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[THE NORTH CAROLINA AIDS DRUG ASSISTANCE PROGRAM: A PRIMER AND OPTIONS GOING FORWARD]



NORTH CAROLINA COMMUNITY
AIDSFUND

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EXECUTIVE SUMMARY

The AIDS Drug Assistance Program (ADAP) is a federal-state program that provides prescription drugs to HIV positive individuals who are under-insured or uninsured and low income. The purpose of the program is to provide access to medication treatment and prevent health deterioration of those living with HIV. Because ADAPs are not entitlements and are financed through discretionary funding, there are times when ADAPs must balance increases in utilization with resources that are subject to change. Indeed, in January 2010 North Carolina capped enrollment in the program and limited the medication formulary, the quantity and type of drugs available. These actions took place as a result of tenuous economic conditions that have caused increases in unemployment and uninsured rates across the state, along with increases in ADAP utilization and drug costs.

North Carolina's current cost containing measures, including a wait list, will have a significant impact on clients, providers, community based organizations, and local communities. Without access to antiretroviral drugs through ADAP, many of North Carolina's low income HIV positive citizens will go without life saving medication, posing significant community and individual costs in form of higher rates of illness, loss of productivity, and medical costs. Providers will face a greater burden of increased use of services without the necessary resources to match the need.

Cost controlling measures taken by state officials are not new, and are not limited to North Carolina. As of May 2010, over fifteen other states have taken cost containment measures in response to budget shortfalls and increased utilization. There are a number of options states may choose, each with potential benefits in savings, and draw backs. These options include establishing wait lists, changing clinical and financial eligibility, managing prescription utilization, and using ADAP funds to purchase or continue insurance place for people eligible for ADAP.

In moving beyond the North Carolina ADAP crisis, there are steps that can be taken, and are currently being taken, to address the immediate need and the long term stability of the program. The National Alliance of State and Territorial AIDS Directors (NASTAD) has identified a three pronged strategy that include advocacy at the state and federal level, and creating working partnerships with pharmaceutical companies. Additionally, the Patient Protection and Affordable Care Act will have significant implications for the HIV community and state ADAPs.

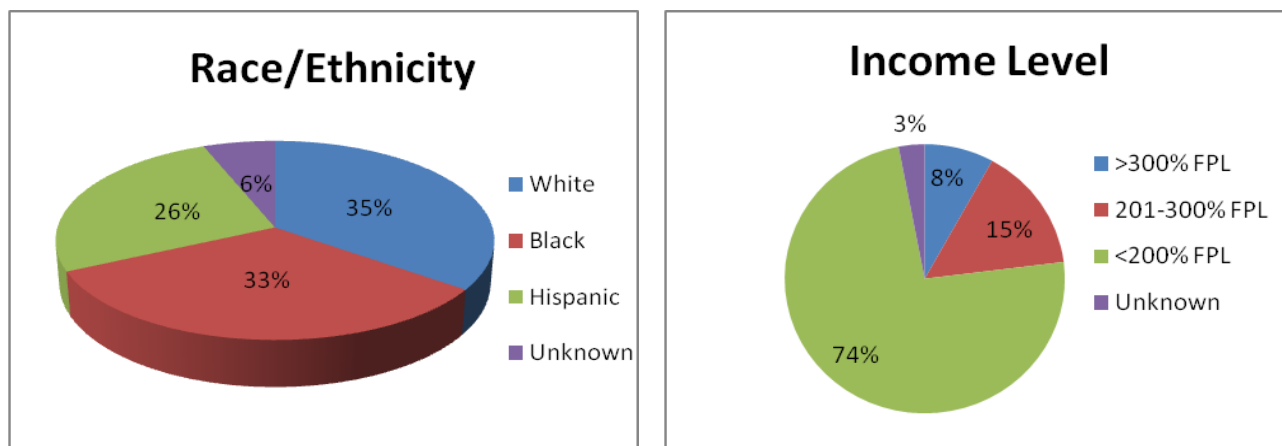
Absent secure and stable state and federal funding, there is no single solution, or panacea, to address the gap between resources and need within North Carolina ADAP. The ADAP waiting list in North Carolina is the highest in the country, and current efforts by NCAAN to advocate for funds to reopen the program at 125% is an important strategy to address the immediate need. This paper discusses additional steps that can be taken that may ensure a more sustainable fiscal path for ADAP in the future.

INTRODUCTION

The AIDS Drug Assistance Program (ADAP) is a federal-state program that provides prescription drugs to HIV positive individuals who are under-insured or uninsured and low income. The purpose of the program is to provide access to medication treatment and prevent health deterioration of those living with HIV. Because ADAPs are not entitlements and are financed through discretionary funding, there are times when ADAPs must balance increases in utilization with resources that are subject to change. Indeed, North Carolina has capped enrollment in the program and limited the medication formulary, the quantity and type of drugs available. These cost containing measures have a significant impact on clients, providers, community based organizations, and local communities. Cost controlling measures taken by state officials are not new, and are not limited to North Carolina. As of May 2010, over fifteen other states have taken cost containment measures in response to budget shortfalls and increased utilization, including enrollment caps and stricter eligibility requirements (Carbaugh, Kates et al. 2009). Wait lists for accessing ADAP have expanded into 10 states, with a total of 1,143 people on the list as of May 20th, 2010 (NASTAD 2010). In order to better understand the impact of ADAP on providers and clients, and the challenges of ADAP in North Carolina, it is helpful to understand what the AIDS Drug Assistance Program looks like on a nation level. By briefly reviewing how ADAP is structured, who enrolls, and current trends, one can understand the context in which North Carolina faces enrollment caps, and the likely impact it will have on communities.

