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EXECUTIVE SUMMARY

PURPOSE

To examine the evaluation systems established by Ryan White AIDS Drug Assistance Programs (ADAPs) to monitor program compliance, measure client outcomes and measure overall effectiveness.

BACKGROUND

In 1990, Congress passed the Ryan White Comprehensive AIDS Resource Emergency (CARE) Act as a comprehensive response to the HIV epidemic and its impact on individuals, families, communities, cities and States. The AIDS Drug Assistance Program provides medications to low-income people living with HIV/AIDS that are uninsured or under-insured and lack coverage for medications. In fiscal year (FY) 1999, Congress appropriated $461 million of Title II funds to finance drug assistance programs. This is an increase of 61 percent over FY 1998 when States received $285.5 million in Title II ADAP funds.

The Ryan White CARE Act will be considered for re-authorization in the year 2000. As Congress debates this re-authorization, questions are certain to be asked about the effectiveness and impact of the programs funded. This inspection examines the capacity of AIDS Drug Assistance Programs to answer those questions.

We conducted an examination of the evaluation mechanisms used by eight Title II ADAPs through an extensive documentation review and on-site interviews. The States visited represent 68 percent of the living AIDS cases reported in 1997 and 61 percent of the Title II funding for FY 1998.

FINDINGS

The AIDS Drug Assistance Programs in the Eight States We Visited Have Sufficient Programmatic and Fiscal Monitoring Mechanisms in Place

The ADAP administrators closely monitor program and fiscal activity through the review of routine reports. Fiscal control over expenditures is further maintained by employing a variety of cost containment strategies to purchase the drugs at the lowest possible price. Program enrollment is monitored through the use of standardized enrollment procedures
and centralized processing. All ADAPs rely on regular, automated matches with Medicaid databases as the primary tool to assure that ADAP funds are being used as the payor of last resort.

**While Most ADAPs Rely on Process Measures to Gauge Program Progress, a Few are Developing Ways to Measure Client Outcomes**

Most ADAP administrators reported that they rely on program utilization data to assess the success of their program. However, an increasing number of administrators are taking on the responsibility of monitoring program impact to improve program efficiency and effectiveness and to respond to demands for greater accountability. On the other hand, some ADAP administrators are of the opinion that measuring outcomes is not an appropriate way to expend limited resources. They argue that it is best to rely on medical research professionals to measure clinical outcomes and that requiring ADAPs to measure outcomes would duplicate work already being done in the medical field.

**ADAPs are Conducting Minimal Assessments of Whether They are Reaching Populations in Need**

All ADAPs indicated that they match the demographics of enrolled clients to the demographic profile of the epidemic as a measure of how they are meeting population needs. Despite the understood disadvantages of relying on this method to assess program effectiveness, ADAPs have not found other, more sophisticated means to assess whether they are reaching populations in need.

**RECOMMENDATIONS**

**To Promote Outcome Measurement, HRSA Should Encourage ADAPs to Compare Utilization Data to Recommended Clinical Guidelines**

The Health Resources and Services Administration (HRSA) should require drug assistance programs to review whether drugs are dispensed in accordance with the *Guidelines for the Use of Antiretroviral Agents in HIV Infected Adults and Adolescents*. Requiring ADAPs to compare their utilization data to these recommended clinical guidelines provides a means to extrapolate medically indicated client health outcomes from utilization data.

Given that ADAP clients may also be receiving HIV-related drugs from other sources, HRSA should encourage ADAPs to expand their relationships with Medicaid to enable an annual exchange of information on prescription drugs dispensed to ADAP clients.

While not a rigorous scientific measure of program impact, with or without secondary data sources, this comparison would provide a general sense of ADAP’s contribution to
client health outcomes. It would also allow for the analysis of patterns and trends that would suggest more in-depth explorations of client outcomes and program impact. Finally, it is a logical next step in understanding the impact of the ADAP program. The current Ryan White application guidance requires ADAPs to report the number of clients receiving protease inhibitors. The HRSA could simply expand this requirement to include a broader range of drugs along with a narrative comparison of how utilization patterns match the recommended clinical guidelines.

The HRSA Should Encourage Collaborative Efforts among Ryan White Titles to Monitor Client Adherence to Drug Regimens

Since positive health outcomes cannot be expected unless clients adhere to prescribed drug regimens, HRSA should work with adherence initiatives where they exist and encourage other Title I and Title II grantees, in consultation with ADAP, to promote and evaluate adherence. Given the difficulty of this complex behavioral and socio-economic issue, initiatives will likely require a combination of local resources.

The HRSA Should Instruct ADAPs to Collaborate with Title I and Title II Needs Assessment Efforts to Assure That They Explicitly Evaluate Medication Therapy Needs

To better assess unmet need, ADAP liaisons should work with and support current Title I or Title II needs assessment efforts. The ADAP liaisons should also ensure that needs assessment efforts actively solicit information from current ADAP clients as well as HIV-infected persons currently not enrolled in ADAP.

AGENCY COMMENTS

The HRSA provided comments on the draft report in which they did not concur with the first and third recommendations. The complete text of HRSA’s comments can be found in Appendix A.

Regarding the first recommendation, HRSA stated that they did not have the statutory authority to require ADAPs to match client utilization data to NIH/PHS guidelines. The HRSA also stated that the data available to ADAPs would be insufficient to make this analysis meaningful.

In response to HRSA’s concern regarding appropriate authority, the recommendation was altered to remove the implication of a statutory requirement. However, developing outcome measures for ADAP remains an important step in the evolution of the program. Matching utilization patterns to the National Institutes for Health/Public Health Service (NIH/PHS) Guidelines for the Use of Antiretroviral Agents in HIV Infected Adults and Adolescents would provide a general sense of ADAP’s contribution to client health
outcomes. It is also a logical first step in outcome development. The HRSA already requires ADAPs to present a break-out of the utilization of protease inhibitors in their annual application for funds. Our recommendation would simply broaden this requirement to include an analysis of utilization by nationally recommended drug therapies.

We appreciate HRSA's concerns regarding the impact of incomplete utilization data. It is for this reason that we suggested ADAPs expand their current relationships with Medicaid to include a data match on drug utilization. This data sharing agreement could be based on the model data sharing agreement disseminated as part of the 1998 HRSA, Health Care Financing Administration (HCFA), and Centers for Disease Control (CDC) inter-agency agreement to promote the development of integrated public health information systems.

Even with data limitations, the comparison of utilization data to drug therapy guidelines provides a sense of program contribution. Our recommendation to use this limited measure of program outcome builds on the United Way model which allows programs to take credit for their contribution to client outcomes while recognizing the practical limitations of assessing attribution in the absence of complete data.

