

ADAP ADVISORY COMMITTEE MEETING
December 12, 2007
HENRICO DOCTORS HOSPITAL

Members Present: Linda Eastham RN FNP, George Kelly, Craig Parrish RPh, Donald Walker, Edward Oldfield MD, Greg Townsend MD, Peg Tipple MD, Karen Council OSS.

Guests: Johanna Brown MD, Rochelle Klinger MD, Kevin Jackson, Mark Baker

VDH Staff: Carrie Dolan, Khalid Kheirallah, Diana Jordan RN MS, Steve Bailey LCSW, Faye Bates RN

Diana Jordan, Director of Health Care Services, called the meeting to order at 10:15 a.m. Introductions were made. As a courtesy to guests, members and other attendees, ground rules were reviewed. The ADAP Advisory Committee is a public meeting and guests are welcome to attend. Guests are observers and were asked to refrain from commenting unless asked a question by a member or VDH staff person. The minutes of the September 18, 2007 meeting were reviewed and approved as written.

Diana Jordan presented an update on the state budget shortfall. ADAP funding was not affected, but the State Pharmaceutical Assistance Program (SPAP) was, resulting in a 5% funding reduction and therefore, a decrease in the number of clients who can receive full cost sharing assistance. In addition, two other state funded programs, Virginia HIV/AIDS Resource and Consultation Center, and the Arthur Ashe Program were impacted by the Governor's 5% budget reduction. VDH is working to reallocate some federal funds to both programs, either directly or through the regional lead agency to mitigate the impact. Federal regulations prohibit the use of federal funds for SPAP and VDH is not able to make up the shortfall created by the reduction to SPAP at this time.

Steve Bailey presented an update on the SPAP. The contractor has started enrolling clients for full cost sharing assistance. The contractor, Patient Services Incorporated (PSI), has completed a data run to ensure all medications currently accessed through ADAP are covered under each client's Medicare Part D policy. The data sharing agreement is in place with the Centers for Medicare and Medicaid Services (CMS) and is moving forward. An update was given on the progress of the centralized eligibility. The Request for Proposal (RFP) is due to be released soon. Hopefully, a vendor will be identified by April.

Diana Jordan gave an update on unobligated funds and carryover. Guidance is still being clarified, but it looks like we may have the ability to strategically use ADAP purchasing to ensure that at least 98% of funding is obligated during this grant year. Any unobligated funds would be obligated to ADAP via purchase order that would allow them to be utilized in the subsequent grant year. This mechanism will assist in meeting the

requirement to use 75% of service dollars for core services and to obligate 98% of funds by the year's end.

VDH received slightly over \$700,000 for implementation of the, "Expanded and Integrated HIV Testing for Populations Disproportionately Affected by HIV", with the focus of this initiative expanding routine testing in health care settings. VDH is targeting a community health center on Virginia's Eastern Shore, emergency rooms in Northern, Central, and Eastern Regions, jails in the Eastern and Central Regions and other sites, including a social marketing pilot in the Northern Region.

Diana Jordan gave an update on surveillance activities. CDC has not released incidence and resistance information for local use. Publication on incidence data is anticipated in the near future in a major peer reviewed journal. It is expected that a presentation could be planned for the next ADAP Advisory Committee meeting. Although Virginia received increased funding for incidence, resistance funding was discontinued. In addition, the National HIV Behavioral Surveillance Project did not receive funding for 2008. The project will terminate at the end of the month. Progress on the Medical Monitoring Project continues. All selected sites except the Veterans Administration agreed to participate. Client sample lists are currently being communicated to sites with interviews anticipated to begin in the next few weeks.

Steve Bailey gave a presentation on the possibility of increasing the federal poverty level (FPL) for ADAP services. There has not been a standard method used by other states to proactively assess the programmatic impact of increasing FPL, generally evaluating the impact after the increase was made. Data from states that have a greater than 300% FPL range in eligibility for ADAP was reviewed, and data was compared between states that have a similar distribution of poverty levels, similar ranking in national wealth, and similar numbers of ADAP clients to Virginia. (Information was obtained from the April 2007 National ADAP Monitoring Project Annual Report and 2006 U.S. Census data). Based upon this information, it is estimated that Virginia ADAP could experience an increase in client enrollment ranging between 4% and 5.58%. The estimated cost impact to ADAP would be between \$1.9 and \$2.7 million annually. Another question raised was "should the FPL be increased to 500%?" Additional information to consider before deciding whether to increase FPL eligibility includes the potential impact of CDC testing guidelines, a planned "exit strategy" should funding be significantly decreased, and whether to also increase FPL eligibility for other Ryan White Part B services. This will continue to be investigated; the Committee will be updated at the next meeting.

If the FPL were raised for ADAP, the increase would not apply to the SPAP, as SPAP eligibility is set by the General Assembly.

