The Center for Disease Control (CDC) has the primary responsibility for the Federal role in the venereal disease prevention and control program and has expended an average of about $32 million annually since 1972. With these funds, CDC conducts research, develops program guidelines and performance standards, provides technical assistance to State and local governments, and supports educational activities. The CDC uses reported syphilis and gonorrhea cases as its primary indicator of actual disease trends and program effect. Monitoring reported cases and cases identified through casefinding provides CDC with insufficient information to demonstrate the effectiveness of current control strategies; the relative benefits of each control program component; and the optimal level of Federal, State, and local support for venereal disease control. Reported case trends are susceptible to influence by factors other than actual disease trends, such as changes in private physician reporting habits, the extent of public casefinding, public clinic availability, and disease diagnostic practices.

Regardless of the accuracy of reported case trends as indicators of actual disease trends, actual disease incidence is the product of various interacting factors; consequently, even declines in actual disease trends cannot be solely attributed to CDC-supported activities. CDC should conduct a study to develop a methodology for improving the reliability of reported data on identified and treated cases and to determine the numbers of people who comprise the venereal disease problem. CDC should use the resultant data to assess the impact of its efforts in controlling the incidence of venereal disease. (RRS)
B-164031(5)

The Honorable
The Secretary of Health,
Education, and Welfare

Dear Mr. Secretary:

We have recently completed a review of the Department's venereal disease prevention and control program funded under section 318 of the Public Health Service Act (42 U.S.C. 247c). We found program officials convinced that venereal disease control efforts are effective at reducing the incidence of disease. However, available data neither supports nor refutes this conviction. Program policies and procedures are influenced by certain assumptions, which although logical, are based on opinion rather than facts. Alternative assumptions, equally logical, might alter program direction.

The absence of or inadequacies in program evaluation data limit measurement of program effectiveness. Better information is needed for making program management decisions, and to assure efficient and effective use of Federal funds.

SCOPE OF REVIEW

Our review included an examination of (1) the laws which authorize the program and affect its scope, (2) the information used to measure the health problems caused by venereal diseases and the effects of the control program, and (3) the rationale and methods for carrying out the venereal disease control grant program. We interviewed program and project officials and reviewed published literature, program management records, individual project files, and reports of special studies. Our work was done primarily at the Center for Disease Control (CDC), with additional work at the Department's Atlanta regional office, the project office for the State of Georgia, and venereal disease clinics in Montgomery County, Maryland; Washington, D.C.; and Atlanta, Georgia.

BACKGROUND

As you know, the Federal Government has cooperated with State and local governments for many years to control venereal
Since 1957, CDC has had primary responsibility for the Federal role, and has expended an average of about $32 million annually since 1972. With these funds CDC conducts research, develops program guidelines and performance standards, provides technical assistance to State and local governments, and supports educational activities. Most of CDC's funds, however, are expended as grants to supplement State and local activities as part of a national venereal disease control program. The national program focuses on two venereal diseases, syphilis and gonorrhea, because (1) serious complications can result if these diseases are untreated, (2) reported incidence is high—over 20,000 syphilis cases and nearly 1 million gonorrhea cases in 1977, and (3) CDC officials believe the control methods for these diseases are effective.

Through the grant program, CDC provides direct manpower and financial assistance primarily to supplement State and local government efforts to identify, locate, and bring to treatment persons infected or potentially infected with syphilis or gonorrhea. The intent of such direct intervention methods, called casefinding, is to reduce disease incidence by improving the timeliness with which individuals are brought to treatment, thereby reducing disease spread. CDC officials believe this approach significantly reduces total disease incidence.

UNCERTAIN PROGRAM EFFECT

CDC uses reported syphilis and gonorrhea cases as its primary indicator of actual disease trends and program effect. In recent years trends in reported cases show decreases in the rate of case growth, and reported cases declined in fiscal year 1977 in comparison to fiscal year 1976. CDC officials believe the reported case trends represent similar trends in actual disease levels. Consequently, they cite the decreases in reported case trends as evidence of a successful control program. However, CDC has insufficient data to conclude that reported case declines reflect actual disease declines or to assess the extent that CDC-supported control activities contribute to such declines.

Other factors influence reported cases

Reported case trends are susceptible to influence by factors other than actual disease trends, such as changes in private physician reporting habits, the extent of public casefinding, public clinic availability, and disease diagnostic practices. For example:
--CDC estimates indicate that private medical providers treat most venereal disease cases, but do not report to public health authorities most of the cases treated. Therefore, a small change in the proportion of cases private medical providers report could make a significant change in the total reported cases without similarly affecting the number of actual cases.

--In contrast to private cases, CDC officials presume that public health providers report all cases treated. Therefore, changes in conditions which influence a disease victim's choice of public or private medical care can also influence reported cases without similarly affecting actual cases. For example, more extensive public health case-finding activities or increased public clinic availability may cause some victims to be treated by public medical providers who would otherwise be treated by private medical providers, but not reported to public health authorities. The reverse could also occur.

--Changes in diagnostic practices could also cause reported case trends to differ from actual disease trends. Improved diagnoses may cause a change in the classification of cases for reporting purposes. For example, in past years females treated for gonorrhea could not be confirmed as actual cases because most females have no symptoms and because no feasible laboratory test existed. These treatments may or may not have been classified and reported as diagnosed gonorrhea cases. A feasible laboratory test has been developed, and CDC encourages public and private medical providers to use it. Increased use could cause reported cases to increase or decrease, depending on how the treatments were previously classified, without a similar change in actual cases.