The AIDS Drug Assistance Program Background. ADAP has served clients since 1987 when Congress appropriated \$30 million to help states finance antiretroviral medications for low income HIV positive individuals (NASTAD, 2009). Since then, the ADAP budget has grown to \$1.5 billion. The federal government has earmarked funds through Part B of the Ryan White HIV/AIDS Treatment Modernization Act, approximately \$827 million (57%), in 2009. Nationally, states contribute around \$328 million (21%) of the total budget, with drug rebates through pharmaceutical companies contributing \$327 million (21%) (Carbaugh, Kates et al. 2009). When looking at the trend in the revenue source for ADAP over the past ten years, one notices that federal funding accounted for 68% in 2000, and has since declined as a proportion of the budget to 51% in 2008 (Carbaugh, Kates et al. 2009). Federal funding for ADAP's Part B supplemental has remained flat since 2003 (Cross 2010). State funding and drug rebates have been the principal replacement of revenue. Drug rebates accounted for 60% of the growth in the ADAP budget from 2007 to 2008, and increased from 6% of the total budget in 1996 to 21% in 2008 (Carbaugh, Kates et al. 2009).

Nationally, there are over 183,000 enrolled in the ADAP program, with approximately 110,000 utilizing services. Most states have experienced an increase in clients served each year. In terms of the number individuals served by ADAPs, utilization increased by 69% from 2001 to 2008 (Carbaugh, Kates et al. 2009). Clients who utilize ADAPs tend to be mostly minority and low income. The chart below profiles ADAP demographics.



Source: (Carbaugh, Kates et al. 2009)

Around 60% of clients enrolled are African American and Hispanic, 74% have income less than 200% of the poverty level (NASTAD). About half of enrolled have CD4 counts > 350, with 28% below a CD4 count of 200, meaning that the HIV has progressed to later stages of the disease. Around 72% of those served by ADAP are uninsured (Carbaugh, Kates et al. 2009). ADAP provides a safety net for individuals who need antiretroviral drugs to survive, yet do not have means to access them.

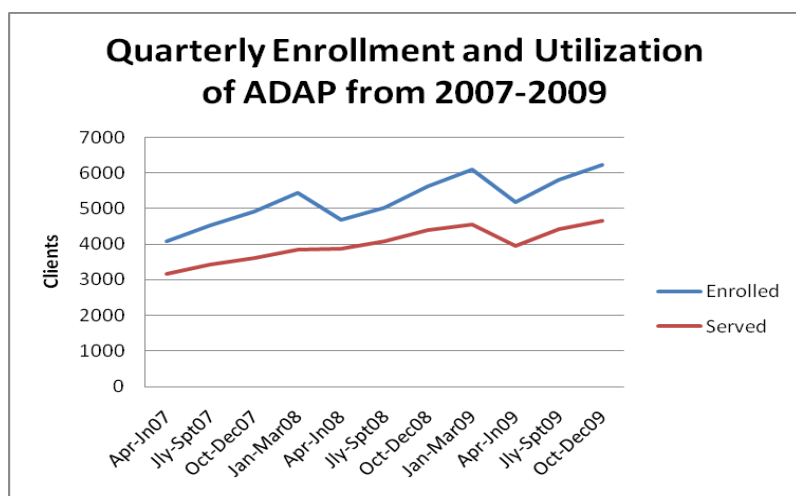
Since state ADAPs need to balance the demand for services with a fixed amount of resources, some have implemented cost containment measures that involve a reduction in benefits and/or caps in enrollment. For example, if the ADAP program for a particular state has eligibility at 300% of the federal poverty level, it may drop eligibility to 125% to control costs. When caps to enrollment are implemented, waiting lists accrue. While waiting lists were eliminated on a national level in 2007, they began accruing again in 2008. As of May 2010, there were 1,143 people on the ADAP waiting list, an increase in 43% from the just two months ago (NASTAD, 2010). Fourteen states so far have reduced their formularies. Changes in ADAP formularies reduce or eliminate eligibility for medications for diabetes, hypertension, and other co-occurring health conditions among PLWHA. In addition a smaller number of antiretroviral medications are covered. A more thorough explanation of cost containment options are discussed below.

The national outlook of the ADAP program is very similar to trends in North Carolina. The recent cap in enrollment and changes to the formulary speaks to the drastic nature of cuts state agencies in North Carolina have had to make. The cap in enrollment will have a significant impact on clients, community organizations, and local communities. Before illustrating the impact of the enrollment cap and steps being taken to address this issue, it is useful to understand recent ADAP trends in North Carolina.

