AIDS Drug Assistance Program Report

Prepared by
The Virginia Commissioner of Health
for
The Chairmen of the House Appropriations and Senate Finance Committees

October 1, 2013

The following report was developed in response to the directive under the VA ACTS OF ASSEMBLY – CHAPTER 890, Item 284:

G. The Commissioner of Health shall monitor patients who have been removed or diverted from the VA AIDS Drug Assistance Program due to budget considerations. At a minimum, the Commissioner shall monitor patients to determine if they have been successfully enrolled in a private Pharmacy Assistance Program or other program to receive appropriate anti-retroviral medications. The Commissioner shall also monitor the program to assess whether a waiting list has developed for services provided through the ADAP program. The Commissioner shall report findings to the Chairmen of the House Appropriations and Senate Finance Committees annually beginning October 1, 2011.

Summary

The Virginia Department of Health (VDH) restored Virginia (VA) AIDS Drug Assistance Program (ADAP) enrollment criteria and eliminated the ADAP waiting list in August 2012. ADAP has implemented measures creatively and effectively to increase program sustainability. However, current enrollment and utilization of the program has reached the highest recorded levels to date because of a number of external factors. The collaborative efforts of medical providers, community partners and advocates, local health departments, elected officials, ADAP staff, and Virginia's client community will be essential for ADAP to continue to meet the needs of people living with HIV/AIDS in the Commonwealth. Additional funds will also be required to sustain the program and avoid instituting another waiting list, as well as to maintain positive health outcomes for those living with HIV and reduce transmission of HIV across the Commonwealth.

Background

VA ADAP provides access to life-saving medications for the treatment of HIV and related illnesses for low-income clients through the provision of medications or through assisting with insurance premiums and medication co-payments. The program is primarily supported with federal Ryan White (RW) Treatment Extension Act Part B grant funding, which is distributed by a formula based on living HIV and AIDS cases to all states and territories in the United States. ADAP also receives support from state general funds. Other funding sources include Medicaid

reimbursements for clients who receive retroactive eligibility and rebates from pharmaceutical manufacturers.

VA ADAP provides direct medication and insurance cost support in the following ways:

- Direct Purchase ADAP: Medications are purchased at discounted rates by the Central Pharmacy, and distributed to local health departments and other distribution sites to provide to clients.

- Medicare Part D Patient Assistance Program (MPAP): The Medicare Part D program pays premiums, medication co-payments and deductibles for ADAP eligible clients who are enrolled in Medicare Part D. VA ADAP began paying for MPAP clients in 2007, supported by state appropriated State Pharmaceutical Assistance Program (SPAP) funds. As client need for this program has increased, both SPAP and ADAP funding support the assistance. SPAP funds continue to support premium payments for those clients at or below 300% of the federal poverty level (FPL), while ADAP funds support medication deductibles and copayments, and the few premiums for clients between 301 and 400% FPL. VA ADAP can support 3 clients annually on MPAP for the cost of 1 Direct Purchase ADAP client.

- Pre-Existing Condition Insurance Plan (PCIP) and other insurance: PCIP, a program of the federal Patient Protection and Affordable Care Act (ACA), provides insurance to persons who have previously been denied coverage for pre-existing conditions. ADAP pays premiums, medication co-payments and deductibles to meet the $6,250 individual annual total out of pocket (OOP) expense. VA ADAP began paying for PCIP clients in January 2013, and supports 2 clients annually on PCIP for the cost of 1 Direct Purchase ADAP client. This program ends on December 31, 2013 and clients will be transitioned to newly available insurance options through the ACA. Additionally, ADAP will begin supporting medication co-payments for all eligible clients who have insurance in order to generate program revenue through rebates, described later in this report.

The ADAP medication formulary includes antiretroviral medications indicated for the treatment of HIV, selected vaccines, antilipidemics, antiglycemics, mental health treatment medications, and medications to treat or prevent opportunistic infections (OIs). Eligible clients must have family incomes at or below 400% FPL; however, the majority of enrolled clients (85%) have incomes below 250% FPL, and 63% of the ADAP population lives at or below 100% FPL. Enrolled clients are assessed every six months to ensure continued eligibility for the program.

During the RW Part B Grant Year (GY) 2010 (April 2010-March 2011)[1], VA ADAP experienced steep increases in program utilization compared to the prior two years; and pharmaceutical expenditures reached a historic high. Additionally, rising unemployment rates and corresponding loss of insurance, expanded HIV testing efforts, new HIV treatment guidelines recommending initiation of HIV treatment as early as possible, and new medication regimens all contributed to the steep growth in ADAP utilization and expenditures during this

[1] RW Part B GYs run from April 1 to March 31 and are named for the year in which they begin.

period. Data analysis from 2007 to 2009 indicated that client enrollment and monthly medication costs steadily increased by 21% and 15% respectively.

Subsequently, in November 2010, aggressive cost containment measures were instituted. These included the implementation of a waiting list for ADAP services, the transition of some clinically stable patients to other sources of medication access, a reduction to the ADAP formulary, and enrollment restrictions. At that time, ADAP enrollment criteria were limited to pregnant women, individuals 18 years old or younger, and people who were currently receiving treatment for an active OI.

In November 2011, due to increased program and pharmaceutical efficiencies and the availability of additional federal and state ADAP funds, VDH began enrolling new and wait-listed clients back onto ADAP who met certain clinical criteria. As funds were identified to sustain clients on ADAP over time (throughout GYs 2011 and 2012), a medical triaging process using client CD4 count (a marker of immunity, with lower CD4 counts indicating increased risk for illness) was used to identify clients for transition onto ADAP. In July 2012, based on the effectiveness of this approach and supported by weekly monitoring of ADAP service utilization and expenditures, VA ADAP began the final steps toward elimination of the waiting list. By August 30, 2012, the ADAP waiting list had been entirely eliminated.

National Recognition of Program Management and the Provision of Technical Assistance

Virginia has continued to be recognized for excellence in program management during the waiting list time period and for steps taken to eliminate the waiting list. Since receiving the Program Excellence Award from the National Alliance of State and Territorial AIDS Directors (NASTAD) in May 2011, VDH staff has represented the agency in a variety of forums.

VDH is an invited member of the Professional Expert Educational Roundtable (PEER) sponsored through a cooperative agreement between NASTAD and the Health Resources and Services Administration (HRSA). PEER is an advisory group comprised of staff from selected health departments from across the country with the primary purpose of providing expert, peer-based guidance and technical assistance to ADAP programs on current issues. This assistance is provided through national calls held every two months.

In November 2012, several staff represented Virginia at the RW All Grantees Meeting (AGM) held in Washington, DC. The AGM provides an opportunity to present to all states, territories, metropolitan areas, and clinical programs that receive RW funding. Staff presented a poster entitled *Journey of Virginia ADAP: From Shortfall to Sustainability* and conducted a workshop in collaboration with North Carolina entitled *Management of an ADAP Wait List*. Staff also presented an additional workshop with the District of Columbia and West Virginia on the *Impact of DC EMA Cross-Part Collaborative on DC/WV/VA AIDS Drugs Assistance Programs*.

