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)

Reinstatement with Changes

OMB No. 0920-1357

Section B: Supporting Statement

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1. Respondent Universe and Sampling Methods

The GAIN study will develop, implement, and evaluate models for use of point of care nucleic acid tests (POC NAT) among HIV-negative persons seeking HIV testing, post-exposure prophylaxis (PEP), and pre-exposure prophylaxis (PrEP) and HIV-positive persons in community and clinical settings. Aims 1 and 2 will evaluate the sensitivity and specificity of a qualitative POC NAT in persons not known to be HIV-positive and will determine the impact of its use on PrEP uptake and persistence among persons testing HIV-negative and on time to HIV continuum of care outcomes among persons testing HIV-positive. Aim 3 will implement a POC NAT-tailored behavioral intervention to evaluate impact on time to virologic suppression among persons living with HIV (PLWH) receiving antiretroviral therapy (ART). Aim 4 will quantify the acceptability and feasibility of implementation of POC NAT in community and clinical settings. Finally, in Aim 5, a distinct but related study will compare the sensitivity, specificity, and agreement of multiple POC NATs over a range of HIV RNA levels.

This project will collect data on the performance of POC NAT and associated clinical outcomes, patient and provider perspectives regarding acceptability and feasibility, and implementation science outcomes. Employing a research team with substantive expertise in HIV testing including POC NAT, PrEP and HIV clinical care and programming, community and public health expertise, and medication adherence interventions, this collaboration will work to implement POC NAT with the goal of documenting real world performance and developing models to improve HIV care and prevention outcomes.

City Selection

This study will be carried out in the Seattle, Washington metropolitan area. King County is one of the 57 priority jurisdictions designated in Ending the HIV Epidemic in the United States (EHE).[1]

There are an estimated 7,468 people living with HIV in King County.[2] Over the past decade, the county has met numerous goals related to HIV prevention, treatment, and care. However, that success was accompanied by a troubling trend in the social marginalization of HIV. HIV incidence continues to disproportionately affect Black and Latinx men who have sex with men (MSM), and both viral suppression and PrEP use is lower among Black MSM than among White MSM.[3] Also, the time from contraction to diagnosis among MSM has not changed for more than a decade.[3] Finally, King County faces a new and locally unprecedented HIV epidemic among persons who inject drugs (PWID). Fueled by growing epidemics of homelessness and injection drug use, the number of non-MSM PWIDs newly diagnosed with HIV increased over four-fold in 2018, resulting in the largest one-year increase in the number of new HIV diagnoses in King County since 2002.[3]

Study Sites

The purpose of this information collection is to determine the acceptability and feasibility of POC NAT technology in clinical and community settings. Two sites were selected to carry out this goal. Seattle's Gay City center will be the community partner site, which is essential to meeting the study objective of testing the feasibility and utility of POC NAT in a community-based setting. The organization was established in 1995 and is the largest community-based testing program in WA. In 2017, there were 5000 HIV testing visits by MSM, and 45 (0.9%) persons tested newly HIV-positive. Seattle's Gay City center is the second largest source of new diagnoses in WA. From 2016-2018, 10,490 persons had 13,849 visits. Clients also visit Gay City for STI testing and PrEP services. These clients provide a

unique opportunity to evaluate POC NAT and the potential ways that community-based implementation can contribute to reducing overall healthcare costs

The second site, Madison Clinic, is an ideal location for meeting the study objectives of ascertaining feasibility and utility of POC NAT in a clinical setting. Madison Clinic is a Ryan-White funded clinic and is the largest provider of HIV care in Washington state. Research has been well-integrated into the clinic since the 1980s. The Mod Clinic, a satellite location, serves patients that are more difficult to retain in care, with the aim of reducing barriers as much as possible for these clients by providing walk-in appointments, transportation, and other client-focused features. Madison Clinic is an ideal partner for the GAIN study because of this history and expertise with research, high patient volumes, clinical services, and large-scale data systems, as well as their focus on providing care to lower income patients and racial/ethnic minorities.

