Structural Barriers to Continuity of HIV Care: Characterizing and Evaluating the Impact of Patient Discontinuation from AIDS Drug Assistance Programs

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A dissertation

submitted in partial

fulfillment of the requirements for the degree of

Doctor of Philosophy

University of Washington

2021

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Public Health – Epidemiology

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Abstract

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The Ryan White HIV/AIDS Drug Assistance programs (ADAPs) are the largest source of medical care for people living with HIV (PLWH) in the United States. They pay for insurance and medical care for 20% of people living with HIV in the United States, and people on the program have high rates of viral suppression, the central measure of successful HIV treatment. In spite of the benefits of the program, clients have difficulty staying enrolled in the program and subsequently lose benefits. Until recently, federal policy required that ADAP clients provide documentation of their eligibility every 6 months or be removed from the program. In October of 2021, these restrictions were relaxed, and states were given the authority to set their own recertification procedure.

Although this policy change has the potential to reduce the burden of recertification, there is a lack of information about how recertification affects clients and the cost of the

program. This dissertation sought to fill this knowledge gap by quantifying the effect of disenrollment on the ADAP clients and building a model to project the effect of extending the recertification timeline to every 12-months.

First, we used Ryan White data from Washington State to describe the prevalence of ADAP disenrollment and identify factors associated with being removed from the program. We categorized all PLWH enrolled in ADAP clients by the success of their recertification applications as continuously enrolled, ruled ineligible, disenrolled if they failed to recertify. We compared individuals who were disenrolled to those who were continuously enrolled by demographic and socioeconomic characteristics and use of case management services. Next, we sought to quantify the impact of disenrollment from ADAP on viral suppression. Using this same population, we estimated the risk difference of viral suppression before and after enrollment using clients who were continuously enrolled as a comparator. We used quantitative bias analysis to identify how much of the effect of client disenrollment could be attributed to other unmeasured confounders. Lastly, we used the results of the first two aims to develop a Markov model to analyze the cost and health impact of changing the existing 6-month recertification schedule to a 12-month schedule. We predicted the change in annual program costs, program enrollment, and population viral suppression over a 5-year time horizon.

We found that disenrollment is common and disproportionately affects marginalized populations in Washington State. Over the two-year study, 26% of clients were disenrolled from the program at least once due to failure to recertify, which is much greater than the 18% of clients who were removed due to ineligibility. Compared to those who were continuously enrolled, disenrolled PLWH were more likely to be Black (prevalence ratio vs White 1.31, 95% CI

1.17-1.46), uninsured (PR vs private insurance 1.24, 95% CI 1.10-1.40), and younger (PR 25-34 vs 35-44 years 1.23 95% CI 1.08-1.41). We also found that disenrollment negatively impacts the viral suppression of PLWH who are removed from the program. Of the 1336 ADAP clients who were disenrolled, 83% were virally suppressed before disenrollment versus 69% after (RD 12%, 95%CI 9-15%). Our quantitative bias analysis suggested that unmeasured confounders are unlikely to explain the entirety of this effect. Our budget impact analysis suggested that a 12-month recertification policy would yield a program that costs 7% more per year ($40.2M vs $37.7M, 95% CI 6-8%), but produces greater health benefits (245 more individuals virally suppressed by the end of 2025).

The results of this dissertation demonstrate that the current ADAP recertification policies, which were formerly required by federal policy, are disruptive to the health of a large proportion of ADAP clients. In Washington state, a change to a 12-month recertification policy has the potential to reduce the number of virally unsuppressed PLWH by 10% at a modest cost relative to the overall cost of the program.

Contents

List of Tables 7

List of Figures 8

Chapter 1. Introduction 9

Chapter 2. Characterization of the Population Impacted by the 6-Month Recertification Criterion of the Ryan White HIV/AIDS Program's AIDS Drug Assistance Program in Washington State, 2017-2019 11

- Abstract 11
- Introduction 12
- Methods 14
- Results 19
- Discussion 21
- Tables 25

Chapter 3: DOES RYAN WHITE PROGRAM CERTIFICATION POSE A STRUCTURAL BARRIER TO HIV TREATMENT? AN EVALUATION IN WASHINGTON STATE, 2017-2019 28

- Abstract 28
- Introduction 28
- Methods 30
- Results 36
- Discussion 37
- Tables 41
- Figures 43

Chapter 4: Budget Impact Analysis of Implementing 12-Month Recertification Criterion for Ryan White HIV/AIDS Program's AIDS Drug Assistance Program in Washington State 45

- ABSTRACT 45
- Introduction 46
- Methods 47
- Results 51
- Discussion 53
- Tables 56
- Figures 58
- Equations 60

Chapter 5 Conclusion 61

Acknowledgements 63

References 64

List of Tables

Table 1.1. Number and Outcome of Recertification Attempts by AIDS Drug Assistance Clients by 6-Month Period, Washington State 2017-2019

Table 1.2. Demographic Characteristics of ADAP Clients Who Were Disenrolled Versus Clients Who Were Continuously Enrolled, Washington State 2017-2019

Table 1.3. Characteristics of Census Tract of Residence of ADAP Clients Who Were Disenrolled Versus Clients Who Were Continuously Enrolled, Washington State 2017-2019

Table 2.1. Viral Suppression Status Before and After Removal from ADAP or Reenrollment by Insurance Status, Washington State 2017-2019

Table 2.2. Probabilistic Quantitative Bias Analysis for Unmeasured Confounders of ADAP Disenrollment and Viral Suppression, Washington State 2017-2019

Table 3.1. Parameters for Markov Model of Population Currently and Formerly Enrolled in Washington ADAP, 2021-2025

Table 3.2. Simulation of 6 and 12-Month Recertification Requirements, WA State 2021-2025

Table 3.3 Simulated Program Costs by Category for 6- and 12-Month Recertification Requirements, WA State 2021-2015

List of Figures

Figure 2.1. Quantitative Bias Parameters to Adjust the Relationship Between ADAP Disenrollment and Viral Suppression for Key Barriers to Engagement in HIV Care

Figure 2.2. Risk Difference (RD) of Viral Suppression from ADAP Disenrollment and Viral Suppression After Correction for Unstable Housing, Poor Mental Health, Heavy Drinking, and Illicit Substance Use, Washington State 2017-2019

Figure 3.1. Model Structure of Population Currently and Formerly Enrolled in Washington ADAP

Figure 3.2. 1-Way Sensitivity Analysis of Annual ADAP Costs, 12-Month Recertification Minus 6-Month Recertification

Figure 3.3. Model Validation, Washington State 2017-2019

Figure 3.4. Comparison of 6-Month Recertification Projection to 12-Month Recertification

Chapter 1. Introduction

The Ryan White AIDS Drug Assistance Program (ADAP) is a financial safety net program for people living with HIV in the United States designed to ensure that all people living with HIV (PLWH) have access to antiretroviral therapy. It is a cost-effective program, and the 240,000 clients who use ADAP services have a high rate of viral suppression compared to other PLWH in the United States.[1,2] Despite the benefits of being in the program, maintaining enrollment is a challenge for many people. At the initiation of this project, federal policy mandated that recipients of Ryan White services provide documentation of their eligibility every 6-months or they lose eligibility for the program. This policy was intended to ensure that Ryan White Part B services are only used as a last resort and that enrollees were not using Ryan White funds to pay for care that could be obtained through some other mechanism such as Medicaid or a private insurance company.

In October of 2021, the federal Ryan White Program eliminated the federal requirement for biannual recertification. Individual ADAP programs, which are administered at the state-level, now have the opportunity to set their own eligibility verification process and timeline. In this new context, there is a lack of evidence to guide the decision-making for this important policy decision. Without a full understanding of the impact of disenrollment on the health of the clients, the cost of the program, and the demographic disparities of the state, it will be difficult to make an informed decision about keeping or replacing the recertification requirement. To fill this gap in knowledge, this dissertation uses data from the Washington State ADAP and HIV surveillance systems to 1.) Estimate the size of the population affected by

disenrollment and characterize how disenrollment may contribute to population health disparities; 2.) Quantify the effect of disenrollment on viral suppression, an indicator of successful HIV care; and 3.) Estimate the effect of a change to a 12-month recertification requirement on the cost of ADAP and the number of people virally suppressed in Washington State. We will conclude by discussing the implications of these findings in Washington State and how they may guide the same decision in other states.

Chapter 2. Characterization of the Population Impacted by the 6-Month Recertification Criterion of the Ryan White HIV/AIDS Program's AIDS Drug Assistance Program in Washington State, 2017-2019

Abstract

Introduction: AIDS Drug Assistance Programs (ADAPs) provide financial support for medical care for people living with HIV (PLWH) in the US. Federal policy requires that clients recertify for the program every 6 months, which has been described as a barrier to care access. Our objective was to describe the prevalence and factors associated with ADAP disenrollment in Washington State.

Methods: Between 2017 and 2019, we categorized ADAP clients by the success of their recertification applications as: 1) continuously enrolled, 2) ruled ineligible, or 3) disenrolled if they failed to recertify. We compared individuals who were disenrolled to those who were continuously enrolled by demographic and socioeconomic characteristics and engagement with case management using data from the Washington State HIV Surveillance and Ryan White data systems.

*Results***:** From 2017 to 2019, 5480 clients were enrolled in ADAP, of whom 1423 (26%) were disenrolled and 984 (18%) were ruled ineligible at least once. Compared to those who were continuously enrolled, disenrolled PLWH were more likely to be Black (unadjusted prevalence ratio (PR) vs White 1.31, 95% CI 1.17-1.46), uninsured (PR vs private insurance 1.24, 95% CI 1.10-1.40), and younger (PR 25-34 vs 35-44 years 1.23 95% CI 1.08-1.41). The median time to return after disenrollment was 12 months (95% CI 8-19 months).

Conclusions: Disenrollment after failure to recertify was the most common reason why PLWH lost ADAP coverage in Washington. ADAP recertification procedures disproportionately impact Black, young, and uninsured PLWH and may contribute to disparities in HIV outcomes.

Introduction

Despite previous progress in reducing HIV incidence, transmission rates of HIV in the United States (US) have not changed significantly in the past 5 years.[3] Increasing viral suppression among people living with HIV (PLWH) is a cornerstone of federal efforts to prevent HIV transmission and maintain the health of PLWH. [4–6] Barriers to viral suppression span system, social, and individual factors.[7,8] The Ryan White HIV/AIDS Program's (RWHAP) AIDS Drug Assistance Program (ADAP) is intended to remove financial barriers to treatment and is tremendously successful in improving access to HIV care.[1,9] Two prior studies demonstrated that ADAP was associated with higher rates of viral suppression and retention in care among women, [10,11] even among patients with other health insurance.[12] Conversely, interruptions in ADAP coverage may diminish access to treatment, and ADAP policies that affect continuity of coverage have potential to pose system-level barriers to viral suppression.

Per federal requirements, recipients of ADAP services must provide documentation of their residence, income, and insurance status every 6 months to maintain enrollment in the program.[13] This policy is intended to ensure that the HRSA RWHAP is the payor of last resort by verifying that an individual continues to meet the recipient eligibility requirements.[13] The implementation of this requirement is controlled by the individual ADAPs and practices vary between jurisdictions. Jurisdictions have also been given the ability to allow clients to renew eligibility once a year via patient attestation that their eligibility has not changed.[13]

There is evidence to suggest that the 6-month recertification requirement may be a barrier to HIV care access. Prior qualitative studies have found that maintaining enrollment and accessing benefits is challenging for many people and contributes to ADAP underutilization.[14,15] In a 2018 request for information (RFI) by RWHAP, Ryan White programs, clients, and providers frequently identified the 6-month recertification requirement as a barrier to program effectiveness and a potential disruptor to HIV care for people who are least able to navigate healthcare and payor systems.[16] This suggests that recertification requirements for continuing ADAP coverage may pose a structural barrier to treatment continuity and, to the extent that recertification policies differentially impact subpopulations of PLWH, have the potential to contribute to existing health disparities.

A 12-month recertification requirement has been proposed as an alternative policy, which may decrease the number of eligible PLWH who are disenrolled from ADAP due to failure to complete recertification procedures.[16] The first step to understanding the role of the recertification criterion is to characterize the population who lose coverage due to failure to recertify. To our knowledge, there are no published reports describing how many people leave the ADAP each year and how this population compares to those who remain in ADAP in terms of demographics and program usage. We hypothesized that the populations with lower rates of successful engagement in HIV care, such as racial/ethnic minority populations and people who inject drugs would be more likely to be disenrolled from ADAP.[10,17]

In this study we examined the prevalence of disenrollment from the ADAP in Washington State, the length of benefits disruption, and the characteristics of the population that loses coverage. The objectives of this study were to: 1) Estimate the frequency of ADAP

disenrollment due to failure to recertify and discontinuation based on ineligibility in Washington State between 2017 and 2019; 2) Estimate the average length of benefits disruption for those who are removed from the program; 3) Describe the population that failed to recertify and compare it demographically to those who remained in the program; and 4) Describe the neighborhood contextual characteristics of the population that failed to recertify and compare them to those who remained in the program.

