should be acknowledged that directly observed therapy is integrally linked to a large number of interventions that contribute to successful patient outcomes.[7] □

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Jereb et al. re: Bayer et al.

Directly observed therapy is a powerful tool for tuberculosis (TB) control. An article by Bayer et al.[1] examines the extent to which different rates of directly observed therapy affect the therapy completion rate. We concur with the discussion of the study's limitations, especially the problems with estimating directly observed therapy rates and the ecological nature of the analysis. Additionally, we emphasize serious shortcomings in the data for directly observed therapy and completion of therapy during the study period of 1989 through 1994.

The therapy completion data, in various formats, have been reported by state and local health departments to the Division of Tuberculosis Elimination of the Centers for Disease Control and Prevention since 1973.[2] These data are one part of the program management reports, a set of aggregate tabular indicators collected locally and compiled nationally. The reports were designed to assist health departments in planning their TB control programs, and the reporting methods have not been evaluated systematically for comparability between programs. We have observed interprogram variability in determining therapy completion rates, as well as intraprogram variability from year to year.

For the 1993 surveillance year, the Division of Tuberculosis Elimination and the 68 national reporting areas integrated the reporting for completion of therapy into the national surveillance system for TB morbidity. The system now has standard definitions for the reasons for stopping treatment in each case under surveillance. The therapy completion rates for the 1994 surveillance year onward have been derived from these data. For the majority of the reporting areas our preliminary analyses have shown longitudinal discontinuities of the completion rates across the transition from the old program management reports (through 1993) to the newly standardized methods (1994 onward).

The older, aggregate methods for deriving the therapy completion rates did not address drug-resistant cases separately, although the current ones do. With the previous methods, multidrug-resistant TB probably decreased the rates of therapy completion at 1 year, because treatment regimens longer than 1 year are necessary for TB that is resistant to (at least) rifampin. Several multidrug-resistant TB outbreaks were prominent during the period studied by Bayer et al., and this confounds the comparison of therapy completion rates in different cities. Directly observed therapy is advocated for TB that is resistant to any first-line medications, and the multidrug-resistant TB outbreaks gave urgency to this message.[3] During the study period, when programs were focusing their directly observed therapy on drug-resistant TB, their reported rates of completion at 1 year probably were depressed by the prolonged treatment regimens, even while directly observed therapy improved actual completion rates.

The directly observed therapy strategy itself influences the surveillance for completion of therapy. Without separate validations of how medications are taken, TB control programs that rely on self-supervised therapy can overestimate rates of completion, because the data depend partly on patients' self-reports. Directly observed therapy provides a rigorous confirmation of completed treatment regimens because each dose is documented, and directly observed therapy is definitive for detecting incomplete therapy.

Any directly observed therapy data raise the question, When is directly observed therapy really directly observed therapy? As defined, directly observed therapy is achieved when a health care worker or another trained person watches the patient swallow each dose of the treatment regimen. During our visits to health departments, we have seen this definition reinterpreted, and actual practices vary. At one extreme, a practice labeled as directly observed therapy has amounted to delivering weekly supplies of medication throughout a treatment regimen, without seeing the patient. The extent of the variability is unknown, and we are evaluating proposals for on-site surveys of directly observed therapy practices.

The social and programmatic determinants predicting low therapy completion rates probably vary from site to site and need to be determined more precisely. Nardell and Farmer[4] point out that directly observed therapy is a necessary but insufficient intervention, because it is only one link in a comprehensive strategy for providing TB control services. We agree. However, the many problems interfering with completion of therapy are generally unstable over time, and they are integral to the interpretation of the longitudinal analyses by Bayer et al.

Because of the shortcomings inherent to the data, the completion-of-therapy analyses reported by Bayer et al. should be interpreted cautiously. Data from more uniform surveillance are needed to permit an accurate assessment of the impact of directly observed therapy on the completion of TB therapy. □

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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