Informed consent form

Antiretroviral Improvement among Medicaid Enrollees (AIMS): An Insurance-based Data to Care Initiative for Medicaid Enrollees in Virginia

NCT05477485

02/22/2024

CONSENT SUMMARY

Great. This research study is about the experiences that Virginia Medicaid members have in taking their prescribed medication and filling their prescriptions, so they can stay healthy. This study is also about how resources can support members in filling their prescriptions.

You won't be paid for your participation in this research study. You don't have to participate unless you want to and you can stop participating at any time. If you don't want to take part, it won't affect your Medicaid or health plan benefits or your relationship with your doctors. You will still have the same access to support from your healthcare prpoviders, pharmacists, and health plan, along with community support services.

Would you like to hear more about the study?

[NO] I understand. Thank you for your time. If you'd like to hear more about the study later, you can call me back at [**lc_phone**].

[YES] Great. My job is to make sure you understand what the study will involve so that you can make an informed decision about whether or not you're going to participate. I am going to read all the information about the study. It will take me about **11-12** minutes, and I'll stop at certain points to see if you have questions.

Once we get through the information, I'll ask you a few questions to make sure I was clear. Then you'll have the chance to decide if you want to participate.

You can interrupt me at any time to ask questions, take a break, or end this call.

COMPLETE CONSENT

This research study is about your experiences taking your prescribed medication and filling your prescriptions. The research is part of a quality improvement initiative at Virginia Medicaid. Virginia Commonwealth University (VCU) is conducting this study on behalf of Virginia Medicaid.

Virginia Medicaid and VCU are working together to learn about the experiences, including challenges, that Virginia Medicaid members have in taking their HIV medication and filling their prescriptions. They are also working together to learn about how resources can support members in filling HIV prescriptions. We think that talking about challenges and, when needed, receiving support may increase how often HIV prescriptions are filled, improve your health and increase HIV viral suppression.

Our other study partners are the Virginia Department of Health, the University of Virginia, the Centers for Disease Control and Prevention (CDC), and the National Institutes of Health. The study is funded by the CDC and the National Institutes of Health.

We are asking you to be in this research study because you may have recently missed an HIV prescription fill, for example in the past year. We believe this because there is no insurance record for an HIV prescription that was expected to be filled during this time. Because we want to learn about your experiences in taking your HIV medication and filling your prescriptions, we are interested in your participation even if you do not believe that you have missed a prescription fill. About 1,000 members will participate in this study.

1. During the study, you will be asked to take part in phone calls and give us permission to collect your health information. There will be two or three phone calls with the study team. The calls will last about 30 minutes each. The calls will happen about once per month for up to 3 months. The total time for all the calls will be about 2 hours.

2. During these phone calls, we will ask you questions and take notes about how you receive healthcare and any challenges you may have in filling your HIV prescriptions. We can skip any question you don't want to answer. We will have a conversation about what can make it hard for you to take your HIV medication and/or fill your HIV prescriptions. We may also talk about different ways to support you in filling them.

3. In our phone conversations, we may offer to connect you to resources to address an individual challenge you have experienced. You do not have to be connected to resources if you do not want to or do not believe you need them. Resources might include information or assistance from your health plan, your health care provider, your pharmacy, or resources in the community.

   For example, if you want more support from other people with HIV, we might connect you to support groups in the community. None of the resources are experimental, but connecting you to the resources is.

   If you are interested in being connected to a resource, you will choose if you'd like to call together. We may assist with navigating the referral process if needed. We may give you contact information for additional resources.

4. We will ask you to agree to share some of your health information from Virginia Medicaid insurance records and health information that is routinely reported to the Virginia Department of Health. Sharing your health information helps us understand how this quality improvement research study improves your health. We will only use information that is needed for the study.

5. Finally, you may have the opportunity to join PositiveLinks, a mobile app platform for people with HIV. PositiveLinks has tools and resources to help you take better care of yourself. If you are offered PositiveLinks and decide to join, you will have access to the mobile app for at least 3 months, which is the duration of this study. If you are offered PositiveLinks and decide to join:

    a. You will be asked to download the PositiveLinks mobile app onto a smartphone or tablet, with my help. You'll agree to share some information, like your phone number, so that we can set up your PositiveLinks account.
    b. You will be asked to agree to the terms of use. The terms of use tell you how you can use the PositiveLinks mobile app platform, what to expect in the PositiveLinks app, what to expect in terms of communication through the app, and rules for how you can, and cannot, use PositiveLinks to ensure the app is a safe and welcoming space for all users.
    c. You will be asked to participate in the PositiveLinks mobile app platform. Participation will involve things like privately responding to weekly quiz questions about general health or living with HIV. Participation will also involve daily check-ins about your mood or commenting in the anonymous (to other users) community message board. You will be able to participate as much or as little as you want. Daily use of the platform typically takes about 5 minutes of your time per day.
    d. You will be asked to give permission to follow up with you. This might happen if you ask for help directly by messaging the study team through the app, if you have not used the app in a while, or if we think you need additional help. In these cases, someone from the study team will message you directly through the app or call you to talk about how we can help.
    e. You will be asked to give permission for us to review how you use the app. This includes anything you write in messages to study staff. It also includes anything you post on the community message board; this board is anonymous to other users, but the study team will know who wrote what. It includes information on how often you log in or whether you respond to quiz questions. It also includes health information that you report via the app about your mood, stress level and medication doses.