VDH staff presented during a national webinar entitled “ADAP Crisis: Lessons Learned,” targeted to all ADAPs in the states and territories. VDH staff also presented on a call for the National Quality Center in April 2013 to discuss viral suppression (reducing the amount of HIV in a person to increase health quality and reduce transmission to others) and the ways ADAP supports this goal through the collection and tracking of lab markers for ADAP. VA ADAP staff also contributed data and technical assistance to the development of a manuscript that is

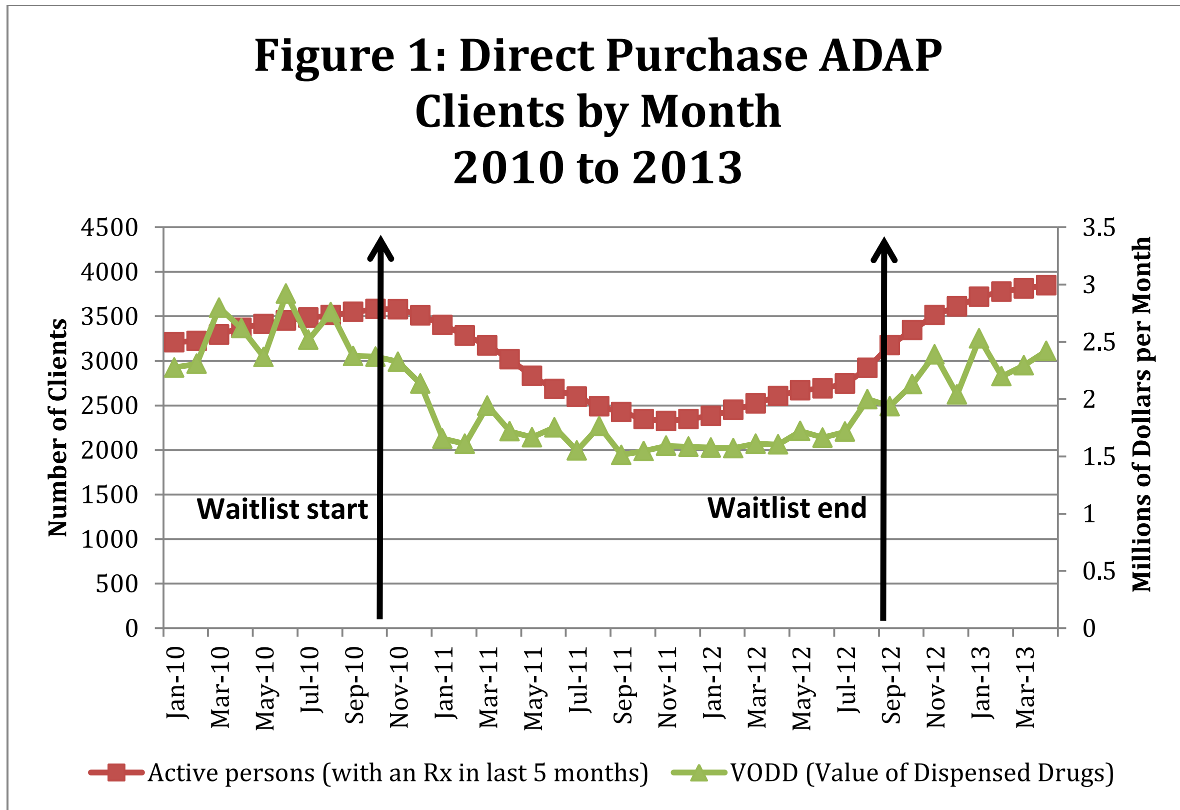
currently being prepared for publication by the University of Virginia[2], which finds that ADAP clients had better retention in care than non-ADAP clients in a large university medical center setting. The study also showed that clients prescribed medications for diabetes and cholesterol control that were removed from the ADAP formulary during the waiting list time period did not suffer negative health effects. Presumably, the efforts by community partners and VDH to ensure clients accessed medications through pharmaceutical company patient assistance programs (PAPs) minimized negative health impact.

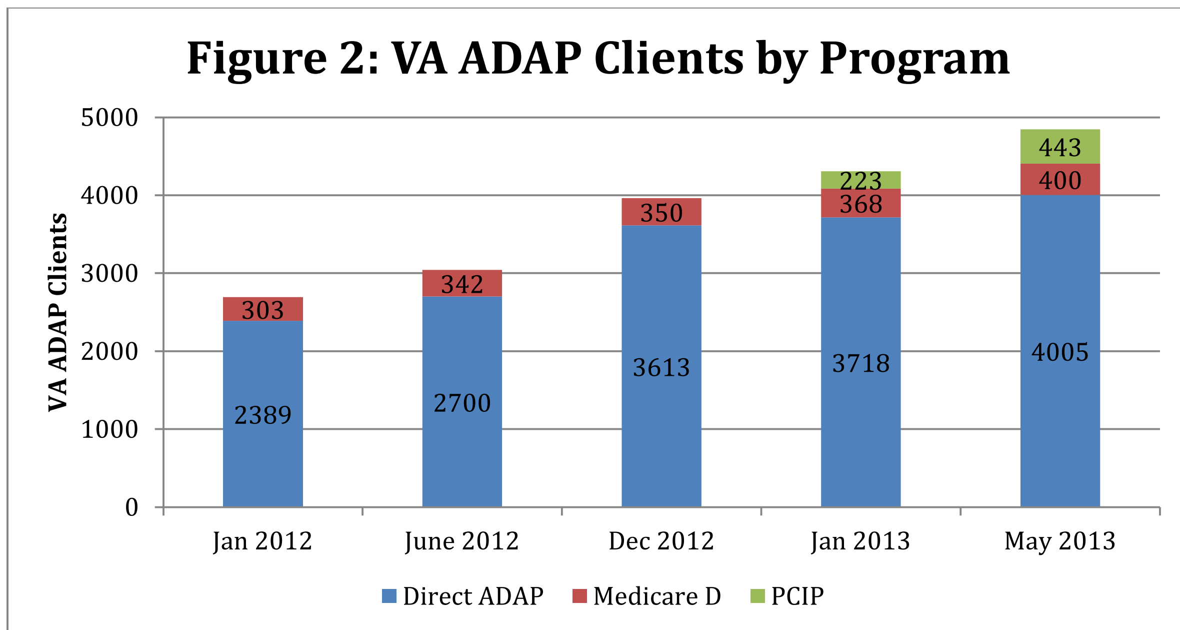
Current Utilization

The VA ADAP waiting list was eliminated in August 2012 and enrollment was opened to all persons who met current ADAP criteria. Figure 1 provides a summary of Direct Purchase ADAP utilization and costs by month from January 2010 through March 2013, which demonstrates a steady increase in client utilization since the end of the waiting list, with an average of 121 new clients per month between September 2012 and March 2013. While active clients served per month are currently higher than pre-waiting list levels, total costs have not increased at the same rate because of decreased medication costs resulting from national negotiations with pharmaceutical companies and increased utilization of less expensive antiretroviral regimens.

As VDH began enrollment in PCIP in January of 2013 and continued to refine its eligibility and recertification procedures for all ADAP programs (Direct Purchase, MPAP and PCIP/insurance), monitoring enrollment and utilization is increasingly important to ensure resources can meet the growing need. Currently, the ADAP Leadership Team (consisting of program, fiscal, pharmacy and administrative staff) reviews program enrollment and utilization numbers by program component on a weekly basis, as well as the number of recertifications completed and the number of disenrollments and denials by reason. Figure 2 provides program enrollment at key points during the period January 2012 to May 2013. For the first time in its history, ADAP had over 4,800 total clients enrolled in May 2013.