Methods

Study Population and Setting

We conducted a series of cross-sectional analyses of all PLWH who resided in Washington State and were enrolled in the Washington ADAP between 1/1/2017 and 12/31/2019. We divided this time period into six-month periods to mirror the 6-month recertification cycle. If a client died or was reported to live at an address outside of Washington State during a 6-month analysis period, they were excluded from analysis for that period.

Washington State's ADAP enrolled 4273 PLWH and served 3569 PLWH in 2017, which represents 34% and 29% of the state population of PLWH respectively.[17,18] In comparison, 20% of PLWH nationwide used an ADAP service in 2017.[18] Washington State is one of 12 states that offers an open formulary for some of its clients, meaning that these clients can use the assistance to purchase drugs of any type. It is one of 39 states that pays for insurance premiums and one of 43 states that pays for other, non-HIV medical costs. The annual cost per client served in 2017 was $3,459, which is below the national average of $8,554.[18]

Like all ADAPs, eligibility for Washington's ADAP is primarily based on income.[18,19] All PLWH who have an income between 139% and 425% of the Federal Poverty Level (FPL) are eligible for the program ($17,608 to $54,230 for a household size of 1 in 2020)[20]. PLWH who are below 139% FPL are typically eligible for the state's expanded Medicaid program which covers healthcare and drug-related costs. If a person's income is below 139% FPL and they are ineligible for the expanded Medicaid program (e.g. certain non-citizens) or have limited benefits as dual Medicare-Medicaid clients, then they are eligible for Washington ADAP.

As required by RWHAP, enrollment in Washington State's ADAP requires a person to complete an application and provide proof of Washington residency (driver's license, voter registration, utility bill, lease, etc.), proof of income, documentation of insurance (or attestation of lack of insurance), and documentation of their HIV diagnoses from a healthcare provider.[21] To reenroll, clients must submit the same information except for documentation of their HIV diagnosis every 6 months. If a client fails to recertify, the client will be disenrolled from ADAP. ADAP staff will send letters for two months to try to reengage the client. Clients who have been disenrolled are permitted to reenroll once a year by submitting a form attesting continued eligibility, which does not require additional documentation if the client's information has not changed.

Data Sources and Definitions

We extracted the number of people enrolled in ADAP semiannually from the Washington State Department of Health's Ryan White Administrative database from 2017 to 2019. For each ADAP client enrolled, we ascertained the result of their recertification for each

6-month period and classified them as 1) continuously enrolled (i.e. the client successfully recertified), 2) disenrolled (i.e. the client failed to recertify), or 3) ineligible (i.e. the client submitted recertification information but did not meet the requirements for the program) for that 6-month period. Clients who newly enrolled in the program during a 6-month period were not categorized, as they did not have an opportunity to recertify. On the first time a client was categorized as disenrolled or ineligible, we calculated the time between their removal from the program and their reenrollment, if it occurred.

We characterized client demographics using multiple data sources. Age (<25, 25-35, 35-44, 45-54, 55-64, >65 years)[17], race/ethnicity (Black, Hispanic, White, multiple/other), sex at birth (male, female), HIV acquisition risk (male sex with male, injection drug use, male sex with male and injection drug use, heterosexual contact, and other), time since diagnosis (<1 year, between 1-5 years, >5 years), and region (Western Washington, Eastern Washington or Seattle/King County) were extracted from the Washington State HIV surveillance system. We extracted income 0-135% FPL, 135-250% FPL, 250-425% FPL), insurance type (private, dual Medicare-Medicaid, other public insurance, uninsured), and receipt of case management services in the prior six months from the WA State Ryan White Database. Case managers in Washington State are tasked with helping eligible clients maintain enrollment in ADAP, and ADAP clients who use case management may be less likely to be disenroll. We considered characterizing the population in terms of gender instead of sex at birth, but the number of transgender individuals (N=30 and 3, respectively) presented concerns about the quality of gender data and risk of individual identifiability.

We geocoded the residence of all ADAP participants and described each client's neighborhood socio-economic status (SES) via census tract measures of income (median household income, median home price, and percent of residents below federal poverty level), educational attainment (percent of residents with less than a high school diploma in census tract of residence) and unemployment (percent of residents unemployed in census tract of residence) using data from the 2015-2019 American Community Survey.[22,23] We chose these particular SES indicators to capture the three common dimensions of SES: education, income, and occupation.[24] SES is related to engagement in HIV care on both an individual and neighborhood level.[25,26] While individual SES has a clear connection to the ability to access care, neighborhood SES has been shown to have an independent effect on health beyond SES on the individual level.[27,28] We also described census tract eviction rate (percent of occupied renting households evicted per year) using data from the Princeton Eviction Lab and classified each client's census tract of residence as rural or urban based on USDA Rural-Urban Commuting Area Codes (Non-rural 1-3; rural 4-9).[2922,30] We categorized continuous census-tract measures into quartiles defined by the distribution of census tracts in entire state of Washington. For time-varying characteristics (residence, time since diagnosis, age), we selected the value corresponding to a person's earliest disenrollment. For individuals continuously enrolled in ADAP, we used the value corresponding to their first 6-month recertification opportunity.

Analysis

We calculated the total number and proportion of clients who were continuously enrolled, disenrolled, or ruled ineligible for each 6-month period and overall. Since a client's

motivation to reenroll may change over the course of a year as insurance benefits change, we compared the proportion who disenrolled in the first half of a year to the proportion who disenrolled during the second half of a year with a rate ratio and 95% confidence interval (CL).

For those who were disenrolled or ruled ineligible, we calculated the proportion who were disenrolled more than once and the proportion who returned to the program within 1 and 3 months after their first removal from the program. We used the Kaplan-Meier method to estimate the median time to return and 95% confidence intervals and compared the median between those who were disenrolled and those who were ruled ineligible using a log-rank test.

We characterized the demographics of clients who were disenrolled by comparing the number and proportion of each attribute between those who were ever disenrolled from the program and those who never left the program (both categories excluded those who were ruled ineligible at any point). For individual demographic variables, we calculated prevalence ratios (PR) and 95% CI using a Poisson model with robust standard error estimates. For census-tract measures, we calculated prevalence ratios using multi-level Poisson models with random effects for census tract adjusted for region. We used likelihood ratio test to assess the significance of each census tract variable in its entirety. Finally, we calculated adjusted prevalence ratios using a multi-level model incorporating both the client demographics and census tract characteristics.

As a sensitivity analysis, we repeated this comparison excluding clients who were disenrolled and did not return within 6 months, as these clients may be more likely to have access to care elsewhere or have moved away from Washington State. All demographic data was complete for clients of ADAP apart from county of residence, which contained a small number of missing values from invalid addresses. We did not perform any correction for missing data. All

analyses were performed for program evaluation and received exemption from review from the University of Washington IRB.

Results

Frequency of Disenrollment

From 2017 to 2019, a total of 5480 clients were enrolled in ADAP, of whom 3304 (60%) received premium payment assistance to pay for their insurance. During this time, 1423 (26%) clients were disenrolled due to a failure to recertify and 984 (18%) clients were ruled ineligible, representing averages of 6.8% and 4.7% of clients for each recertification opportunity (range 6.0-8.2% and 3.6-6.4%, Table 1). Of the clients who disenrolled, 15% did so more than once in the 2-year study period. There was no significant difference between the proportion of clients who disenrolled in the second half of the year as compared to the first half (PR: 1.08, 95% CI 0.98-1.18).

Time away from Services

Of the 1424 clients who were disenrolled during the study period, 29% (95% CI 26-29%) reenrolled within a month of disenrollment and 38% (95% CI 36-38%) returned within 3 months. The median time to return was 12 months (95% CI 8-19 months). Those who were ruled ineligible stayed out of the program for longer; 10% retuned within a month (95% CI 8-10%) and 21% returned within 3 months (95% CI 19-22%). The median time to return for those ruled ineligible was 38 months (95% Cl lower bound 23 months, upper bound not estimable due to censoring; log-rank p-value compared to those disenrolled <0.01.

Demographic Comparison

Compared to those who were continuously enrolled in ADAP, those who were disenrolled from ADAP at least once were more likely to be Black (PR vs White: 1.31, 95% CI 1.17-1.46), younger, and uninsured (PR vs private insurance: 1.26, 95% CI 1.10-1.40). Clients who were disenrolled were less likely to have recently received case management services (PR 0.63, 95% CI 0.58-0.69). They were less likely to have dual Medicare-Medicaid (PR vs private insurance: 0.48 95% CI 0.38-0.60) or other public insurance (PR vs private insurance 0.58 (0.52-0.65) and have an income below 139% FPL (PR vs >425% FPL: 0.73 95% CI 0.65-0.81, Table 1.2). After adjustment for all of the individual and neighborhood characteristics, there was attenuation of the prevalence ratio for Black race (PR vs White: 1.14, 95% CI 0.99-1.32). The results of our analyses did not change when we removed clients who were disenrolled for more than 6-months.

Neighborhood Characteristics

Ninety-three percent of clients had addresses that could be assigned to a census tract. After adjustment for region, the census tracts where people who were disenrolled lived were not statistically different from the tracts of people who never disenrolled in any of our measures. The full results, along with adjusted prevalence estimates can be found in Table 1.3. The results of our analyses did not change when we removed clients who were disenrolled for more than 6-months.

Discussion

Our study found that ADAP disenrollment is common. In our two-year study period, 26% of clients were disenrolled from ADAP due to failure to recertify, which is 44% more clients than were found to be ineligible (26% vs 18%). We also found that the population that was disenrolled was disproportionately young, Black, uninsured, and not engaged with case management services. We did not find any association between disenrollment and census tract SES.

The number of disenrollments suggests that there may be a large proportion of clients who are eligible for ADAP in Washington State but are denied services due to a program policy barrier. This is consistent with research from Alabama and North Carolina, which found that the ADAP recertification requirement was a barrier to ADAP utilization.[14,31] This reduction in ADAP clients serves the 6-month recertification policy's goal of ensuring that RWHAP's limited grant resources are spent on eligible clients, but the number of disenrollments relative to ineligibility rulings means that the policy is more often removing clients who do not complete the recertification procedure than clients who are confirmed ineligible for ADAP.

The demographics of PLWH who are disenrolled from ADAP reveal an overlap with populations that have lower viral suppression rates in Washington State and nationwide. Black PLWH (78% viral suppression) and young PLWH (74% viral suppression among those between 25 and 34) have the lowest viral suppression rates in the state (82% viral suppression overall).[17] The disproportionate impact of ADAP disenrollment on Black PLWH is noteworthy and may represent a modifiable barrier for a population that has not benefitted from statewide increases in viral suppression in Washington.[17] The attenuation of this association after

adjustment for demographic factors does not diminish the importance of the observed disparity but rather highlights the interconnectedness of race and other social determinants of health.

Our finding that disenrollment was not associated with neighborhood SES may indicate that neighborhood SES is not related to a person's ability to complete the 6-month recertification, or it may represent limitations in our measurement of neighborhood SES. Our measures are, at best, proximal measures of SES, and census tracts do not define perfect boundaries around a person's social environment. Associations between neighborhood SES and disenrollment may be too subtle to measure with census tract measures.

Our study has several limitations. It is possible that some clients who do not recertify choose not to do so because they know that they are ineligible or no longer need ADAP services. If the latter were common, however, we might expect to see an increase in disenrollment in the second half of the year when privately insured individuals reach their policies' deductible, which we did not. We did not have data available to describe homelessness, which may be an important factor driving the length of disenrollment as Washington uses letters to try to reengage clients. Our study also did not examine HIV clinical outcomes in relation to disenrollment. This is a key area for future study; due to the length of benefits disruption we observed, disenrollment could lead to disruptions to antiretroviral medication if former clients are unable to access care through other mechanisms. Finally, this study was conducted in the years just prior to the COVID pandemic, which led to substantial changes in HIV care provision, medication dispensation, and ADAP policies. Many states rapidly implemented more flexible policies for continuing ADAP benefits with the intention of

preventing disruptions on coverage. The impact and durability of these policies is not yet fully known.[32,33]

The implications of this study for national policy depend on whether disenrollment in Washington is representative of disenrollment in other programs. Washington State is one of 59 different ADAP jurisdictions, and the burden of recertification may stem from Washington's recertification processes rather than the requirements set by federal policy. However, the standard recertification procedures in Washington State represent only the minimum federal requirements, which is not the case in all other jurisdictions.[13,32] Although Washington State does not offer self-attestation to current ADAP clients, it does not seem likely that recertification in Washington is unusually difficult compared to other ADAP's; self-attestation still requires engagement on the part of the client, and does not completely eliminate the burden of reenrollment. Regardless of the size of the barrier that recertification represents in each jurisdiction, moving to a 12-month recertification interval, as suggested in response to HRSA's 2018 RFI, would reduce the frequency of disruption.[16]

In summary, our study found that the 6-month ADAP recertification policy in Washington State excludes a large number of people from receiving ADAP services on the basis of their ability or willingness to complete the recertification process. This policy disproportionately affects populations with the lowest probability of viral suppression and may contribute to the disparities in HIV incidence and outcomes in the state. While the 6-month recertification requirement is effective in ensuring that RWHAP's limited grant resources are spent on eligible clients, the impact of this policy in Washington state is unjust. If this finding is consistent in other areas, jurisdictional approaches to how the recertification requirement is

operationalized should be re-examined and alternatives to the 6-month recertification requirement should be considered.

