as effective as or more effective than investing in mandatory programs."[9]

We believe that the evidence, from modeling, clinical trials, and the examination of successful programs, argues for the following principles:

• Programs that offer patients more services and require fewer interruptions of daily life are more attractive to patients than programs that offer fewer services and and are more disruptive of daily life.

• Where services provided make voluntary directly observed therapy attractive to patients, patients will choose it. The combination of the acceptability of the program and the observation method will make these programs highly effective.

• Where lack of attention to patients' concerns results in directly observed therapy programs that are unacceptable to patients, directly observed therapy is likely to be less effective than self-administered therapy for patients with average adherence.

• In most cases, directly observed therapy will be more effective than self-administered therapy for patients who have not adhered to previous therapy. □

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References

1. Zwarenstein M, Schoeman J, Vundule C, Lombard C, Tatley M. Randomised controlled trial of self-supervised and directly observed treatment of tuberculosis. *The Lancet.* 1998;352:1340–1343.
2. Devi S. A controlled comparison of self-administered versus supervised treatment in Singapore. *Bull Int Union Tuberc.* 1972;67:15–21.
3. Centers for Disease Control and Prevention. *Reported Tuberculosis in the United States, 1995.* Atlanta, Ga: Centers for Disease Control and Prevention; 1996:5, 55.
4. Centers for Disease Control and Prevention. *Reported Tuberculosis in the United States, 1996.* Atlanta, Ga: Centers for Disease Control and Prevention; 1997:5, 55.
5. World Health Organization. WHO report on the tuberculosis epidemic 1997. *WHO/TB.* 1997;224:47–51.
6. Gerteis M, Edgman-Levitan S, Daley J, Delbanco T. Through the patient's eyes: understanding and promoting patient-centered care. San Francisco, Calif: Jossey-Bass Publishers; 1993.
7. El-Sadr W, Medard F, Berthaud V. Directly observed therapy for tuberculosis: the Harlem Hospital experience, 1993. *Am J Public Health.* 1996;86:1146–1149.
8. Salomon N, Perlman D, Rubenstein A, Mandelman D, McKinley F, Yancovitz S. Implementation of universal directly observed therapy at a New York City hospital and evaluation of an out-patient directly observed therapy program. *Int J Tuberc Lung Dis.* 1997;1:397–404.
9. Heymann SJ, Sell R, Brewer TF. The influence of program acceptability on the effectiveness of public health policy: a study of directly observed therapy for tuberculosis. *Am J Public Health.* 1998;88:442–445.

Directly Observed Therapy and Tuberculosis Treatment Completion

The Journal received an unusual number of letters commenting on an article that we published in the July 1998 issue—"Directly Observed Therapy and Treatment Completion for Tuberculosis in the United States: Is Universal Supervised Therapy Necessary?" by Bayer et al. After the following 4 letters we present a response from 2 of the article's authors.

Bloch re: Bayer et al.

As Bayer et al. mention, it is important to assess the contribution of directly observed therapy to improved outcomes for tuberculosis patients, including completion of therapy.[1] As the authors note in their discussion, the Centers for Disease Control and Prevention (CDC), in a recent analysis, questioned the validity of the 12-month completion data that the CDC provided to Bayer et al. for their analysis.[2] For 3 decades, the CDC collected aggregate 1-page reports on 12-month completion of therapy, submitted semiannually by participating state and local tuberculosis control programs. For most of these years, participation was incomplete. Indeed, 1993 was the only year in which all 50 states submitted such reports. In 1993, the CDC began collecting information on completion of therapy for individual patients as part of expanded surveillance; new variables related to completion of therapy were dates therapy started and stopped and reason therapy stopped.[3] Thus, 1993 afforded a unique opportunity to compare the older aggregate method with the newer surveillance method.