[2]McManus KM, Dillingham R "Effects of Recent Virginia AIDS Drug Assistance Program Policy Changes on HIV patient's Diabetes and Hyperlipidemia Control", University of Virginia Infectious Disease Clinic.





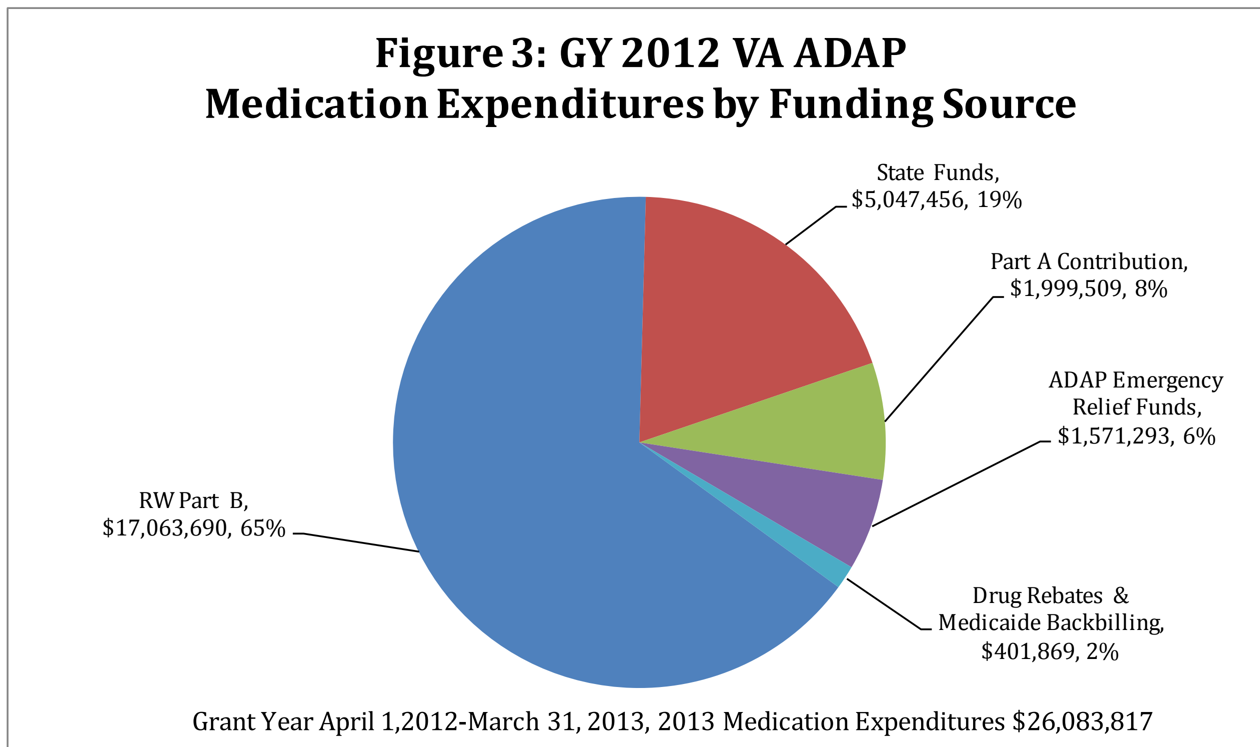
Between June 2012 and May 2013, ADAP eligibility staff processed 1,740 new applications and 1,259 re-certifications. During this period, 277 persons were disenrolled from ADAP or denied upon initial application. Primary reasons included having another payer source for medications, including Medicaid and private insurance (58%), moving out of state (13%), and not completing the application or recertification process (12%). New client growth in ADAP currently outpaces

pre-waiting list levels, and is expected to continue at this rate due to several key factors. Public Health Service HIV treatment guidelines support initiating treatment with medications early in the course of disease to suppress HIV, lowering the amount of virus in the body (measured by a viral load laboratory test). Viral suppression, along with maintaining higher CD4 counts, improves health outcomes for infected clients and reduces transmission to uninfected individuals. About one-third of newly enrolling ADAP clients have a CD4 count over 500, and are initiating treatment early to maintain optimal health. VDH has been awarded several million dollars in federal funds for new, highly visible national demonstration projects to increase early identification of HIV infection, facilitate linkage of newly diagnosed clients to care and improve retention in care, resulting in increased demand for medications through ADAP and, once enrolled, longer consistent periods of medication utilization due to better adherence and retention in care. Additionally, VDH has been expanding testing efforts throughout the state through a federally funded initiative. National estimates indicate about 18% of those people infected with HIV are unaware of their positive status. The goal of these efforts is to reduce that percentage and increase early entry into care. While these efforts increase utilization of ADAP, they also lead to clinically controlled HIV disease, which both reduces overall health care costs for clients and reduces transmission of HIV to others.

Fiscal Status

Consistent with previous years, the largest funding source for medications purchased under VA ADAP consists of federal RW Part B funds administered through HRSA. Annual amounts fluctuate due to changes in Congressional appropriation and changes in living HIV cases nationally, as the award is formula based as described previously. Virginia receives federal funding under RW Part B to provide services to those living with HIV who cannot otherwise afford medications or care. Virginia allocates approximately 80% of the federal award to medication access (Direct Purchase ADAP and MPAP/PCIP/insurance support through ADAP), with only 10% supporting other medical care services and the other 10% (of the allowable 20% under grant terms) supporting agency administration and program infrastructure.

Reflected in the chart below, (Figure 3: GY 2012 ADAP Medication Expenditures by Funding Source), 65% of ADAP medication expenditures were supported by the Part B award (consisting of ADAP earmark, Part B base service funds allocated to medication purchase and ADAP supplemental). VDH also competed for and was awarded $3,500,000 in federal ADAP Emergency Relief Funds for a performance period crossing two RW grant years, expending $1,571,293 during GY 2012 and expending the remainder of the award in GY 2013 to address anticipated increasing resource needs. During GY 2012, both RW Part A grantees that serve jurisdictions in Virginia (i.e., the cities of Norfolk and Washington, D.C.) made one-time substantial contributions to VA ADAP utilizing unspent grant balances at the end of the Part A budget period. Finally, state funds represented in the chart below reflect appropriations made in State Fiscal Year (FY) 2012 that were expended during the RW GY 2012. As noted previously, ADAP is increasingly supporting Medicare Part D and insurance costs for clients to achieve greater cost savings in order to serve growing numbers of ADAP enrollees. While this information reflects medication costs and utilization, which makes up the majority of the program, an additional $2,315,743 was expended on Medicare Part D and PCIP/insurance support (premiums and medication costs) for ADAP clients.



During GY 2012, state contributions to VA ADAP totaled slightly over $5 million and were used to help enroll and sustain clients in the medication program. With average monthly client costs at $870 per person ($10,440 annually), these state funds sustained an estimated 479 clients on the program during this time period.

ADAP resources and expenditures are monitored on an ongoing basis and are reviewed weekly by a multidisciplinary team with monthly summaries reported to the Chief Deputy Commissioner of Public Health. This diligent monitoring and communication enabled assessment of resources and assisted with the elimination of the waiting list, which has allowed ADAP to serve more residents of the Commonwealth.

Procedures to Monitor Medication Inventory and Real-Time Utilization Data

VDH Central Pharmacy continues to maintain a log of all ADAP medication purchases including the balance of available funds for medication purchase, a process that was implemented in 2010. This information is used to calculate the daily medication cost of operating ADAP. This enhanced monitoring of daily medication expenditures provides real-time information on medication costs used to support the ADAP. VDH leadership also uses this data to validate the number of clients served, prescriptions filled, and daily medication cost per client.