CDC has not assessed the relative influence of these factors on case reporting and, therefore, has no assurance that reported case trends reflect actual trends.

Other factors influence actual disease trends

Regardless of the accuracy of reported case trends as indicators of actual disease trends, actual disease incidence is the product of various interacting factors. Consequently, even declines in actual disease trends cannot be solely
attributed to CDC-supported activities. CDC officials recognize that in addition to CDC-supported activities, the availability of health care supported by State and local governments or private medical providers, and social factors such as changing sexual behavior and birth control practices also contribute to the amount of disease in the population. However, they have not assessed the relative effect of all such influences before attributing disease declines to successful control activities.

Casefinding benefits uncertain

In addition to using reported cases as an indicator of total program effect, CDC evaluates the benefits of its primary program component, casefinding, by monitoring the number of cases casefinding brings to treatment. CDC officials believe that identifying such cases demonstrates program success because victims are treated who might otherwise have developed complications or spread the disease to others. However, the relative value of casefinding has not been established.

CDC reported that casefinding activities led to the identification of 378,000 gonorrhea cases, or about 24 percent of the estimated number of cases occurring in fiscal year 1977. CDC also reported that 26,410 infectious syphilis cases, or about 35 percent of the estimated total cases, were identified, treated or reported through casefinding. However, CDC reported only about 10,900 of the 26,410 cases were identified, treated, and reported specifically as a result of CDC-supported casefinding. The remainder were identified by private physicians but are included in the statistics because some casefinding effort was expended to verify or insure that the cases were treated and to get the cases reported.

CDC officials believe casefinding has greater effect than is reflected by these statistics based on the assumptions that:

--In addition to diagnosed cases, exposed and potentially incubating cases are identified and treated through casefinding. Although not reflected in diagnosed case statistics, proportionately more spread is prevented because the disease chain is more extensively interrupted through preventive treatment.
---Casefinding brings cases to treatment more quickly than if they volunteered for treatment or were treated through normal health care channels. Consequently, proportionately more disease spread is prevented by casefinding.

---Some cases that are initially identified through the normal health care channels are treated because of casefinding followup.

---Some volunteer cases and even some unreported cases are treated because victims interviewed through the casefinding process are motivated to get their contacts to treatment, even though the contacts are not identified to public health officials.

Although further spread may be prevented when cases are found and treated, the relative value of casefinding is indeterminable from available data. CDC does not know the extent that cases identified would have volunteered for treatment or been identified through normal health care channels before disease complications or additional spread occurred.

Perhaps more importantly, CDC does not know the extent that the benefits of casefinding are short-lived because of the short time frame in which some treated victims get reinfected by untreated sex partners. Statistical data is collected on a case basis which does not identify the number of individuals affected. Although not measured, CDC officials believe that syphilis reinfecions are infrequent, but that many gonorrhea victims do get rapidly reinfected. To reduce the gonorrhea reinfection rate, CDC has begun to emphasize identification of repeaters and their infection sources. Requesting disease victims to return 4 to 6 weeks after treatment for a retest and increasing efforts to identify sex partners of those found reinfected are part of this emphasis.

CONCLUSIONS AND RECOMMENDATIONS

CDC uses reported syphilis and gonorrhea cases as its primary indicator of actual trends and program effect. Consequently, it cites decreases in reported case trends as evidence of a successful program; increases, as a need for expansion of effort.
Monitoring reported cases and cases identified through casefinding provides CDC insufficient information to demonstrate (1) the effectiveness of current control strategies, (2) the relative benefits of each control program component, and (3) the optimal level of Federal, State, and local support for venereal disease control.

Reporting is incomplete because many private providers do not report all cases treated, and reported trends are susceptible to various factors which individually and collectively influence reported levels. CDC has not assessed the relative effects of these factors before attributing disease declines to successful control activities. Complete and consistent reporting is essential if reported cases continue to be the primary measure of disease trends and program effect.

We recommend that CDC conduct a study to develop a methodology for improving the reliability of reported data on identified and treated cases. Such a study should address

--the extent to which both private, and public providers report the number of venereal disease cases treated and possible alternatives, including incentives, for improving the reporting practices of both groups of providers; and

--the development of strategies to improve diagnostic practices so that there is consistency among organizations in the classification of cases for reporting purposes.

We also recommend that CDC conduct a study to determine the numbers of people who comprise the VD problem. As part of this effort, CDC should address the extent to which changes in the availability of public and private health care and social behavior affect the number of individuals over a period of time.

We further recommend that CDC use that resultant data from the above recommended studies to assess the impact of its efforts in controlling the incidence of venereal disease.
We appreciate the cooperation given our representatives during this review, and we welcome the opportunity to discuss the above matters with you or your staff.

This report contains recommendations to you. As you know, section 235 of the Legislative Reorganization Act of 1970 requires the head of a Federal agency to submit a written statement on actions taken on our recommendations to the House Committee on Government Operations and the Senate Committee on Governmental Affairs not later than 60 days after the date of the report and to the House and Senate Committees on Appropriations with the agency's first request for appropriations made more than 60 days after the date of the report. The 60-day period shall begin on the date of this letter.

We are also sending copies of this report to the Chairmen of the House and Senate Committees on Appropriations, Senate Committee on Governmental Affairs, House Committee on Government Operations, House Committee on Interstate and Foreign Commerce, and; the Senate Committee on Human Resources. A copy is also being sent to the Director, Office of Management and Budget.

Sincerely yours,

[Signature]

Gregory J. Ahart
Director