North Carolina AIDS Drug Assistance Program Background. By the end of December 2009, there were 6,321 people enrolled in the North Carolina's ADAP program. Of those enrolled, 73% were at or below 125% of the federal poverty level, 60% were African American, and 30% were white (John Furnari, 2010). Before the enrollment cap, North Carolina had a relatively generous ADAP program, having expanded eligibility from 125% of FPL in 2005 to 300% by 2008. Additionally, North Carolina contributes a relatively significant amount of state funding to the program. In fiscal year 2008, the

North Carolina ADAP program had a budget of \$33,138,747. The state was responsible for \$14,551,663, or 44% of the total, with the rest coming from the federal government. By comparison, many states do not contribute any funding to their ADAP, financing the program through federal funds or drug rebates. Eligibility for enrollment in North Carolina was changed to 300% FPL up from 125% in 2006. In addition, North Carolina offered Tier II and Tier III medications which included medications for diabetes, hepatitis C, mental illnesses, and other opportunistic infections. In all, the program covers 30 FDA approved antiretroviral medications, and over 30 additional medications for mental health and other co-occurring diseases and infections (Fact sheet, 2010). The opportunity for this expansion was explained in the 2007 North Carolina Epidemiological Profile as the result of savings from a restructuring the drug purchasing model, from reimbursement to direct purchasing with a central pharmacy. These savings netted a 10% reduction in the program's budget for the 2006 fiscal year (North Carolina Department of Health and Human Services, 2007). Projected future savings, and anticipated federal funds, allowed for a gradual expansion of the eligibility and the medication formulary

The implementation of an enrollment cap at the beginning of 2010 came as a result of very hard economic circumstances and increases in drug costs. Indeed, North Carolina's economic picture in 2009 was fairly bleak. The unemployment rate increased 6.6% from a decade low of 4.5% in the spring of 2007 to 11.1% in January 2010 (United States Department of Labor 2010). This steep climb in



unemployment coincided with an increase in the uninsured rate. From 2007 through 2009 there was roughly a 22% increase in the uninsured, one of the highest in the country (Cecil G. Sheps Center for Health Services Research 2009). Currently, the uninsured rate in North Carolina stands at 21% (Center for American Progress 2009). Compounding the increase in the uninsured, and consequently an increase in ADAP enrollment (See chart)¹, is the increase in medication expenditures in

North Carolina. Just in the past year, expenditures on antiretroviral medication and drugs for opportunistic infections increased by 16%, from \$3.5 million in January 2009 to \$4.1 in December 2009 (North Carolina Department of Health and Human Services 2010).

It was in this economic context that the Department of Health and Human Services was asked to make 5% cuts across all of its departments (Community ADAP Meeting 2010). As part of this, an extra \$3 million was cut from the ADAP budget in addition to the exclusion of the \$3.5 million inflationary increase that is usually anticipated. In total, the state budget for ADAP in the fiscal year 2010-2011 was \$11.6 million; the federal government's appropriation was \$23.9 million. While the total ADAP budget

¹ Source: Adapted from data obtained from data analyst John Furnari from the North Carolina AIDS Drug Assistance Program.

was roughly 7% greater than the previous fiscal year, utilization of the program increased by 29% in two years, serving 3162 clients in the summer of 2007 to serving 4659 clients by the fall of 2009 (North Carolina Department of Health and Human Services 2010). By January 2010, ADAP had exhausted its state appropriations, resulting in the enrollment cap and cancellation of Tier II and Tier III medications. To continue to provide currently enrolled clients with HIV medication through the end of the Ryan White fiscal year, the Department of Health and Human Services released \$7.5 million to cover the expenses of those currently enrolled through March 2010. Federal appropriations for the 2010-2011 fiscal year began on April 1st, however the North Carolina ADAP has traditionally spent only state appropriations through June of the fiscal year before utilizing federal program funding. Therefore, more state funding is needed to finance the ADAP program, through June of 2010. Based on the monthly cost projections of \$4.1 million, it is estimated that the state needs \$10.5 to continue financing HIV medication through June 2010 without utilizing federal appropriations. To this end, the North Carolina AIDS Director has made a critical needs request to Governor Perdue. Once the program opens again, it must open at 125% of the federal poverty line, with no prospects of opening Tier II and Tier III drug eligibility anytime soon (Clymore 2010).

At the beginning of May 2010, there were 602 people on the waiting list in North Carolina, higher than any other state (North Carolina Department of Health and Human Services 2010). Before ADAP re-enrollment in April², the waiting list consisted of 75% of clients at or below 125% of the federal poverty line, 67% were African American and 27% were white. Fifty-one percent of those on the wait list had a CD4 count at or below 350 (North Carolina Department of Health and Human Services 2010). This is important because DHHS guidelines suggest the start of antiretroviral therapy for individual CD4 count at or below 350 (Thielman 2010). In addition, there is some evidence that it may be efficacious to begin therapy earlier, when a CD4 count is at or below 500 (Kitahata, Gange et al. 2009).

Efforts are underway to raise awareness of the importance of ADAP for uninsured or underinsured HIV positive individuals, and the implications of an enrollment cap, among policy makers in the General Assembly. The North Carolina AIDS Advocacy Networks (NCAAN) has worked with Equality NC to establish sit down meetings with legislators, coordinate mass e-mailings, and contact news organizations regarding ADAP. These efforts are intended to raise awareness and establish enough political pressure to adequately fund the program at 125% of the federal poverty line starting the next fiscal year. These efforts have resulted in the inclusion of \$14.1 million in Gov. Perdue's budget request, currently up for debate in the North Carolina senate.