Reduction of Federal Budget Due to Sequestration

In accordance with the Budget Control Act of 2011, a series of spending cuts, called sequestration, cancelled approximately $85 billion in budgetary resources across the Federal government for the remainder of the Federal FY 2013. HRSA took steps to mitigate the effects of these cuts, but notified VDH that the RW GY 2013 award would be affected by an approximate 5% reduction. In June 2013, VDH received the final Notice of Grant Award (NOA)

for RW Part B in the amount of $9,895,620 or 94.5% of the GY 2012 award. This reduction of $1,230,154 has contributed to the need to identify additional ADAP resources.

Projections of Program Utilization and Costs

Forecasting for VA ADAP is done on a monthly basis, as data on utilization for each program (Direct Purchase, Medicare Part D, and PCIP/insurance support) within ADAP are tracked monthly. The number of active clients (those regularly receiving ADAP medications or insurance support) is the best predictor for ADAP costs. For GY 2012, 4,647 clients received ADAP services, with 6,286 clients projected to receive services in the current year, and 7,287 clients projected for the subsequent year (which intersects with State FY 2015). The annual number of clients served is estimated through a formula, based on a regression analysis of 15 years of historical data, utilizing monthly rather than annual averages. This methodology of averaging by month is necessary to account for monthly variances due to disenrollment (other payer sources identified, periodic limited coverage by Medicaid or high deductible insurance plans, or clients moved out of state), death or becoming ineligible for ADAP for other reasons. Projections that do not account for monthly variations would result in under projection of program costs and over projection of clients to be served.

Projections for Medicare D and PCIP/insurance support within ADAP account for the calendar year structure of the insurance plans, client eligibility occurring throughout the year as a result of age or disability, as well as variations in out of pocket requirements based on client income and tax credit eligibility. Medicare Part D has larger cost outlays in the early part of the calendar year, as clients proceed through the coverage gap, which is $4,750 in 2013. Most ADAP clients, whose HIV medications are costly, reach this limit by March and then Medicare pays 95% of costs for the remainder of the year. PCIP follows a similar structure, in that clients (under ADAP assistance) must expend $6,250 each calendar year before the insurance begins paying the full medication costs. With insurance that will be purchased through the ACA federal marketplace in 2014, the complete cost structure is not currently known. Initially proposed plans have a maximum out of pocket requirement that is around $6,500 for those who are not subsidized. Currently those with incomes at or below 100% FPL (which is 63% of ADAP clients who would be eligible for the health insurance marketplace) would receive no subsidies. Coverage through insurance would still be more cost effective than purchasing medications due to capped costs and the ability to generate rebates from pharmaceutical companies. Individuals with incomes between 101% and 400% FPL will receive tax credits and subsidies and have a maximum out of pocket requirement between $2,200 and $4,000. For ADAP, this structure results in cost outlays that are significantly higher in the early months of the calendar year for insurance programs, when the majority of these out of pocket limits are paid. The later months of the year will have significantly lower costs, as out of pocket costs are no longer being paid and rebate revenue from medications in previous months is received.

Projections for client cost and utilization under the federal health insurance marketplace have been developed utilizing the current FPL distribution of the ADAP population that would be potentially eligible for ACA. This distribution is shown in Figure 4. These clients include those currently on Direct Purchase ADAP and those on PCIP, but not those on MPAP, as those persons would remain on MPAP, even after implementation of ACA. The majority of clients (63%) are at or below 100% FPL. Consequently, this portion of the ADAP population would be the most expensive to insure but still more cost-effective than medication purchase.

Using estimates from the Kaiser Family Foundation (KFF) for marketplace subsidies[3], average annual costs for the population at or below 100% FPL would be $11,355. This is based on a weighted premium average using the following assumptions: 1) average age of VA ADAP client: 43 years old; 2) tobacco users in ADAP population (based on study of tobacco use in HIV population[4]) = 42%. This annual cost is higher than the average annual cost for a Direct Purchase ADAP client ($10,200), but the ACA cost may be further reduced by pharmaceutical rebates received on cost shares such as co-payments paid for antiretroviral medications. Rebates are discussed in the next section and are not able to be counted as funding for the same period in which the costs that generate them are incurred, because of the time lag in receiving rebates.

Table 1 provides estimates for each FPL using the KFF calculator and other assumptions outlined above. The most cost effective portion of the population to insure under ACA would be those with incomes between 101 and 250% FPL, as they receive both premium and cost sharing assistance, which would translate into an estimated annual cost for VA ADAP of $3,190 before rebates. These clients represent 23% of the current ADAP population eligible for ACA. ADAP will continue to directly provide medications to an estimated 11% of the client population ineligible for insurance under ACA (for example, individuals with undocumented immigration status or seeking insurance between open enrollment periods without a qualifying event).

A variety of strategies have been initiated by VDH to maximize enrollment of those eligible for insurance under the ACA, and to encourage clients to take advantage of the open enrollment period of October 2013 through March 2014. A statewide educational campaign targeting consumers, medical staff and regional planning groups is ongoing, with over 500 people educated thus far. Patient navigation programs are funded throughout the state under RW Part B funds to assist clients with linkage to care including enrolling in and navigating insurance. VDH is also collaborating with major medication institutions' indigent care programs and community health centers to jointly target clients for insurance enrollment.

[3] Kaiser Family Foundation, Subsidy Calculator, http://kff.org/interactive/subsidy-calculator/, accessed 5/31/2013.
[4] Mdodo R, Frazier E, Mattson C , Sutton M, Brooks J, Skarbinski J. Cigarette Smoking among HIV+ adults in care: Medical Monitoring Project, US, 2009. 20th Conference on Retroviruses and OI, March 3-6, 2013, Atlanta.

Figure 4: Distribution of Federal Poverty Levels for ADAP Population (excluding MPAP) and ACA Status