Both study site locations are operated by organizations with whom the study team has collaborated in the past. The Principal Investigator for the GAIN project is the PrEP clinic director at Gay City and also a provider at the Madison Clinic. All locations listed above will have laptops and private rooms available to participants for completing surveys. Private spaces will also be available for participants who opt to join in-person interviews or in-person focus groups.

Target population:
Prior to study expiration in December 2024, GAIN achieved a number of study goals and completed enrollment for study Aim 1,2 and 5 at both study sites and partially completed enrollment for Aim 3 at the Gay City site. Upon reinstatement, GAIN will enroll 61 PLWH seeking or receiving HIV treatment services at Madison Clinic to complete enrollment for Aim 3 of the study. We will also interview 18 health providers at the Madison Clinic. In addition, we will conduct a brief, 5-minute follow up telephone survey with 100 clients who were previously enrolled at Gay City prior to study expiration (12/31/2024). Finally, staff at the Madison Clinic and Gay City (one at each location) will be engaged to collect electronic health record data. All participants will be at least 18 years of age and able to read and speak English.

Inclusion criteria:

All groups:
- Persons 18 years of age and older
- Persons who are able to read and speak English

Inclusion Criteria for study Activities to be Completed Upon Reinstatement:

Aim 3: RCT Group:
- Persons who are HIV-positive and seeking care at Madison Clinic.
- Patient's provider is willing to deliver adherence intervention

Provider group:
- Clinic staff and providers at Madison Clinic

Follow up telephone survey group:
- Aims 1, 2, and 3 participants who were enrolled at Gay City Center prior to study expiration (12/31/2024)

Clinic Data Collection:

- Staff at Gay City and Madison Clinic who are experts in medical record abstraction

Recruitment

Following study reinstatement, for enrollment in the Aim 3 RCT group, GAIN will recruit persons receiving or seeking HIV care at Madison Clinic in Seattle, Washington. Persons will be approached for study participation only if they meet inclusion criteria. Only persons who are 18 year of age or older, HIV positive, and can read and speak in English will be offered study participation. The study will aim to recruit participants who are more likely to have detectable HIV RNA based on prior viral load test results, adherence and visit history, and whose providers are willing to work with the study to deliver a brief adherence intervention based on the POC NAT result. We will recruit participants into the study through a combination of approaches. Our primary recruitment sources will be through in-person outreach conducted by study staff, by word of mouth, and through referrals from clinic staff.

A review of clinical baseline data from Madison Clinic indicates that study enrollment targets can be achieved. From 2017 to 2018, there were 26,931 visits by 5,527 HIV positive patients with 521 of those testing with a viral load of less than 40.

The provider group will be composed of clinic staff and health providers at Madison Clinic. Providers who referred patients to the GAIN study will be invited to participate either in person or via email by study staff.

The telephone survey group will be composed of participants who were enrolled at Gay City center prior to study expiration. Participants will be randomly selected from each of the three study groups (Aims 1, 2, and 3). Participants will be contacted by telephone and asked if they would like to participate in a five-minute follow up survey.

Finally, one staff member each from Gay City and Madison Clinic will be recruited to extract medical record data. Participating staff will have expertise in medical record abstraction.

Rationale for proposed number of subjects

Statistical planning included sample size calculations which indicate that the enrollment plan is appropriate for study aims. The sample sizes are estimated for the evaluation of the effectiveness of POC NAT on participants' clinical outcomes depending on the study aim in which the participant was enrolled. Exhibit 1.1 shows the sample size calculations for the total Aim 3 RCT group at both study sites, adjusted to incorporate a 20% loss to follow up.

