A New Method for the Evaluation of Tuberculosis Control Programs

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HEALTH ADMINISTRATORS agree that health program planning should be based on sound evaluation data which reveal the level or amount of success in achieving predetermined objectives (*1*). Furthermore, these objectives must be specified, measurable end results, not just a listing of activities to be performed.

With increased consumer participation in health programs and continuous demand for scarce dollars, fiscal accountability and responsibility are essential. This responsibility can be met by a program based on a system of measurable objectives, evaluation, and modification. However, evaluation depends on the stage of fundamental knowledge. For example, when tuberculosis was believed to be of genetic origin and influenced by climate, a control program would have been evaluated on the basis of counseling persons with a family history of tuberculosis against intermarriage and on the migration of infected persons to a more favorable climate.

Several stages of knowledge have influenced the usefulness of the evaluation process for tuberculosis control prorams—the discovery of the tubercle bacillus and the advent of specific chemotherapy are the most dramatic.

The Tuberculosis Branch of the Center for Disease Control has routinely included evaluation as an essential part of an effective tuberculosis control program. For many years the traditional morbidity and mortality reports were considered sufficient. After the Surgeon General's Task Force Report in 1963, improvement of outpatient services was emphasized, and objectives were written in terms of performance standards for certain activities known to be effective in tuberculosis control, for example, providing drugs and regular medical evaluation for patients with diagnosed tuberculosis. Evaluation was accomplished by periodic analysis of information from tuberculosis case registers.

Reports on the disposition of persons with suspected tuberculosis and on the examination of contacts of persons with newly diagnosed active disease were also measures of performance in these productive casefinding programs. These reports also identified the number of persons eligible for preventive treatment and were an indication of the performance level achieved in placing patients on preventive therapy.

Through these performance standards, continual improvement in the delivery of outpatient services has been observed (*2*). However, a need was recognized for a more specific way to measure progress against the disease.

As new tools of assessment were developed, three steps in the evaluation process were identified: first, to state measurable objectives in terms of maintaining or improving health; second, to measure the degree of accomplishment of these objectives; and last, to translate this information into modifications of program activities when necessary to accomplish these objectives (*3*).

The American Thoracic Society Committee on Quality Care for Tuberculosis has prepared a

statement of the "Standards for Tuberculosis Treatment in the 1970's," which includes specific objectives or goals for this decade and recommends services that should be provided to tuberculosis patients and their families. These recommendations and short-range objectives are based on the following overall objectives of tuberculosis control:

1. Infectious persons (able to infect others with tubercle bacilli) must become noninfectious.
2. Noninfectious persons (who are infected with tubercle bacilli) must remain noninfectious.
3. Persons not infected (with tubercle bacilli) must remain noninfected.

These objectives are essential to reach the ultimate goal of tuberculosis programs—to eliminate tuberculosis as a cause of human suffering.

Indices of Progress

To measure progress against tuberculosis, the following three indices were developed by an ad hoc advisory committee and the staff of the Tuberculosis Branch, Center for Disease Control: index 1, bacteriological conversion of sputum; index 2, continuity of drug therapy; and index 3, completion of preventive therapy.

Index 1. Bacteriological conversion of sputum is used to measure whether infectious persons are still infectious. This index is based on results of clinical trials which have shown that with effective drug regimens at least 75 percent of sputum-positive persons will convert to sputum-negative within 3 months and 95 percent will convert by the end of 6 months (*4,5*).

Index 1 is used to measure objective 1—infectious persons must become noninfectious—by answering the question: "Of the patients with positive sputum, how many converted to negative within 3 and 6 months?"

Index 2. Continuity of drug therapy indirectly measures objective 2—noninfectious persons must remain noninfectious. This index is based on research findings that at least 95 percent of patients with newly developed active disease will become noninfectious, recover, and remain well if they complete an effective drug regimen (*6*).

To insure that patients remain noninfectious, it is essential to know if they continue chemotherapy for the prescribed time. Concurrent evaluation of the effectiveness of the program therefore requires an answer to the following question at the end of a 12-month period, as well as when therapy has been completed: "How many patients whose sputum has converted to negative have continued to take their drugs?"

The usefulness of these indices is illustrated by some of the data reported to the Tuberculosis Branch. The following table shows the results obtained in a program (area W) with good performance, according to the traditional reports of bacteriological examination, medical evaluation or chest X-ray, and a current prescription for chemotherapeutic drugs during the past 6 months for all ambulatory patients with active disease.