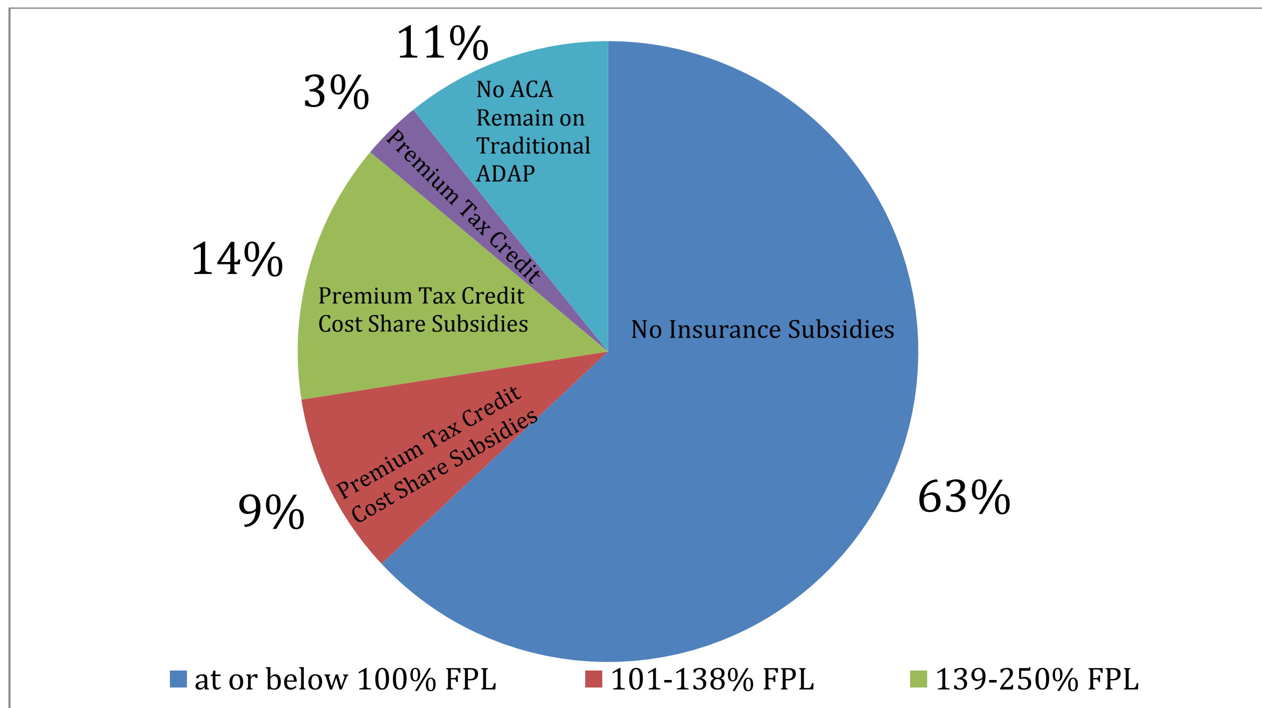


Table 1: Estimates of ADAP Costs for the Health Care Marketplace under ACA by FPL

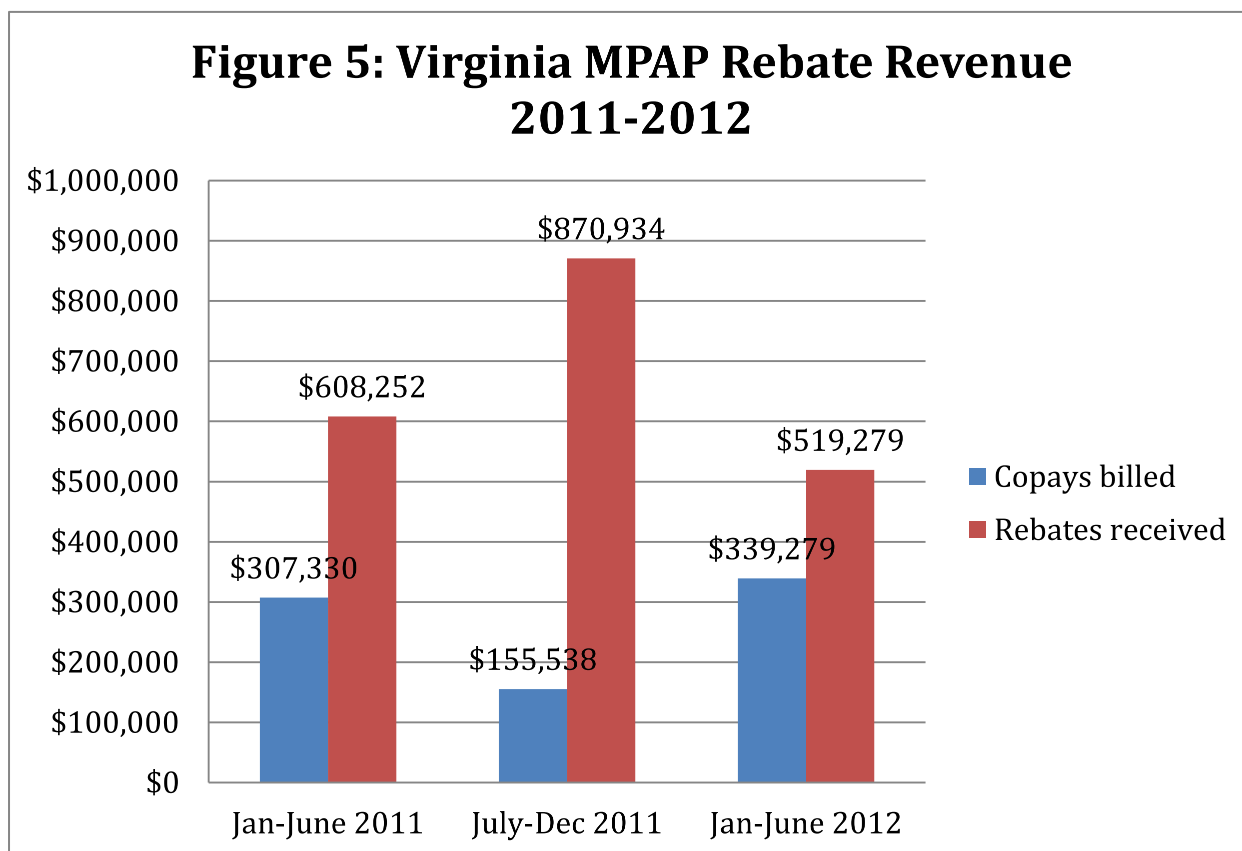
Federal Poverty Level	Premium	Cost Share Cap	Estimated Annual Cost	Percent of ADAP Population
At or Below 100%	$4,955	$6,400	$11,355	63%
101 to 250%	$1,140	$2,050	$3,190	23%
251 to 400%	$3,340	$6,400	$9,740	3%

One important caveat with the information in Table 1 is that these are preliminary estimates for the marketplace, based on existing information. The actual costs for insurance plans under ACA will not be released until Fall 2013 and projections will need to be updated at that time to incorporate the costs and structure of these plans.

Rebates

Rebates on partial pay insurance costs (such as medication co-payments) have become an important source of revenue for VA ADAP over the past two years. These rebates are paid by pharmaceutical companies to state ADAPs through voluntary agreements. As the insurance assistance component of ADAP continues to grow, the rebate revenue is expected to become an even more vital piece of ADAP sustainability over time. Rebates can be strategically used to either purchase medications or offset other costs so that federal dollars can be maximized for medication purchase. For example, some rebates may be used to fund certain services or administrative costs, allowing federal funds to be redirected to ADAP. Figure 5 shows cost

share outlays and rebates received between January 2011 and June 2012, which demonstrate that VDH received almost $2.50 in rebates for each dollar outlaid in co-pays for medications for MPAP during this period.



While rebates are an essential piece of ADAP, revenue projection from the rebates is challenging. As evidenced in Figure 5, the amount of rebate received varies over time and there is not a specific formula to link the rebates to the original cost outlay. Medication prices, upon which rebates are based, are proprietary information that is not released by the pharmaceutical companies. There is also a significant lag time in receiving rebates after the initial cost outlay by ADAP. The rebate can be received from the pharmaceutical company anywhere from 3 to 12 months after the initial co-pay. These factors make it difficult to project rebate revenue and to ensure that the revenue will be available within a specific grant or fiscal year.

In developing projections for ADAP for the next 18 to 24 months, rebates are calculated using a conservative estimate of eighty cents of rebate for each dollar of medication cost share outlay and assuming that rebates are lagged 3 months after the initial cost was paid. Projections are also done with and without rebate revenue, so that total cost outlays for the program are known.

