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Novick and Lipsman re: Bayer et al.

The recent article on directly observed therapy by Bayer et al. suggests that their findings should open discussion about tuberculosis (TB) policy, specifically, universal use of this modality.[1] The authors state that "universal directly observed therapy can result in near-perfect treatment completion rates...." But they further suggest that "pressing toward universal directly observed therapy in settings that have already achieved very high rates of treatment completion may produce only small improvements at very high marginal costs." The authors conclude that TB treatment completion rates of more than 90% can be attained without *universal* application of directly observed therapy.

The rationale for decreasing the utilization of strategies for universal directly observed therapy is not supported by adequate evidence, including the findings of this study. This article did disclose several communities with high TB treatment completion rates achieved without high penetration of directly observed therapy. But these observations are not accompanied by sufficient information on other factors influencing completion rates. Speculation on the role of directly observed therapy in these settings does not negate the abundant and preponderant contemporary experience of success by public health agencies in countering TB by employing strategies with the goal of universal directly observed therapy.

The Council on Linkages Between Academia and Public Health Practice examined the evidence for directly observed therapy as part of an effort to develop public health practice guidelines.[2] As part of the effort to develop public health practice guidelines, a review of all available evidence by a panel of practitioners and a guideline for public health practice was published by Chaulk and Kazandjian.[3] The conclusion of this consensus statement was that

> treatment completion rates for pulmonary tuberculosis are most likely to exceed 90%, as recommended by the Centers for Disease Control and Prevention, when the treatment is based on a patient-centered approach using directly observed therapy with multiple enablers and enhancers. Other less intensive interventions including nonsupervised strategies and modified approaches to directly observed therapy, are unlikely to achieve this recommended treatment completion goal.

The critical element of this strategy is the universal application of directly observed therapy with the goal of reaching completion rates of 90% or more in the affected population.

Opening discussion about TB policy is an admirable goal. Those practitioners, including ourselves, who have reduced the threat of TB in our communities by using directly observed therapy hope that future discussion and resource allocations do not rely on unsupported assertions to remove universal directly observed therapy as the preferable treatment goal and standard of care. More research is definitely needed to determine effective alternative treatment strategies. Any examination of these alternatives must include recognition of the substantial economic benefits of universal directly observed therapy in reducing TB hospitalizations and transmission. □

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Frieden re: Bayer et al.

In their report, Bayer et al. address the issue of evaluating the importance of directly observed therapy as part of an effective tuberculosis (TB) control program.[1] However, there are limitations to the interpretation of nonstandardized data. Estimates of rates of use of directly observed therapy were inconsistently ascertained across geographic areas. Some of the rates used by Bayer et al. were estimated with an algorithm; this algorithm underestimated the proportion of patients given directly observed therapy in New York City by half—this figure rose to 60% of ambulatory patients by 1994,[2] not 33.3%, as estimated by the authors. This error undermines their conclusions, as much of the data they used was driven by the experience of New York City, which accounted for a large proportion of cases in the areas studied and a larger proportion of the improvement seen.

Of the areas studied, 15 achieved less than 85% successful treatment completion in 1990. By 1994, only 6 of these jurisdictions had increased their treatment completion rate to 85% or more, and all of these had greatly expanded their use of directly observed therapy, to more than 50% of cases (except in Long Beach, where the proportion was calculated to be 35%).

Two practical realities also affect the conclusions drawn. First, directly observed therapy often reveals previously unrecognized nonadherence to treatment. As was noted 40 years ago, many patients "keep up the social side" of physician visits, but fail to take their medicines regularly.[3] Programs using directly observed therapy are therefore likely to stop the spread of TB more rapidly than programs that do not. Second, even though it may not be possible to give directly observed therapy to every patient, making directly observed therapy the "default value" and standard of care makes it much easier to implement; patients are simply told that this is the way anti-TB treatment is given. The use of directly observed therapy is a service to patients, greatly increasing their likelihood of cure.

If an area is verified to be achieving at least the global targets of 85% successful treatment and 70% detection of the estimated number of infectious cases, there is no need to change treatment policies.[4] However, a systematic evaluation usually shows that only a full application of good practices for TB diagnosis, treatment, and monitoring can ensure effective control of the disease. WHO terms this strategy "DOTS"—directly observed treatment, short-course. Directly observed therapy is but 1 of the 5 essential components of this strategy, the others being political/administrative commitment, diagnosis primarily by microscopy of patients attending health facilities, regular supply of good quality drugs for short-course chemotherapy, and systematic monitoring and evaluation. It is possible for some areas to treat 85% of patients successfully without directly observed therapy, and it is certainly possible for a poorly managed

directly observed therapy program to achieve less than 85% success. However, in general, given current diagnostic and treatment technology, only application of all 5 of these principles will reliably result in high success rates on a program basis. □