The HRSA also did not concur with the third recommendation that ADAPs should collaborate with Title I and Title II needs assessment efforts. They stated that ADAP was not the appropriate entity to take the lead in collaborative efforts with the other Ryan White programs.

It was not our intention to imply that ADAP should take the lead in collaborating between the Ryan White programs. Rather, our recommendation directed ADAPs to more closely participate in the required Title I and Title II needs assessment efforts in order to have their evaluation needs better met. The HRSA's stated intention to include instructions in the Title I application guidance regarding collaboration with ADAP reflects our intention to promote the level of meaningful collaboration between ADAP and the other CARE Act programs.
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INTRODUCTION

PURPOSE

To examine the evaluation systems established by Ryan White AIDS Drug Assistance Programs (ADAPs) to monitor program compliance, measure client outcomes and measure overall effectiveness.

BACKGROUND

This study complements our reports entitled *Ryan White Evaluation Systems, Title I: Grants to Metropolitan Areas* (OEI-05-98-00392) and *Ryan White Evaluation Systems, Title II: Grants to States* (OEI-05-98-00393).

Ryan White CARE Act

In 1990, Congress passed the Ryan White Comprehensive AIDS Resource Emergency (CARE) Act as a comprehensive response to the HIV epidemic and its impact on individuals, families, communities, cities and States. The Ryan White programs provide health care and support services to persons with HIV/AIDS who would otherwise not have access to care. The Health Resources and Services Administration (HRSA) directs Ryan White resources to various local entities through the Act's four titles and Part F.

The Ryan White programs constitute slightly over $1 billion of the $6.8 billion in HIV/AIDS expenditures included in the U.S. Department of Health and Human Services (DHHS) fiscal year (FY) 1998 budget. The bulk of Ryan White funds are allocated through Titles I and II of the Act. In FY 1998, nearly 90 percent of the Act’s funds were awarded to Title I and Title II grantees.

The Ryan White CARE Act was re-authorized in 1996 through the year 2000. Changes to the Act in the re-authorization included a directive to Title I and Title II grantees to prioritize a portion of their funds for emerging populations.

AIDS Drug Assistance Program

Title II of the Ryan White CARE Act provides grants to States to improve the quality, availability and organization of health care and support services for individuals and families with HIV/AIDS. Section 2616(a) of the CARE Act requires States to use a portion of their Title II funds to establish an AIDS Drug Assistance Program. States are allowed to determine unique financial and medical eligibility for the ADAP in their State.
States are also allowed to determine what drugs will be included in their formularies, how the drugs will be purchased and how the drugs will be distributed to clients.

In FY 1999, Congress appropriated $461 million in Title II funds to be used for ADAP. This is an increase of 61 percent over FY 1998 when States received $285.5 million in Title II ADAP funds. These ADAP funds are typically augmented by contributions from State general revenue funds and, to a lesser extent, Title I grants. The mission of ADAP is to serve low-income people living with HIV/AIDS that are uninsured or under-insured and lack coverage for medications.

The need for financial assistance to support expensive HIV/AIDS drug regimens was first identified in 1987 when Congress provided an emergency appropriation of $30 million to States. Beginning in late 1995, combination antiretroviral therapies, which include protease inhibitors, emerged as a new standard of care and ADAPs experienced explosive growth in enrollment and utilization. In November 1997, DHHS published Guidelines for the Use of Antiretroviral Agents in HIV Infected Adults and Adolescents developed by the Panel on Clinical Practices for Treatment of HIV Infection convened by the Department and the Henry J. Kaiser Family Foundation. These guidelines encouraged aggressive antiretroviral therapy for a broad range of HIV infected individuals, creating even greater demand for the program. In 1998, ADAPs served approximately 108,000 people with HIV/AIDS.

**Ryan White CARE Act Evaluation Requirements**

Section 2616(c)(5) of the Ryan White CARE Act requires that States document the progress made in making therapeutics available to individuals eligible for assistance. Section 2616(d) requires that the Secretary review the current status of State drug reimbursement programs, assess the barriers to the expanded availability of treatments, and examine the extent to which States coordinate with other Ryan White grantees to reduce barriers to the expanded availability of the treatments.

The Ryan White CARE Act includes caps on the amount of funds Title II grantees, inclusive of ADAP, can spend on administrative and planning/evaluation functions. Grantees cannot exceed a 10 percent administrative cap and a 10 percent planning/evaluation cap, the combined total of which cannot exceed 15 percent. Grantees can pay for needs assessments, program evaluation and service delivery assessments out of their planning/evaluation cap.

**HRSA’s Current Evaluation Requirements**

In the FY 1998 Application Guidance, States were asked, for the first time, to complete an ADAP State Profile. The FY 1998 guidance also required a narrative description of
agency administration, funding sources, formulary, eligibility criteria, client utilization, cost-savings strategies and coordination with other Ryan White funded services.

The FY 1998 guidance also asked ADAPs to: 1) describe their system for tracking utilization and expenditure information on a monthly basis, 2) describe any significant changes in client and drug utilization, 3) compare the demographic characteristics of ADAP clients to the demographic characteristics of the HIV epidemic of their State and discuss any discrepancies, and 4) describe the barriers to access and plans to enroll underserved populations. The FY 1999 application asks that ADAPs provide a brief overview of client enrollment and utilization trends. It does not provide direction on how this should be achieved.

The ADAPs are also required, as a condition of their award, to file monthly and annual reports with HRSA. The monthly reports track enrollment and average monthly utilization. They specify a break-out for the utilization of protease inhibitors. The annual administrative report requires ADAPs to document the services they provide and the characteristics of clients receiving services.

As a program administered by the State under Title II, ADAPs are required to outline goals and objectives for the upcoming year in an Implementation Plan. These must be accompanied by the service or outcome measure used to evaluate goal attainment. The application guidance includes people served and units of service as examples of outcome/service measures. The achievement of these goals must be reported in the next year’s application.

Re-authorization

The Ryan White CARE Act of 1990 will be considered for its second re-authorization in 2000. As Congress debates this re-authorization, questions are certain to be asked about the effectiveness and impact of the Ryan White programs. Grantees and administrators will also be asked to account for whether and how the programs have evolved to meet the shifting needs of the communities served.

SCOPE AND METHODOLOGY

This inspection is an examination of the evaluation systems established by State AIDS Drug Assistance Programs. Specifically, this report documents the mechanisms ADAPs use to monitor their program compliance, measure client outcomes, and assess their effectiveness in meeting the evolving needs of the population affected by the epidemic. This evaluation does not judge the compliance, measure the outcomes or assess the effectiveness of the ADAPs, but rather judges whether the drug assistance programs have
and appropriately utilize the tools to perform these evaluation functions. This study also does not examine HRSA’s monitoring and evaluation of the ADAPs.