Exhibit 1.1 Sample size table for evaluation of impact of POC NAT on time to virologic suppression

Standard of Care	10% increase		20% increase		30% increase	
	n per arm	HR	n per arm	HR	n per arm	HR
10%	202	0.47	65	0.30	35	0.21
20%	295	0.63	84	0.44	41	0.32

30%	354	0.70	94	0.52	44	0.39
40%	379	0.74	96	0.56	43	0.42
	Assuming 20% loss to follow-up					
10%	225	0.47	72	0.30	39	0.21
20%	327	0.63	93	0.44	46	0.32
30%	392	0.70	104	0.52	48	0.39
40%	418	0.74	106	0.56	47	0.42

The GAIN study achieved several of its initial enrollment targets since study expiration in December 2024 including enrollment for Aims 1, 2, and 5 at both study sites, enrollment for Aim 3 at the Gay City site, and partial enrollment for Aim 3 at the Madison Clinic site. Upon reinstatement, GAIN will enroll 61 PLWH at the Madison Clinic in order to complete data collection. We anticipate that 50% of persons screened will be eligible and will decide to enroll in the GAIN study; therefore, we expect to screen 122 persons in order to meet our enrollment goal of 61.

For the provider interview group, we plan to interview 18 health providers at Madison Clinic. Because the interview sample will not be randomly selected, qualitative interview findings will not be generalizable and sample size has been determined by desired diversity of responses and saturation of themes (the point in data analysis where new themes no longer emerge).[4] The proposed sample (n=18) from a single study site allows us to meet the objectives of the interview: to explore the experience and perspectives of health providers who used point of care nucleic acid tests (POC NAT) in the clinic. Because clinic encounters can vary greatly according to patient needs and disposition, provider participants will be interviewed up to three times in order to best achieve diversity in themes and assure data saturation.

2. Procedures for the Collection of Information

We will collect four types of information for this study: screening information, quantitative survey information, qualitative focus group and interview information, and medical information including test results from electronic health records.

Participants in the Aim 3 RCT group will be recruited in person by study staff, through referrals by study staff, or through flyers posted at Madison Clinic (**Attachment 3**). Study staff will administer the screening and link survey to ensure eligibility criteria (**Attachment 4a**). Respondents determined to not be eligible would be offered additional resources for HIV or STI testing or other resources upon request. Study staff will provide eligible participants with an overview of the study purpose and procedures and provide them with a copy of the consent form (**Attachment 5**). Following the consent process, study staff will gather participant contact information and complete the final steps of the screen and link process (**Attachment 4a**). Participants will be asked to sign a release of information (**Attachment 4b**) and issued a laptop to complete the study visit survey (**Attachment 4c**). Private rooms will be made available for the screening, linking, and consent processes and survey completion.

Following the completion of enrollment and survey activities, participants will be offered participation in an online acceptability survey (**Attachment 4d**) to be completed at a later time in a private setting of their choosing. If the participant agrees, a link to the online survey will be sent to them via email. The acceptability survey will be delivered via a secure, electronic platform that is optimized for use with computers, laptops, or smart phones.

A subset of the cohort (12 total, 4 annually) will be contacted by study staff and asked if they would like to participate in a focus group or interview (**Attachment 4e Participant Focus Group and Interview Guide**) to further explore their experiences and preferences for HIV testing, and to evaluate their reactions to the intervention. If the participant agrees, study staff will work with the participant to find a day and time to schedule the collection. Whether we conduct an interview or focus group will depend on the volume of patients seen at study visits, as we will attempt to schedule the follow up interview/focus group within 1 month of the study visit. Interviews and focus groups may be conducted in-person or remotely via a HIPPA-compliant teleconference platform (Zoom). Zoom is accessible via computer, tablets, or smart phone.

A subset of participants (100 total) who were enrolled in the Aims 1, 2 and 3 groups at Gay City will be contacted by study staff via telephone and asked if they would like to participate in a survey (**Attachment 4f Follow Up Phone Call Survey**). Study staff may call a participant up to three times in order to discuss the outcome of their study visit. During these calls, study staff will offer to connect the participant to PrEP services or HIV care if the participant is interested. The brief, five-minute survey will provide the information needed to evaluate the impact of POC NAT on the outcomes of respondents who participated in the GAIN study at Gay City prior to study expiration in December 2024.

