Information for Healthcare Providers

This information sheet is for the Antiretroviral Improvement among Medicaid EnrolleeS (AIMS) program, a quality improvement and evaluation initiative for eligible Medicaid members. This sheet is for healthcare providers who have patient(s) eligible for the study. The AIMS program is evaluating whether referrals to support services improve HIV medication adherence and staying in care. More information is available from the study team ([study email] or [study phone]).

Why the AIMS program?

In Virginia, an estimated one out of every three people living with HIV is not in care. People with HIV who stay in care are more likely to reach viral suppression and less likely to transmit HIV. The AIMS program supports at-risk individuals, before they fall out of care. This is done by identifying persons with HIV who fail to fill antiretroviral therapy (ART) in a timely manner and providing referrals to services that support member medication adherence, including filling of ART prescriptions.

Will the AIMS program be effective?

Continuous quality improvement is a priority at Virginia Medicaid and the AIMS program will be rigorously evaluated. To the evaluate the AIMS program, it has been designed as a cluster-randomized, controlled trial. The study has two arms: program and usual care. The program involves direct adherence support for members or their providers from the program team. Usual care involves no direct adherence support for members or their providers. We will compare health outcomes among those receiving the program to those who receive usual care. Outcomes will be ART adherence and viral suppression. Participants receiving usual care will be offered adherence support at the end of the study.

Who is eligible for AIMS?

Adult members of Virginia Medicaid with HIV can participate. Members are eligible if an antiretroviral therapy prescription is not filled within 30–90 days of an expected fill date. Eligible members will consent to be in the program.

How will ART adherence be supported?

All members will be provided patient-centered ART adherence support. Not all of the adherence support offered will be part of the study's program. About 100 members will participate.

Program members with late ART prescriptions will have direct support. Program staff will talk with members about their challenges adhering to ART. Program staff will then offer members referrals to support services. The referrals will be for services to address member challenges to ART adherence (e.g., give example of services). Support will come from existing services. These services may be offered by the participant's insurance plan, pharmacy, or the community. Program staff will discuss members' adherence challenges and make referrals during 2–3 phone calls with each participant.

Other members in the program will have no record of a prior ART prescription. Here, the member's primary HIV provider will be offered support. This support will be through a peer-to-peer consultation. The consult will involve peer mentoring, education, and resources that are tailored to the primary HIV provider. The consult may involve discussion of ART clinical guidelines, strategies to optimize ART adherence, and resources for clinical management and supporting people living with HIV.

Some members will be offered support after the study is complete. These members include patients of providers offered support and those who receive usual care. The support will come from an existing state program—Status Neutral Service Navigation—offered through Virginia Department of Health. The Status Neutral program provides service navigation for Virginians with unknown status, at risk of acquiring HIV, and living with HIV. The program has expertise in supporting transgender individuals, people who inject drugs, and men who have sex with men, all populations disproportionately impacted by HIV. This program is available to members who did not receive support directly from the study.

Who is involved in evaluating the program?

The team includes health services researchers, clinicians, and public health practitioners. Dr. April D. Kimmel at Virginia Commonwealth University (VCU) is leading the evaluation on behalf of Virginia Medicaid. Virginia Department of Health, University of Virginia, the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health are also study partners. The study is funded by the CDC and the National Institutes of Health (award number U01PS005192).

What patient information is involved?

We will use three kinds of information for the study. First, we will collect information directly from members. The information will be about health care, barriers to filling ART prescriptions, and referrals made. Second, we will use insurance claims. Insurance claims will provide information about medical services and filled prescriptions. Finally, some information will come from public health surveillance. This information will be about prior ART prescriptions and HIV viral load test results. We will only collect or use information that is needed to evaluate the program.

How will you protect participant privacy?

All member information will be confidential. It will be securely stored and accessed only by select authorized program staff. The study has ethics approval which includes how we collect, access and use member information. The study complies with state and federal regulations on participant rights, privacy and confidentiality. This study also has a Certificate of Confidentiality from the US federal government. The certificate means we cannot be forced to tell people about a member's involvement in the study. Sometimes it is not possible to keep information confidential. This is rare. This might happen to protect the safety of the member or another person. Member information will not be published or presented to the public. Study results will be shared with members at the end of the study. Members will give permission to access their information. A member can withdraw from the study at any time. Members can share concerns with the study team. They can also share concerns with the VCU Institutional Review Board. Members will be provided contact information for the study team and the VCU Institutional Review Board.

How can I learn more?

You can direct questions to the principal investigator, Dr. April D. Kimmel, principal investigator, at april.kimmel@vcuhealth.org. The study team can also answer any questions. They can be reached at [study_email] and [study_phone].

The study is described on http://www.ClinicalTrials.gov which is required by U.S. law. The website will not include any information about individual study participants.