As I said before, participating in this research study is voluntary. You do not have to participate in this study unless you want to. If you do participate, you can stop at any time. There is no penalty or loss of benefits of any kind if you withdraw or decide not to take part.

If you decide not to participate in this study, you will receive the same Medicaid benefits that you would receive if you were not in the study. If you decide not to participate, it will not affect your relationship with your medical providers or change your health care. If you decide not to participate, we will offer to connect you to resources available through the Status Neutral Service Navigation Program, which is offered by the Virginia Department of Health

What questions do you have so far?

It is important to know there are risks and benefits to participating in this study.

There is a risk that you may feel upset if you talk about what makes it hard to fill an HIV prescription. If you join the PositiveLinks mobile app platform, there is a risk that you may feel upset if you reflect on your mood during PositiveLinks check-ins or participate in the community message board. There is a small risk of disclosure of HIV status or other health information. We have the same protections in place that your doctor does. We take many precautions to prevent disclosure from happening, including rules about who can access your health information, how it is stored and accessed, and verifying your identity during study procedures.

There are some potential benefits to participating in this research study, but they cannot be guaranteed. The study may help you think through challenges to filling your HIV prescriptions and connect you with resources to address those challenges. If you join the PositiveLinks mobile app platform, the study may help you monitor your mood, learn about managing your health, and connect anonymously with a larger support network of individuals with similar experiences through PositiveLinks. Together these may help you fill your HIV prescriptions and take your HIV medication more consistently.

You will not be paid for participating in this research study. If you would like to be connected to resources, you will not have to pay to be connected and we don't anticipate that you will have to pay to use the resources. However, if you are connected to resources, you may have to pay for transportation to reach certain resources. If you join the PositiveLinks mobile app platform, you will not receive a smartphone. However, if you do not have a smartphone, your health plan should be able to provide one as an existing health plan benefit. You do not have to participate in the PositiveLinks mobile app platform to receive this smartphone benefit.

I also want to make sure you know how we'll keep your information private.

To protect your privacy, we will never provide your information to a resource, or third party; only you will provide personal information to resources we call. We will keep your information confidential and securely stored. That means only select authorized study staff will be able to access your information. Your information will only be accessed if we need it for the study. The CDC and the National Institutes of Health will not have access to information that can be used to personally identify you.

This study has a Certificate of Confidentiality from the federal government to make sure we can best protect your privacy. The certificate means that we cannot be forced to tell people about your participation in this study, even if we are asked by courts or police.

However, there are times we can't keep your information or participation confidential. For example, if we find out that keeping it private could put you or someone else in danger, we may have to tell agencies to protect you or another person.

Researchers may also have to give your information if the study is audited. If that happens, personal information about you might be shared with or copied by authorized representatives from:

- The study sponsor, representatives of the sponsor and other collaborating organizations

- Representatives of VCU and the VCU Health System, or
- Officials of the Department of Health and Human Services

The information collected as part of this study will not be used or distributed for future research studies. We will not publish your personal information or present it to the public. At the end of the study, we will tell you the results and explain what they mean. However, we will not provide each participant with their individual research study results.

We disclose the potential for conflict of interest, but have taken steps to minimize this. Drs. Rebecca Dillingham and Karen Ingersoll from the University of Virginia are on the Board of Directors of Warm Health Technology (WHT), a non-profit organization that disseminates a version of PositiveLinks to clinics outside of Virginia. Dr. Dillingham is also a paid consultant for Warm Health Technology. Neither Dr. Dillingham nor Dr. Ingersoll will have any direct involvement in the recruitment, consent, or follow up of participants or in the analysis of research data.

A description of this clinical trial is available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

If you think that you have not been treated fairly in the study, you can contact Dr. April Kimmel, the principal investigator of the study, or the study staff at AIMS@vcuhealth.org. If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact: VCU's Office of Research and Innovation at (804) 827-2157.

I want to make sure that any questions you have are answered. I can answer your questions now or you can direct your questions to the study team by emailing AIMS@vcuhealth.org or calling [**lc_phone**].

What questions do you have?

I really appreciate your time so far. It's important to me that you understand the study and your rights as a participant.

I'm going to ask you 6 questions about this study to be sure that I have been clear. Please indicate 'true' or 'false' after each statement.

1. This research study is about understanding experiences, including challenges, in filling HIV prescriptions. It is also about how support can help with filling HIV prescriptions.
2. You do not have to participate in this research study. You will not receive compensation for participating.
3. If you participate, you may be connected to resources that can address certain challenges in filling your HIV prescription(s).
4. If you participate, you can withdraw at any time and for any reason. You can skip any questions that you do not want to answer.
5. If you decide not to participate or to withdraw, your health plan benefits will not change. The care you receive from your doctor will not change.

6. The study team cannot use your information unless you give permission to use it. We cannot be forced to tell someone you participated in the research study.

Thank you so much. Now I'm going to ask you if you consent to participate in this study.

Do you consent to participate in this research study?