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Bayer and Desvarieux Respond

We began our study of the relationship between directly observed therapy and rates of tuberculosis (TB) treatment completion because we believed that, from a policy perspective, it was critical to replace cant, rhetoric, and anecdotal evidence with nationwide data that could demonstrate the extent to which increasing use of directly observed therapy could benefit public health. From the beginning, we became aware of the limits of the data available. But while far from perfect, the data reported to us and on which we depended for this study were the only data available for that critical period before and after the widespread introduction of directly observed therapy. It is that sense of historic necessity that pushed us to devise a complex formula for estimating directly observed therapy rates, which virtually none of the TB control programs we studied was in a position to provide.

In the end, we believed it better to work with imperfect data than to give up the task of trying to understand the relationship between directly observed therapy and treatment completion. There is no evidence that the data we used, based on reports over a period of 6 years from many cities and counties, are so systematically inadequate that they could not provide us with a unique perspective on the issue with which we were concerned. Indeed, to mitigate the effect of interprogram variability on the relationship between directly observed therapy and treatment completion, we did not stress the comparison of individual jurisdictions but, rather, focused on cohorts with high, medium, and low completion rates. For our results to be wholly invalid, biases would have to have been differential across the 3 cohorts, convergent within cohorts, and consistently so over the years. While we cannot unequivocally exclude this possibilty, we deem it unlikely. We do not claim that the data provide us with precise estimates of directly observed therapy or treatment completion rates. Rather, they permit us to capture trends over time as jurisdictions moved to implement programs of directly observed therapy. Therefore, we believe that these data, with all their limitations, cannot be ignored.

We began our study with the assumption that high rates of directly observed therapy were necessary for high treatment completion rates, and that universal directly observed therapy was the only way to ensure very high rates—over 90%—of treatment completion. We were surprised to find that that was not always the case. San Francisco, Austin, and San Jose stood out in this regard. Perhaps more critical was the case of New York. There, under the leadership of Dr Thomas Frieden, treatment completion rates rose dramatically, from a dismal 60% in 1990 to 89% in 1994; if the special needs of those with multidrug-resistant TB for treatment beyond 12 months were taken into account, the rate was far below the standard of universality. Most pertinent to our discussion, this remarkable feat was attained with a directly observed therapy rate of about 33%. However one wants to read the history of what has happened in New York, it is clear that universal directly observed therapy was not necessary.

Dr. Frieden's letter suggests that our analysis is fatally flawed because of discrepancies between our estimates for directly observed therapy rates and that which he states actually prevailed in New York City. According to Frieden, 60% of New York TB patients were on directly observed therapy in 1994. Looking only at December of that year—the point of reference in the report cited by Frieden—we found the following: our algorithm produced an estimate of a directly observed therapy rate of 37% (1068 of 2920 patients on DOT). The New York City Health Department has now graciously reported to us that 49% of all TB patients in December (1021 of 2071) were on directly observed therapy (New York City Department of Health, Bureau of Tuberculosis Control, unpublished data, 1998). Only when the number of prevalent cases is reduced by eligibility criteia—those the Health Department considered eligible for directly observed therapy—does the figure rise to the approximately 60% cited by Frieden. Our algorithm was remarkably accurate in estimating the *number* of patients on directly observed therapy in December. It was marginally less successful in estimating the number of TB patients in treatment, using our original assumptions; thus the discrepancy in directly observed therapy *rates*. But whether the figure is 37%, 49%, or 60%, it is clear that universal directly observed therapy was not necessary to achieve the remarkable results reported by New York City.

To repeat the public health mantra that universal directly observed therapy is necessary will not advance the discussion or our understanding. In fact, to do so would be to take a critically useful therapeutic tool, directly observed therapy, and turn it into an ideological blinder: a dogma on tuberculosis.

The Centers for Disease Control and Prevention now has a data set that more accurately evaluates the extent to which patients complete therapy. Collected since 1994, these data naturally do not cover the transitional period, which witnessed the widespread introduction of directly observed therapy. They cannot, therefore, begin to address the question with which we were concerned at a critical historic juncture. These data can, however, permit us to trace the relationship between differing rates of directly observed therapy and treatment completion in different jurisdictions over the past 5 years. The time is ripe for a new study that will extend the work we began. Only such research will permit us to quantify the contribution of directly observed therapy to treatment completion and declining rates of multidrug-resistant TB. Analysis of these data will permit us to answer definitively the question of whether, in fact, universal directly observed therapy is necessary for good public health. The time for rhetorical salvos is over. What we need at htis juncture is research, hard data, and careful analysis. □

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