IMPLICATIONS

Individual and Community Implications. Capping enrollment in to ADAP and limiting it's formulary have important implications for individuals and communities. The participants in the ADAP

² Since April, the waiting list has expanded significantly. These percentages may not reflect the current demographic breakdown.

program are receiving medication that they would not otherwise be able to access. In North Carolina, the monthly cost for the 3 most popular antiretroviral medications can range between ~\$300/month to \$1,868/month³. To put these costs in context, 68% of those enrolled in ADAP are at or below 125% of the federal poverty level. For a family of four, this is \$27,563. (North Carolina Department of Health and Human Services 2010). Thus, the cost of accessing HIV medication can be a barrier to treatment for some people. Yet, HIV medication is essential to the maintenance of the individual's health and the extension of their life. In addition, there is a benefit in communities to keeping HIV positive individuals on medication. The impact of medication on health, implications of adherence and non-adherence, and costs for communities are evaluated below.

The health benefits of treating HIV/AIDS are indisputable; therefore, access to medical treatment is critical. Medical treatment for people living with HIV/AIDS (PLWHA) reduces mortality and the risk of opportunistic infections by lowering the level of viral load in bodily fluids (Palella, Delaney et al. 1998). Antiretroviral treatment has been clearly shown to extend the life of a person with HIV. The survival benefit of treating HIV for an individual is calculated to be around 13.3 years (Walensky, Paltiel et al. 2006). This exceeds survival benefits of treatments for other types of chronic illness, like chemotherapy (7 months) and coronary artery disease (50 months) (Walensky, Paltiel et al. 2006). In addition to the individual health and survival benefit of treatment, some studies suggest that medical treatment that results in a reduction of viral load may have public health implications as well. That is, the reduction in viral load may reduce the infectivity of the person with HIV. (Wainberg and Friedland 1998; Abbas, Anderson et al. 2006). Looking at population effects of the introduction of treatment suggests a reduction in HIV incidence within the community. Abbas and colleagues (2006), for example, used an epidemic simulation model to look at the individual and population effects of the introduction of antiretroviral treatment in resource limited settings. They found that early introduction of treatment for HIV positive populations predicted a reduction in HIV transmission and cumulative deaths from AIDS after 10 years. Similarly, Porco et al. (2004) observed a 60% reduction in the rate of infection in men who have sex with men after the introduction of antiretroviral therapy.

There is a clear benefit, both for the individual and the public, for having PLWHA receive treatment. Yet there are also implications for adherence failures. This is important to consider in the context of an ADAP enrollment cap because some people will have their therapy disrupted (Community ADAP Meeting 2010). Non-adherence to HIV medication can predict the progression to AIDS and other poor health outcomes, including mortality (Bangsberg, Hecht et al. 2000; Hogg, Heath et al. 2002). It has also been shown that inconsistent medication adherence is predictive of the failure of the medication to reduce the viral concentration in the blood (Paterson, Swindells et al. 2000). Non adherence contributes to HIV drug resistance, compromising future treatment (Gifford, Bormann et al. 2000). These findings are consistent with predictions made by some directors of AIDS service organizations around the state (Ore, 2010; Warren, 2010). They report that limits placed on enrollment and eligibility to ADAP will result in individuals not receiving needed treatment, which will result in an increase in infection rates

³ Based on prescription costs at CVS Pharmacies in Durham and in Carrboro, NC. The drugs included were Atripla, Truvada, and Kaletra (February, 2010)

within their respective communities. Thus, there are serious individual and community consequences for therapy disruption that may result from capping enrollment into ADAP.

Community Costs and Provider Implications. While local data on cost implications of untreated HIV positive individuals are not available, there are a number of scholarly works that attempt to understand the cost-effectiveness of treatment versus non-treatment. The cost-effectiveness of using antiretroviral drug treatments for HIV patients has been widely discussed in the literature, and has been shown to be cost-effective compared to no treatment (Sendi, Bucher et al. 1999; Moore 2000; Freedberg, Losina et al. 2001; Beck, Mandalia et al. 2004).⁴

In addition to community costs for non-adherence, there are costs to providers that result from changing eligibility requirements and the enrollment cap. Interviews with directors of AIDS service organizations in Charlotte and Greensboro suggest that capping enrollment to ADAP places an additional burden on service delivery (Ore 2010). For example, one AIDS service organization in Greensboro sees over 100 clients who are on ADAP; many of these clients depend on upwards of 10 additional medications from Tier II and Tier III of ADAP. The reduced formulary requires more time spent by case managers to link clients with Patient Assistance Programs, which have different application and eligibility requirements for each drug and each company⁵ (Community ADAP Meeting 2010). In addition,