For the purposes of this analysis, we define compliance as serving the population, providing the services and spending the resources as agreed to in return for the award of program funds. Outcomes are defined as measures of the benefits clients derived as a result of the program. Finally, we define overall effectiveness as how well the mix of services meets the evolving needs of the population affected by the epidemic.

A purposive sample of eight Title II drug assistance programs were selected for this evaluation. The sampled ADAPs consist of New York, New Jersey, Maryland, Florida, Illinois, Texas, California and the District of Columbia. The sites were selected based on the number of reported AIDS cases, FY 1998 Ryan White funding, high incidence of intravenous drug use transmission, the demographics of the AIDS/HIV population, and the regional diversity of the sites. These seven States and DC represent 68 percent of the living AIDS cases reported in 1997 and 61 percent of the Title II funding for FY 1998.

For each of the eight drug assistance programs selected, we conducted an extensive document review. We reviewed their FY 1998 grant application, templates of their programmatic and fiscal reports, enrollment guidelines, client satisfaction surveys and any other documents pertaining to their use of outcomes or evaluations of the overall effectiveness of the program.

We also conducted on-site interviews with the sampled ADAPs between October and December 1998. We interviewed the ADAP administrator and any staff responsible for monitoring, outcomes or evaluation.

In addition to our survey work, we interviewed knowledgeable organizations such as the Center for Disease Control (CDC), the HIV/AIDS Bureau of the Health Resources and Services Administration and the Office of HIV/AIDS Policy. These meetings were complimented by background materials on the Ryan White program provided by HRSA.

We conducted our review in accordance with the *Quality Standards for Inspections* issued by the President’s Council on Integrity and Efficiency.
The AIDS Drug Assistance Programs in the eight States we visited have sufficient programmatic and fiscal monitoring mechanisms in place

Routine program and fiscal reports

The ADAP administrators monitor program activity through the review of routine programmatic reports. These activity reports are typically reviewed on a monthly and, sometimes weekly, basis. They contain aggregate data on program processes such as the number of clients enrolled, newly approved applications, the number of clients served, the number of prescriptions filled by drug and the number of clients receiving each covered drug. One ADAP receives a standard set of 13 tables every month that includes an unduplicated client count, new enrollees by ethnic group and county, CD4 count by age group, client income by county, insurance status, etc. Typically, the point-in-time data provided on a monthly basis is analyzed longitudinally to detect enrollment and utilization trends and project utilization needs for the future.

The ADAPs ensure the fiscal integrity of their programs by monitoring regular reports of their program expenditures. Weekly batches of pharmacy claims are bundled into monthly expenditure reports. These financial reports usually provide an accounting of expenditures during the reporting month and year-to-date figures. Some ADAPs produce more complex financial reports that include items such as average cost per prescription, average cost per client and average fills per client. Expenditure reports are typically accompanied by supporting documentation such as the payroll register, pharmacy claims for drugs dispensed and orders for drugs.

Centralized databases facilitate routine reporting, but remain under-utilized

All of the programmatic and fiscal reports used to monitor program performance are created off of centralized computer data management systems. These administrative data systems track confidential client demographic and service information as well as claims information. One State maintains 1,000 fields on each client including basic demographics, income information, insurance, CD4 count, viral load, disease staging information, treatment history, risk factor, and so forth.

Despite the rich resource of data contained in these centralized data systems, some administrators do not fully utilize the capabilities at their disposal. Most of the ADAP
administrators indicated that their centralized data systems allow instant and easy access to a variety of up-to-the-minute, client level program data and analyses. Further, they stated that the databases provide the capacity to respond to emerging program and policy issues with quantitative analysis. However, only half of the ADAPs mentioned actually using their databases in this manner. For example, one of these ADAPs recently used their database to respond to concerns regarding the number of pediatric cases, the number of women served, and high utilization rates in particular counties and pharmacies. Other administrators feel that while they are collecting all of the necessary programmatic data, they have yet to realize the full potential of the data to assist in program management and evaluation.

**Standard eligibility criteria are uniformly enforced**

Standard enrollment forms, and training on how to appropriately complete them, are used to ensure that all required eligibility information is obtained in a consistent manner. Standard forms enhance the efficiency of enrollment procedures and the ability to evaluate the accuracy of the data. These forms are extensive and typically request demographic, financial and medical information in accordance with State eligibility rules. Appropriate support documentation is also required such as personal identification cards, income verification statements and a physician signed medical certification of HIV diagnosis. One State AIDS Drug Assistance Program trimmed 2,000 duplicates from its rolls last year when it standardized its eligibility screening and enrollment practices.

All ADAPs centrally review enrollment forms and the supporting documentation for completeness and accuracy. The central screening and processing of enrollment applications helps ensure a uniform enforcement of the program eligibility rules. It also helps prevent duplication of services and other fraud. Some ADAPs have further centralized the enrollment process by requiring all application forms to be sent to the central administration office for initial eligibility determination.

Seven of the ADAPs visited re-determine eligibility on an annual or semi-annual basis. One AIDS Drug Assistance Program only initiates re-determination procedures if alerted to a potential change in Medicaid status or other eligibility criteria.

**Payor of last resort status ensured mainly through automated Medicaid matches**

All ADAPs rely on regular, automated matches with Medicaid databases as the primary tool to assure that ADAP funds are being used as the payor of last resort. The ADAPs focus their enforcement energies on Medicaid since they feel it is the most likely source of overlapping funding and they have the greatest ability to enforce compliance. Other techniques used to enforce payor of the last resort status include explicit instructions
written into pharmacy contracts and highlighted on enrollment forms and soliciting information regarding other third-party insurance on client enrollment forms.

Medicaid matches are a part of the standard ADAP enrollment process. In the majority of ADAPs we visited, Medicaid receipt disqualifies applicants from ADAP eligibility. In order to enforce this, ADAPs automatically cross check all applicants against the Medicaid rolls. The ADAPs we visited all have on-line capacity to perform this check. The ease and speed with which this automated match occurs allows ADAPs to perform this check with every application at the time of application and without compromising a client’s access to necessary drugs.

Periodic matches of enrollment files to Medicaid membership files are also conducted to monitor client Medicaid eligibility status which can fluctuate over time. It is typical procedure to approve applicants for ADAP who appear to be Medicaid eligible while also helping them apply for Medicaid benefits. Medicaid eligible HIV-infected persons can also receive ADAP to aid in spend down or cost sharing requirements of Medicaid or if they have limited Medicaid coverage. The periodic checks against the Medicaid rolls allows the ADAPs to monitor on-going client transitions from ‘Medicaid Pending’ status to full Medicaid benefits so the appropriate program is billed. The ADAPs vary tremendously in how often they perform this on-going, automated check. Some ADAPs check on a monthly basis, some weekly, and others check with every prescription request.

