Commentary

MANDATORY PUBLIC HEALTH PROGRAMS: To What Standards Should They Be Held?

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Implicitly and explicitly, human rights have played a significant role in public health debates for decades. At the turn of the century, when health department officials in the United States were debating measures to control sexually transmitted diseases, it was argued that "the progress of preventive medicine has been a history of the conflict between the so-called rights of the individual and the higher rights of the community."[1] In the U.S., the government has historically treated human rights in the area of infectious disease control differently than in any other area of social policy. In comparing the Department of Health to other municipal departments in New York, Stephen Smith, a Department of Health member from its establishment in 1868 until 1875, wrote: "The Department of Health of the City of New York is an anomaly. It has the power to make laws, to execute those laws and to sit in judgment on its own acts. Its acts within this sphere of its jurisdiction can not be interrupted or even reviewed by the courts."[2] W. A. Purrington commented further: "*salus populi suprema lex* . . . there is no branch of the law in which, of late years, individual liberty has been curtailed more than in sanitary legislation."[3]

While the roles of public health departments have

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changed significantly since then, many issues remain regarding how public health policymakers balance the rights and needs of individuals and communities. It is valuable to reexamine public health policies in this context.

Standards Needed for Mandatory Programs

Public health programs in which patients participate voluntarily because of the services they receive should be held to the same standards as other voluntary programs.

Before participation in a particular public health program is mandated, the program should meet at least three additional standards. First, it should be clear that failure to implement the mandatory program would impact on the rights of others. John Stuart Mill summarized this precept when he wrote:

> As soon as any part of a person's conduct affects prejudicially the interests of others, society has jurisdiction over it . . . but there is no room for entertaining any such question when a person's conduct affects the interests of no persons besides himself or needs not affect them unless they like.[4]

This precept is also articulated in Article 29 of the Universal Declaration of Human Rights, which reads in part:

> In the exercise of his rights and freedoms, everyone should be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a democratic society.[5]

Second, even if a mandatory program is shown to be effective at preventing individuals from causing harm to others, it needs to be the least restrictive feasible alternative. The International Covenant on Civil and Political Rights clearly states that the right to freedom of movement should only be restricted when "*necessary* to protect national security, public order, public health or morals or the rights and freedoms of others [emphasis added]."[6] Clearly, a mandatory program must be not only effective but *more* effective than a voluntary program.

Finally, the program must be fairly and equitably administered. There should be no differences in administration of the program based on "race, color, sex, language, religion, political or other opinion, national or social origin, property, birth or other status."[7] Both the Universal Declaration of Human Rights and the International Covenant on Civil and Political Rights clearly prohibit any such discrimination.[8]

The Case of Directly Observed Treatment

These three standards drawn from human rights principles—that failure to implement the mandatory program would impact negatively on the rights of others, that the mandatory program is the least restrictive feasible alternative, and that the mandatory program is implemented without purposeful or inadvertent bias—may be concretely applied to any program that public health officials are considering mandating. This article will apply these three standards to the example of mandatory directly observed treatment (DOT) for tuberculosis (TB).

In response to the epidemic of overall and drug-resistant TB cases, the U.S. Centers for Disease Control and Prevention (CDC) and the World Health Organization (WHO) have recommended that DOT replace self-administered treatment for TB.[9] DOT has been recommended as a way to ensure that patients take every single dose of each medicine prescribed by their physician for the full duration of the prescription.[10]

With DOT, health care or other service providers watch each time patients take their medications over a period of several months to ensure patient compliance. DOT may be provided to patients on a voluntary basis; however, DOT may also be mandated for some or all patients according to local regulations and laws. With mandatory DOT, patients have no choice about entering the DOT program, even if they would readily comply with treatment on their own.

While DOT can be offered in a range of ways when programs are not universal, DOT programs must by definition be mandatory if all treatment for tuberculosis is to be provided under DOT. Because of the numerous visits to health care facilities that are required of the patient for clinic-based DOT and because of the privacy implications of numerous visits by an observer to the patient's workplace or home in field-based DOT, many patients prefer self-administered treatment. While the quality of particular DOT programs undoubtedly affects the number of patients who prefer self-administered treatment over DOT, there will always be some patients who prefer self-administered treatment. To implement universal DOT in the United States, DOT would have to become mandatory.