Health providers and clinic staff at Madison Clinic who referred patients to the GAIN study and saw patients enrolled in the study will be invited by study staff, either in person or via email, to participate in an interview to describe their experiences with POC NAT and preferences for HIV testing (**Attachment 4g**). Participants will have the option to attend focus groups and interview in-person or via a secure, HIPPA-compliant teleconference platform (Zoom) accessible via computer, tablets, or smart phone.

Electronic health record information will be collected by clinic staff at the Madison Clinic (**Attachment 4h**) and Gay City (**Attachment 4i**). Cohort participants are asked to sign a Release of Information (**Attachment 4b**) approving this collection during the enrollment process. Information will be collected by staff who have expertise in medical record data collection. All data will be secured during transmission with encryption and all data will be maintained in a firewall-protected, encrypted server at University of Washington.

3. Methods to Maximize Response Rates and Deal with Non-responses

We will use the following procedures to maximize cooperation and to achieve the desired high response rate:

- Recruitment and retention rates will be monitored by study staff to maintain consistent and accurate procedures.
- If recruitment falls short, we will work with study staff to determine the best course of action, including changing the mix of recruitment strategies
- Data quality and completeness will be examined weekly allowing for issues to be identified in a timely fashion and corrective actions taken if indicated
- Active recruitment will be carried out at Madison Clinic by study staff
- Participant retention will also be facilitated through tokens of appreciation
    - A $45 token of appreciation will be provided to respondents upon study enrollment and completion of the study visit survey
    - A $10 token of appreciation will be provided to respondents upon completion of the acceptability survey

- For the subset of participants that are selected to take part in the focus groups or interviews (n=12), a $40 token of appreciation will be provided to respondents upon completion of this qualitative data collection
- Health providers and clinic staff who participate in the provider interview will be offered a $5 token appreciation; up to 3 interviews may be conducted for a total of $15

- The acceptability survey is delivered online and is optimized so that participants may may complete them using a computer, laptop, or smart phone. This will allow participants to complete the survey at a time and place that is most convenient and comfortable for them.
- Participants also have the option to complete focus groups and interview online. This optional electronic format allows participants to complete these study activities at a time and place that is most convenient and comfortable for them.

4. Tests of Procedures or Methods to be Undertaken

Our research team comprises experts in clinical epidemiology, HIV clinical care, HIV prevention sciences, PrEP research, and measurement of HIV prevention behaviors and qualitative research. We will use this expertise to implement the proposed research aims to provide accurate, complete, consistent and timely data to meet the scientific goals of this study. Our study team has a productive history of innovation in multiple areas including mixed-methods recruitment; the innovative use of online survey software to capture data in research participants; and the use of prospective data collection in HIV prevention research. These innovative elements will facilitate the rapid collection, analysis, and study of data. The grantee study team has pretested the screening tool and quantitative and qualitative assessments to assess question wording, skip patterns, question sensitivity, and overall flow of the data collection tools. All staff will undergo training prior to initiating recruitment including review of standard operating procedures and respective roles and expectations for each study component. Focus group and interview guides have been reviewed by members of the research team to ensure that all concepts are being applied effectively.

5. Individuals Consulted on Statistical Aspects and Individuals Collecting and/or Analyzing Data

Exhibit 5.1 below lists the study investigators who were consulted on the aspects of research design and those who will be collecting and analyzing the data. CDC staff are primarily responsible for providing technical assistance in the design and implementation of the research; assisting in the development of the research protocol and data collection instruments for CDC Project Determination and local IRB reviews; working with investigators to facilitate appropriate research activities; and analyzing data and presenting findings at meetings and in publications. CDC staff will neither interact with nor collect data from study participants. Data will be collected by the grantee, University of Washington. Data will be jointly analyzed by CDC and grantee study staff. Uniquely identifying information will be stripped from all data shared with or accessible by CDC staff.

Exhibit 5.1: Study Investigators and Research Consultants

Name	Title	Organization	Phone	Email
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