⁴ **Cost effectiveness of ARV Medication.** Antiretroviral (ARV) treatment extends the life of the client, this incurs direct medical cost. However, the expanded life of the client includes productivity that would have otherwise been lost had there been no therapy given. Using data from the AIDS Clinical Trials Group 320 Study and other data sets, Freedman et al. (2001) attempted to analyze the cost effectiveness of the 3 drug antiretroviral (ARV) regimens based on life expectancy, life-time direct medical costs and cost effectiveness in dollars per quality-adjusted year of life gained. This study found ARV treatment increased the projected quality-adjusted life expectancy by 1.38-2.67 years, with cost effectiveness ratio ranging from \$13000 to \$23000 per quality adjusted year of life gained compared to no therapy (Freedman et al. 2001). That is, it is cost effective to provide ARV treatment as opposed to no treatment since opportunistic infections incur greater medical costs and productivity loss (Moore, 2000). Similarly using data from the Swiss HIV Cohort Study, Sendi et al (1999) found that while ARV treatment increases expected survival time and medical costs, the productivity gains are such that society saves costs over time, making ARV treatment a cost effective intervention for individual with HIV and AIDS. Finally, as a Durham Infectious Disease doctor notes, "If you don't treat on the front end, you will treat on the back end [by] shifting costs to the emergency room, Intensive Care Units, and hospitalizations" (Theilman, 2010).

⁵ **Increased role for Patient Assistance Programs.** While capping ADAP to those already enrolled leaves out people who would benefit from ADAP, it does not necessarily mean that these individuals will not receive HIV medication. The Patient Assistance Program (PAP) offered by pharmaceutical companies can provide free or low cost HIV medications to those who are uninsured, low income, and have the medication prescribed by a medical provider. Indeed, since 2000, PAP have delivered over \$80 million in free medications for people who cannot afford them. For those who are placed on the ADAP waiting list in North Carolina, applying for medication through patient assistance programs is an option. States that have ADAP waiting lists have worked aggressively to enroll eligible clients into patient assistance programs.

There are limitations to relying on PAPs to fill the need for antiretroviral medication. Accessing medication through patient assistance programs can be a complicated process. In North Carolina, there are over 19 PAPs that offer different sets of medication. Someone who is HIV positive must complete a different application for each medication that they are prescribed. In addition, each pharmaceutical company has a different set of eligibility requirements, application process, and renewal requirements. According to a number of community representatives in North Carolina, the complexity of using a PAP makes for a burdensome and time consuming effort by case managers

as more individuals become infected with HIV, or are HIV positive and become unemployed and lose their insurance, the more demand there will be for the services offered by community AIDS service organizations. Overburdened AIDS service organizations will ultimately, result in increases in viral load and reduced immunity to illness for some clients, and a possibility of increased infection rates in the community (Ore 2010; Warren 2010)

COST CONTAINMENT OPTIONS

Many states have taken steps to contain the costs of their ADAP. One way to control costs is to establish a waiting list, which 10 states have already done. Yet, there are additional ways to control for costs other than instituting a waiting list. The structure and stability of ADAPs are generally unique to each state. Thus, cost containment steps are unique to political and economic climate of each state, as well as the strength of existing Medicaid programs (NASTAD 2010). Some of these mechanisms may be helpful to consider as a way to both limit the individual and public health implications of the current enrollment cap, as well as create fiscal sustainability going forward. As outlined by NASTAD technical assistance briefs, cost containment measures included changing eligibility criteria, formulary management, waiting list management, insurance purchasing, client cost sharing, and managing prescription utilization (National Alliance of State and Territorial AIDS Directors (NASTAD) 2007).

Waiting List Management. Establishing a wait list is a mechanism used to limit access to ADAP benefits when there are limited resources available. There have been many states that have used a waiting list within the past 10 years (NASTAD 2007). Currently 10 states that have established a wait list, with North Carolina having the largest waiting list at 602 people (As of May 2010).

There are two ways to manage a wait list. Most states use a first come, first serve mechanism which puts individuals on the list in order of receipt of enrollment application. Another way to manage wait list is to use hierarchical criteria. This means placing people on the list in order of clinical category, like pregnant women, individuals already on antiretroviral treatment, viral load/CD4 count, individuals with co-infections, and other clinical categories (NASTAD 2007). Some states use a combination of both.

A recent study noted that the complexity of patient assistance programs may act as a barrier to receiving medication for those applying to the program (Chauncey et al 2006). In response to the enrollment cap, headway is being made among some prescription assistance programs in North Carolina on establishing a universal application form for people who are HIV positive (Clymore, 2010). This has been long advocated by HIV service providers and patients in North Carolina (Clymore, 2010).

It should also be noted that the multiplicity of eligibility requirements and applications pose additional burdens for providers and patients in need of HIV medication that would not otherwise occur if the individual was insured or enrolled in ADAP. Some individuals have negative side effects to certain medications, other medications are contraindicated based on co-occurring illnesses, like hypertension (Theilman, 2010). Whereas ADAP offers over 25 different antiretroviral drugs, through a PAP an individual may be eligible for an ARV that does not work for the individual, and not be eligible for the medication that works best for them (Theilman, 2010)

North Carolina has mainly a first come first serve approach to the wait list, though pregnant women can automatically enroll in ADAP. Kentucky has a wait list of 183, as of March 26th, 2010, and prioritizes pregnant women and people with CD4 counts below 200 (Conference Call, 2010).