Methods for Examining the Case of DOT

We surveyed DOT programs in the United States to examine the extent to which they meet the criteria recommended above for public health programs before they are mandated:

> 1. Failure to implement the mandatory program would impact negatively on the rights of others;
> 2. The mandatory program is the least restrictive feasible alternative; and
> 3. The mandatory program is implemented equitably without purposeful or inadvertent bias.

Key DOT personnel at ten sites chosen to represent different geographic regions of the United States, as well as areas with high and low incidence rates of TB, were interviewed. Three of the sites were in the West, one in New England, two in the Middle Atlantic region, one in the South Atlantic region, one in the North Central region, and two in the South Central region. Participants were informed that site names would remain confidential. Confidentiality regarding site names allowed participants to share information that they otherwise might have been hesitant to provide concerning the effectiveness and costs of their programs and the populations they serve. We consulted available site records and documents to confirm findings.

Findings

DOT was *not* shown to be consistently more effective than spending the same resources on a high-quality self-administered treatment program. Within DOT programs, the least restrictive alternative was not consistently used (as demonstrated by variations in frequency, duration, and location of treatment), nor was DOT always applied equitably.

Effectiveness at Preventing Negative Impact on the Rights of Others

Before it is universally mandated, DOT should be demonstrated to be more effective than self-administered treatment at preventing the spread of TB. The majority of programs had incomplete information about their own effectiveness. Estimates of patient completion rates ranged widely from 67% to 100%, and several programs had only limited information on completion rates. Four sites had no information on patients who moved away. One site did not track treatment completion rates as such; rather, it estimated them by dividing the number of patients finishing DOT by the number starting DOT monthly—producing a ratio that would not be an accurate estimate of effectiveness if the number starting DOT were increasing or declining. No program had information on its effectiveness at preventing the spread of TB to others. Such gaps in knowledge raise serious policy concerns. When programs designed to prevent the spread of disease have inadequate information on their own effectiveness, it is impossible to build a compelling case for making them mandatory.

Least Restrictive Feasible Alternative

The least restrictive form of DOT would mandate only the minimum number of visits by observers required for the program to be effective. The duration of the program would be no longer and the frequency of visits no greater than necessary. In addition, patients would have a reasonable choice regarding the location of observation.

Programs did not always use the least restrictive form of DOT, even though to do so would not necessarily have involved lower effectiveness. The frequency of DOT varied markedly among sites. The duration of DOT also varied—from two weeks to six months or more, with overall treatment duration ranging from 6 to 12 months.

Offering all patients a choice of location for DOT would help to minimize the burden placed on patients. However, the determination of whether DOT would be provided in the field—at a patient's home, workplace, or other mutually agreed-upon site—or at the clinic was frequently made by providers. The total number of clinic visits required per patient ranged from 7 to 126. The number of field visits required ranged from 47 to 227.

Often the argument is made that safeguarding rights is not financially feasible for a particular polity. The data on the United States clearly show that more restrictive DOT options were not necessitated by cost. Differences in total costs were primarily explained by the number of visits required of patients. Higher numbers of visits meant higher program costs and greater imposition on patients but bore no relationship to program completion rates as estimated by individual sites (correlation coefficient = 0.06). Similarly, requiring patients to be observed in a clinic was more restrictive but not always less expensive. The costs of providing DOT ranged from \$329 to \$2,648 in the clinic and from \$552 to \$3,271 in the field.[11] The least expensive program providing DOT in the field (at \$552) was less expensive than several programs providing DOT in the clinic and one-fifth as expensive as the most expensive DOT clinic program (at \$2,648).

It is important to note that, in addition to the number and location of visits, there are many other factors that differentiate the restrictiveness of a program for patients. One of the most significant factors from a human rights perspective is the means of enforcement used. Seven sites used mandatory confinement to enforce compliance with DOT. The average duration of confinement at the sites varied markedly, from three weeks to nine months.

Equity

Nine out of the ten sites did not administer DOT to all patients with tuberculosis. Rather, they allowed individual providers and programs to select patients whom they believed might not otherwise complete treatment adequately. Most did not have standardized criteria. We examined the race and ethnicity of individuals selected to receive DOT in these nine sites. Data on social class of DOT participants were requested but not available.

In the nine sites examined here, even after controlling for the higher rates of tuberculosis among African-Americans, we found a statistically significant overall trend: African-Americans were more likely to receive DOT ($p < 0.001$) than expected. No statistically significant difference was found in the rate at which Hispanic patients were placed on DOT.

It is important to note that while DOT was not always equitably applied across the country, some sites did select patients equitably. In contrast, the disparity in some sites was marked. At one site where only 19% of all tuberculosis patients were African-American, 42% of patients placed on DOT were African-American.