Projections

Table 2 presents ADAP projections for the current and next RW GYs. As stated earlier, the RW GY runs from April through March. The projections assume enrollment into the health care marketplace of 3,000 persons through Virginia ADAP by January 1, 2014. This is the current goal of ADAP, and the efforts underway to meet this goal are detailed in a separate section of

this report. These projections assume continued growth in the program at approximately 100 new clients per month and slightly increasing Direct Purchase ADAP costs per month, based on the current patterns of medication costs. Marketplace projections are based on the KFF rates presented in the previous section. Rebates are based on a conservative estimate of eighty cents for each dollar of medication co-pay outlays. The marketplace insurance cost projections result in an estimated cost before rebates of almost $45M in GY13, an increase of $18.8M from the previous year, when VA ADAP spent $26.2M before rebates. The main driver of the increased costs is the growth in number of persons, with a projected client base of 6,286 compared to 4,647 in the previous year. Another driver of increased costs is the initial cost outlay for the marketplace, which would occur in January through March of 2014. Any rebates for these months would not be recouped until later in the calendar year, which is the next grant year.

Table 2. Projections for VA ADAP as of 6/1/2013: Marketplace Enrollment

	Enrollment into Marketplace (3000 by 1/1/2014)	
	4/2013-3/2014	4/2014-3/2015
Total Persons on Direct Purchase ADAP	5,059	3,241
Total Persons on PCIP/Marketplace	3,170	3,425
Total Persons on MPAP	501	621
Total ADAP Clients (Unduplicated*)	**6,286**	**7,287**
Cost for Direct Purchase ADAP	$28,808,180	$19,131,090
Total PCIP/Marketplace Cost	$13,792,666	$30,510,050
Total MPAP Cost	$2,394,564	$4,166,535
TOTAL ADAP PROGRAM COST	**$44,995,410**	**$53,807,675**
Rebates (lagged 3 months)	$2,665,844	$14,127,000
Total Program Cost after Rebates	**$42,329,566**	**$39,680,675**

***"Unduplicated Clients" accounts for clients served by more than one program, as clients may transition between programs depending on eligibility criteria changes within the current year.**

Sustainment

Evolution of ADAP Eligibility and Monitoring

Criteria for enrollment into ADAP currently requires the applicant to reside in the Commonwealth, have no other sources or personal ability to pay for medications or insurance coverage and co-pays, income of 400% or less of the FPL, and have a documented diagnosis of HIV infection from a medical provider. Enrollment in ADAP occurs with the submission of a complete application, proof of income documents, medical provider information form, and clinical update data. ADAP eligibility staff utilizes a number of resources to verify that each new applicant does not have any third party medication coverage, including a state Medicaid portal, and verification of insurance benefits through the insurance company.

Each ADAP enrollee is recertified for eligibility every six months. This process ensures that enrollees continue to qualify financially for ADAP. Additionally, VDH is able to obtain the

most up-to-date clinical information to determine trends in care, utilization of resources and changes in medication needs. The recertification process allows VDH to quickly know if a current ADAP enrollee has been approved for Medicaid, Medicare, or private insurance coverage for medications so that a client can be served by the most cost-effective component of ADAP (Direct Purchase, MPAP or PCIP/insurance support) or disenrolled if they are no longer eligible.

Insurance Continuation and Support
Individuals with private insurance coverage with medication benefits are eligible for ADAP assistance with medication co-payments and deductibles if all other eligibility criteria are met. This service is coordinated through a contracted pharmacy benefits manager (PBM). This allows ADAP to assist persons with limited income and fiscal resources to continue insurance benefits coverage in an effort to ensure a continuum of care. Additionally, at any point in time, if an individual loses insurance coverage, Direct Purchase ADAP becomes available for medication access. As described above, this aspect of ADAP was implemented during GY 2012, and as this grows, so will program revenue through rebates which will help sustain the program.

Enrollment of Eligible ADAP Clients into PCIP
Efforts to enroll clients into PCIP began in late September 2012, after a small pilot project was completed to test the enrollment process designed by VDH. Enrollment was implemented regionally using an analysis of the PCIP provider network's inclusion of RW-funded providers to minimize disruption to the client-provider relationship. Enrollment began in December 2012 and ended February 16, 2013, when the Federal government unexpectedly announced that PCIP enrollment was suspended due to funding concerns. As of the suspension date, VDH had submitted 449 applications to the PCIP for processing. As of June 2013, 425 ADAP clients had active coverage in PCIP. The average monthly cost for a client on PCIP is projected to be about half of the cost of a Direct Purchase ADAP client.

Increasing Rebates to ADAP
Prior to GY 2013, VDH provided RW funds to external contracted entities to pay private insurance co-pays and operate local pharmacy assistance programs to assist persons with HIV disease. In GY 2013, the process will change to centralize all co-pays and pharmacy assistance in-house, utilizing ADAP funds. This will allow new rebate revenue generation through the use of those funds.

ADAP Data System Improvements
In the past year, VA ADAP has made a number of improvements to its data systems and tracking, which have made more effective use of existing resources and consolidated processes for eligibility and data management. A newly created database contains all application and recertification data for clients and all historical data. Reports are available for eligibility staff to run in real-time and include lists of currently enrolled clients by program and their last date of service, clients who have completed their recertification, clients who have been disenrolled and the reasons for disenrollment and clients who have had prescriptions filled through the PBM. Local health departments are able to receive weekly updates of clients enrolled in ADAP from their medication distribution site, which includes the date of enrollment and date of last prescription filled.

Insurance continuation modules were also added to the database this year, including tracking MPAP and PCIP clients. This includes processes for uploading data weekly to the PBM via a secured file transfer protocol (FTP) site and downloading data from the PBM website for import into the VDH ADAP database. This process prepares VDH to carefully track insurance assistance in anticipation of ACA implementation.

Data sharing within other units of the Division of Disease Prevention at VDH has helped to improve data quality. Data from HIV surveillance and RW services have been utilized to supplement missing laboratory data in ADAP, including CD4 counts and viral loads. Medical data from the Department of Medical Assistance Services (DMAS), which oversees Medicaid, is now obtained on a quarterly basis, and a match is run with ADAP data. Eligibility data from DMAS is obtained every two weeks and is matched with ADAP to determine which clients may no longer be eligible for ADAP and may also be eligible for Medicaid backbilling, recouping ADAP expenditures if clients become retroactively eligible for Medicaid.

Current data initiatives include adding large medical provider sites to the eligibility website, so that the medical providers can access lists of their currently enrolled ADAP clients and adding additional reports for disenrolled and inactive clients. As eligibility for ADAP is changed to align with ACA requirements, the database will be updated as well.

ADAP Advisory Committee

The ADAP Advisory Committee (AAC) was created in 1996, and is comprised of HIV/AIDS medical providers, a pharmacist, consumers, and local health department representation. Members represent the five health regions of the state as well as grantees funded through other RW Parts. The AAC advises VDH on formulary changes, as well as programmatic, clinical, and educational issues as needed. The committee evaluates the impact of changes to statewide HIV services on medication access and uses its findings to formulate recommendations. The Committee reviews data on ADAP utilization and assesses implications of trends and program changes, including the impact on other statewide HIV services. Involvement of the AAC will be critical in monitoring program growth and utilization, and supporting collaboration with increased numbers of providers that will see ADAP-eligible clients once they are insured through the ACA.

