The National
ADAP
Working Group

An AIDS Drug
Assistance Program
Advocacy Coalition

1773 "T" Street, NW
Washington, D.C. 20009

Ph: (202) 588-1775
FAX: (202) 588-8868
Email: weaids@tiicann.org

aaa+ ADAP Advocacy Association
Abbott Laboratories
AIDS Alabama
AIDS Action Council
AIDS Alliance for Children, Youth & Families
AIDS Foundation of Chicago
AIDS Project Los Angeles
AIDS Treatment Data Network
American Academy of HIV Medicine
Amgen
Boehringer Ingelheim
Bristol-Myers Squibb
Broward Log Cabin Club of Florida
Cities Advocating Emergency AIDS Relief Coalition
EMD Serono, Inc.
Georgia ADAP Task Force
Glaxo Smith Kline
Hoffmann-La Roche
Log Cabin Republicans
Los Angeles Gay & Lesbian Center
Magic Johnson Foundation
Merck & Co.
National AIDS Treatment Advocacy Project
National Association of People With AIDS
National Minority AIDS Council
Positive Opportunities
SAVE ADAP Inc.
Southern AIDS Coalition (SAC)
The AIDS Institute
Tibotec Therapeutics
Title II Community AIDS National Network
2/08

Director
William E. Arnold

Ryan White CARE Act, Title II

AIDS Drug Assistance Program (ADAP)

Annual
Ryan White CARE Act –Part B (Title II)
ADAP Needs Projection.

ADAP Program Year
(1 April, 2009 – 31 March,2010)

Funded by the Federal Budget
For

FY 2009

Budget Projection

#44

Summary 7 Pages

10 February, 2008

Copies of this pharmacoeconomic model projection are available electronically on www.tiicann.org or - contact us.

Introduction to the ADAP Budget Projection Model, Fiscal Year 2009

The National ADAP Working Group is a unique ad hoc coalition of HIV/AIDS community-based organizations, health care providers, biotechnology and pharmaceutical research companies. Our mission is to ensure adequate access to HIV/AIDS-related therapies through the AIDS Drug Assistance Program (ADAP), funded under Title II of the Ryan White CARE Act.

ADAP has played a key role in the federal and state response to the U.S. domestic AIDS epidemic. Since the advent of Highly Active Anti-Retroviral Therapy (HAART) in 1996, ADAP has provided preventative medications to hundreds of thousands of Americans living with HIV who are uninsured or underinsured, keeping them out of costly hospital care and off Medicaid. With advances in treatment research, managing HIV disease has become a life-long commitment. Combined with new HIV infections at the rate of 60,000 per year, the demand for ADAP continues to grow.

In order to quantify this growing need, the National Alliance of State and Territorial AIDS Directors (NASTAD), working with national ADAP experts, have utilized a pharmacoeconomic model[1] to project the amount of funding needed to adequately treat Americans eligible for ADAP in upcoming fiscal cycles. Using current utilization trends as reported in a June 2007 survey through the National ADAP Monitoring Project[2], this model computes the increased annual cost of pharmaceuticals to ADAP, based on current program dispensing patterns, increases in new ADAP clients at historical rates and drug cost inflation.

This pharmacoeconomic model enables us to estimate the economic need of the ADAP program for the upcoming fiscal year. This "need" number represents the amount that would allow each state to provide treatment for ADAP clients under the current eligibility rules for each individual state.

For the next fiscal cycle, however, two recent changes to the environment in which ADAP operates suggested the need for a revised approach to estimating the budget need. First, reauthorization of the Ryan White Care Act has resulted in a significant shifting of ADAP Earmark funds between states due to a revised

[1] J Acquire Immune Defic Syndr. 2000 Apr 1;23(4):302-13. Impact of zidovudine-based triple combination therapy on an AIDS drug assistance program. Mauskopf JA, Tolson JM, Simpson KN, Pham SV, Albright J. Research Triangle Institute, Research Triangle Park, North Carolina, USA.

[2] The National ADAP Monitoring Project is a collaborative project of the Kaiser Family Foundation and the National Alliance of State and Territorial AIDS Directors (NASTAD).