Financial Eligibility. ADAP financial eligibility around the country ranges from 125% to 500% of the federal poverty level. Some states, including North Carolina, Arkansas, and Illinois, have lowered the financial eligibility as a cost containing strategies. For example, North Carolina's ADAP was open for people at or below 300% FPL, when the North Carolina's ADAP opens again it will open at 125% FPL. However, the cost savings implications of this measure are only realized if a majority of clients fall within certain income criteria that will be reduced (National Alliance of State and Territorial AIDS Directors (NASTAD) 2007). That is, if the majority of clients are at or below 125%, there may not be significant savings. Indeed, only 4% enrolled in ADAP in North Carolina have incomes between 200% and 300% FDL (North Carolina Department of Health and Human Services 2010).

Clinical Eligibility. In thinking about managing limited resources with a growing need, it may be helpful to consider ADAP eligibility based on clinical characteristics. In 2008, seven states had clinical eligibility criteria, based on pregnancy, CD4 count or viral load ranges. Since then, more states have utilized clinical eligibility criteria to manage their ADAP. Recently, for example, Hawaii began limiting enrollment for individuals with a CD4 count <350 cells unless they have been on ARV treatment previously (NASTAD 2010).

Clinical eligibility for ADAP may be a useful way to optimize the allocation of limited resources. A study of data from Massachusetts's ADAP concluded that a CD4 count based eligibility scheme served a more-diverse population, and saved \$2.7 million by serving less clients (Linas, Zheng et al. 2006). By contrast, a first come, first served system enrolled more patients, but would have included patients with CD4 counts >500 and would excluded patients with CD4 counts <260 (Linas, Zheng et al. 2006). This speaks to the reality that in a first come first serve model, minorities tend to be at a disadvantage because they are often diagnosed late and are slower to enroll in ADAP (Sabin, Smith et al. 2004; Swindells, Cobos et al. 2006). Further research has also suggested that CD4 count based eligibility for ADAP has a greater benefit in keeping clients from getting sick or dying, than a first come, first served model (Linas, Losina et al. 2009).

While research supports the benefits of a CD4 count based eligibility criteria among resource strapped ADAPS, there are a number limitations to consider. Recent evidence suggests clinical benefits to beginning ARV treatment with CD4 counts >500 cells/ul (Kitahata, Gange et al. 2009). In addition, the administrative costs of implementing a CD4 count based eligibility system can be significant. A recent talk by Jacquelyn Clymore suggested North Carolina would not implement a CD4 based system because of the administrative difficulties of implementing it (Clymore 2010).

Managing Prescription Utilization. Given resource limitations, some states cap monthly or annual expenditures on individual clients. For example, a state may determine that the ADAP will not exceed \$1,500 in monthly prescription drug expenses for any individual. Illinois, Wyoming, and North Dakota, are currently considering capping monthly and annual costs (NASTAD, 2010). In addition, states may restrict the supply or refill of prescriptions. For example, ADAPs may limit when and how often an individual can refill their prescription in a given month, as a way to cut down unnecessary refills due to regimen changes or changes in eligibility (NASTAD 2007). Another approach is to cap monthly

expenditures on the most expensive ARV medication, like Fuzeon (NASTAD 2010). As discussed in NASTAD's technical assistance brief (2007), in 2005, Missouri capped expenditures on their spend down Medicaid assistance, from \$500 per client to \$200. Though Medicaid had simultaneously lowered the income level, it is thought that this cap, combined with other measures, increased client growth in their ADAP because there were more resources available to take in more clients (NASTAD 2007). However, generally most states do not attempt to manage or cap expenditures per client, as it can be very difficult to administer (NASTAD 2010).

Insurance Purchasing and Continuation. Another mechanism ADAPs can use to contain costs is to offer payments for insurance premiums, deductibles, or co-payments. Since 1999, states have been able to use ADAP funds to purchase new insurance policies or underwrite the continuation of health insurance policies for people eligible for ADAP (Meyerson and Sutton, 2003). While it can be hard to quantify the amount of savings, the underlining assumption is that payment towards monthly medication costs (which can range from ~\$300 to \$1800 per month) are more expensive than paying a \$1,000 deductible. A cost comparison analysis prepared for the National AIDS State and Territorial Directors by the Policy Resource group (2003) demonstrated that access to a formulary through an insurance mechanism had lower monthly costs, saving at least \$200/month per client, than purchasing antiretroviral treatment through ADAP.

Florida has used an AIDS Insurance Continuation Program (AICP) that purchases private insurance for clients who are HIV positive and are covered by private insurance. This program is set up separate from Florida's ADAP and is administered by the Health Council of South Florida to ensure efficiency⁶. AICP receives funding from Ryan White Part B (41%) and Florida general revenue (59%) (Health Council of South Florida 2008). AICPs annual expenditures per client is \$5,184 (Health Council of South Florida 2008). In contrast, Florida ADAP spends over \$6,500 per client through traditional ADAP services. In addition, Florida's ADAP assists with out of pockets costs of those enrolled in their AICP if the client's monthly costs are greater than \$250 or 10% of the client's income. Florida's ADAP may also provides assistance if the client's insurance has cap on pharmaceutical expenditures, or does not cover brand named drugs.