A request from the previous meeting was to have an experienced mental health clinician address the committee members on mental health medications. Rochelle Klinger MD was the guest speaker for the committee meeting, arranged through the Pennsylvania/Mid-Atlantic AIDS Education and Treatment Center (AETC). Dr. Klinger is a psychiatrist for the Hanover County Community Services Board, a Clinical Professor

of Psychiatry at Virginia Commonwealth University, and is in private practice. Dr. Klinger's presentation was entitled, "HIV and Psychiatric Comorbidity: Characteristics and Treatment." The objectives of the presentation included reviewing characteristic features of major comorbid psychiatric conditions, review of medications and drug-to-drug interactions (particularly antiretrovirals) and reviewing characteristics of the public mental health system in Virginia. Some of the drugs recently added to the ADAP formulary were discussed with some recommendations and potential issues with drug-to-drug interactions.

Dr. Klinger suggested considering removing thiorazine from the formulary due to efficacy and monitoring issues. She suggested adding valproate/divalproex sodium (Depakote) as an alternative medication to treat bipolar disorder, given potential renal involvement with lithium. Other formulary related comments offered were the side effects of Zyprexa (causes an increase in weight gain, elevated blood lipid levels and elevated blood glucose levels), adjusting Geodon dosage for patients taking protease inhibitors, and anecdotal information about abuse potential of Seroquel (not on ADAP formulary).

The next item on the agenda was a follow up from the previous meeting to discuss the overall mission of the ADAP Advisory Committee. Linda Eastham and Faye Bates led the discussion of the mission statement. The questions for discussion were, "What is the vision of the Virginia ADAP Program?" And, "What are the priorities of the ADAP Program?" Discussion followed with suggestions and ideas for the vision statement, which included:

- To oversee the responsible provision and distribution of medications and/or supplements needed for people living with AIDS (PLWHAs) to maintain a good quality of life while living with an often long term chronic illness. This should be done with as minimal barriers as possible to ensure equal access for all PLWHAs and to prevent loss of life which in all likelihood could have been preventable.
- No HIV positive Virginian will live without medications
- No waiting list for ADAP
- No medication expenditure or medication caps
- ADAP should be a "safety net" to ensure that qualified people that need medications will be able to access them
- Expanding the formulary to include medications for smoking cessation, and nutritional supplements
- Medication decision making should be based upon the Department of Health and Human Services (DHHS) Standards of Care
- Dissemination of information to medical prescribers.
- Impose no harm
- Medications added to the formulary must be FDA approved and supported by scientific studies
- Provide services to Virginia residents regardless of immigration status
- Provide medications for all DHHS and HIV related care
- Examine if ADAP should serve more clients versus increasing the number of medications on the formulary

- Assisting ADAP clients with insurance premiums

HIV-related care led into another brief discussion on what is “HIV-related”. Items identified were:

- Adherence
- Antiretrovirals and all medications to treat opportunistic infections
- Equitable access to ADAP
- Looking at a reduced co-payment system for generics, such as Walmart’s program.
- Providing medications to clients that are not available through pharmaceutical industry patient assistance programs. Also to ensure that ADAP is the payer of last resort.

ADAP mission and scope discussion will be a continuing agenda item for the next ADAP Advisory Committee Meeting and future meetings.

A draft of the By-Laws was submitted in the meeting packets. However, it was suggested to view other states that have Advisory Committee By-Laws prior to a discussion for Virginia ADAP.

Anne Rhodes presented the ADAP Data Report. The value of filled prescriptions from April 2007 to March 2008 is projected to be \$23,521,365. The monthly expenditure range is 1.9 to 2 million dollars per month. The number of prescriptions per person per month has decreased due to antiretroviral combination regimens with fewer prescriptions, but more drugs prescribed. Medication utilization for Hepatitis C treatment has declined significantly.

The presentation also revealed that the newer ADAP population has a higher percentage of Hispanic males and African American females. The population that has remained on ADAP for more than 3 years has a higher percentage of white males. The new ADAP enrollees are younger. The average age of new clients in the last 3 years is 40.16 years compared to 45.4 years. The largest enrollment increase has been in the 13 to 34 year age range with 28% of new clients in this category, compared with 10.8% of continuing clients.

There was a request from the committee to look at the length of time clients have been on ADAP with a breakdown of new clients by year with demographic information. It was suggested to communicate to medical prescribers regarding the availability of Hepatitis C treatment available through ADAP.

Faye Bates gave a formulary update. Raltegravir was added to the formulary on November 8, 2007. The contract with Monogram Biosciences for the Trofile blood test is pending. Ryan White Part B funds will be used to pay for the Trofile test. Another antiretroviral medication, a second generation NNRTI (TMC-125) is due for approval soon.

A request was made at the September meeting to revisit the medication exception criteria for darunavir. After a lengthy discussion, the committee decided to change the exception criteria for darunavir, enfuvirtide, and tipranavir as follows:

“NRTI and NNRTI experienced or contraindicated, with either a viral load greater than 400 or intolerance to current regimen **and** prior experience with one or more PIs.”

It was also decided that the medical exception criteria for raltegravir is as follows:

“NRTI and NNRTI experienced or contraindicated, with either a viral load greater than 400 or intolerance to current regimen **or** prior experience with one or more PIs.”

Once the new second-generation NNRTI medication is FDA-approved, the need for exception criteria will be determined.

The next meeting will be scheduled in March 2008. The committee will be notified of date and time. The meeting was adjourned at 2:00 p.m.

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