The NATIONAL ADAP WORKING GROUP 1775 "T" St. NW Washington, DC 20009
(202) 588-1775

distribution formula and an increased proportion of the allocation set aside for ADAP Supplemental funds to address access disparities in FY07. Waiting lists have been eliminated, and formularies and income eligibility criteria have been increased in states, where access has been limited for years.

The second change that has impacted ADAPs nationally is implementation of Medicare Part D. Many individuals who had previously relied on ADAP for access to medications have enrolled in Part D. Those eligible for the Low Income Subsidy (LIS) have the vast majority of their drug expenses paid by Part D. However, many other individuals with Part D coverage continue to receive assistance from ADAPs to meet their deductibles and co-payments, and receive full coverage from ADAP when they reach the "donut hole".

Due to both of the environmental changes (Ryan White funding changes and Medicare Part D) and an increase in State appropriations for ADAP and increased rebates from drug companies, ADAPs nationally were in a state of budget "equilibrium" in FY07 and were able not only to reduce formulary and eligibility disparities between states but to provide access to medications to all eligible individuals. This has led to a revised focus of the projection model, to estimate the incremental costs required to provide coverage for new clients enrolled in ADAPs in FY08 and FY09. Total funding is calculating by adding the incremental costs to the inflation-adjusted drug costs for the base population of ADAP clients enrolled in FY07. Additionally, rather than estimating medication costs through modeling, ADAP drug expenditure data are used to calculate the average monthly medication cost per client.

The analyses does not attempt to account for further possible changes in eligibility criteria; drug formularies; changes in state Medicaid or other public health insurance programs; or other possible variables that could impact state ADAPs in the future.

Projection Summary

For FY2009, ADAP needs a federal increase of **$134,845,718** to adequately meet the projected program demand. In addition, the model estimates a federal ADAP shortfall in the amount of **$39,591,618** for FY2008.

Summary Table

	FY 2008	FY 2009
Model Projected Cost for New ADAP clients	$25,207,129	$73,810,172
Base Program Drug Inflation Component	+ $43,282,393	+$45,257,453
FY08 Revenue Need Remaining		+$49,489,522
Total ADAP Budget Increase Required	**$68,489,522**	**$168,557,147**
FY 2007 Federal Appropriation Increase	- $19,000,000	-$0
Total Revenue Increase Needed	**$49,489,522**	**$168,557,147**
80% Federal Share of Increase	**$39,591,618**	**$134,845,718**
20% State Share of increase	$9,897,904	$33,711,429

Projection Model Details

1. Base population and estimated monthly program growth

Using annual ADAP utilization data (number of clients who have filled at least one prescription), from June 2006-June 2007, the monthly program growth rate is estimated to be approximately 386 clients. The increase in new clients is shown in the accompanying chart, starting at the beginning of FY08 (April 2008). Also shown is the total client population, based on the 101,049 clients utilizing ADAP in June 2007. Monthly client utilization is projected forward from the beginning of ADAP FY2008 (April 1, 2008) to the end of FY2009 (March 31, 2010).

Population Growth Chart

Year	Month	Cumulative New Clients	Total Clients
2008	April	386	104,904
	May	771	105,290
	June	1157	105,675
	July	1542	106,061
	August	1928	106,446
	September	2313	106,832
	October	2699	107,217
	November	3084	107,603
	December	3470	107,988
2009	January	3855	108,374
	February	4241	108,759
	March	4626	109,145
	April	5012	109,530
	May	5397	109,916
	June	5783	110,301
	July	6168	110,687
	August	6554	111,072
	September	6939	111,458
	October	7325	111,843
	November	7710	112,229
	December	8096	112,614
2010	January	8481	113,000
	February	8867	113,385
	March	9252	113,771

2. Cost of therapy per-member-per-month (PMPM)
The cost of providing drugs to ADAP clients (inflation adjusted for the projection period) is based on the weighted average cost ($997.54) reported by ADAPs in June 2007. This approach takes into account the variability of client needs for ADAP support for both ADAP full pay and "partial pay" (e.g., partial private insurance and Medicare Part D) clients. The cost is adjusted based on the rate (19.1%) of additional "discount" that ADAPs are able to achieve through rebates and cost recoveries to arrive at a net cost of $807.01 in June 2007. For FY2009 the PMPM for drugs is calculated to be $862.46.