HEALTH REFORM

With the recent passage of the Patient Protection and Affordable Care Act, it is important to consider the impact the new health reform law might have on ADAPs around the country. ADAPs will eventually benefit from the new health care law. The expansion of Medicaid and the inability of insurance companies exclude PLWHA from insurance based on pre-existing conditions, will inevitably reduce the demand for ADAP enrollment (NASTAD 2010). Under the new federal law, Medicaid eligibility will expand to 133% of the federal poverty level, and removes the disability, and single parent eligibility. This requirement will no doubt take some pressure off of ADAPs around the country as low income HIV

⁶ Alex Bello, of the Florida Department of Health, notes that if AICP was administered by ADAP, a separate state contract would need to be completed for each client who purchased insurance through the program.

positive individuals will be eligible to receive Medicaid benefits for which they would otherwise not be eligible (NASTAD 2010). However, the expansion of Medicaid does not take place until 2014. This is a major critique of the bill's impact on the HIV/AIDS population (Greenwald 2010). As of May 2010, there were 1,143 people on ADAP waiting lists across the country. Thus, relief to ADAPs may not come soon enough.

Additional benefits include allowing ADAP expenditures on clients who have reached the Medicare part D coverage gap (the donut hole) to count towards the true out of pocket costs (TrOOP). This should also help ADAPs as patients will more quickly exit the donut hole and Medicare Part D will assume more of the drug costs (NASTAD 2010). This change takes place in 2011.

MOVING FORWARD

The above sections outlines a number of steps that ADAPs can, and do, take to address rising expenditures coupled with limited resources. These different approaches demonstrate that there is no silver bullet to fill the gaps left by a discretionary public program that serve a low income, uninsured, and chronically ill population.

Absent adequate funding due to current economic conditions or politics, ADAPs must balance great need with limited resources. The above cost containment measures may be helpful to consider as ways to manage ADAPs resources and increase efficiency. NASTAD outlined three strategies to combat the crisis. They include the following (NASTAD 2010):

- Take action to ensure additional funding at the federal levels, specifically an additional \$370 million (NASTAD 2010). This includes educating and meeting with elected officials, and increasing public awareness on a national level
- Take action to ensure additional funding at the state level. In North Carolina, around \$14 million is needed to ensure the reopening of the program at 125% of the federal poverty level. The North Carolina AIDS Action Network, a partnership of individuals and organizations who work in the HIV/AIDS service profession, has held numerous public events to raise awareness of the ADAP crisis, including meeting one on one with state representatives and engaging the local media. Thus far, this effort has had some demonstrable impact as evidenced by the recent release of the Governors Budget, which included \$14 million for ADAP.⁷
- The third strategy suggested by NASTAD includes partnering with pharmaceutical industry groups to negotiate rebates and discounts for their antiretroviral medications (NASTAD 2010). The ADAP Crisis Task Force, which negotiates drug pricing with the pharmaceutical industry, saved ADAPs \$222 million in 2008. In North Carolina, ADAP already negotiates low drug prices with the pharmaceutical industry, and it is believed that North Carolina has already maxed out its potential savings through purchasing drugs at a lower price (Clymore 2010). However, as mentioned above, North Carolina

⁷ As of this writing, the NC House and Senate are negotiating \$14.1 million for ADAP on a recurring basis.

has worked with pharmaceutical representatives to standardize pharmaceutical assistance program applications and processes. This will help to increase the efficiency of accessing needed medications for individuals on the wait list.

CONCLUSION

This white paper has attempted to highlight the importance of accessing antiretroviral medication for individuals, providers, and communities. In addition, it seeks to discuss the unique financial challenges facing the North Carolina ADAP and ways other ADAPs have responded. There is no single solution, or panacea, to address the gap between resources and need within North Carolina ADAP. The ADAP waiting list in North Carolina is the highest in the country and current efforts by NCAAN to advocate for funds to reopen the program to at least 125% FPL is an important strategy to address the immediate need. But there are, as illustrated above, additional steps that can be taken that may ensure a more sustainable fiscal path for ADAP in the future.