One weakness in the current system is the difficulty of recouping payments from Medicaid for those ADAP clients who cycle onto Medicaid while still receiving benefits through ADAP. Since the matches do not occur on a daily basis, and some ADAPs go as long as a month before checking the Medicaid rolls, there is the potential for ADAPs to incur costs for Medicaid-covered services. Of the eight ADAPs interviewed, only one mentioned having a way to bill Medicaid retroactively. Upon discovering an overpayment, this drug assistance program withholds future payments to the respective pharmacy for the amount billable to Medicaid. One other ADAP indicated in their application for funds that they have negotiated a way to retroactively bill Medicaid.

Cost containment strategies are used to limit drug expenses

Fiscal control over expenditures is further maintained by employing a variety of cost containment strategies to purchase the drugs at the lowest possible price. Six of the eight ADAPs purchase drugs through Section 602 of the Veteran’s Health Care Act. This allows them to purchase drugs at a discounted Public Health Service (PHS) price or access a rebate option. The Office of Drug Pricing that administers the Federal Drug Pricing Program for purchasing drugs at the PHS price requires ADAPs to follow established regulations in order to qualify. These regulations were designed to avoid the diversion of drugs purchased under this program to non-eligible patients. Thus, for these drug assistance programs, there is an additional level of Federal control.
For those States where the Federal drug discount pricing program is not an available option due to program structure, multiple other strategies are pursued. These include negotiating savings off of the Average Wholesale Price (AWP) and voluntary rebate programs. The States we visited have negotiated from 10 to 15 percent off of the AWP. These States also typically search for further savings through avoiding or reducing infrastructure costs potentially incurred through storing and distributing the drugs.

Despite the efforts individual State ADAPs are making to ensure they are purchasing drugs at the lowest possible price, variations in the purchase prices States are paying remain. Each AIDS Drug Assistance Program is allowed to craft their own cost containment strategy. This allows for maximum State flexibility, but it also means States have only their own resources and ingenuity to rely upon to overcome the barriers to accessing the lowest drug prices. Some ADAPs suggested that HRSA and the Health Care Financing Administration (HCFA) assume a leadership role at the national level in order to obtain the best possible drug prices for the ADAP program.

While most ADAPs rely on process measures to gauge program progress, a few are developing ways to measure client outcomes

The AIDS drug assistance program was conceived as a means to provide prescription drugs to HIV infected individuals who were uninsured or underinsured. In response to this and tremendous funding pressures, some ADAPs have limited their activities to the process of supplying prescription drugs to HIV-infected persons in need. They view the program primarily as a financing and distribution mechanism. However, an increasing number of administrators are taking on the responsibility of monitoring program impact to improve program efficiency and effectiveness and to respond to demands for greater accountability.

Most ADAPs track client utilization of drugs to monitor program success

Most ADAP administrators reported that they rely on the utilization data reported in their regular program reports to assess the success of their program. The utilization reports typically provide, in aggregate, the number of clients actively enrolled and the number of drugs prescribed by drug class or specific drug. Often they will break out utilization by gender, race/ethnicity and age. A few ADAPs also regularly track enrollment and utilization trends by sub-population or targeted neighborhoods. Utilization goals are outlined in the Implementation Plan in each year’s application for funding.

A few of the AIDS Drug Assistance Programs currently, or plan to, take this review of utilization data a step further by using the data as a basis to extrapolate health outcomes.
This analysis involves reviewing drug utilization data to determine how closely the drugs dispensed match the aggressive drug regimens recommended by the National Institutes of Health/Public Health Service (NIH/PHS) *Guidelines for the Use of Antiretroviral Agents in HIV-Infected Adults and Adolescents*. If the analysis reveals that ADAP prescriptions accurately mirror NIH/PHS guidelines, these ADAP administrators assume their clients are benefitting from the positive health outcomes attributed to these drug therapies in the medical research. One ADAP conducts a quarterly analysis comparing drug usage to NIH/PHS guidelines. Another ADAP is planning on examining prescribing patterns as well as utilization patterns by reviewing a random selection of ADAP clients’ medical charts.

**A few ADAPs are planning on tracking individual client health outcomes to determine program success**

While the majority of AIDS Drug Assistance Programs are currently using process measures to track program functioning and outcomes, a few ADAPs are planning on incorporating client health outcomes into their tracking systems in order to document program impact. Outcome measures under consideration include CD4 counts, viral loads, opportunistic infections, and hospital admissions. One ADAP is struggling to move beyond strict measures of health outcomes by developing broader measures of quality of life. They are interested in tracking how long their clients are ambulatory, to what extent their clients can take care of themselves, the number and length of hospitalizations, and the development and duration of opportunistic infections.

Most ADAPs developing outcome measures plan to track the data for these measures by augmenting their current client-level, administrative data systems. They plan to request pertinent clinical information on the original enrollment form and subsequent forms submitted for re-eligibility determination. A few ADAPs are already capturing CD4 counts in this manner, but none are currently tracking the variations over time as a measure of client health. The clinical information obtained on the enrollment form will be input into the current database where it can be linked to existing client utilization data for analysis. One ADAP indicated they would be tracking outcome measures in another year. Other ADAPs felt the development of outcome measures would take a few years.

One of the ADAPs planning on developing outcome measures also plans to assess client outcomes by means of an independent evaluation. Over the next year and a half, they plan

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1. These guidelines contain recommendations for the clinical use of antiretroviral agents in the treatment of HIV-infected adults and adolescents. A separate document contains pediatric-specific issues related to antiretroviral therapy. These guidelines were developed to serve as a companion document to the therapeutic principles formulated by the National Institute of Health Panel to Define Principles of Therapy of HIV infection.
to review a random selection of clients. This special project will focus on client’s clinical outcomes, length of participation in the ADAP program and the extent to which non-adherence to the prescribed drug regimen negatively impacts health outcomes.

**Some ADAP administrators feel that assessing client health outcomes is beyond the scope of ADAP**

Some ADAP administrators feel that measuring outcomes is not an appropriate way to expend limited resources. They believe the process measures tracked in their utilization reports are sufficient to judge their program’s performance against the goal of efficiently distributing prescription drugs on the formulary to uninsured or underinsured HIV-infected individuals. As one ADAP administrator stated, “We are just responsible for getting drugs to folks who need them and this is where our limited money should go.”

Some ADAP administrators also argue that it is best to rely on medical research professionals to measure clinical outcomes. According to these respondents, in order to get reliable results on clinical outcomes, outcome evaluations should be controlled clinical studies. These types of studies are best directed by skilled researchers who have the expertise to properly conduct such evaluations and access to the necessary resources.