Tables

Table 1.1. Number and Outcome of Recertification Attempts by AIDS Drug Assistance Clients by 6-Month Period, Washington State 2017-2019[a]

Beginning of Period	Recertification Attempts	Reenrolled	Disenrolled	Ineligible
1/1/2017	3518	3088 (87.8%)	291 (8.3%)	139 (4.5%)
7/1/2017	3587	3123 (87.1%)	323 (9%)	141 (4.5%)
1/1/2018	3623	3229 (89.1%)	244 (6.7%)	150 (4.6%)
7/1/2018	3808	3308 (86.9%)	270 (7.1%)	230 (7.0%)
1/1/2019	3891	3441 (88.4%)	263 (6.8%)	187 (5.4%)
7/1/2019	4040	3483 (86.2%)	297 (7.4%)	260 (7.5%)
Total	22467	19672 (87.6%)	1688 (7.5%)	1107 (5.6%)

a. Clients were categorized as enrolled if they successfully recertified, disenrolled if they failed to recertify, and ineligible if they recertified but did not meet the income or insurance requirements for the program.

Table 1.2. Demographic Characteristics of ADAP Clients Who Were Disenrolled Versus Clients Who Were Continuously Enrolled, Washington State 2017-2019[a]

Variable[b]	Value	Disenrolled	Continuously Enrolled	Prevalence Ratio (95% CI)	Adjusted Prevalence Ratio (95% CI)[c]
Total		1390	3169		
Race	Hispanic	275 (20%)	683 (22%)	1.00 (0.88-1.12)	0.80 (0.69-0.92)
	Black	308 (22%)	509 (16%)	1.31 (1.17-1.46)	1.14 (0.99-1.32)
	White	667 (48%)	1646 (52%)	Reference	Reference
	Other/Multiple	141 (10%)	331 (10%)	1.04 (0.89-1.21)	0.94 (0.81-1.08)
HIV Acquisition Risk Category	MSM	837 (60%)	1920 (61%)	Reference	Reference
	IDU	65 (5%)	132 (4%)	1.09 (0.88-1.34)	1.34 (1.06-1.68)
	MSM+IDU	128 (9%)	301 (9%)	0.98 (0.84-1.15)	1.12 (0.97-1.31)
	Heterosexual Contact	127 (9%)	350 (11%)	0.88 (0.75-1.03)	0.95 (0.76-1.19)
	Other	234 (17%)	466 (15%)	1.10 (0.98-1.24)	1.08 (0.91-1.29)
Age	<25	23 (2%)	39 (1%)	1.02 (0.73-1.42)	1.05 (0.73-1.51)
	25-34	220 (16%)	269 (8%)	1.23 (1.08-1.41)	1.18 (1.02-1.37)
	35-44	300 (22%)	522 (16%)	Reference	Reference
	45-54	383 (28%)	813 (26%)	0.88 (0.78-0.99)	0.91 (0.8-1.04)
	55-64	331 (24%)	991 (31%)	0.69 (0.6-0.78)	0.78 (0.68-0.9)
	65+	133 (10%)	535 (17%)	0.55 (0.46-0.65)	0.68 (0.55-0.83)
Birth Sex	Female	220 (16%)	525 (17%)	Reference	Reference
	Male	1170 (84%)	2644 (83%)	1.04 (0.92-1.17)	1.18 (1.00-1.40)
Insurance	Dual Medicare-Medicaid	70 (5%)	331 (10%)	0.48 (0.38-0.60)	0.50 (0.39-0.64)
	Other Public Insurance	330 (24%)	1229 (39%)	0.58 (0.52-0.65)	0.64 (0.55-0.75)
	Private Insurance	778 (56%)	1360 (43%)	Reference	Reference
	Uninsured	212 (15%)	249 (8%)	1.26 (1.1-1.4)	1.31 (1.15-1.49)
Geography	Eastern WA	154 (11%)	480 (15%)	0.87 (0.75-1.02)	0.84 (0.71-0.99)
	King County	769 (57%)	1531 (49%)	1.20 (1.09-1.33)	1.03 (0.89-1.2)
	Western WA (Not King County)	429 (32%)	1114 (36%)	Reference	Reference
Time from Diagnosis	<1 year	143 (10%)	364 (11%)	0.92 (0.79-1.08)	0.59 (0.49-0.73)
	1-5 years	243 (17%)	357 (11%)	1.40 (1.25-1.56)	1.06 (0.93-1.2)
	>5 years	1004 (72%)	2448 (77%)	Reference	Reference
Income	0-135% FPL	461 (33%)	1236 (39%)	0.73 (0.65-0.81)	1.06 (0.92-1.21)
	135-250% FPL	465 (33%)	1131 (36%)	0.79 (0.71-0.88)	0.96 (0.86-1.08)
	250-425% FPL	463 (33%)	802 (25%)	Reference	Reference
Received Case Management in past 6M	Yes	961 (69%)	2591 (82%)	0.63 (0.58-0.69)	0.69 (0.63-0.77)
	No	430 (31%)	579 (18%)	Reference	Reference

Abbreviations: MSM= Male-Male Sexual Contact, IDU = Injection Drug Use, FPL = Federal Poverty Level, CI = Confidence Interval

a. Clients who failed to recertify one or more times between 2017 to 2019 were categorized as disenrolled. Clients who never failed to recertify were categorized as continuously enrolled. Those who were ruled ineligible at any point were excluded. Time varying variables (age, insurance, geography, income, and time from diagnosis) were measured at a client's first disenrollment for those who disenrolled and first recertification opportunity for those who were continuously enrolled.

b. Reference groups were selected to maximize sample size and interpretability.

c. Adjusted prevalence ratio from a mixed Poisson model with a random effects term for census tract adjusted for all demographic and census-tract variables

Table 1.3. Characteristics of Census Tract of Residence of ADAP Clients Who Were Disenrolled Versus Clients Who Were Continuously Enrolled, Washington State 2017-2019[a, 21, 29]

Variable[b]	Value	DIsenrolled (n=1276)	Continuously Enrolled (n=2975)	Prevalence Ratio[c]	P-value[d]	Adjusted Prevalence Ratio[c]	P-value[d]
Rural vs Urban[e]	Urban	1206 (95%)	2808 (94%)	0.89 (0.72-1.1)	0.30	1.07 (0.84-1.38)	0.58
	Rural	70 (5%)	167 (6%)	Reference		Reference	
% with <HS Degree	Q1 (≤3.9%)	331 (26%)	648 (22%)	1.05 (0.93-1.18)	0.06	1.05 (0.90-1.23)	0.03
	Q2 (3.9-7.1%)	227 (18%)	601 (20%)	0.89 (0.78-1.02)		0.89 (0.76-1.03)	
	Q3 (>7.1-11.3%)	278 (22%)	722 (24%)	0.91 (0.80-1.03)		0.89 (0.78-1.02)	
	Q4 (>11.3%)	440 (34%)	1004 (34%)	Reference		Reference	
% below Poverty Level	Q1 (≤5.7%)	217 (17%)	438 (15%)	1.11 (0.97-1.27)	0.39	1.00 (0.83-1.20)	0.85
	Q2 (>5.7-9.3%)	279 (22%)	609 (20%)	1.06 (0.94-1.21)		0.97 (0.83-1.12)	
	Q3 >9.3-14.7%)	317 (25%)	767 (26%)	1.01 (0.89-1.13)		0.95 (0.83-1.09)	
	Q4 (>14.7%)	463 (36%)	1161 (39%)	Reference		Reference	
% of Homes Rented	Q1 (≤18.5%)	97 (7.0%)	331 (8.4%)	1.02 (0.85-1.22)	0.44	0.90 (0.73-1.12)	0.81
	Q2 (>18.5-31.6%)	180 (12.9%)	521 (13.3%)	1.06 (0.92-1.22)		0.98 (0.83-1.16)	
	Q3 >31.6-48.3%)	332 (23.9%)	915 (23.3%)	1.10 (0.98-1.22)		0.98 (0.87-1.12)	
	Q4 (>48.3)	665 (47.8%)	1940 (49.4%)	Reference		Reference	
% Unemployed	Q1 (≤1.9%)	292 (23%)	656 (22%)	1.06 (0.93-1.21)	0.21	1.05 (0.92-1.21)	029
	Q2 (>1.9-2.9%)	280 (22%)	573 (19%)	1.14 (1.00-1.3)		1.14 (1.00-1.31)	
	Q3 >2.9-4.0%)	344 (27%)	838 (28%)	1.01 (0.90-1.15)		1.03 (0.91-1.17)	
	Q4 (>4.0)	360 (28%)	908 (31%)	Reference		Reference	
% of Lessees Evicted	Q1 (≤0.2)	284 (23%)	616 (22%)	1.01 (0.86-1.18)	0.43	1.00 (0.82-1.23)	0.81
	Q2 (>0.2-0.61)	369 (30%)	818 (29%)	1.02 (0.89-1.18)		1.02 (0.86-1.22)	
	Q3 >0.61-1.15)	319 (26%)	708 (25%)	1.11 (0.96-1.27)		1.09 (0.95-1.25)	
	Q4 (>1.15)	263 (21%)	722 (25%)	Reference		Reference	
Median Home Value	Q1 (≤232)	225 (18%)	620 (21%)	1.04 (0.87-1.25)	0.91	1.13 (0.87-1.46)	0.70
	Q2 (>233-318)	256 (20%)	635 (22%)	1.04 (0.89-1.21)		1.02 (0.83-1.26)	
	Q3 >319-435)	328 (26%)	751 (25%)	0.99 (0.88-1.12)		1.02 (0.87-1.19)	
	Q4 (>436)	458 (36%)	941 (32%)	Reference		Reference	
Median Household Income	Q1 (≤55)	331 (26%)	937 (31%)	0.84 (0.73-0.97)	0.07	0.83 (0.67-1.02)	0.19
	Q2 (>56-72)	380 (30%)	833 (28%)	0.95 (0.83-1.08)		0.97 (0.82-1.15)	
	Q3 >73-94)	302 (24%)	714 (24%)	0.88 (0.77-1.01)		0.98 (0.84-1.13)	
	Q4 (>95)	263 (21%)	491 (17%)	Reference		Reference	

a. Clients who failed to recertify one or more times between 2017 to 2019 were categorized as disenrolled. Clients who never failed to recertify were categorized as continuously enrolled. Those who were ruled ineligible at any point were excluded. Census tract of residence was ascertained at a client's first disenrollment for those who disenrolled and first recertification opportunity for those who were continuously enrolled.

b. Reference groups were selected to maximize sample size and interpretability.

c. Prevalence ratios and confidence interval from multi-level Poisson model with random effects for census tract adjusted for region (Eastern Washington, King County, Western Washington other than King County). Adjusted prevalence ratios from a mixed Poisson model with a random effects term for census tract adjusted for all demographic and census-tract variables.

d. P-value from type 3 test of fixed effects.

e. Rural census tracts defined as those with a USDA Rural-Urban Commuting Code of 1, 2, or 3. All other tracts were classified as urban

Chapter 3: Does Ryan White Program certification pose a structural barrier to HIV treatment? An evaluation in Washington State, 2017-2019

Abstract

AIDS Drug Assistance Programs (ADAPs) are state-administered programs that pay for medical care for people living with HIV in the US. Maintaining enrollment in the programs is challenging, and a large proportion of clients in Washington state (WA) are disenrolled due to a failure to recertify. We sought to quantify the impact of disenrollment from ADAPs on viral suppression. We conducted a retrospective cohort study of the 5238 clients in WA ADAP from 2017 to 2019 and estimated the risk difference (RD) of viral suppression before and after disenrollment. We performed a quantitative bias analysis (QBA) to assess the effect of unmeasured confounders as the factors that contribute to disenrollment and medication discontinuation may overlap. Of the 1336 ADAP clients who disenrolled at least once, 83% were virally suppressed before disenrollment versus 69% after (RD 12%, 95%CI 9-15%). The RD was highest among clients with dual Medicaid-Medicare insurance (RD 22%, 95%CI 9-35%) and lowest among privately insured individuals (RD 8%, 95%CI 5-12%). The results of the QBA suggested that unmeasured confounders do not negate the overall RD. The current ADAP recertification procedures negatively impact the care of clients who struggle to stay in the program; alternative procedures such as less frequent recertification may reduce this impact.