3. Base program drug cost inflation component
In FY2007, the total reported budget of all ADAPs was $1,502,860,871. Under the Federal 340B Drug Program, in which all ADAPs participate, the increase in drug prices is limited to the Consumer Price Index for All Urban Consumers (CPI-U). An annual inflation rate of 2.88%, the average CPI-U for the past five years, was applied to the total budget to project the cost of maintaining coverage for the ADAP "base" population.

4. Health system costs
The model estimates the impact on health care system costs as a function of clients' health status and their access to antiretrovirals and medicines for the prevention and treatment of opportunistic infections. When individuals are not provided access to these medications their HIV disease continues to progress, resulting in an increased incidence of opportunistic infections, and increased medical treatment and hospitalization costs. The model was used to estimate the FY2009 health system costs that would be incurred if funding is not available to cover new client growth. The disease status of these new clients was modeled using the CD4 count distribution of new clients in 2007 from four large states (CA, FL, NJ and NY) which represent 44.5% of June 2007 clients served. If funding limitations for ADAP in FY2009 were to leave the estimated 386 clients per month without access to medications, it is projected that 7,375 additional cases of opportunistic infections would occur. This includes 5,000 more cases of cancer (Kaposi's sarcoma and lymphoma) and an additional 1,251 cases of pneumocystis carinii pneumonia (PCP), a fungal infection that is a major cause of death in people with HIV. In this scenario the national health care system would spend $83,944,327 on medical treatment for opportunistic infections. This represents an increase of $58,496,443 over what would be spent on such treatment if ADAPs had sufficient funding to enroll and provide medications to these clients.

5. Funding needs and clients
The following chart illustrates the number of ADAP clients that could be served by the model's estimate of needed revenues in FY09:

Funding Source	Need Amount	Number of Clients
Federal Share (80%)	$134,845,718	13,029
State Share (20%)	$33,711,429	3,257

Total Need	$168,557,147	16,286

Conclusions

- ADAPs achieved a measure of stability in FY2007 due to environmental changes and increased revenues, which allows a revision in the model to focus on the future incremental costs to ADAP.

- The revised methodology reduces the number of assumptions required and provides more accurate assessment of actual drug costs.

- There is an estimated need for $49,489,522 in additional revenue in FY2008 to allow continued growth.

- The Federal Need in FY2009 is estimated to be $134,845,718 to allow ADAPs to continue to meet the enrollment demands of new clients, as well as pay for the annual inflation costs for drugs to their base population.

- The model estimates that the national health system would avoid costs of $58,496,443 for medical treatment of opportunistic infections if ADAPs are able to provide access to antiretroviral therapy for new clients in FY2009.

The ADAP Working Group endorses the enclosed budget estimates as an accurate projection of the costs of providing necessary HIV/AIDS treatments to uninsured and underinsured ADAP clients in Fiscal Year 2009, (April 1, 2009 - March 31, 2010).

It is not possible to anticipate changes in the standard of HIV care that may occur within the timeframe of this projection. The projection will be updated whenever new and validated information that impacts the projection becomes available.

It is not possible to anticipate all potential Medicare and Medicaid actions which have the potential to change access to drugs for thousands of HIV+ patients in state level Medicaid "cutback" actions or all possible impacts of the evolution of Medicare Part D in FY2008 & 2009. What we can say is ADAP history clearly indicates that "normal conditions" have produced a net monthly increase in the number of HIV+ Americans who will need ADAP services in every state, territory and political jurisdiction. With adequate ADAP resources we will be able to treat them. If resources to ADAP are inadequate – ADAPs will NOT be able to treat them, but health care costs will increase in other areas as medical providers seek to treat opportunistic infections resulting from disease progression.

The NATIONAL ADAP WORKING GROUP 1775 "T" St. NW Washington, DC 20009
(202) 588-1775

William E. Arnold
Director, The National ADAP Working Group

This is the 11th consecutive year that this ADAP projection has been generated using data reported by ADAP and the same basic pharmacoeconomic modeling.

A set of slides illustrate the methods utilized, the results projected (in additional detail) and provide additional information. It is available separately from this summary. Contact weaids@tiicann.org if you need them or the complete __ page projection (which includes this summary AND the complete slide set).

These documents are all available electronically – contact us for electronic copies or web site locations.

# # # #