According to the aggregate method, the rate of completion within 12 months for 19 143 evaluable cases was 82.5%. According to the surveillance method, after more than 3 years of follow-up (through February 14, 1997), 99.5% of 23 643 reported patients had a disposition with a reason therapy stopped, and 97.9% had complete dates for both date therapy started and stopped. Excluding patients who died or moved, 19 533 patients treated with 2 or more drugs remained for calculating completion of therapy. For those patients with complete dates, 66.6% completed therapy within 365 days. After more than 3 years of follow-up, 91.9% of patients completed therapy.

By the aggregate method, 12 states had 12-month completion rates of 90% or higher, 21 states had rates of 80% to 89%, 9 states had rates of 70% to 79%, and 8 states had rates below 70%. In contrast, by the surveillance method, 1 state with 10 cases had a 365-day completion rate of 90%, 11 states had rates of 80% to 89%, 15 states had rates of 70% to 79%, and 23 states had rates below 70%. After more than 3 years of follow-up, 42 states had rates of 90% or higher, 5 states had rates of 80% to 89%, 1 state had a rate of 70% to 79%, and 2 states had rates below 70%. By the surveillance method, none of the 25 areas in the study by Bayer et al. had 365-day completion rates of 90% to 100%, whereas, after more than 3 years of follow-up, 18 areas had rates of 90% to 100%.

In conclusion, compared with the surveillance method, the aggregate method overestimated completion rates at 1 year. It also could not calculate the proportion of patients who ultimately completed therapy. In addition, there was no standardization of patient population, time period, definitions of completion, or procedures for calculating completion of therapy. For these reasons, aggregate reporting has been discontinued. In contrast, the surveillance method gives a much more accurate picture of national performance on the highest priority of tuberculosis prevention and control.

Since the information on directly observed therapy in Bayer and colleagues' analysis is also aggregate in nature, there are similar concerns about its validity. In addition to the role of directly observed therapy on completion of therapy, it is important to consider other potential benefits, such as interruption of transmission by rapidly rendering patients noninfectious, preventing the acquisition of drug resistance, and reducing morbidity.[4–7] Finally, it

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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References

1. Bayer R, Stayton C, Desvarieux M, Healton C, Landesman S, Tsai W-Y. Directly observed therapy and treatment completion for tuberculosis in the United States: is universal supervised therapy necessary? *Am J Public Health.* 1998;88:1052–1058.
2. Bloch AB, Simone PM, Kelly GD, Danebury KG, McCray E, Castro KG. Comparison of two methods for calculating completion of tuberculosis (TB) therapy in the U.S., 1993. *Am J Respir Crit Care Med.* 1997;155:A256.
3. Bloch AB, Onorato IM, Ihle WW, Hadler JL, Hayden CH, Snider DE Jr. Expanded tuberculosis surveillance in the United States: the need for epidemic intelligence [erratum appears in *Public Health Rep.* 1996;111:98]. *Public Health Rep.* 1996;111:26–31.
4. Weis SE, Slocum PC, Blais FX, et al. The effect of directly observed therapy on the rates of drug resistance and relapse in tuberculosis. *N Engl J Med.* 1994;330:1179–1184.
5. Chaulk CP, Moore-Rice K, Rizzo R, Chaisson RE. Eleven years of community-based directly observed therapy for tuberculosis. *JAMA.* 1995;274:945–951.
6. Bloch AB, Simone PM, McCray E, Castro KG. Preventing multidrug-resistant tuberculosis. *JAMA.* 1996;275:487–489.
7. Bloch AB, Sumartojo E, Castro KG. Directly observed therapy for tuberculosis in New York City. *JAMA.* 1994;272:435–436.

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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References

1. Bayer R, Stayton C, Desvarieux M, Healton C, Landesman S, Tsai W-Y. Directly observed therapy and treatment completion for tuberculosis in the United States: is universal supervised therapy necessary? *Am J Public Health.* 1998;88:1052–1058.
2. *Tuberculosis Programs 1973.* Atlanta, Ga: Centers for Disease Control; 1974. DHEW publication CDC 75-8189.