Introduction

The Ryan White HIV/AIDS Drug Assistance programs (ADAPs) are the largest source of medical care for people living with HIV (PLWH) in the United States and a critical part of federal plans to reduce HIV incidence by 90% by 2030.[4] ADAPs pay for insurance and medical care for

20% of people living with HIV in the United States, and people on the program have high rates of viral suppression, the central measure of successful HIV treatment.[2,18] Despite the benefits of the program, many PLWH struggle to complete the procedures required to maintain enrollment in the program and subsequently become disenrolled. [1,9] However, the effect of ADAP disenrollment, particularly temporary disruptions in coverage, on HIV clinical outcomes is unclear.

In October of 2021, the Federal Ryan White HIV/AIDS program announced that they were removing the federal requirements for client recertification.[34] Prior to this, recipients of ADAP services needed to provide documentation of their eligibility every 6 months or they would be removed from the program and lose access to services.[13] This policy was identified as a barrier to client access to ADAP's. In a prior study, we found that 26% of ADAP enrollees in Washington State were disenrolled due to failure to recertify in a 2-year period.[35] If they so choose, individual programs now have the authority to modify the recertification requirement which may improve retention in the program. However, retaining more clients in the program may increase the cost of the program, and the impact of disenrollment on HIV care has not been established.

There is evidence to suggest that disenrollment from ADAP may disrupt access to antiretroviral medications and HIV medical care. A 2018 HRSA request for information from Ryan White programs, clients, and providers identified the 6-month recertification requirement as a disruptor to HIV care.[16] Changes to insurance coverage have been demonstrated to be disruptive to ART use; a 2016 study found that PLWH who lose insurance were less likely to be virally suppressed.[10,36] A loss of ADAP coverage may occur at a particularly vulnerable time for

clients; if a person is unable to complete the recertification procedures, it may indicate that they have a reduced capacity to navigate medical and payer systems. To our knowledge there is no published data examining the effect of ADAP disenrollment on viral suppression or how this may be modified by a client's existing insurance coverage.

In this study we examined the change in viral suppression associated with ADAP disenrollment. The objectives of this study were to: 1) Compare the risk of viral suppression between those who disenroll in ADAP or are ruled ineligible for ADAP and those who are continuously enrolled; 2) Estimate the risk differences by co-insurance type; and 3) Describe the potential effect of confounding by mental health, binge-drinking, illicit substance use, and homelessness on the measured risk difference using quantitative bias analysis.

Methods

Study Design and Data Sources

We performed a longitudinal analysis of PLWH enrolled in Washington State's ADAP between 2017 and 2019. To be eligible for inclusion in our analysis, ADAP clients had to either be continuously enrolled in ADAP until the end of 2019, receive a viral load in Washington state within 12 months of leaving ADAP, or live in Washington state for 12 months after leaving ADAP.

The primary data sources were Washington HIV surveillance system and the Washington Ryan White Data System. The Washington HIV surveillance system is a longitudinal database of PLWH based on laboratory results collected during the course of routine HIV care and reported to the state by law.[37] The laboratory results are supplemented by active collection of additional information about new HIV diagnoses, changes of residence, death, and demographics which

yields a data system that can be used to describe the population of PLWH in Washington and follow individuals' clinical outcomes over time. The Ryan White data system is an administrative database of eligibility, benefits, and services provided for all Ryan White-funded activities in Washington State that is used for claims administration, eligibility determination, enrollment, program administration, and program evaluation.

The exposure of interest was recertification success, which we measured using data from the Ryan White data system. We characterized each client's recertification success over the study period by categorizing them as 1) continuously enrolled (i.e. the client successfully recertified throughout the two year time period), 2) disenrolled (i.e. the client failed to recertify one or more times), or 3) ineligible (i.e. the client submitted recertification information but did not meet the requirements for the program one or more times). More information about how clients were categorized is described elsewhere.[35] If a client was both disenrolled and ruled ineligible during the study period, they were assigned the status corresponding to the event that occurred first.

Our outcome was viral suppression status before and after clients' recertification opportunities, which we measured using data from the HIV surveillance system. Viral suppression is the central indicator of successful treatment of HIV and represents a health state with a reduced risk of HIV-associated illness and no risk of HIV transmission.[38] It is assessed via viral load testing, which is generally performed every 6 to 12 months for PLWH in continuous care. We measured viral suppression before a recertification opportunity by the result of a client's last viral load test before the recertification date and measured viral suppression after a recertification opportunity by the result of the viral load test immediately following their

recertification date. We used a cutoff of 200 viral copies per milliliter and considered clients to be not suppressed if they did not have a viral load test in the 12 months preceding or following a recertification.[39]

To characterize the demographics of our population, we extracted age, race and ethnicity, sex at birth, HIV acquisition risk (male sex with male, injection drug use, male sex with male and injection drug use, heterosexual contact, and other), and region (Western Washington, Eastern Washington, or Seattle/King County) from the HIV surveillance system and insurance type (private, dual Medicare-Medicaid, other public insurance, uninsured) and enrollment in case management from the Ryan White data system.

Primary Analysis

We estimated the risk difference in viral suppression associated with disenrollment and ineligibility rulings using a generalized linear model with the Poisson distribution, an identity link function, and subject-level random effects.[40,41] With time as a binary variable indicating before or after a recertification opportunity using the following model equation:

$$\mathrm{P}(Viral\ Suppression = 1 | Disenrolled, Ineligible, Time) = \\ \alpha + \beta_1 * Disenrolled + \beta_2 * Ineligible + \beta_3 * Time + \beta_4 * Disenrolled * Time + \\ \beta_5 * Ineligible * Time + \beta_6 * Covariates$$

Each ADAP client contributed one recertification opportunity to the model. For clients categorized as disenrolled or ineligible, we modelled viral suppression surrounding the date they were first disenrolled or ruled ineligible. For clients who were continuously enrolled, we modelled viral suppression surrounding their first successful recertification. We constructed adjusted models that included age (linear splines with cut points at 25, 50, and 75), sex, race,

HIV transmission category, region, insurance type, and case management status. As the value of ADAP services may depend on a client's ability to afford care via other means, we repeated our analyses with an interaction term between the disenrollment and ineligibility terms and insurance type to estimate risk differences specific to insurance type. This was an a priori decision. We also performed a sensitivity analysis where we excluded clients who did not have a viral load before or after their recertification opportunity of interest. (In primary analyses we categorized individuals who did not have labs as not virally suppressed). This was motivated by concern about individuals moving out of Washington; laboratory results for someone who has moved away would not be reported to the Washington State Department of Health and can give the appearance that the person is not receiving medical care. This may be overrepresented among people who disenroll, as people who leave the state likely would not apply for ADAP recertification. To quantify the impact of this analytic decision, we repeated our analysis while excluding clients who did not have a viral load before or after their recertification opportunity of interest.

Quantitative Bias Analysis

Quantitative bias analysis (QBA) is a technique for describing the influence of systematic error on an epidemiologic study's estimate of association.[42] In our study, we used QBA to examine the impact of unmeasured confounders. When individual-level confounder information is not available, QBA can be used to simulate adjusted estimates using descriptions of population characteristics from external data sources. Through review of the literature and consultation of HIV care providers, we identified four variables that we could not measure

directly for the entire analytic sample, but may be confounders of the association between ADAP disenrollment and viral suppression: poor mental health[43], heavy drinking[44], illicit substance use[45], and housing instability[46]. To develop adjusted estimates three parameters are required: 1.) the risk difference of viral suppression between those who were exposed to each confounder and those who were not exposed to each confounder among those who were in ADAP, 2.) the prevalence of the confounders among those who remained enrolled in ADAP, and 3.) the prevalence of the confounders among those who disenrolled from ADAP (Figure 2.1.)[42] To estimate these parameters, we used data collected from current or former ADAP clients who participated in the Medical Monitoring Project (MMP) between 2015 and 2018. MMP is a surveillance system that captures detailed information on behavioral and clinical characteristics of a sample of people living with HIV in the US via structured phone interview and medical record abstraction.[47] The data is collected by health department staff, who are assigned a random sample of PLWH to contact via letter and phone call. The data is accompanied by weights to correct for non-response bias. We measured our confounders using the following interview questions:

- Poor Mental health[43]- Yes/No, reflecting a participant's answer to the question, "Now thinking about your mental health, which includes stress, depression, and problems with emotions, for how many days during the past 30 days was your mental health not good?", using a cutoff of 14 or more days as poor mental health.[48]
- Heavy Drinking[44]- Yes/No, reflecting the CDC criterion of "heavy drinking" in the past 30 days, which is an average of more than 2 alcoholic drinks per day for men, more than 1 alcoholic drink per day for women.

- Illicit Substance use[45]- Yes/No reflecting whether a participant reported using cocaine, heroin, or methamphetamine in the past 12 months
- Housing Instability[46]- Yes/No reflecting whether a participant reported living on the street, shelter or car; needing housing, rent, or utility assistance; or living with friends in the past 12 months.

To estimate the first parameter, we used a single Poisson model (including all 4 confounders) to estimate the risk difference of viral suppression at the time of interview for each confounder. We derived parameter 2 from the proportion of our MMP sample who selected 'Yes' for each confounder. For parameter 3, we simulated a range of values ranging from 0% to 100% higher than parameter 2. We used these 3 parameters together to calculate corrected risk differences using the methodology described in Lash et al.[42] We obtained 95% confidence intervals using 10,000 Monte Carlo simulations. We used a normal distribution to represent uncertainty in our Parameter 1 & 2 estimates using the standard errors from our regression model and the asymptotic standard errors of the binomial distribution. We treated parameter 3 as a fixed value. We estimated a corrected risk difference using each confounder individually and for all confounders together. All analyses using MMP data were performed with subject-specific weights to account for non-response. All analyses met the criteria for program evaluation and received exemption from review from the University of Washington IRB.

Results

From 2017-2019, 5238 clients enrolled in ADAP and met the inclusion criteria for our analysis. Of these, 1336 (26%) were categorized as disenrolled, 896 (17%) as ineligible, and 3006 (57%) as continuously enrolled. The characteristics of the overall ADAP population and those disenrolled from ADAP are described in detail in a prior publication and supplementary table.[35] In the period immediately preceding the recertification opportunity, 1109 (83%) of those who were disenrolled were virally suppressed, 806 (90%) of those who were ruled ineligible were virally suppressed, and 2756 (92%) of those who were continuously enrolled were virally suppressed. Following removal from the program, 927 (69%) of those who were disenrolled were virally suppressed (adjusted risk difference 12%, 95% CI 9-15%) and 730 (81%) of those who were ruled ineligible were virally suppressed (adjusted risk difference 7%, 95% CI 4-10%). Following recertification, 2700 (90%) of those who were continuously enrolled were virally suppressed (Table 2.1).

For those who were disenrolled, the adjusted risk difference of viral suppression was highest among clients with dual Medicare/Medicaid (22%, 95% CI 9-35%), and lowest among those with private insurance (8%, 95% CI 5-12%). For those who were ineligible, the highest risk difference was also among clients with other public insurance (21%, 95% CI 11-33%), but was lowest among the uninsured (4%, 95% CI -5-13%).

Our sensitivity analysis excluding participants who did not have a viral load measurement before or after their recertification yielded attenuated risk differences. Among those who received viral load tests 12 months before and after their recertification date, the adjusted risk difference of viral suppression was 3% (95% CI 1-5%) for those who were disenrolled and was 2% (95% CI 0-4%) for those who were ruled ineligible.

Quantitative Bias Analysis

Between 2015 and 2018, there were 308 MMP participants who were current or previous clients of ADAP. From a model including each variable, the risk difference for viral suppression was -13.8% (95% CI -1.94 to -8.1%) for unstable housing, -2.3% (95% CI -13.6 to -8.1%) for poor mental health, -4.1% (95% CI -24.3 to 16.1%) for heavy drinking, and 3.8% (95% CI -8.7 to 16.4%) for illicit substance use. The prevalence of these confounders was 39%, 23%, 5%, and 16%, respectively. If the prevalence of these confounders were 50% higher among those who disenroll from ADAP, the corrected risk difference for viral suppression from our main analysis would be 9% (95% CI 5-13%) instead of the 12% unadjusted risk difference. If the prevalence of these confounders were 100% higher among those who disenroll from ADAP, the corrected risk difference for viral suppression would be 6% (0-12%) (see Figure 2.2). The effect of the individual variables is shown in Table 2.2.