Finally, several ADAP administrators feel that requiring ADAPs to measure client outcomes would duplicate work completed by the medical evaluation field. Medical studies already exist on the effects of the drugs since all approved drugs are put through extensive clinical trials prior to Food and Drug Administration approval. These studies demonstrate what the expected outcomes for a given drug regimen should be. Only drugs that are proven to reduce HIV/AIDS symptoms and prolong life are placed on the formulary to be distributed by ADAP. Thus, the ADAP administrators reason, as long as the program ensures that it is fulfilling prescriptions according to the prescribed guidelines, they should be able to assume that their medical outcomes reflect the outcomes demonstrated in medical research. As one administrator put it, “ADAP outcomes can only be the outcomes predicted by medical studies.”
ADAPs are conducting minimal assessments of whether they are reaching populations in need

While all of the sample ADAPs conduct periodic matches of client and epidemiological data, they conduct little additional research to determine whether they are reaching the populations in need

All ADAPs indicated that they match client demographics to the demographic profile of the epidemic to measure how they are meeting population needs. The majority of ADAPs perform this analysis annually. Some ADAPs perform this analysis more frequently, on an “as needed basis.” Typically, the analysis consists of comparing the demographics of enrolled clients to AIDS surveillance data broken out by gender, race/ethnicity and age. A few of the ADAPs we visited make use of HIV prevalence estimates. The two data sets are compared in order to locate any discrepancies. These discrepancies are explored as possible areas of unmet need to address in the future.

However, many ADAP administrators expressed great reservations about judging the effectiveness of their programs by this simple methodology. Their major concern is that Ryan White AIDS Drug Assistance Programs are not the only source of funding for HIV/AIDS medication. A certain proportion of HIV/AIDS cases access drugs through State Medicaid programs, private insurance or clinical trials. One ADAP study found that 90 percent of the HIV-infected residents in an area with disproportionately low ADAP enrollment rates were enrolled in Medicaid.

Despite the disadvantages of relying on an epidemiological match to assess program effectiveness and growing pressure to better assess the needs of traditionally underserved populations, ADAPs have not found other, more sophisticated means to assess whether they are reaching populations in need. The sources ADAPs mentioned they rely on for information regarding unmet need and access to services include activist groups, the ADAP advisory boards, and the Statewide Coordinated Statement of Need’s assessment of overall State needs. Only three of the ADAPs we visited indicated receiving information from planning council or consortia needs assessment efforts.
RECOMMENDATIONS

To promote outcome measurement, HRSA should encourage ADAPs to compare utilization data to recommended clinical guidelines

As a first step in gathering a better sense of program impact, HRSA should encourage drug assistance programs to review whether drugs are dispensed in accordance with the NIH/PHS Guidelines for the Use of Antiretroviral Agents in HIV Infected Adults and Adolescents. To the extent that the comparison reveals that drug distribution accurately mirrors the guidelines, ADAP administrators and HRSA can assume that clients are benefitting from the positive health outcomes attributed to specific drug therapies evaluated in medical research studies.

To create a more meaningful picture of program impact, HRSA should also encourage ADAPs to expand their relationships with Medicaid to enable an annual exchange of information on HIV-related drugs dispensed to ADAP clients. The resulting data match would render a more complete picture of clients’ access to prescription drugs. It would also be helpful, where possible, to establish data exchanges with the other drug reimbursement sources such as private insurance companies and other pharmacy assistance programs.

Most ADAPs already have data relationships with State Medicaid offices in order to verify payor of last resort status. The HRSA could encourage ADAPs to expand these data sharing arrangements to include an interchange of utilization data. The model data sharing agreement disseminated as part of the 1998 inter-agency agreement between HRSA, HCFA, and the CDC could be used. This inter-agency effort was undertaken to facilitate data sharing between State Medicaid and other health agencies to support program monitoring, promote the development of common performance measures across multiple programs and improve the quality of care for vulnerable populations.

While matching ADAP distribution patterns with the NIH/PHS guidelines would inevitably lack some information regarding drug utilization, it would, nonetheless, provide a general sense of ADAP’s contribution to client health outcomes. This approach to outcome measurement corresponds with a highly regarded method of outcome development promoted by the United Way. This approach recognizes the practical limitations faced by program administrators searching for a way to gage program impact. These limitations typically mean that rigorous program impact evaluations are beyond the means and scope of these agencies. Thus the United Way endorses using outcome measures of contribution as the first step in building meaningful outcome measures.
Beyond providing a broad measure of contribution, this comparison would also allow for the analysis of patterns and trends that would suggest more in-depth explorations of client outcomes and program impact. For example, if disparities in the quality of care are detected in the client population through this broad analysis, ADAPs could engage in a more in-depth examination of utilization in specific sub-populations. This data and analysis could be provided to clinical providers as a form of feedback. The ADAPs might also want to take the next step of surveying physician prescribing practices.

This approach to outcome measurement also integrates the United Way philosophy of using data sources readily available to agencies. Most AIDS drug assistance programs are already relying on client utilization data as a means to gauge program success. Asking them to analyze these utilization patterns against a national standard is a logical next step to a more sophisticated understanding of program impact. In fact, some ADAPs already routinely perform this analysis. All of the ADAPs that we interviewed have utilization data at their disposal and the capacity to perform this analysis. Further, the current Ryan White application guidance already requires ADAPs to report the number of clients receiving protease inhibitors. The HRSA could simply expand this requirement to include a broader range of drugs along with a narrative comparison of how utilization patterns match the recommended clinical guidelines.

**HRSA should encourage collaborative efforts among Ryan White Titles to monitor client adherence to drug regimens**

Since positive health outcomes cannot be expected unless clients adhere to prescribed drug regimens, HRSA should work with adherence initiatives where they exist and encourage other Title I and Title II grantees, in consultation with ADAPs, to promote and evaluate adherence. Given the difficulty of this complex behavioral and socio-economic issue, initiatives will likely require a combination of resources and a collaboration of organizations. Medical providers funded by Title I and Title II are responsible for prescribing the most appropriate drug regimen for the patient. Medical and other support service providers that have ongoing personal interaction with the clients have the capacity to educate and monitor patients on adherence issues. The ADAP program could contribute utilization trend data and information on which drugs clients are obtaining.

The HRSA could encourage collaborative adherence initiatives by disseminating the latest medical research on the impact of non-adherence and offering technical assistance on how to promote and evaluate adherence. Recommendations, best practices and implementation models could stem from adherence studies currently underway.