REFERENCES

- Abbas, U., R. Anderson, et al. (2006). "Potential impact of antiretroviral therapy on HIV-1 transmission and AIDS mortality in resource-limited settings." JAIDS **41**: 632-641.
- Bangsberg, D., F. Hecht, et al. (2000). "Adherence to protease inhibitors, HIV-1 viral load, and development of drug resistance in an indigent population." AIDS **14**: 357-366.
- Beck, E., S. Mandalia, et al. (2004). "The cost-effectiveness of highly active antiretroviral therapy, Canada 1991-2001." AIDS **18**: 2411-2418.
- Carbaugh, A., J. Kates, et al. (2009). National ADAP Monitoring Project Annual Report. NASTAD and K. F. Foundation. Washington, DC.
- Cecil G. Sheps Center for Health Services Research (2009). Updating Uninsured Estimates for Current Economic Conditions: State Specific Estimates. Chapel Hill, Nc, University of North Carolina North Carolina Institute of Medicine.
- Center for American Progress (2009). Dramatic Increase in the Uninsured Rate in Every State: Number of Uninsured Americans Increased Almost 13 Percent since 2007. Washington DC, Center for American Progress.
- Clymore, J. (2010). The ADAP Crisis. The North Carolina ADAP Crisis, Chapel Hill, NC.
- Community ADAP Meeting (2010). Information Session. Community ADAP Meeting, Raleigh, NC.
- Cross, L. (2010). Information Session. Community ADAP Meeting, Raleigh, NC.
- Freedberg, K., E. Losina, et al. (2001). "The cost effectiveness of combination antiretroviral therapy for HIV disease." The New England Journal of Medicine **344**: 824-831.
- Gifford, A., J. Bormann, et al. (2000). "Predictors of self-reported adherence and plasma HIV concentrations in patients on multidrug antiretroviral regimens." JAIDS **23**: 386-395.
- Greenwald, R. (2010). Health Care Reform: Update on Federal Efforts to Improve Access to Care for People Living with HIV/AIDS. Treatment Access Expansion Project, Health Law and Policy Clinic, Harvard Law School,.
- Health Council of South Florida (2008). AICP: Cost Benefit Analysis, Calendar Year 2008, Florida Department of Health.
- Hogg, R., K. Heath, et al. (2002). "Intermittent use of triple-combination therapy is predictive of mortality at baseline and after 1 year of follow-up." AIDS **16**: 1051-1058.
- Kitahata, M., S. Gange, et al. (2009). "Effect of early versus deferred antiretroviral therapy for HIV on survival." The New England Journal of Medicine **360**: 1815-1826.

Linas, B., E. Losina, et al. (2009). "Improving outcomes in states AIDS drug assistance programs." JAIDS **51**: 513-521.

Linas, B., H. Zheng, et al. (2006). "Optimizing resource allocation in United States AIDS drug assistance programs." Clinical Infectious Diseases **43**: 1357-1364.

Moore, R. (2000). "Cost effectiveness of combination HIV therapy: 3 years later." Pharmacoeconomics **17**: 325-331.

NASTAD (2007). Managing Prescription Utilization. AIDS Drug Assistance Programs and Cost Containment Strategies. Washington, DC.

NASTAD (2007). Waiting List Management. AIDS Drug Assistance Programs and Cost Containment Strategies. Washington, DC, National Alliance of State and Territorial AIDS Directors.

NASTAD (2010). The ADAP Watch. The ADAP Watch. Washington, DC, National Alliance of State & Territorial ADIS Directors.

NASTAD (2010). A Coordinated Strategy to Save America's ADAPs: March 2010. NASTAD.

NASTAD (2010). Interview with Murray Penner. April 7th.

National Alliance of State and Territorial AIDS Directors (NASTAD) (2007). AIDS Drug Assistance Programs and Cost Containment Strategies: Eligibility Criteria Options. ADAP TA Brief No. 1. Washington, DC, NASTAD.

North Carolina Department of Health and Human Services (2010). Chart: 2009 ADAP Clients Enrolled and Associated Costs. North Carolina AIDS Drug Assistance Program. Raleigh, NC Epidemiologic Section.

North Carolina Department of Health and Human Services (2010). Table: Data per quarter 07-09. North Carolina AIDS Drug Assistance Program. Raleigh, NC, Epidemiologic Section.

North Carolina Department of Health and Human Services (2010). Table: North Carolina ADAP Demographics as of 3/31/2010, Epidemiological Section.

Ore, A. (2010). Interview with Executive Director of the Triad Health Project. Greensboro, NC.

Parella, F., K. Delaney, et al. (1998). "Declining morbidity and mortality among patients with advanced human immunodeficiency virus infection." The New England Journal of Medicine **338**: 853-860.

Paterson, D., S. Swindells, et al. (2000). "Adherence to protease inhibitor therapy and outcomes in patients with HIV infection." Annals of Internal Medicine **133**: 21-30.

Porco, T., J. Martin, et al. (2004). "Decline in HIV infectivity following the introduction of highly active antiretroviral therapy." AIDS **18**: 81-88.

Sabin, C., C. Smith, et al. (2004). "Late presenters in the era of highly active antiretroviral therapy: Uptake of and responses to antiretroviral therapy." AIDS **18**: 2145-2151.

Sendi, P., H. Bucher, et al. (1999). "Cost effectiveness of highly active antiretroviral therapy in HIV-infected patients." AIDS **13**: 1115-1122.

Swindells, S., D. Cobos, et al. (2006). "Racial/ethnic differences in CD4 T cell count and viral load at presentation for medical care and in follow-up after HIV-1 infection." AIDS **16**: 1832-1834.

Thielman, N. (2010). Phone interview with Nathan Thielman. Durham, NC.

United States Department of Labor (2010). Local Area Unemployment Statistics, Bureau of Labor Statistics.

Wainberg, M. and G. Friedland (1998). "Public health implications of antiretroviral therapy and HIV drug resistance." JAMA **279**: 1977-1983.

Walensky, R., A. Paltiel, et al. (2006). "The survival benefits of AIDS treatment in the united states." The Journal of Infectious Diseases **194**: 11-19.

Warren, D. (2010). Interview with Executive Director of Regional Interfaith AIDS Network. Charlotte, NC.