Discussion

We found that 12 out of every 100 PLWH (12%) who were disenrolled from ADAP lost viral suppression due to their disenrollment. This effect was largest among clients who had dual Medicaid/Medicare insurance (22/100) and smallest among clients who had private insurance (8/100). Our quantitative bias analysis showed that the barriers to viral suppression of housing instability, poor mental health, binge-drinking, and illicit substance use partially explain but do not entirely account for the effect. This suggest that loss of ADAP coverage has a direct effect on reducing viral suppression.

The large drop in the proportion virally suppressed for those who are disenrolled from the program suggest that a subset of clients who are removed from ADAP are left without a way to access care. This is consistent with ADAP's role as a 'last resort' payer and a survey of PLWH in Alabama, of whom 21% had lapses in treatment due to problems with ADAP or medication costs.[31] The larger effect sizes among individuals with dual Medicare/Medicaid (who necessarily have a disability) and uninsured individuals (who may have to pay full price for medical care) are consistent with a situation where a subset of the clients who are disenrolled do not have the resources to continue accessing HIV care.

Our quantitative bias analysis demonstrates that the major barriers to care that we measured (mental health, substance use, and housing instability) are not sufficient to explain the associations we observed, unless the prevalence of these factors are more than twice as high among those who are disenrolled as those who are not. This would require an extremely high prevalence of certain comorbidities among those who disenroll (e.g. over 78% homelessness and 32% illicit substance use in the past 12 months) which seems unlikely. Our findings provide evidence that disenrollment is a direct cause of clients falling out of HIV care, rather than simply a consequence of the same barriers that cause PLWH to fall out of HIV care or stop antiretroviral medications. This is consistent with responses to the HRSA request for information about the Ryan White program's administrative burdens, where program staff and HIV care providers described the recertification requirement as a barrier to keeping clients in care, and with literature that found insurance changes to be disruptive to HIV care more generally.[16,36]

Our study had several limitations. First, some people who have left Washington state may be misclassified as virally unsuppressed. However, our sensitivity analysis that includes only people who have labs reported in Washington confirms the presence of an attenuated risk difference even in a situation where this misclassification is not possible. The variables used in our quantitative bias analysis are imperfect measures and come from a data source (MMP) that may rely on a biased sample. As such there likely is residual confounding or additional confounders that bias our estimates. However, it would require a very strong confounder or many additional weak confounders to explain the entire remaining effect after controlling for variables in our analysis. Finally, it is possible that some clients who do not recertify choose not to do so because they know that they are ineligible. However, this would only serve to attenuate the risk difference among those disenrolled, as it would cause clients in our study who are ineligible to be misclassified as disenrolled.

The generalizability of these findings to other ADAP programs depend on the similarity of their ADAP benefits and the care alternatives for people who leave ADAP. Washington's ADAP offers a wider range of services than many other state ADAP programs, some of which can pay for little more than direct HIV care.[49] Although the range of services in Washington undoubtedly contribute to clients' ability to achieve viral suppression, it also means that some clients in Washington ADAP may only enroll in ADAP for supplemental services. This suggests that disenrollment from ADAP in other states could have a larger impact on viral suppression, as in some cases every client would experience changes to their access to ART, rather than only the portion of clients in Washington who use HIV prescription benefits. Further, Washington is a Medicaid expansion state, which means that the lowest income populations in the state are in

Medicaid rather than ADAP. In non-expansion states, where it is more difficult to enroll in Medicaid, ADAP may be serving populations that have fewer resources to accommodate disenrollment. Taken together, this suggests that the impact of disenrollment on viral suppression may be the same or larger in other jurisdictions.

We found that in Washington State, a significant proportion of PLWH who were removed from ADAP due to failure to recertify lost viral suppression immediately afterwards. This suggests that the default 6-month recertification policy serve as a barrier to achieving federal goals for HIV incidence and to the health of PLWH generally. In light of these findings, we recommend that ADAP programs make use of the new flexibility in federal recertification policy and examine alternatives to the 6-month recertification requirement such as less frequent recertification or simpler procedures.

Tables

Table 2.1. Viral Suppression Status Before and After Removal from ADAP or Reenrollment by Insurance Status, Washington State 2017-2019

Population	Recertific-ation Outcome[a]	N Total	Virally Suppressed Before Recertification or Removal[b]	Virally Suppressed After Recertification or Removal	Change in Viral Suppression	Unadjusted Risk Difference[c]	Adjusted Risk Difference[d]
All	Disenrolled	1336	1109 (83%)	927 (69%)	14% (10-17%)	12% (9-15%)	12% (9-15%)
	Ineligible	896	806 (90%)	730 (81%)	8% (5-12%)	7% (4-10%)	7% (4-10%)
	Enrolled	3006	2756 (92%)	2700 (90%)	2% (0-3%)	Reference	Reference
Uninsured	Disenrolled	201	142 (71%)	118 (59%)	12% (3-21%)	9% (1-18%)	12% (3-20%)
	Ineligible	132	102 (77%)	96 (73%)	5% (-6-14%)	2% (-7-11%)	4% (-5-13%)
	Enrolled	234	204 (87%)	198 (85%)	3% (-3-9%)	Reference	Reference
Private	Disenrolled	763	668 (88%)	594 (78%)	10% (6-14%)	9% (5-12%)	8% (5-12%)
	Ineligible	670	618 (92%)	569 (85%)	7% (4-11%)	6% (3-9%)	6% (3-10%)
	Enrolled	1289	1205 (93%)	2288 (92%)	1% (0-3%)	Reference	Reference
Dual Medicare/ Medicaid	Dropped	66	52 (79%)	36 (55%)	24% (9-40%)	22% (9-35%)	22% (9-35%)
	Ineligible	24	21 (88%)	17 (71%)	17% (-6-39%)	14% (-8-4%)	16% (-8-39%)
	Enrolled	316	277 (88%)	270 (85%)	2 (-3-8%)	Reference	Reference
Other Public Insurance	Dropped	308	248 (81%)	181 (59%)	22% (15-29%)	20% (13-26%)	19% (14-26%)
	Ineligible	72	67 (93%)	50 (69%)	24% (11-36%)	21% (10-32%)	22% (11-33%)
	Enrolled	1170	1072 (92%)	1046 (89%)	2% (0-5%)	Reference	Reference

a. Clients who were ruled ineligible one or more times between 2017 and 2019 were categorized as ineligible unless they were previously categorized as disenrolled. Clients who were never removed from ADAP were categorized as continuously enrolled.

b. Viral suppression measured after a client's first removal from ADAP or first recertification if they were never removed. Clients were categorized as virally suppressed before recertification if they had a viral load of 200 copies/mL or less in the 12 months prior to the recertification. Clients were categorized as virally suppressed after recertification if they had a viral load of 200 copies/mL or less in the 12 months after recertification.

c. Risk difference from a generalized linear model with the Poisson distribution, an identity link function, and subject-level random effects.

d. Adjusted risk difference from model adjusted for age, region, HIV acquisition risk, race, sex at birth, receipt of case management services, and insurance type (for non-stratified models).

Table 2.2. Probabilistic Quantitative Bias Analysis for Unmeasured Confounders of ADAP Disenrollment and Viral Suppression, Washington State 2017-2019[a]

			Corrected Risk Difference of Viral Suppression with Assumption of Prevalence Among Disenrolled vs Continuously Enrolled		
Confounder[b]	**Prevalence Among MMP Participants in ADAP (SE)**	**Estimated Risk Difference (SE) of Viral Suppression[c,d]**	**0% Greater Prevalence Among APAP Disenrollees**	**50% Greater Prevalence Among APAP Disenrollees**	**100% Greater Prevalence Among APAP Disenrollees**
Unstable Housing	39% (0.31)	13.8% (0.053)	12% (9-15%)	9% (6-12%)	6% (1-11%)
Poor Mental Health	23% (0.26)	2.3% (0.058)	12% (9-15%)	11% (8-15%)	11% (7-15%)
Heavy Drinking	5% (0.14)	4.1% (0.103)	12% (9-15%)	11% (9-15%)	11% (9-15%)
Illicit Substance Use	16% (0.23)	-3.8% (0.064)	12% (9-15%)	15% (11-19%)	18% (12-24%)
All	-	-	12% (9-15%)	9% (5-13%)	6% (0-12%)

a. Quantitative bias analysis performed using the prevalence of the unmeasured confounders among ADAP participants, the risk difference for viral suppression between those with and without the unmeasured confounders, and assigned values for prevalence of the unmeasured confounders among those who are disenrolled from ADAP. 95% confidence intervals were calculated using a normal distribution for the parameters and Monte Carlo sampling.
b. Unstable housing defined as living on the street, shelter or car; needing housing, rent, or utility assistance; or living with friends in the past 12 months. Poor mental health defined as having 14 or more self-reported days or poor mental health in the past 30 days. Heavy drinking defined as consuming more than 2 alcoholic drinks per day for men or more than 1 alcoholic drink per day for women on average in the past 30 days. Illicit substance use defined as use of cocaine, heroin, or methamphetamines in the past 12 months.
c. Viral suppression measured after a client's first removal from ADAP or first recertification if they were never removed. Clients were categorized as virally suppressed before recertification if they had a viral load of 200 copies/mL or less in the 12 months prior to the recertification. Clients were categorized as virally suppressed after recertification if they had a viral load of 200 copies/mL or less in the 12 months after recertification.
d. Risk difference from a generalized linear model with the Poisson distribution and identity link function that included all 4 confounders.

Figures

Figure 2.1: Quantitative Bias Parameters to Adjust the Relationship Between ADAP Disenrollment and Viral Suppression for Key Barriers to Engagement in HIV Care

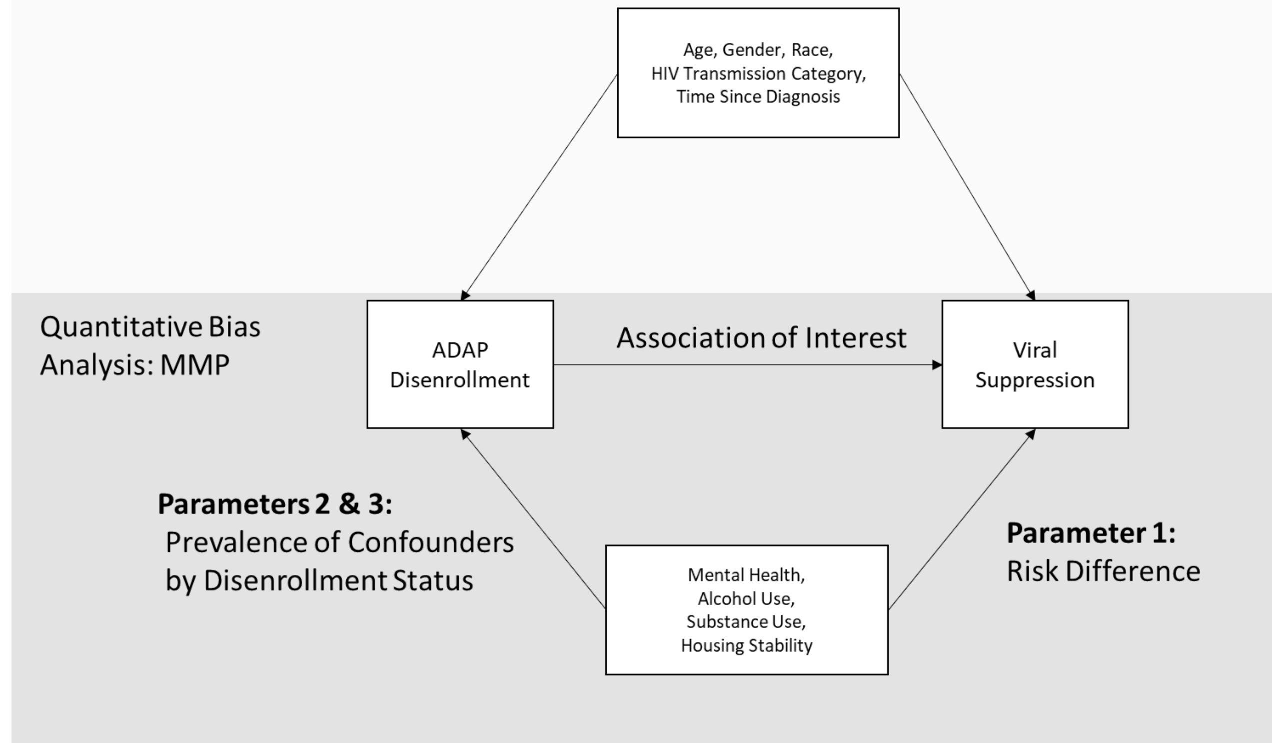
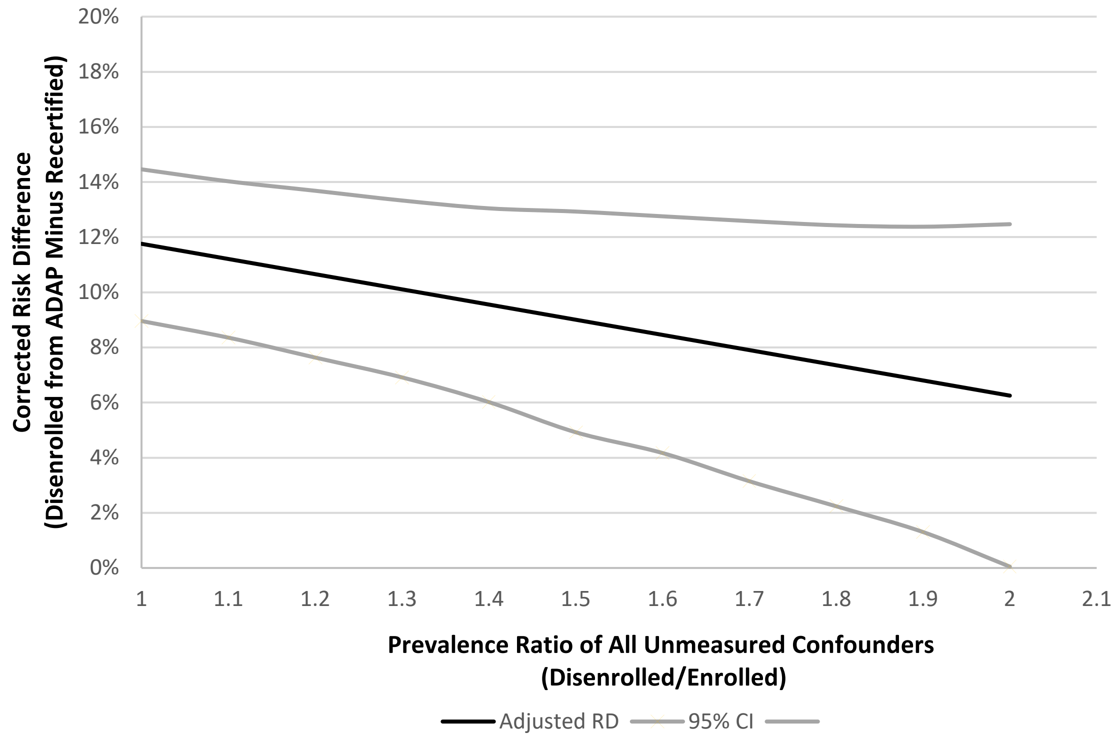