Recognizing that adherence ensures their clients will obtain the maximum benefit from advanced drug therapy, several locations are already grappling with this difficult issue. One planning council outlined their plans to make adherence a service category in order to...
allocate funds to an adherence initiative. One of the grantees we visited has been awarded funds through the Special Projects of National Significance program to study adherence. Two of the ADAPs we interviewed are involved in adherence initiatives. One is monitoring patient adherence by generating a list of clients who do not pick up their refills from the pharmacy and are past due to receive their medications. Pharmacists perform a weekly manual review of refill logs to see which patients have not picked up their prescriptions. The file is flagged for further follow-up initiatives including contacting the patient directly or contacting the patient’s case manager.

Techniques for adherence promotion include the creation and dissemination of patient education materials and behavior modification programs. Monitoring methods include supervised drug intake, on-going contact through beepers and regularly convened peer-support groups. In cases where limited resources do not allow for such intense monitoring, adherence information could be collected through limited adherence studies using random sampling techniques.

The HRSA should facilitate the spread of these efforts to help ensure that clients are reaping the benefits of advanced drug therapy. Gathering adherence information is the only way that ADAP programs can assure their clients are benefitting from the drugs the program is providing and that the drugs are having the intended impact.

The HRSA should instruct ADAPs to collaborate with Title I and Title II needs assessment efforts to assure that they explicitly evaluate medication therapy needs

The ADAPs need a more sophisticated way to assess whether or not they are meeting the medication needs of the HIV/AIDS population. The ADAPs are being called to greater accountability for their efforts to reach and serve traditionally underserved populations.

The current method of matching the demographics of ADAP clients with the demographics of local HIV cases provides useful information on the needs of infected persons. However, as ADAP administrators indicated, it is a simple method that paints an incomplete picture. Several ADAP administrators pointed out that relying on a match of ADAP cases to existing public health data overestimates unmet need since it does not take into account other programs providing drug therapy. Other shortcomings include lack of HIV prevalence data in some States and the reliance on enrollment data rather than active cases to estimate program utilization.

Not only is the currently utilized methodology unreliable, but it only provides a general picture of unmet need. It does not provide the ADAPs with a reliable way to pinpoint specific subpopulations in various regions of the State. It also does not present a
qualitative picture of unmet need. Barriers to care, historic mistrust of the medical profession and the stigma of HIV add a complexity to the needs of various sub-populations of infected persons which are often not reflected through a quantitative analysis of unmet need.

Finally, properly judging unmet need is essential not only to ensure that medications are equitably distributed to populations in need, but also to better target current ADAP outreach efforts. The U. S. Surgeon General David Satcher has called for ADAP programs to do a better job of targeting minority populations. The ADAP programs must have a reliable way to determine the subpopulations in their State that require further attention in order to better target their outreach initiatives.

While ADAPs may lack the resources and funding to conduct intensive outreach efforts aimed at specific subpopulations, they do have the responsibility to make sure that all those in need of HIV medication are aware of the program in order to ensure that existing access to health care disparities are not simply perpetuated by ADAP. One way to accomplish this would be to target outreach efforts to specific organizations that focus on traditionally underserved populations.

To better assess unmet need, HRSA should instruct ADAPs to appoint liaisons or create a mechanism to work with and support Title I and Title II needs assessment efforts to assure a comprehensive assessment of prescription drug needs. Title I and Title II grantees are required to conduct routine needs assessments as part of their priority setting and allocation processes. The surveys and focus groups used to collect information for these needs assessments typically capture information regarding unmet need for prescription drugs. However, since the goal of the assessment is to gather information on primary medical care and support services, the information on medication therapy needs tends to be very basic. Furthermore, it does not appear that this information is routinely relayed to ADAP administrators.

The ADAPs should also collaborate with Title I and Title II needs assessment efforts to make sure that the Title I and Title II grantees actively solicit respondents from the currently enrolled ADAP population as well as those HIV-infected persons who are currently not enrolled in the ADAP. This would allow ADAPs to access information from a broader spectrum of HIV-infected individuals and provide a richer understanding of unmet need and barriers to care.

The ADAP needs assessment liaison could be appointed from the administrative staff or the ADAP advisory boards. In some States, these advisory boards already take on responsibilities beyond determining the ADAP formulary. In particular, two of the ADAPs visited have advisory bodies that provide overall program and policy guidance and recommendations. Like Title I planning councils and Title II consortia, they advise on all programmatic issues and strive to be representative of the epidemic. The liaison could
work with the Title I and Title II planning bodies to assure that they collect needed information to assist the ADAPs in fulfilling their mission of supplying drug therapy to HIV-infected individuals in need.
The HRSA provided comments on the draft report in which they did not concur with the first and third recommendations. Where appropriate, we changed the report to reflect their comments, concerns and technical corrections. The complete text of HRSA’s comments can be found in Appendix A.

Regarding the first recommendation to encourage ADAPs to match client utilization data to NIH/PHS guidelines as a broad measure of program impact, HRSA stated that they did not have the statutory authority to require ADAPs to perform this analysis. The HRSA also stated that the data available to ADAPs would be insufficient to make meaningful comparisons and extrapolate client health outcomes.

In response to HRSA’s concern regarding their ability to require ADAPs to perform evaluative functions, the recommendation was altered to remove the implication of a statutory requirement. However, developing outcome measures for ADAP remains an important step in the evolution of the program. In our interviews, we found that many ADAPs have moved beyond a limited sense of mission and accountability. They do not view the drug assistance program as merely a financing mechanism and recognize the importance of documenting program impact. They recognize that measuring outcomes provides a means to promote the achievements of the program in terms of its most valuable contributions - the quality and prolonged life of its clients.

Further, the match is a logical first step in outcome development. The HRSA already requires ADAPs to present a break-out of the utilization of protease inhibitors in their annual application for funds. Our recommendation would simply broaden this requirement to include an analysis of utilization of nationally recommended drug therapies.

We appreciate HRSA’s concerns regarding the impact of incomplete utilization data. Since ADAP is only one of many reimbursement mechanisms for HIV drug therapies, it is true that any picture of client drug utilization constructed by ADAP would not accurately represent total client access to HIV medication. It is for this reason that we suggested that ADAP expand their current relationships with Medicaid to include a data match on drug utilization. This data sharing agreement could build on the relationships already established with Medicaid in order to verify payor of last resort status and the 1998 HRSA, HCFA and CDC inter-agency agreement to promote the development of integrated public health information systems.