	Percent of patients receiving—		
Area W	*Bacteriological examination*	*Medical evaluation or X-ray*	*Current drugs*
Register reports:			
June 1970	100	97	97
December 1970 .	100	85	85
June 1971	92	100	100

However, for the same area W program, the indices of conversion of sputum and of continuity of therapy suggest that either the drugs are not effective or that not all the patients are taking the drugs. Only 47 percent of the patients had conversion of sputum within 3 months, 84 percent within 6 months, and only 64 percent were still taking drugs at the end of the first year.

The conversion of sputum index is an early indication that patients are receiving effective treatment, becoming noninfectious, and recovering. The index of continuity of therapy indicates the percentage of patients who can be expected to remain well and noninfectious, and it also suggests where program changes are needed. An index of completion of therapy gives a final assurance that those patients can be expected to remain well. This index separates patients into two groups—those who can be discharged from followup when there is reasonable assurance that they have satisfactorily completed an effective course of therapy and those with inadequate treatment who require the highest priority for followup because they are at high risk of reactivating their disease.

The following table for area P illustrates good performance on program reports and fairly good performance in continuity of therapy, but the conversion of sputum index suggests ineffective therapy; either inadequate drugs are being prescribed or the drugs are not being taken. This comparison also illustrates the need to be sure that the index of continuity of therapy reflects that drugs are actually being taken.

Area P	*Percent of patients*
Register reports:	
Bacteriological examination	79
Medical evaluation or X-ray	94
Current drugs	94
Continuity of therapy, 12 months	84
Conversion of sputum:	
3 months	44
6 months	70

The register reports for area H, that follow, indicate that for the last five reporting periods the percentage of patients with active disease who were at home and receiving therapy was within the standards set and, in fact, remained approximately 13 percent higher than the national average during those periods.

Area H	*Percent of patients*
Register reports, current drugs:	
June 1969	89
December 1969	88
June 1970	87
December 1970	94
June 1971	93
Conversion of sputum:	
3 months	72
6 months	100
Continuity of therapy:	
12 months	71
24 months	4

This area H program has good performance according to the register reports. In this area also, the index of conversion of sputum verifies the impression that patients with active disease are being actively treated, since all sputum-positive patients converted to negative within 6 months. Apparently all of these patients were either noninfectious or became noninfectious.

However, the index of continuity of therapy gives the first indication of a problem in area H. Only 71 percent of the patients placed on drugs continued to take their drugs through the first 12 months. They started off well, as indicated by the data for conversion of sputum, but somehow followthrough or recordkeeping was inadequate. Although the index does not show the reason, it does raise a question which should alert the program administrator toward a search for the cause.

Further examination reveals that after 2 years only 4 percent of the patients in area H completed therapy. However, 30 percent of the patients were still on drugs, 30 percent had actually discontinued their treatment, and the remainder had died, moved, or were lost to followup.

This review reveals that area H is accomplishing the first objective—for infectious persons to become noninfectious. There is little indication, however, that the second objective is being accomplished—that noninfectious persons will remain noninfectious. If these patients reactivate, they will undoubtedly infect others; thus the third objective, to keep the noninfected from becoming infected, also is not being accomplished.

The same procedure for evaluation can be used with other persons known to be infected who have never been treated with antituberculosis drugs. Experience has shown that by the time they have been found with sputum-positive active disease, they will have infected others. Most of these persons can be kept noninfectious if they take isoniazid as preventive therapy for 1 year.

Index 3. Completion of preventive therapy is another indirect measure of objective 2—noninfectious persons must remain noninfectious. This is based on the knowledge that preventive treatment can reduce the probability of disease up to 90 percent (*7*). Indices for continuity of therapy and completion of preventive therapy can be assumed to measure patients' health status if there are specific followup procedures to determine that patients are taking their medications.

To evaluate the effectiveness of the preventive treatment program, the following questions are asked: "How many persons are started on preventive isoniazid?" And, "Of these, how many have completed the recommended course of preventive treatment?"

The amount of success in accomplishing the first two objectives will be reflected in accomplishment of the third objective—for noninfected persons to remain noninfected (*8*). It would not be practical to measure achievement of this objective directly in most situations, since such evaluation would require tuberculin testing of literally thousands of people to identify the few reactors among them.