Figure 2.2. Risk Difference (RD) of Viral Suppression from ADAP Disenrollment and Viral Suppression After Correction for Unstable Housing, Poor Mental Health, Heavy Drinking, and Illicit Substance Use, Washington State 2017-2019



Chapter 4: Budget Impact Analysis of Implementing 12-Month Recertification Criterion for Ryan White HIV/AIDS Program's AIDS Drug Assistance Program in Washington State

ABSTRACT

Objectives: AIDS Drug Assistance Programs (ADAPs) are state administered programs that pay for medical care and antiretroviral medication for people living with HIV (PLWH) in the US. In October 2021, the federal policy requiring that clients recertify for the program every 6 months was repealed, giving states the authority to set their own recertification policies. Our objective was to analyze the cost and health impact of changing the legacy 6-month recertification schedule to a 12-month schedule in Washington State (WA) to inform policy decisions regarding recertification.

Design: Markov model

Methods: We designed a Markov model to describe the cohort of individuals with HIV in WA who are eligible or enrolled in ADAP. Model inputs and validation data were obtained from the WA Ryan White database. We estimated the budget impact of 12-month recertification interval compared to a 6-month interval over a 5-year time horizon. Model outputs included annual program costs, population size, and number of people virally suppressed in each scenario.

Results: Compared with 6-month recertification, a 12-month interval is projected to cost 7% (95% CI 6-8%) more per year on average ($40.2M vs $37.7M) but produced greater health benefits, with 245 more individuals virally suppressed by the end of 2025. On average, only 244 ineligible clients were retained in the program at each month.

Conclusions: Switching to a less-frequent ADAP recertification process in WA can improve health outcomes at a reasonable cost.

Introduction

The AIDS Drug Assistance Programs (ADAPs) are state-administered programs that pay for medication and medical care for over 240,000 people living with HIV (PLWH) in the United States.[2] Clients of the program have a high rate of viral suppression relative to other populations in the United States and ADAP is shown to be cost-effective for increasing viral suppression.[1,50] ADAPs are funded by the Ryan White Act, which requires that the programs only pay for services that could not be afforded through other means. Historically this has been implemented by HRSA in the form of a requirement that programs ensure that an individual's residency, income, and insurance statuses continue to meet the recipient eligibility requirements every 6-months.[13] However, completing the 6-month recertification process was challenging for some clients, particularly for those at higher risk of disengaging from care. In Washington State, 26% of clients were removed from the ADAP program in a two year period due to failure to complete the recertification proceedings, and 12% of these clients lost viral suppression. [3551] Studies in other jurisdictions found the recertification requirement to be a contributor to ADAP underusage and a barrier to viral suppression.[10,14]

In October of 2021, The Ryan White HIV/AIDS Program released Policy Clarification Notice (PCN) 21-02, which substantially reduced the requirements for programs to verify eligibility of clients of the nationwide AIDS Drug Assistance Program (ADAP).[34] Programs now have individual authority to set the frequency and manner that people living with HIV (PLHW) are assessed for their financial need for the program. This presents an opportunity for improvement of the system, but the impact of this policy change on costs and HIV health

outcomes is unknown. Before announcing the change, HRSA hosted an opportunity for the public to comment on the recertification process in its 2018 Request for Information on Administrative Streamlining and Burden Reduction.[10] One commonly mentioned suggestion was to change the recertification requirement from every 6 months to every 12 months. This change was proposed to reduce the number of opportunities for clients to miss recertification and to lower the administrative costs of verifying eligibility. Such a change has precedent in Medicaid for children and the Children's Health Insurance Program (CHIP), where 27 states have implemented 12-month continuous eligibility and have seen a decrease in churn.[52,53] Although a 12-month recertification requirement has advantages, it is important to understand the impact it would have on the program's budget.

To examine the effect of this proposed policy change, we conducted a budget impact analysis of changing from a 6-month to a 12-month recertification requirement in Washington (WA) state. Specifically, we assessed the impact of extending the recertification timeline on cost of the Washington ADAP program, the number of people virally suppressed in Washington, and number of clients who received services while ineligible for the program. Results can provide insight to policymakers on the feasibility and impact of implementing a 12-month recertification requirement is in Washington state.

Methods

Model Structure

We developed a Markov model of the population living with HIV in Washington who were currently and formerly enrolled in ADAP using R software.[54] A Markov model is a decision analytic framework that simulates health states and transitions between them using discrete

time intervals. The model contains four health states: enrolled in ADAP and eligible, enrolled in ADAP and ineligible, disenrolled from ADAP due to failure to recertify, and removed from ADAP due to ineligibility (Figure 3.1). The model assumes a constant number of individuals enroll in ADAP every month. Clients can transition from being on ADAP to being disenrolled and back to ADAP. Clients enrolled in ADAP and eligible can also transition to being enrolled and ineligible at a fixed rate. We did not include death or emigration in the model, as this occurred at a negligible rate over the model time horizon. We used a time-step of 1 month, a 5-year time horizon, and a perspective of WA state department of health (DOH) ADAP and other insurance providers. The model is stratified by insurance type (public, private, or uninsured) and receipt of case management services in a given year. Individuals can change insurance type at any month and case management status at the beginning or end of each year.

Model parameters

We derived transition probabilities using enrollment data from the WA DOH in its administration of the program from 2017-2019 (Table 3.1.) Insurance status was updated every 6-months for clients in the program during recertification and carried forward after a client left the program. Case management status was reassigned annually based on receipt of case management services. Due to the large amount of transition at the beginning of the calendar year, we estimated two sets of transition probabilities representing the month of January and the months between February and December. We extracted initial population sizes and the population sizes by month from the WA DOH Ryan White administrative database.

Costs

We included costs of ADAP services, and recertification (if enrolled in ADAP). As case managers are also funded via Ryan White and are responsible for assisting their clients in recertification, clients receiving case management services were assigned an additional cost to represent this effort. We also estimated a fixed overhead cost of the ADAP program and the cost of healthcare for PLWH who are not in ADAP. We obtained the monthly cost of ADAP services by insurance type and case management status from the WA DOH administrative database. In collaboration with financial staff at the WA DOH, we estimated the fixed annual overhead cost of the program, the cost of recertification staff, and the cost of case management staff. The cost per recertification was estimated as the annual cost of recertification staff divided by the number of recertifications in a year. The additional cost of case management assistance in recertification was estimated as the annual cost of case management staff multiplied by the proportion of time spent by case managers assisting clients in this task (as estimated by program leadership and former case managers). This value was divided by the number of recertifications in a year by clients who use case management services. The cost of medical care for PLWH not in ADAP and the probability of viral suppression in each state were derived from published values.[51,55]

Model scenarios

We compared the current ADAP with a 6-month recertification schedule to a scenario of ADAP with 12-month recertification. In the 6-month recertification scenario, clients who are enrolled in ADAP while ineligible are immediately identified and are removed from the

program. In the 12-month recertification structure, these clients are either be removed from the program as ineligible every 6 months (rate=0.167) or return to being eligible. Clients who are removed for ineligibility return to the program at a constant rate. Model outcomes included annual ADAP cost from the perspective of WA DOH and other insurance providers, average monthly ADAP enrollment, final proportion of population virally suppressed, and the proportion of ADAP clients who are enrolled while ineligible.

Model validation

We validated the model by comparing model output for the years 2017-2019 in the 6-month recertification scenario compared to empiric data on average number of enrolled clients, clients dropped per month, clients ruled ineligible per month, program cost, cost per client, and percent of individuals virally suppressed at the end of the simulation. We also assessed the monthly number of people in each health state category (enrolled in ADAP, disenrolled from ADAP due to failure to recertify, and removed from ADAP due to ineligibility) over time.

Analysis

We simulated the years 2021-2025 using the 2017-2019 transition probabilities and the study population as of 1/1/2021. To simulate a 12-month recertification, we modified the transition probabilities in the following ways: 1.) The rate of disenrollment was halved to simulate individuals being removed for failure to recertify half as often; 2.) the rate of transition from ineligible and enrolled to ineligible and removed was changed from 1 to 1/6 to represent

ineligible ADAP clients staying in the program for 6 months before bring removed ; 3.) For the initial 6 months, no one is removed from the program as everyone would have an additional 6 months of eligibility. We compared the model output from the 6-month and 12-month recertification scenarios for: average number of clients enrolled in ADAP, total number of clients dropped from ADAP, total number of clients ruled ineligible for ADAP, cost of recertification staff, cost of case management contribution to recertification, program cost, other healthcare cost, annual program cost per client, and percent of population virally suppressed.

Sensitivity analyses

We assessed uncertainty in our model output using a Monte Carlo simulation with 10,000 iterations. We calculated 95% confidence intervals by taking the 2.5th and 97.5th percentile for each outcome metric. The probability distribution for each parameter is displayed in Table 3.1. We performed a 1-way best case/worst case scenario sensitivity analysis of cost with each transition probability and cost parameter at the upper and lower bound of their 95% confidence intervals.

Results

Model validation

Model output displayed close fits to program data from 2017-2019 (0% to 5% of the empiric data, Figure 3.4). The model fit most closely to empiric data for viral suppression at year 3 (actual 88.4%, modelled 88.7%) and total annual program cost per client (actual $2,233, modelled $2,418), overestimated the program cost by 5% (actual $26,235,486, modelled

$27,583,835) and underestimated the size of the ineligible population at year 3 (actual 1,225, modelled 1,057).

Budget impact analysis

Assuming a continuation of the 6-month recertification criteria, the model estimated that ADAP would enroll 4,727 (95% CI 4,490-5,033) clients per month at a per-client cost of $7,966 (95% CI $7,514-$8,458) over the next 5 years (Table 3.2, Figure 3.4). At the end of the 5-year period, we estimated that 6,834 (95% CI 6,300-7408) ADAP clients would be virally suppressed. The total cost of the program to the WA DOH was estimated to be $37,663,379 (95% CI $34,578,846-$41,486,126) and the total healthcare costs for the population were estimated to be $90,622,353 (95% CI $83,979,858-$97,097,126). In a scenario with a 12-month recertification requirement, we estimated that ADAP will enroll 5,331 (95% CI 5,067-5,669) clients per month at a per-client cost of $7,543 (95% CI $7,101-$8,022). At the end of the 5-year period, we estimated that 7,079 (95% CI 6,525-7,674) clients would be virally suppressed. The total cost of the program to the WA DOH will be $40,217,341 (95% CI $36,842,790-$44,400,647) and the total healthcare cost for the population will be $89,783,932 (95% CI $83,161,185-$95,933,364). The disaggregated costs by category and year are presented in Table 3.3.