While matching ADAP distribution patterns with the NIH/PHS guidelines would inevitably lack some information regarding drug utilization, it would, nonetheless, provide a general sense of ADAP’s contribution to client health outcomes. In fact, the measure
was never intended to serve as a rigorous measure of program impact. We recognize that this type of evaluation is beyond the scope of ADAP agencies and that leading medical institutions around the country are involved in efforts to understand the impact of various drug combinations on client health outcomes. Our recommendation is based on the United Way model which allows programs to take credit for their contribution to client outcomes while recognizing the practical limitations on assessing attribution in the absence of complete data. A few ADAPs are already engaged in this type of analysis and have found it a useful tool for understanding program impact.

The HRSA also did not concur with the recommendation that ADAPs should collaborate with Title I and Title II needs assessment efforts. They stated that the drug assistance programs were not the appropriate entities to take the lead in collaborative efforts with the other Ryan White programs. They were also concerned by the suggestion that the ADAP advisory boards could take on the responsibility of collaboration since ADAP advisory boards are typically clinical bodies supplying ADAP formulary advice.

It was not our intention to imply that ADAP should take the lead in collaborating between the Ryan White programs. Rather, our recommendation directed ADAPs to more closely participate in the required Title I and Title II needs assessment efforts in order to have their evaluation needs better met. We offered the ADAP advisory boards as a possible liaison source only where the board was already functioning in a larger capacity than formulary advisement. The specific designation of liaison responsibilities would be the responsibility of each ADAP administration. Of ultimate importance is that meaningful collaboration happens on a continuing basis. The HRSA’s stated intention to include instructions in the Title I application guidance regarding collaboration with ADAP reflects our intention to promote the level of meaningful collaboration between ADAP and the other Ryan White programs.
TO: Inspector General
FROM: Deputy Administrator

Attached, in response to your May 26 request, are HRSA's comments to the subject draft reports. Staff questions may be referred to Jeanelle Kallevang on (301) 443-5181.

Thomas G. Morford

Attachment
Agency Comments


RYAN WHITE EVALUATION SYSTEMS: THE AIDS DRUG ASSISTANCE PROGRAM

OIG RECOMMENDATION

To initiate outcome measurement, HRSA should require ADAPs to compare utilization data to recommended clinical guidelines.

HRSA COMMENTS

We do not concur with the recommendation as written. Even if HRSA had statutory authority to require ADAPs to compare their utilization data to NIH/PHS guidelines, the data available to ADAPs would be insufficient to extrapolate client health outcomes. However, we do agree with the objective of equitable access to treatments for all persons with HIV-infection.

AIDS Drug Assistance Program (ADAP) data alone would not be adequate to perform the comparison. As acknowledged in the report, many ADAP clients receive medications from other sources, including Medicaid, other Ryan White local pharmacy assistance programs, and private insurance. In fact, some clients switch between systems in a single reporting period. In addition, most ADAP programs are administratively distinct from clinical care sites. Therefore, the available data could give an incomplete drug therapy history, and therefore distort the results of the comparison, and may not be linked to client-level medical files. Meaningful comparisons can only be accomplished with longitudinal client-level data sets which include all payers (Ryan White, Medicaid, private insurance, HICP, etc.) and all HIV related health information regarding the stage of disease and types of clinical diagnoses of the individual client. These requirements are beyond the data management and administrative capacity of current ADAP grantees.

HRSA does, however, maintain an ADAP formulary database in order to monitor national formulary trends. HRSA also works continually with ADAPs on formulary development in order to ensure that, to every extent possible, the appropriate drugs are included on the formulary.
OIG RECOMMENDATION

The HRSA should encourage collaborative efforts among Ryan White Titles to monitor client adherence to drug regimens.

HRSA COMMENTS

We concur with this recommendation. HRSA has sponsored a number of technical assistance activities focused on this issue and encourages collaborative efforts among Ryan White Titles to monitor client adherence to drug regimens. Additionally, under the Special Projects of National Significance Program, FY 1999 funds will be used to support "Projects to Evaluate the Effectiveness of Existing Programs to Promote Adherence to Anti-Retroviral Therapies".

OIG RECOMMENDATION

The HRSA should instruct ADAPs to collaborate with Title I and Title II needs assessment efforts to assure that they explicitly evaluate medication therapy needs.

HRSA COMMENTS

We do not concur with this recommendation, although we agree that there should be collaboration. First, it is important to note that ADAP advisory boards and needs assessment activities are not required by statute. Furthermore, ADAPs may not be the most appropriate entities to take the lead in coordinating needs assessment efforts. As noted in the OIG report, ADAP Advisory Boards are typically comprised of individuals who first and foremost provide the clinical expertise necessary to make formulary decisions. We believe that those ADAP Advisory Boards whose members are already coordinating needs assessment efforts with Title I and II will provide additional insight in future Title I applications regarding this matter.

At present, all Title I Planning Councils have a Title II representative on the board. HRSA, through the Title II application guidance, has instructed the Title II programs to collaborate with ADAPs on needs assessment. HRSA will expand this initiative to include the Title I application guidance, so that both Titles coordinate with the ADAPs on this important issue.
TECHNICAL COMMENTS

Please note an incorrect reference in the draft report on page 6, paragraph 2, under Ryan White CARE Act Evaluation Requirements. This paragraph should be re-written with proper citation of the 10% administrative cap and 10% planning/evaluation cap as follows:

"The Ryan White CARE Act includes caps on the amounts of funds Title II grantees, including ADAPs, can spend on administrative and planning/evaluation functions. Grantees cannot exceed 10% administrative cap and 10% planning/evaluation cap, the combined total of which cannot exceed 15% allowed under the Title II program, inclusive of ADAP. Grantees can pay for needs assessments, program evaluation and service delivery assessments out of their planning/evaluation caps."

RYAN WHITE EVALUATION SYSTEMS: TITLE I: GRANTS TO METROPOLITAN AREAS

OIG RECOMMENDATION

The HRSA should promote the development of metropolitan-wide data systems to further improve the program management activities of the sub-grantees.

HRSA COMMENTS

We concur with the recommendation in concept and agree with the objective. However, we must note the following activities being conducted by HRSA and the limitations on HRSA’s ability to comply with the OIG’s recommended action plan.

Activities (ongoing or planned) related to this recommendation:

- Current data requirements are being revised in the form of a cross-Title Annual Administrative Report (AAR). This effort will involve substantial external feedback that likely will generate interest in the possibilities of client-level data.

- New software for the existing AAR is being developed that will include a voluntary module on health-related client-level information.

- Expertise in using data for program planning and management is being developed via 7 client-level demonstration sites.
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- HRSA is analyzing responses to a data collection/MIS query of CARE Act grantees and is identifying a number of grantees that have initiated their own client-level reporting systems to analyze health service utilization and program outcomes. There is a plan to host a late FY 1999 meeting of grantees with such experience in an effort to launch a more proactive, peer-based technical assistance effort.