Conclusion

Implications for Tuberculosis

It is unacceptable to mandate that patients follow a program that restricts their rights without first documenting that (1) the health of others will be adversely affected without a mandatory program; (2) the program is the least restrictive option; and (3) the program is fairly administered. In many parts of the world, participation in DOT for tuberculosis is voluntary, and DOT programs offer benefits that make them appealing to patients.[12] Voluntary DOT programs should be held to the same ethical standards as voluntary self-administered treatment.

When proposals for *mandatory* DOT for tuberculosis are raised, however, these proposals need to be held to a higher standard. To begin with, these programs need to be shown to be more effective than self-administered treatment. The reported treatment completion rates of some DOT programs were no better than the completion rates for self-administered treatment.[13] Indeed, previous research has shown that changes in patient behavior in response to mandated public health programs may offset potential gains or even produce paradoxical increases in disease spread: some patients may delay seeking treatment to avoid mandatory treatment or detainment.[14] A recent randomized control trial of DOT in Africa found self-administered treatment to be more effective than DOT because of differences in program acceptability to patients.[15]

Secondly, the least restrictive effective alternative should be used. In the case of mandatory DOT, patients should be the ones to choose a site of observation from all feasible sites.

Our findings show that patients frequently were not given a choice of site and were required to have clinic-based care, even though clinic-based care was frequently as expensive as or more expensive than field-based care. No more visits should be mandated than necessary. Our findings, however, revealed a wide variation in the number of mandated visits despite the lack of evidence that those sites with the highest number of mandated visits were significantly more effective.

Finally, it must be clear that DOT is equitably applied. The intention of nine of the programs using DOT was to give DOT to patients less likely to complete self-administered treatment, but the lack of specific criteria for selecting the majority of patients often left the process vulnerable to untested preconceptions and misconceptions. Our findings that African-Americans were more likely to be required to have DOT are particularly troubling. Preventing the development and spread of drug-resistant tuberculosis is often used as justification for DOT, and drug-resistant tuberculosis may result from incomplete self-administered treatment. But we are aware of no evidence that African-Americans are less likely to complete self-administered treatment. The ethnic groups known to have a higher rate of drug-resistant tuberculosis, Asian and East Pacific islanders, received less DOT than either African-Americans or whites in our survey.[16]

The benefits provided by mandatory DOT programs to the health of the entire population need to be shown to outweigh the burden placed on the individuals who are mandated to participate. The programs also need to provide care in the least restrictive and most effective way that is feasible. Finally, they need to be applied equitably. In the United States, directly observed treatment for tuberculosis does not yet meet these standards.

Beyond Tuberculosis: Implications for Other Public Health Programs

The limited information on DOT program effectiveness; the wide range of restrictions placed on patients; the lack of correlation among restrictions, cost, and degree of effectiveness; and the lack of clearly equitable implementation are problems that undoubtedly affect a number of public health programs.

Variability in physician practice has been an important area of health services research.[17] However, less attention has been paid to the variability in public health programs. These findings suggest the importance of examining the variability in human and economic costs and the effectiveness of public health programs in general.

Similarly, the racial differentials we found have implications that extend beyond TB. Increasingly, differences in hospital care provided by race have been studied.[18] Like many of these studies, our findings raise troubling questions about differences among a set of public health programs, although they do not provide final answers. As data were not available on social class, and social class is highly correlated with race in the United States, we could not distinguish between race and class differences. Nonetheless, the findings underscore the need to examine whether racial and/or class bias is the cause of the differentials in who receives DOT and whether there are racial and/or class inequities in the application of other public health programs.

Even among voluntary programs, the level of restrictions placed on patients under treatment, the necessity for those restrictions, and the equity of implementation need to be critically examined. When mandatory programs are considered, it becomes imperative to know whether the least restrictive effective approach is being applied equitably.

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7. International Covenant on Civil and Political Rights (see note 6), art. 2.1. See also Article 26:

> All persons are equal before the law and are entitled without any discrimination to the equal protection of the law. In this respect, the law shall prohibit any discrimination and guarantee to all persons equal and effective protection against discrimination on any ground such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or other status.

8. Article 2 of the Universal Declaration of Human Rights (see note 5) reads in part:

> Everyone is entitled to all the rights and freedoms set forth in this Declaration, without distinction of any kind such as race, color, sex, language, religion, political or other opinion, national or social origin, property, birth, or other status.

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