Over the 5-year time horizon, these differences amounted to an average annual increase of 13% (95% CI 11-12%) for ADAP enrollment, 7% (95% CI 6-8%) for program cost, and 3% (95% CI 3-4%) for the number of people virally suppressed in the study population. The 12-month recertification allowed an average of 224 (95% CI 209-247) clients to be enrolled in

ADAP who were ineligible and would otherwise be excluded (4% of enrolled clients, 95% CI 4-5%).

Sensitivity Analysis

Our model-projected costs were robust to changes in transition rates and cost parameters in 1-way sensitivity analyses. Results were most sensitive to changes in the number of new clients added to ADAP each month, the rate at which clients fail to recertify, and rate at which those who are disenrolled return to ADAP (Figure 3.2.)

Discussion

Our analysis projects that changing the ADAP recertification requirement from a 6 to 12-month schedule would increase the number of persons virally suppressed in Washington at a and result in only a small increase in ineligible clients who remain in ADAP in WA. A 12-month recertification program is projected to cost 7% more than the current program structure but would cost less per client served due to the reduction in staff time and costs. While this is the first analysis to evaluate a change in ADAP recertification criterion, our results are similar to evaluations of Medicaid which found that twelve-month "continuous eligibility" policies for children programs were associated with better health outcomes and lower administrative costs compared to more frequent eligibility updates.[53] For Medicaid programs in general, churn is associated with high administrative costs and poorer health outcomes.[56] Models of change to Medicaid as a whole have estimated that continuous eligibility would improve the stability of healthcare coverage at only a modest cost.[52,53] ADAP serves a similar role to Medicaid in providing healthcare for low-income individuals who would not otherwise be able to access it.

Therefore, the health and cost impact of changes to Medicaid enrollment would likely be similar to what would be expected in ADAP. Our sensitivity analyses showed that our results are not dependent on the value of any single parameter or the combined uncertainty of all the parameters.

Our analysis has several limitations. Although viral suppression is the main metric used to measure the success of HIV care programs, it only encompasses one aspect of the health of PLWH; A 12-month recertification requirement would increase access to care for all health conditions. Further, our model does not incorporate HIV transmission, so we do not account for the impact of increasing viral suppression on onward HIV infections averted. Therefore, our analysis underestimates the health benefits associated with extending time to recertification. Next, our Markov model assumes that individuals within the same health state are homogenous, which is likely an oversimplification of the population who disenroll; people may leave ADAP for different reasons and may have differing access to medical care outside the program. Therefore, our model may overestimate the number of people who return to ADAP over time if there is a subset of people who do not want to return to the program. Finally, our model assumes that a 12-month recertification process would result in halving the disenrollment rate, although the reality may be more complex. For example, a 12-month recertification process may leave case managers with more time to help clients with enrollment activities which could improve recertification rates.

The recertification requirement for ADAP presents a significant barrier to healthcare access and viral suppression in WA.[35,51] Our results suggest that a change in policy from a 6-month to a 12-month recertification requirement would result in a more efficient ADAP

program with lower administrative costs and a larger population served. This change could improve HIV health outcomes at a reasonable cost; 245 additional people virally suppressed represents more than 10% of the people living with HIV who were not virally suppressed in WA in 2019.[17] Although this simulation is specific to Washington state, it is likely that similar results would be found elsewhere; the challenges of the legacy eligibility determination process have been identified in other jurisdictions.[16] With the newfound flexibility granted by HRSA in PCN 21-02, our results support switching to a less-frequent recertification process in WA.

Tables

Table 3.1. Parameters for Markov Model of Population Currently and Formerly Enrolled in Washington ADAP, 2021-2025[1]

Parameter	Value	Probability Distribution	Source
Initial Population Size			
Number of PLWH enrolled in ADAP and eligible	3118 (Total)[1]	None, Exact Value	Ryan White Data System
Number of PLWH disenrolled from ADAP due to failure to recertify	1029 (Total)[1]	None, Exact Value	Ryan White Data System
Number of PLWH ruled ineligible and removed from ADAP	1392 (Total)[1]	None, Exact Value	Ryan White Data System
Number of PLWH enrolled in ADAP and ineligible	0 (Total)[1]	None, Exact Value	Ryan White Data System
Transition Probabilities			
Probability of an ADAP client becoming ineligible for ADAP	0-1%[1]	Beta Distribution	Ryan White Data System
Probability of an ineligible ADAP client becoming eligible	0-3%[1]	Beta Distribution	Ryan White Data System
Probability of an ineligible ADAP client being removed from the program	100% or 17%[2]	Beta Distribution	Ryan White Data System
Probability of an ineligible PLWH becoming eligible and enrolling in ADAP	0-4%[1]	Beta Distribution	Ryan White Data System
Probability of an ADAP Client being removed for failure to recertify	0-5%[1]	Beta Distribution	Ryan White Data System
Probability of a disenrolled ADAP client reenrolling in ADAP	1-8%[1]	Beta Distribution	Ryan White Data System
Probability of a person switching insurance types or case management status	0-12%[1]	Beta Distribution	Ryan White Data System
Number of New ADAP Clients per Month	36 (Total)[1]	Poisson Distribution	Ryan White Data System
Viral Suppression			
Probability of viral suppression for clients of ADAP	90% (89-91%)	Beta Distribution	Erly et al 2021
Probability of viral suppression for former ADAP clients who failed to recertify	69% (66-71%)	Beta Distribution	Erly et al 2021
Probability of viral suppression for former ADAP clients who were removed due to ineligibility	81% (78-83%)	Beta Distribution	Erly et al 2021
Program Costs			
Fixed Annual Costs of ADAP Program	$40,161 ($36,813-$43,507)	Normal[3]	DOH Budget Reports
Direct Service Costs Per Client	Variable[2]	Gamma	Ryan White Data System
Per recertification cost for clients not in case management	$98 ($89-$219)	Normal[3]	DOH Budget Reports
Per recertification cost for clients in case management	$202 ($185-$219)	Normal[3]	DOH Budget Reports
Cost of medical care for PLWH not in ADAP	$2189 ($2006-$2371)	Normal[3]	Gebo et al, 2010

1. Initial population size represents the sum of the categories of case management and insurance subgroups. Transition probability values represent the range of values in these categories.
2. 100% corresponds to the 6-month recertification model where no ineligible clients linger on ADAP. 17% corresponds to the 12-month recertification model where ineligible clients may be in ADAP for as long as 6 additional months.
3. No estimate of uncertainty was available for this value. Normal distribution used with a 95% confidence interval corresponding to +/-10% of the mean.

Table 3.2. Simulation of 6 and 12-Month Recertification Requirements, WA State 2021-2025[1]

Metric	Current Requirements (95% CI)	12-Month Recertification (95% CI)	% Change (95% CI)
Mean Number of Clients	4,727 (4,490-5,033)	5,331 (5,067-5,669)	13% (12-13%)
Mean Ineligible Clients in ADAP	0	224 (209-247)	-
Total Clients Dropped	3,250 (3,025-3,575)	1,785 (1,656-1,965)	-45% (45-45%)
Total Clients Ruled Ineligible	2,543 (2,366-2,825)	2,034 (1,894-2,42)	-20% (19-22%)
Costs (Annual)			
Overhead	$481,926 ($444,398-$552,668)	$481.926 ($444,398-$552,668)	-
Services	$33.3M ($31.9M-$38.3M)	$37.3M ($35.1M-42.4M)	12% (11-13%)
Recertification Staff	$926,576 ($838,812-$1,028,179)	$522,486 ($473,356-$578,971)	-44% (-43-45%)
Case Management Recertification	$1.5M ($1.3M-$1.7M)	$817,740 ($736,826-$909,527)	-45% (-45-45%)
Program Cost (Total)	$37.7M ($34.6M -$41.5M)	$40.2M ($36.8M-$44.4M)	7% (6-8%)
Societal Cost	$90.6M ($84.0M-$97.1M)	$89.8M ($83.1M-$95.9M)	-1% (0-2%)
Mean Program Cost Per Client	$7,966 ($7,514-$8,458)	$7,543 ($7,101-$8,022)	-5% (-5-6%)
# People Virally Suppressed (12/1/2025)	6,834 (6,300-7408)	7,079 (6,525-7,674)	4% (3-4%)

1. Markov model of population enrolled and formerly enrolled in ADAP consisting of 4 compartments: enrolled in ADAP and eligible, enrolled in ADAP and ineligible, disenrolled from ADAP due to failure to recertify and ruled ineligible and removed from ADAP. Parameters derived from ADAP data between 2017 and 2019 and literature values.

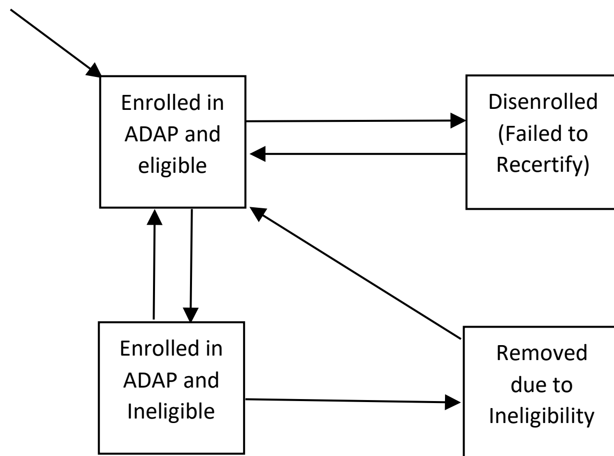
Table 3.3 Simulated Program Costs by Category for 6- and 12-Month Recertification Requirements, WA State 2021-2015[1]

Simulation	Cost Category	2021	2022	2023	2024	2025
Current Requirements (6-Month)	Overhead	$481,926	$481,926	$481,926	$481,926	$481,926
	Services	$27,815,325	$30,466,194	$32,240,438	$36,705,905	$39,578,175
	Recertification Staff	$826,971	$878,812	$929,646	$974,087	$1,023,368
	Case Management Recertification Support	$1,336,678	$1,405,349	$1,476,903	$1,556,528	$1,650,371
	Total Program Cost	$31,769,798	$34,593,019	$36,540,484	$41,174,459	$44,239,133
	Population Payer Costs	$79,889,392	$85,228,015	$89,813,780	$96,478,739	$101,701,840
12-Month Recertification	Overhead	$481,926	$481,926	$481,926	$481,926	$481,926
	Services	$30,294,756	$33,999,012	$36,201,073	$41,509,121	$44,949,920
	Recertification Staff	$446,899	$492,632	$527,085	$557,747	$588,069
	Case Management Recertification Support	$712,793	$768,792	$816,595	$868,519	$922,001
	Total Program Cost	$32,865,198	$36,716,920	$39,035,689	$44,456,986	$48,011,912
	Population Payer Costs	$78,689,876	$83,183,369	$88,000,330	$96,312,134	$102,733,951

1. Markov model of population enrolled and formerly enrolled in ADAP consisting of 4 compartments: enrolled in ADAP and eligible, enrolled in ADAP and ineligible, disenrolled from ADAP due to failure to recertify and ruled ineligible and removed from ADAP. Parameters derived from ADAP data between 2017 and 2019 and literature values.

Figures

Figure 3.1. Model Structure of Population Currently and Formerly Enrolled in Washington ADAP[1]



1. Displayed model represents one strata of population split by insurance type (private, public, uninsured) and annual receipt of case management services (yes, no). Individuals can move between insurance compartments at any time point and case management status at the beginning of each year.