Current Limitations:

- Grantees reported problems with inaccessible and/or incompatible data bases and reporting delays. In response to these findings, the OIG recommends additional technical assistance and financial resources from HRSA’s HIV/AIDS Bureau to develop and implement these systems among Ryan White grantees. It would be unreasonable to expect technical assistance and financial resources from HRSA’s HIV/AIDS Bureau to be sufficient to fully develop and implement those systems in an appropriate manner. Developing outcomes solely on Ryan White resources and data will limit the types of information necessary to do meaningful outcomes assessment. In addition, client-level data often includes various data sets at sub-grantee levels that may be incompatible. Thus, access to diverse and compatible data sets, along with the administrative resources and skills necessary in managing these data sets, may need to include the participation of public health agencies beyond the Ryan White CARE Act programs, as well as across the various Titles. A commitment may be necessary at a local and State health level (beyond agencies and providers funded by Ryan White) to standardize, link, and share public health data related to providing the full array of services used by HIV infected persons across multiple agencies.

- One-percent set-aside evaluation funds that HRSA receives are severely limited and there is no specific designation of funds in the CARE Act, at HRSA or grantee levels, for data collection and evaluation. HRSA cannot put the entire responsibility for eligible metropolitan areas (EMA)-wide data systems on the Ryan White grant recipients. This activity would be considered administrative in nature. There are specific limitations within the CARE Act that restrict the use of funds to a 5% administrative cap, with other funds supporting various categories of direct services.

- Given current funding and staffing limitations, HRSA is open to discussions with the OIG on other potential sources of funds available to assist grantees in building client-level data systems that were alluded to in the report.

OIG Recommendation

The HRSA should implement a Multi-year outcomes initiative including grantee requirements and technical assistance.
HRSA COMMENTS

We concur with this recommendation. However, we must note the following activities being conducted by HRSA and the limitations on HRSA’s ability to comply with the OIG’s recommended action plan.

Activities (ongoing or planned) related to this recommendation:

- HRSA, in partnership with constituency groups, will be developing a strategy for development and implementation of just such an outcomes initiative. The initiative recommended in this document (i.e., core outcomes and the United Way approach) will be included in the various models for discussion.

- An effort is underway to develop a guidance manual on program outcomes and outcomes measurement, with a focus on primary medical care. Additionally, using one-percent evaluation funds, HRSA is ready to release a Request for Quotation for “An Evaluation of Outcomes among PLWH Receiving Services from Ryan White Care Act-Funded Programs”, open to current CARE Act-funded grantees and including non-medical care services.

- HRSA has supported the use of HIV-specific continuous quality improvement program (HIVQUAL) activities at numerous Ryan White funded community health center sites (Title III sites). Several sites are recipients of Titles I and II funds. We plan to continue to support such program activities among our grantees.

Current limitations:

- Many of the same limitations, as identified above, relate to the development and implementation of a provider-based client-level data set and COI practices. Limitations on accessibility and compatibility of data sets and restrictions on the use of Ryan White funds for administrative costs (including quality assurance activities) impact a Grantees’ ability to optimize access and use of complex data sets for outcome studies.

- To the extent that client information is shared among and between Ryan White service provider groups, issues of confidentiality and privacy are an important consideration.

OIG RECOMMENDATION

The HRSA should provide technical assistance to improve the ability of grantees to estimate the needs of infected persons not in HIV/AIDS care.
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HRSA COMMENTS

We concur with this recommendation. HRSA will work collaboratively with CDC in its effort to better estimate and document HIV infection. Additionally, using one-percent evaluation funds, HRSA is ready to release a Request for Quotation for "Population- and Data-Based Assessment of Unmet HIV Service Needs", open to current CARE Act-funded grantees. This effort is expected to produce both usable data for jurisdictions that are funded and a methodological approach that can be documented and replicated in other areas.

TECHNICAL COMMENTS

On page 6, paragraph 2, the eligibility requirements for formula grants were modified during the 1996 reauthorization. Therefore, please revise the 1st sentence to read as follows: "Metropolitan areas are eligible for Title I formula funding if they have a population of 500,000 or more and have a total of more than 2,000 cases of AIDS reported to the CDC for the most recent period of 5 calendar years."

RYAN WHITE EVALUATION SYSTEMS: TITLE II: GRANTS TO STATES

OIG RECOMMENDATION

The HRSA should implement a Multi-year outcomes initiative.

HRSA COMMENTS

We concur with this recommendation. HRSA, in partnership with constituency groups, will be developing a strategy for development and implementation of just such an initiative. Please refer to our response on pages 3 and 4 of these comments regarding Ryan White Evaluation Systems, Title I (OEI-05-98-00392) for additional comments related to accessibility/incompatibility of data systems.

An effort is underway to develop a guidance manual on program outcomes and outcomes measurement, with a focus on primary medical care. Additionally, using one-percent evaluation funds, HRSA is ready to release a Request for Quotation for "An Evaluation of Outcomes among PLWH Receiving Services from Ryan White Care Act - Funded Programs", open to current CARE Act-funded grantees.
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OIG RECOMMENDATION

The HRSA should provide technical assistance to improve the ability of grantees and consortia to estimate the needs of infected persons not in HIV/AIDS care.

HRSA COMMENTS

We concur with this recommendation. HRSA will work collaboratively with CDC in its effort to better estimate and document HIV infection. Additionally, using one-percent evaluation funds, HRSA is ready to release a Request for Quotation for "Population- and Data-Based Assessment of Unmet HIV Service Needs", open to current CARE Act-funded grantees. This effort is expected to produce both usable data for jurisdictions that are funded and a methodological approach that can be documented and replicated in other areas.

TECHNICAL COMMENTS

Under HRSA’s current evaluation requirements on page 7, the second paragraph, the first sentence is not accurate. There is no legislative mandate for Title II to use needs assessment data to allocate Title II funds. Therefore, we recommend the 1st sentence be deleted.
# Related Office of Inspector General Reports

The Ryan White CARE Act: Local Implementation Issues (OEI-05-93-00336)

The Ryan White CARE Act: Examples of Local Coordination (OEI-05-93-00335)

The Ryan White CARE Act: Special Projects of National Significance (OEI-05-93-00332)


The Ryan White CARE Act: Funding Formulas (OEI-05-93-00330)

Medicaid Managed Care and HIV/AIDS (OEI-05-97-00210)

Audit of State AIDS Drug Assistance Programs’ Use of Drug Price Discounts (A-01-97-01501)

Review of Maximizing Drug Discounts Under the Missouri Ryan White Program (A-01-97-00926)

Audit of the Ryan White Comprehensive AIDS Resource Emergency Act of 1990, Title II, Administered by the Health Resources and Services Administration (A-01-97-01500)

