

Form Approved  
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**The Greater Access and Impact with NAT (GAIN) Study: Improving HIV Diagnosis,  
Linkage to Care, and Prevention Services with HIV Point-of-Care Nucleic Acid  
Tests (NATs)**

**Attachment 4f  
Participant Focus Group and Interview Guide**

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**Draft Participant Focus Group Guide**  
**Madison Clinic HIV-positive (RCT)**

**Introduction:**

Thank you for participating in this discussion. You have been invited to participate in this conversation because you recently participated in a GAIN study visit. The purpose of the GAIN Study is to better understand patient perspectives on how we can use point-of-care nucleic acid tests or NAT in different types of settings. In this conversation, we hope to learn more from you about your thoughts on the point-of-care NAT.

This focus group will last about 45 minutes to 1 hour. We will audio-record the conversation. We are doing this so that we can listen to the recording and create a written transcript of the conversation. This way we can capture all of the details of the conversation. We will provide you with a \$40 gift card for your participation. If you have any questions about the study, please contact Joanne Stekler (206-744-8312).

Do you have any questions or concerns? *[The interviewer will answer any questions that arise.]* Okay, thank you. I am going to start recording our conversation now. *[The interviewer will turn on the audio recorder.]*

**Sample Questions:**

- The point-of-care NAT is the test you got at your study visit. What were you told about this test at your study visit?
  - Probe: How is the point-of-care NAT different from standard viral load testing?
  - Probe [FG]: Does anyone know anything else about point-of-care NAT?
  - Probe: What are some reasons or situations where point-of-care NAT may be useful as compared to standard viral load testing?
- Describe your overall experience of taking the point-of-care NAT and receiving your results.
  - Probe: What would you change about the way you were tested and/or how you received your results?
  - Probe: Describe how you were tested using point-of-care NAT. i.e. blood draw, wait times
  - Probe: How did you receive your point-of-care NAT result? i.e. via in person, phone, text, or email?
  - Probe: What did you like or not like about that method of testing and/or receiving the test result from the point-of-care NAT?
  - Probe: What would you change about the process of being tested and/or receiving the test result from the point-of-care NAT?
- As you may know, the point-of-care NAT test usually takes around 2 hours to return a result. Since that is the case, what would be the best way to get your result during your visit?
  - Probe: Would you be willing to come in before your appointment?
  - Probe: Would you be willing to return after your appointment?

- How did getting your point-of-care NAT results compare with how you usually get your viral load results?
  - Probe: do you usually get your viral load results in person, over the phone, or some other way?
- Based on your current knowledge, how trustworthy are the results you received from the point-of-care NAT?
- Would you recommend point-of-care NAT to others? Why or why not?
- What did you do with the information gained after receiving your point-of-care NAT results?
  - Probe: Who did you, or will you, share this information with, if anyone?
  - Probe: How did you change your behavior, or, what actions did you take, if any, after receiving your results?
  - More specific probe: Did getting your NAT results change whether or how you took your HIV medicines
  - More specific probe: Did getting your NAT results change anything about your sexual health, for example your number of partners or whether you would use condoms with your sex partners?
- The typical detection limit of laboratory viral load tests is between 40-200 copies in a milliliter of blood (if asked, can say that there are 5 mL in a teaspoon). The detection limit of this point-of-care NAT is about 1000 copies of the virus. How does the limit of detection of the point-of-care NAT affect your opinion of how good it is for monitoring your HIV and medicines?
  - Probe: How does knowing about that limit of detection change what you think about what the test can tell you about your own health and how well your medicines are working?
  - Probe: What limit would you want to see? Why?
- People living with HIV who have an undetectable viral load by taking their anti-HIV medicines have no risk of transmitting the virus to others. The chance of transmission of the virus goes up as the viral load goes up. How confident do you feel that you would not transmit the virus if the point-of-care NAT said you had a viral load of <1000 copies?
  - Probe: How confident do you feel if the laboratory viral load test said <200 copies?
- How did your provider incorporate point-of-care NAT results in addressing medication adherence at your last visit?
  - Probe: Does your provider normally discuss adherence at your visits?
  - Probe: How did your provider ask you about how well you've taken your meds?
  - Probe: How helpful was that conversation?
  - Probe: What strategies did your provider talk about that might help you to take your pills?
  - Probe: What is the chance that you will be able to do those things?
  - Probe: How did you feel about your provider using the point-of-care NAT results to discuss your medication adherence?
  - Probe: What was/wasn't helpful in these discussions?

- o Probe: How much does your provider trust that you are answering honestly when you talk about taking your medicines?

*[Prepare and distribute individual show cards for viral load testing options that describe type of test (PCR, several point-of-care NAT options), wait times, limits of detection, quant/qual results, etc.]*

- Here are placards that describe several options for HIV viral load monitoring that may or may not be familiar to you. As a group, please discuss these options aloud based on their appeal and your preferences. Then, as a group, rank order them from most preferred (first) to least preferred (last).

*[Cards to be shown:]*

	PCR	POC NAT 1 (SAMBA)	POC NAT 2 (Cepheid)
<b>Specimen type:</b>	Blood draw	Fingerstick	Blood Draw
<b>Result type:</b>	Quantitative	Semi Quantitative	Quantitative
<b>Time to results:</b>	2 days	2 hours	2 hours
<b>Limit of Detection:</b>	40 copies	1000 copies	40 copies
<b>Performed by:</b>	Laboratory	Clinic staff	Clinic staff

- Remember to describe your rationale and logic when making any relevant statements.  
Probes to understand different components of preference if not voiced aloud:
  - o What specimen collection method do you prefer?
  - o Which test type do you trust the most to give you the correct test result?
  - o What is the most important factor in your ranking?
- Is there anything else you would like to add regarding the study or the point-of-care NAT test?

Thank you very much for sharing your thoughts and opinions! We will follow up with a \$40 gift card as a stipend for your participation. If you have any questions about the study, please contact Joanne Stekler (206-744-8312).