Figure 3.2. 1-Way Sensitivity Analysis of Annual ADAP Costs, 12-Month Recertification Minus 6-Month Recertification

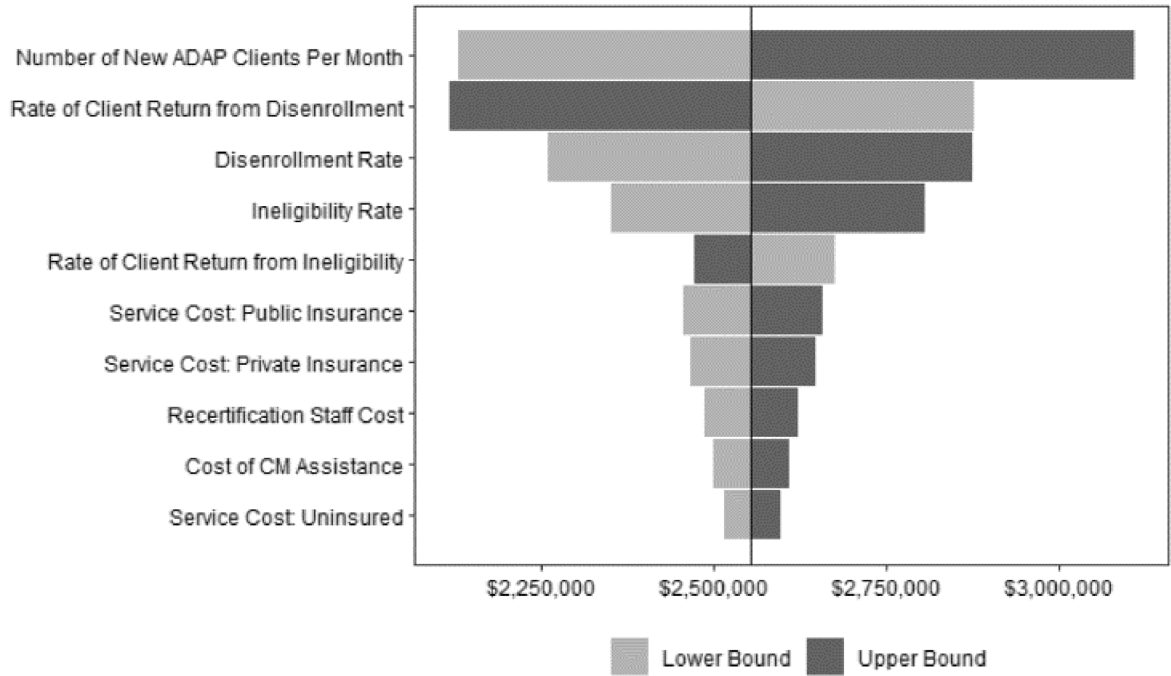


Figure 3.3. Model Validation, Washington State 2017-2019

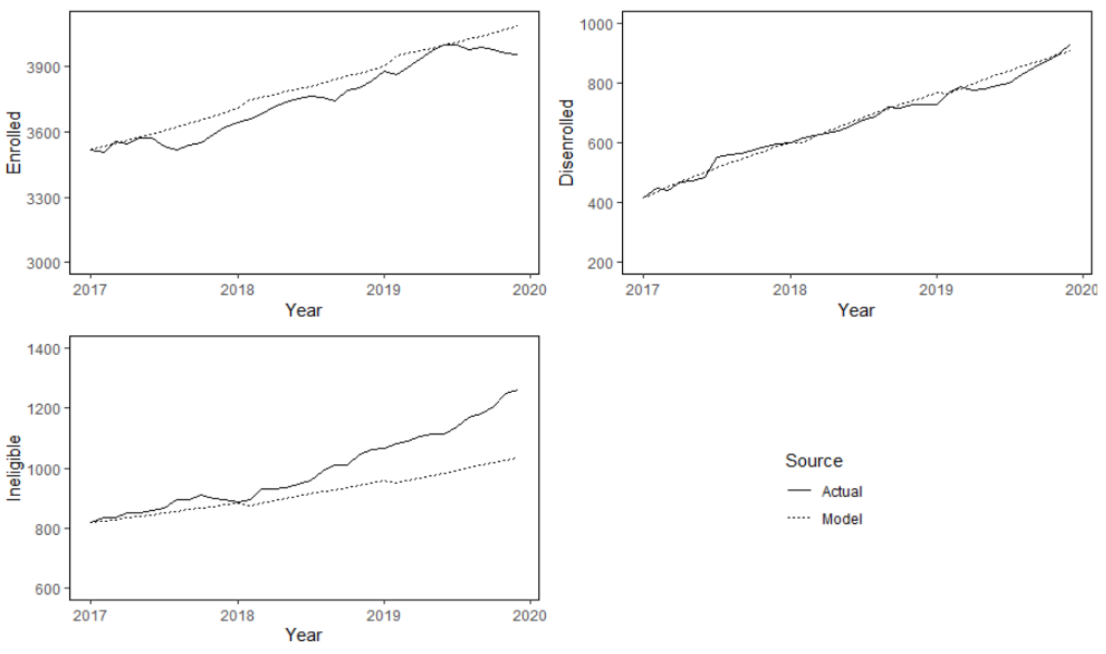
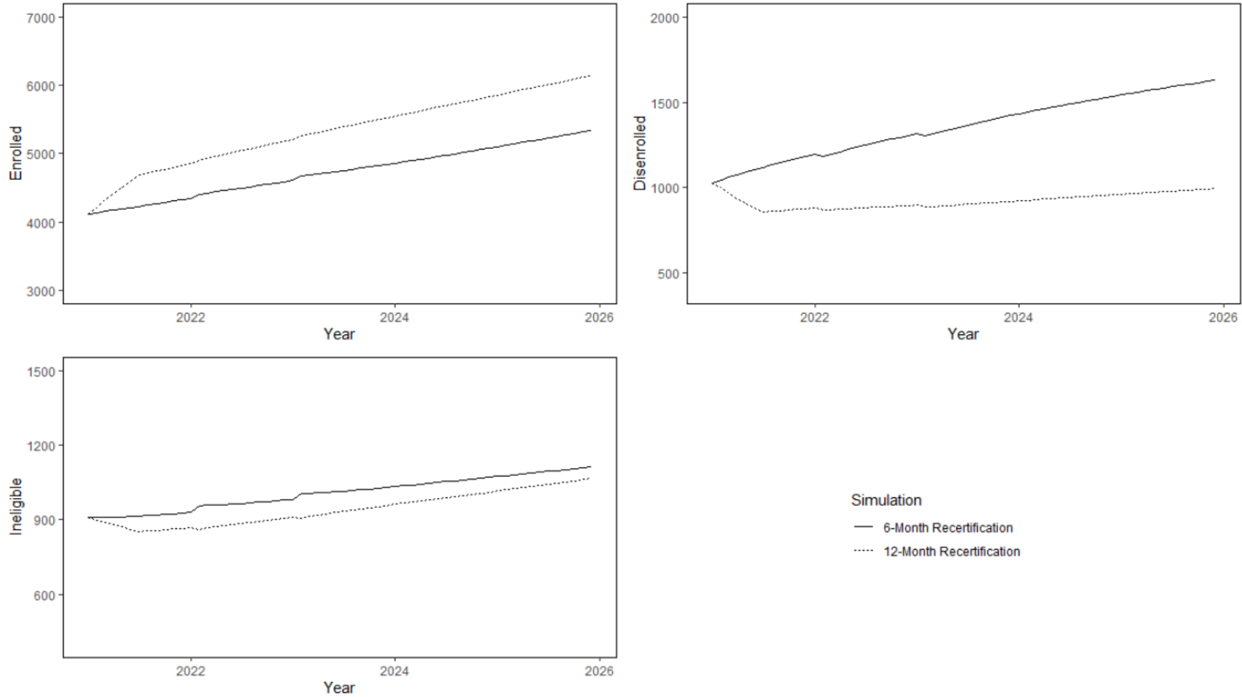


Figure 3.4. Comparison of 6-Month Recertification Projection to 12-Month Recertification



Equations

Equation 1. Model Equations for Markov Model of Washington State ADAP Enrollees and Former Clients

$$\frac{dA_j}{dt} = \zeta_j + \sum_{i=1}^{6} (D_i * \delta_{i,j}) + (I_i * \gamma_{i,j}) + (N_i * \mu_{i,j}) - A_i * (\alpha_{i,j} + \varepsilon_{i,j})$$

$$\frac{dN_j}{dt} = \sum_{i=1}^{6} (A_j * \alpha_j) - N_j * (\mu_j + \beta_j)$$

$$\frac{dI_j}{dt} = \sum_{i=1}^{6} (N_j * \beta_j) - (I_j * \gamma_j)$$

$$\frac{dD_j}{dt} = \sum_{i=1}^{6} (A_j * \varepsilon_j) - (D_j * \delta_j)$$

Abbreviations

A_j=Number of enrolled ADAP Clients

D_j=Number of former ADAP Clients who failed to recertify

I_j=Number of former ADAP clients who were removed due to ineligibility

N_j=Number of enrolled ADAP clients who are ineligible

$\alpha i_{,j}$=Probability of an ADAP client becoming ineligible for ADAP

$\mu_{i,j}$=Probability of an ineligible ADAP client becoming eligible

$\beta_{i,j}$=Probability of an inelgible ADAP client being removed from the program

$\gamma_{i,j}$=Probability of an ineligible PLWH becoming eligible and enrolling in ADAP

$\varepsilon_{i,j}$=Probability of an ADAP Client being removed for failure to recertify
$\delta_{i,j}$=Probability of a disenrolled ADAP client reenrolling in ADAP
ζ_{j}=Number of New ADAP Clients per Month
i=Insurance/Case Management Status at time t-1
j=Insurance/Case Management Status at time t

Chapter 5 Conclusion

In this dissertation we examined the impact of the federal 6-month recertification policy on the population that is enrolled in ADAP and their health outcomes. We found that in Washington State, the 6-month recertification requirement excluded a large number of PLWH from accessing ADAP services on the basis of their ability to complete the eligibility application. The clients who were disenrolled from the program were disproportionately from populations with poor HIV outcomes. When we followed the health outcomes of these clients after they were removed from the program, we found that 12% of clients lost viral suppression without ADAP benefits.

From these findings, we created a model of the Washington State ADAP program and found that over the next 5 years, a 12-month recertification would increase enrollment in ADAP

and the proportion of PLWH virally suppressed in Washington state. It would also increase the cost of the program by a modest amount.

These findings have important implications for decision-makers in Washington state and other ADAP jurisdictions. In Washington State, the results suggest that reducing the frequency of ADAP eligibility assessments would reduce the number of people who are not virally suppressed at a relatively low cost. A 10% reduction in the number of people who are not virally suppressed in Washington State (which is what our model estimates amount to), could have a tangible impact on the future number of new HIV infections in Washington state. The impact of a similar change in other jurisdictions is less clear, but there is reason to believe that it would be beneficial as well. Although the recertification proceedings are not identical from state to state, the requirements for recertification in Washington represent nearly the minimum requirements of the former federal mandate. Further, the Washington ADAP program offers a range of services that may appeal to PLWH who do not need assistance to get their HIV care. Other states have far more limited programs, and it is conceivable that a larger proportion of clients in these states experience disruption to their ability to obtain ART and HIV care when they are removed from ADAP.

These studies identify additional knowledge gaps that may be useful for setting ADAP policy. First, although we examined a 12-month eligibility schedule, it would be useful to model Washington ADAP with a range of schedules to determine the optimal timeframe. Next, although reducing the frequency of recertification would decrease the burden on clients, it does not address the underlying issue which is that recertification is difficult for clients to complete. An in-depth study of the challenges that the process presents and how it can be

improved would be a good step towards developing a better system. An eligibility determination process that was able to exclude ineligible PLWH without burdening eligible clients would be an improvement over a longer recertification timeline, which allows some ineligible individuals to stay in the program for longer.

In conclusion, the federal 6-month recertification requirement was a policy that adversely affected clients of the ADAP program and contributed to health disparities in Washington state. The new authority granted to ADAPs by HRSA in PCN 21-02, presents an opportunity to improve retention in ADAP and increase the number of people virally suppressed in Washington State. The results of this project strongly suggest that the Washington state ADAP move to a 12-month or longer recertification schedule and continue investigating the barrier of ADAP recertification.

Acknowledgements

I would sincerely like to thank my dissertation chair and mentor, Julie Dombrowski, for her support, guidance, and for unwavering enthusiasm for this project and my academic success. Thank you to Christine Khosropour whose generosity with her time and thoughts opened so many opportunities and set the stage for this project. Thank you to, Monisha Sharma and Anjum Hajat who were incredibly patient and giving in sharing their expertise. And finally, thank you to Pam Kohler, who shared her time and energy to serve as the committee GSR.

Many others supported this work and deserve recognition. This study would not have been possible without the support of the Washington State Department of Health and in

particular, Jen Reuer, who was generous in giving me the flexibility to pursue this degree and the support to build this project. Many others from the Department of Health also contributed to the work presented in this dissertation, including Martha Grimm, Beth Crutsinger-Perry, Kelse Kwaiser, and Kandis Boersema.

With humility I would like to thank the staff of the Epi SAS office, who were always kind with their answers to my many questions about tuition exemption, registration, and requirements. Without their openness and guidance, I would likely not have even attempted to juggle working and being a part time student.

Finally I would like to thank my family, friends, classmates, and most importantly my partner Kseniya, for their unwavering support and enthusiasm for the project.

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