Data from another local control program illustrate the use of this third index. This program, in area S, has excellent performance according to register reports; consistently more than 95 percent of the patients with active tuberculosis are on current drug therapy, as follows;

Area S	*Percent of patients*
Register reports, current drugs:	
June 1970	97
December 1970	96
June 1971	97
Conversion of sputum:	
3 months	54
6 months	97
Continuity of therapy:	
12 months	98

Area S also has excellent performance in providing continuity of care, as illustrated by the indices of conversion of sputum and continuity of

drug therapy. This program seems to be accomplishing the first two objectives (even though not enough time has elapsed to measure completion of therapy) and accomplishment of the third objective can be expected. In addition, annual case reports from this community have shown a decreasing trend, although the tuberculosis problem continues to be large.

A defect in the area S program is revealed, however, by the third new measure, as shown in the following table. Only 62 percent of the patients have completed preventive therapy. When this group is broken down into various risk groups, good performance is seen in two high-risk categories—91 percent for recent converters and 88 percent for patients with inactive tuberculosis. But, only 41 percent of the contacts of patients with active disease have completed preventive treatment.

Area S	*Initial number*	*Completed therapy*	
		Number	*Percent*
Total patients	653	405	62
Contacts	359	146	41
Converters	221	200	91
Patients with inactive disease	60	53	88
Other reactors	13	6	46

Examination of other reports from area S revealed that only 50 percent of the household contacts were placed on preventive therapy. Household contacts should receive top priority because they are at high risk of being the future new patients. The health department in area S has demonstrated good followup performance for patients with active tuberculosis and for some persons receiving preventive treatment; therefore, with some changes in activities, the staff should be able to do well with this high-priority service, thereby rapidly reducing the number of cases of newly developed active disease and accomplishing the three objectives.

Program Effectiveness

For the first time in tuberculosis control, program effectiveness can be reviewed while changes are being made to increase effectiveness, as illustrated in the following table for area A. When the agency in area A first used the new evaluation indices, it selected a group of patients whose tuberculosis was diagnosed 3 months previously (period 1). Because of the poor performance revealed by the indices, some program changes were made. These changes were reflected almost immediately in the results shown for the next group of patients (period 2).

Area A	*Conversion of sputum*	
	Number	*Percent*
Period 1, 24 patients positive:		
3 months	9	38
6 months	15	63
Period 2, 28 patients positive:		
3 months	16	57
6 months	26	93

As this illustration demonstrates, the percentage (or index) itself is less important than the translation of the information gained into the program changes that result in improvement of health of both the individual and the community. The ultimate measure of success is an accelerated reduction of the incidence of new cases of tuberculosis.

Conclusion

The three new indices (conversion of sputum, continuity of therapy, and completion of preventive therapy) have been introduced in 39 tuberculosis control programs and have been found to be feasible and useful. To collect the data, it is necessary to provide close supervision of patients and to systematically maintain records and communication between hospitals, public health agencies, and private physicians. When these indices are used, they appear to stimulate professional health workers to plan and implement changes that will improve the outcome of their services.

REFERENCES

(1) Schulberg, H. C., Sheldon, A., and Baker, F.: Program evaluation in the health fields. Behavioral Publications, Inc., New York, 1969.

(2) Public Health Service: Tuberculosis programs, 1970. Tuberculosis Branch, State and Community Services Division, Center for Disease Control, Atlanta, Ga., November 1971.

(3) Public Health Service: Tuberculosis program evaluation. Tuberculosis Branch, State and Community Services Division, Center for Disease Control, Atlanta, Ga., October 1971.

(4) Doster, B., et al.: Ethambutol in the initial treatment of pulmonary tuberculosis. Am Rev Resp Dis 107: 177–190, February 1973.

(5) Newman, R., et al.: Rifampin in initial treatment of pulmonary tuberculosis. Am Rev Resp Dis 103: 461–476, April 1971.

(6) Grzybowski, S., et al.: Reactivations in inactive pulmonary tuberculosis. Am Rev Resp Dis 93: 352–361, March 1966.

(7) Comstock, G. W., and Ferebee, S. H.: Preventive treatment of untreated nonactive tuberculosis in an Eskimo population. Arch Environ Health 25: 333–337, November 1972.

(8) Kaplan, J., Fraser, I., and Comstock, G. W.: Tuberculosis in Alaska. The continued decline of the tuberculosis epidemic. Am Rev Resp Dis 105: 920–926, June 1972.