Implementing Provisions of the ACA

VDH has engaged in continued in-depth legislative and policy research on the ACA since 2011. This continued research allows VDH to engage in significant planning in advance of implementation of the ACA, which will maximize the cost-effectiveness of the program to serve the needs of eligible clients. Research findings include a detailed overview of the ACA and key features for people living with HIV/AIDS, the impact of Virginia’s benchmark plan selection on RW services and medication access in the Commonwealth, and steps required for provider sites to continue financial stability in a changing health care landscape that will increasingly rely upon third party reimbursement rather than grant funding. Briefings are provided regularly to ADAP leadership on policy and legislative changes, including potential impact to clients and the HIV service delivery system.

Prior to implementation of open enrollment into health insurance through the federally facilitated marketplace, a statewide educational campaign is being conducted by VDH that educates clients,

medical providers, and other stakeholders on the ACA and its intersection with RW. As of June 2013, 489 stakeholders, including medical providers, have attended VDH-facilitated educational forums on ACA. Presentations are updated regularly to incorporate new federal or state guidance to provide stakeholders the most accurate and complete information available. This educational campaign will evolve to include full details of the plans available through the marketplace once released and specifics on next steps for VA ADAP and RW sites to facilitate entry into newly available health insurance.

While VDH will assist eligible clients with enrollment into plans available in the marketplace, continued collaboration between public health and partners in both the public and private sectors will be crucial to discern best practices for enrollment into these newly available forms of coverage. Long standing partnerships with the large medical centers and community health centers that serve people living with HIV across the Commonwealth make this transition feasible.

Future Budget Needs

Based on growth of enrollment and other factors described in this report, additional funds will be needed to support ADAP during State FY 2015. Current projections for this time period indicate that the program may need as much as $18.6 million in additional funding to meet need above current available resources to ensure all eligible clients receive medications to treat HIV infection. To address some of the need, a budget amendment is being prepared for submission to the next session of the General Assembly to request additional state funds.

A number of other actions are being taken to identify additional resources to meet this need. Service funds will need to be redirected to ADAP to ensure medication access, despite the negative impact on the provision of medical care that supports reduced transmission to the uninfected and maintains adherence to medication regimens for greater health outcomes. As described earlier in this report, 80% of the RW Part B grant is allocated to ADAP services. Support for medical care (including laboratory tests to monitor medication safety and effectiveness), medical case management and medical transportation to clinic visits make up the majority of the 10% of funding supporting other medical care services. This funding amount has decreased over recent years in order to shift resources to ADAP. However, a level of support for medically-related services is critical to assist clients in benefitting from medication treatment and achieving viral suppression (a reduction in the amount of HIV in the body). HIV medications require a very high level of adherence to the prescribed regimen in order to be effective. Adherence of less than 95% leads to viral resistance and increased volume of virus in the body. This results in increased risk of HIV transmission to others, including transmission of HIV that is resistant to treatment. Viral suppression is a key measure of treatment effectiveness, resulting in improved health outcomes for the infected client, decreased mortality, reduced medical costs such as hospitalizations and delay or avoidance of need for more expensive second and third line medication treatments. Any additional federal grant opportunities, such as ADAP Emergency Relief Funds and other supplemental grants, will be pursued if available.

ADAP is now serving almost 5,000 clients, the highest number in the history of the program and enrollment continues at approximately 100 new clients monthly. Projections indicate that enrollment will increase by at least 16% during RW GY 2014 (April 1, 2014 – March 31, 2015).

As described earlier, the increase in program enrollment and thus program need is expected to continue due to several key factors. Current Public Health Service HIV treatment guidelines support initiating treatment with medications early in the course of disease to suppress HIV and improve health outcomes. Demonstration projects in Virginia seek to increase early identification of HIV infection, facilitate linkage of newly diagnosed clients to care and improve retention in care, resulting in increased demand for medications to treat HIV. VDH is expanding HIV testing efforts throughout the state. Early testing and treatment strategies are key to long term control of the HIV epidemic and are addressed more fully in the last section of this report.

As described in the 2011 and 2012 General Assembly Reports and as referenced at the beginning of this report, several actions were taken to increase the efficiency of ADAP, resulting in the ability to serve more clients at reduced costs. Federal funds previously allocated to HIV services have been reallocated to ADAP. Client eligibility determination has been moved in-house to VDH, and clients are recertified for eligibility every 6 months (as opposed to the prior annual schedule) to ensure only those eligible are served. State residency, eligibility for other payer sources such as Medicaid, and consistent use of services are verified continuously, and inactive or ineligible clients are immediately disenrolled. Additional cost savings are seen through aggressive medication inventory management and the restriction of medication refills to 30 days at a time, allowing maximum reimbursement through Medicaid backbilling and reducing medication wastage. The cost of medications was reduced by an overall average of 8% through participation with national negotiations with pharmaceutical companies through the ADAP Crisis Task Force.

Most impactful is the use of ADAP funds to support medication access through paying clients' share of insurance costs (including PCIP and Medicare D), resulting in the ability to serve 2-4 clients for the same cost as 1 client served through Direct Purchase medications. This is achieved through a net cost reduction per client after recouping rebates that pharmaceutical companies provide when ADAP pays any portion of medication costs.

These cost savings measures have resulted in sustaining clients on ADAP at a lower cost. The projected net program cost (cost after receiving rebates) for ADAP in RW GY 2014 is approximately 6% less expensive than in RW GY 2013 ($39,680,674 vs. $42,329,566) due to the increased ability to support clients on plans available through the federal health insurance marketplace, beginning January 2014. However, even though the program will be 6% less expensive to operate while serving approximately 16% more clients (7,287 unduplicated clients in GY2014 versus 6,286 in GY 2013), the program will experience a shortfall in resources to sustain all clients in need of medications.

VA ADAP plans to initially serve approximately 3,000 clients enrolled in the health insurance marketplace, which is about 65% of the total 4,593 ADAP clients projected to be actively receiving services by that time. The gross program cost (before rebates) for RW GY 2014 of $53,807,674 will be lowered to a net program cost (after rebates) of $39,680,674 due to the increased numbers of clients being assisted with medication copayments resulting in rebate revenue. Program costs include $19,131,090 for direct medication purchase for clients not eligible for insurance or those transitioning to insurance, and the remaining funds would support insurance assistance.

The ability to serve clients enrolled into insurance through the federal marketplace lowers program costs and contributes to the ability to serve increasing numbers of clients. Serving clients with insurance is more cost effective than serving all clients with direct purchase medications, which would be approximately 36% more expensive ($53.9 million) if insurance were not available. Options for obtaining additional resources other than increased General Funds are limited at this time. Due to budgetary constraints (sequestration) at the Federal level, the RW budget for GY 2013 has been reduced by 5.5%, and there is no indication that these funds will be restored. There is some indication that there may be additional Federal funding reductions for this program in future years.

As stated previously, ADAP provides resources to treat HIV disease which both reduces overall health care costs for clients and reduces transmission of HIV to others. Studies have demonstrated that untreated HIV creates an increased rate of HIV transmission from infected to uninfected persons. Mortality rates are also much higher when persons do not receive the medications that ADAP provides. Studies have shown that individuals with HIV infection, regardless of immune system function, have higher rates of death when their HIV is untreated than when they are on antiretroviral therapy. Figure 7 demonstrates that antiretroviral therapy provides benefits to those with HIV that have been shown to exceed survival gains from treatment for many other diseases, including heart disease and certain forms of cancer.

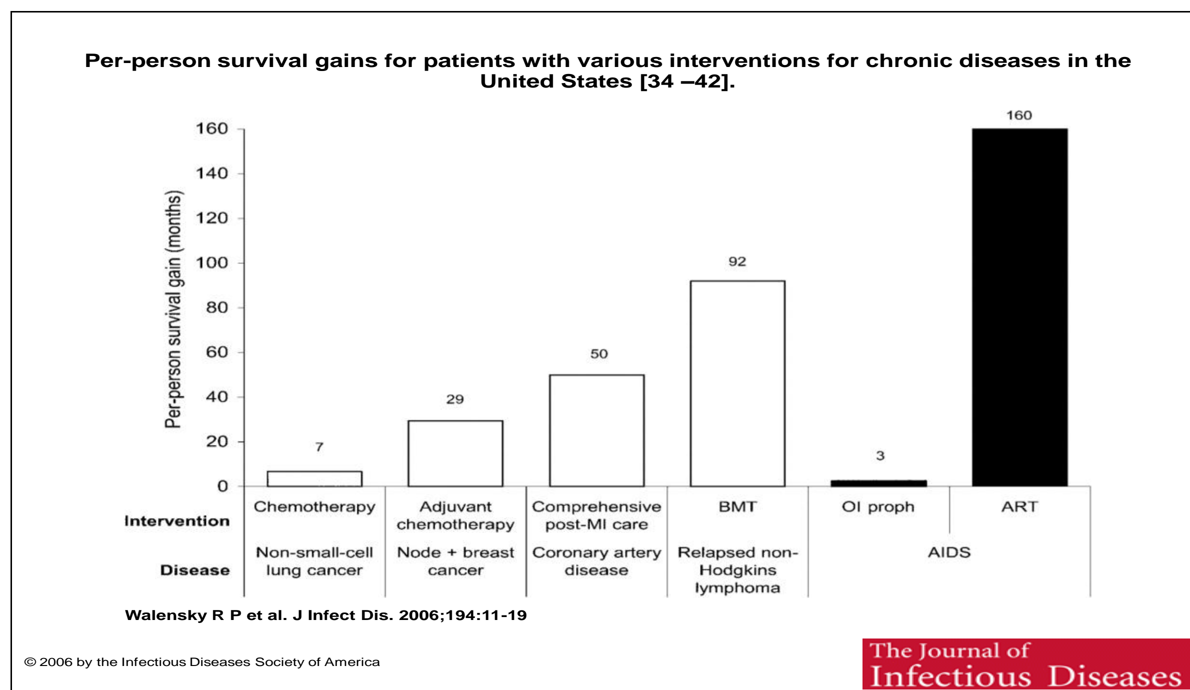


Figure 7

Consequence of limited access to HIV treatment

If ADAP does not have adequate resources to serve its clients, resulting untreated HIV disease has significant consequences. At the end of 2012, 24,700 people in Virginia were living with HIV/AIDS. A recent national survey shows HIV has broad impact with over four in ten

Americans now reporting they know someone who is HIV-positive or has died of AIDS.[5] Availability of HIV treatment affects families, employers, and communities of those with HIV disease.

Worldwide, HIV is the strongest risk factor for tuberculosis (TB) and an estimated 1.4 million people living with HIV developed TB causing 500,000 (23%) of total HIV-related deaths[6], illustrating the role HIV plays in diseases with broad public health impact.

If additional resources are not available to support Virginia's ADAP, enrollment in the program will have to be capped and a waiting list re-instituted statewide, jeopardizing reliable access to HIV treatment. Alternative medication sources (e.g., PAPs) may not be available: pharmaceutical companies may cap or limit their PAPs since other states are also experiencing need outpacing resources. Untreated individuals experience declining health outcomes, leading to increased hospitalizations and mortality. In addition untreated individuals are more likely to transmit infections to uninfected persons, leading to increased morbidity. Inconsistent access to medications increases the development of treatment resistant forms of HIV which can be transmitted to others.

Current guidelines support HIV treatment as soon as possible after HIV is diagnosed; in order to improve individual health, reduce transmission and eventually change the course of the HIV epidemic. The public health and economic impact of untreated HIV disease is significant. An analysis by national experts describes transmission rate as an underutilized measure of the speed at which the epidemic is spreading. Their review of data showed a HIV transmission rate of approximately 4 transmissions/100 living cases/year.[7] If applied to Virginia, this equates to approximately 988 new HIV infections each year. Mathematical modeling of the impact of an aggressive testing initiative followed by immediate access to HIV treatment (sometimes referred to as "Test and Treat") suggests the possibility of eliminating HIV in the future. Models estimate transmission rate reductions ranging from a low of 26% to as high as 91%.[8] Using the conservative 26% estimate, this would equate to 257 averted HIV infections/year in Virginia. At a typical lifetime cost of HIV care of $500,000 (range $400,000-$670,000)[9,10] yearly averted transmission would save $128 million in healthcare costs.

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[5] The Washington Post/Kaiser Family Foundation 2012 Survey of Americans on HIV/AIDS available online at http://kaiserfamilyfoundation.files.wordpress.com/2013/01/8334-f.pdf

[6] Granich R, Crowley S, Vitoria M, Smyth C, Kahn JG, Bennett R, Lo YR, Southeyrand Y, Williams B. Highly active antiretroviral treatment as prevention of HIV transmission: Review of scientific evidence and update. Current Opinion in HIV and AIDS. 2010;5:298–304 available online at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3501989/.

[7] Holtgrave DR, Hall HI, Prejean J. HIV transmission rates in the United States, 2006–2008. Open AIDS J 2012;6:26–8. Available online at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3319908/

[8] Granich R, Crowley S, Vitoria M, Smyth C, Kahn JG, Bennett R, Lo YR, Southeyrand Y, Williams B. Highly active antiretroviral treatment as prevention of HIV transmission: Review of scientific evidence and update. Current Opinion in HIV and AIDS. 2010;5:298–304 available online at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3501989/.

[9] Sloan CE, Champenois K, Choisy P, et al. Newer drugs and earlier treatment: impact on lifetime cost of care for HIV-infected adults. AIDS. 2012;26(1):45–56 available online at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3237010/

[10] Schackman BR, Gebo KA, Walensky RP, et al. The lifetime cost of current human immunodeficiency virus care in the United States. *Medical Care*. 2006;44(11):990–997.

If ADAP enrollment is limited or closed, Virginia would not be able to ensure its residents receive the national standard of care for HIV disease, “Test and Treat.” Virginia could experience several hundred preventable HIV infections annually. Neighboring jurisdictions, such as the District of Columbia, are currently engaged in a national research project to implement “Test and Treat.” A Virginia waiting list for ADAP would result in a jurisdictionally-based health disparity with potential long-term epidemiological impact.

In summary, VA ADAP eliminated the prior waiting list through implementing program efficiencies, working closely with community partners, and receiving additional financial resources. Program enrollment has continued to grow dramatically due to factors such as changing treatment guidelines and efforts to engage and retain more people into HIV care. ADAP will benefit from assisting 80% of the current client population with enrollment into insurance offered through the new federal insurance marketplace, and will support premium and medication co-payments through that mechanism at a lower net cost than providing direct purchase medications to those clients. However, VA ADAP will again face a resource shortfall by State FY 2015 without additional financial contributions. Consequences of implementing another medication waiting list in Virginia can include poor (and more expensive) health outcomes for those living with HIV and can lead to increased transmission of HIV throughout the Commonwealth.