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Greater Access and Impact through Point-of-Care Nucleic Acid Testing: Protocol for the GAIN Study

Lisa A Niemann, Lauren R Violette, Andy Cornelius-Hudson, Maggie Murphy, Carl Capili, Mindy Dai, Anjuli Wagner, Sarah Frey, Shireesha Dhanireddy, Shaneil E Taylor, Jeffrey A Johnson, Jeff Wiener, Kevin P Delaney, Karen W Hoover, Joanne D Stekler

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Abstract

Background: Accurate HIV testing is important for individual and population level health for persons with and without HIV. With shorter window periods than serologic point-of-care (POC) tests and faster turnaround than laboratory-based nucleic acid testing (NAT), POC NATs could be valuable tools in improving early detection of HIV. Furthermore, semi-quantitative POC NAT could provide real-time monitoring for persons with HIV (PWH). There have been limited evaluations of POC NAT implementation in the United States to date.

Objective: This paper describes protocols and procedures to evaluate acceptability and feasibility of POC NAT implementation in a clinical and community setting in Seattle, Washington.

Methods: The Greater Access and Impact through POC NAT (GAIN) Study was a CDC-funded study that enrolled participants at a Ryan White-funded, hospital-based clinic (Madison Clinic) and a community site (Seattle's LGBTQ+ Center, formerly Gay City). Persons seeking HIV testing, non-occupational post-exposure prophylaxis (nPEP) or pre-exposure prophylaxis (PrEP) who enrolled at either site received standard-of-care plus the SAMBA II HIV-1 Qualitative Whole Blood Test (SAMBA Qual) and a back-up pooled (1:10) laboratory HIV NAT. PWH enrolled at Seattle's LGBTQ+ Center (the Center) received standard-of-care STI testing plus the SAMBA II HIV-1 Semi-Quantitative Whole Blood Test (SAMBA Semi-Q) and laboratory viral load. PWH from Madison Clinic were recruited into a randomized clinical trial (RCT) to compare the clinical standard-of-care versus the addition of the SAMBA Semi-Q (backed up by the U.S. Food and Drug Administration (FDA) approved laboratory NAT). Participants randomized to receive the POC NAT also received a brief adherence counseling intervention delivered by their physician who was trained by the study team. All participants completed a demographic survey during their study visit and contributed prospective data via electronic medical records. Subsets of participants from each group were invited to complete an online, in-depth acceptability survey after their study visit and an individual interview. Finally, patient flow was observed in Madison Clinic to assess how POC testing impacted timing of patient clinic visits.

Results: From January 2022 to December 2024, 734 participants completed 754 GAIN research visits. Of those visits, 491 visits were completed by 489 participants seeking HIV testing and/or PrEP at the Center and 61 visits were completed by 43 participants seeking HIV testing, PEP and/or PrEP at Madison Clinic. Seven PWH were enrolled at the Center and 194 PWH

were enrolled in the Madison Clinic RCT. In-depth acceptability surveys were completed by 193 participants, and 41 interviews were conducted. Time and motion observations made in 2021 and 2023 were collected on 47 patients.

Conclusions: The GAIN Study protocol described here is an important evaluation of POC NAT implementation in the United States in community and clinical care settings for HIV diagnosis and viral load monitoring. Results will be reported elsewhere. Clinical Trial: NCT04880200

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ABSTRACT (449/450 words)

Background: Accurate HIV testing is important for individual and population level health for persons with and without HIV. With shorter window periods than serologic point-of-care (POC) tests and faster turnaround than laboratory-based nucleic acid testing (NAT), POC NATs could be valuable tools in improving early detection of HIV. Furthermore, semi-quantitative POC NAT could provide real-time monitoring for persons with HIV (PWH). There have been limited evaluations of POC NAT implementation in the United States to date.

Objective: This paper describes protocols and procedures to evaluate acceptability and feasibility of POC NAT implementation in a clinical and community setting in Seattle, Washington.

Methods: The Greater Access and Impact through POC NAT (GAIN) Study was a CDC-funded study that enrolled participants at a Ryan White-funded, hospital-based clinic (Madison Clinic) and a community site (Seattle's LGBTQ+ Center, formerly Gay City). Persons seeking HIV testing, non-occupational post-exposure prophylaxis (nPEP) or pre-exposure prophylaxis (PrEP) who enrolled at either site received standard-of-care plus the SAMBA II HIV-1 Qualitative Whole Blood Test (SAMBA Qual) and a back-up pooled (1:10) laboratory HIV NAT. PWH enrolled at Seattle's LGBTQ+ Center (the Center) received standard-of-care STI testing plus the SAMBA II HIV-1 Semi-Quantitative Whole Blood Test (SAMBA Semi-Q) and laboratory viral load. PWH from Madison Clinic were recruited into a randomized clinical trial (RCT) to compare the clinical standard-of-care versus the addition of the SAMBA Semi-Q (backed up by the U.S. Food and Drug Administration (FDA) approved laboratory NAT). Participants randomized to receive the POC NAT also received a brief adherence counseling intervention delivered by their physician who was trained by the study team. All participants completed a demographic survey during their study visit and contributed prospective data via electronic medical records. Subsets of participants from each group were invited to complete an online, in-depth acceptability survey after their study visit and an individual interview. Finally, patient flow was observed in Madison Clinic to assess how POC testing impacted

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Conclusions: The GAIN Study protocol described here is an important evaluation of POC NAT implementation in the United States in community and clinical care settings for HIV diagnosis and viral load monitoring. Results will be reported elsewhere.

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INTRODUCTION (7,638/10,000 words)

HIV testing is the critical entry point for the status neutral continuum of care. HIV screening allows for early detection of new HIV infections to then link individuals to care and initiate treatment quickly, which can prevent further transmission [1-5]. Furthermore, HIV testing is an important entry point for pre-exposure prophylaxis (PrEP) and is an essential PrEP monitoring tool [6]. Laboratory-based HIV testing can be highly sensitive, but results can take days or weeks and are less likely to be returned to a patient compared to point-of-care (POC) tests [7-9]. In contrast, the POC tests currently approved by the FDA provide results in minutes, but they have longer window periods and are therefore more likely to misdiagnose persons with acute HIV infection (AHI) [9-21]. POC nucleic acid tests (NATs) have shorter window periods and can provide a result in about two hours, which make them a promising tool to help identify AHI and provide rapid HIV testing for PrEP patients [22]. No POC NAT is currently FDA-approved, although several are approved for use outside of the United States for early infant and adult diagnosis and viral load monitoring [23-27].

For people with HIV (PWH), viral load monitoring is a critical component of HIV care, yet laboratory-based viral load testing does not provide for real-time feedback while a patient is in the clinic. One study in South Africa suggested that providing results of a near-POC NAT along with tailored counseling was associated with improved care outcomes at 12 months [28]. If implemented in the U.S., POC NATs could provide a similar opportunity to provide immediate feedback on viral load levels and tailored adherence counseling [24, 29].

In 2019, the Centers for Disease Control and Prevention (CDC) awarded the University of Washington (UW) research funding to conduct the Greater Access and Impact through POC NAT (GAIN) Study. The aims of the study are to 1) implement POC NAT among HIV testing programs, 2) evaluate sensitivity, specificity and clinical outcomes, 3) evaluate the impact of a semi-quantitative POC NAT on time to virologic suppression among PWH in a clinical setting and assess acceptability of viral load testing in a community setting among PWH and 4) to describe the feasibility of POC

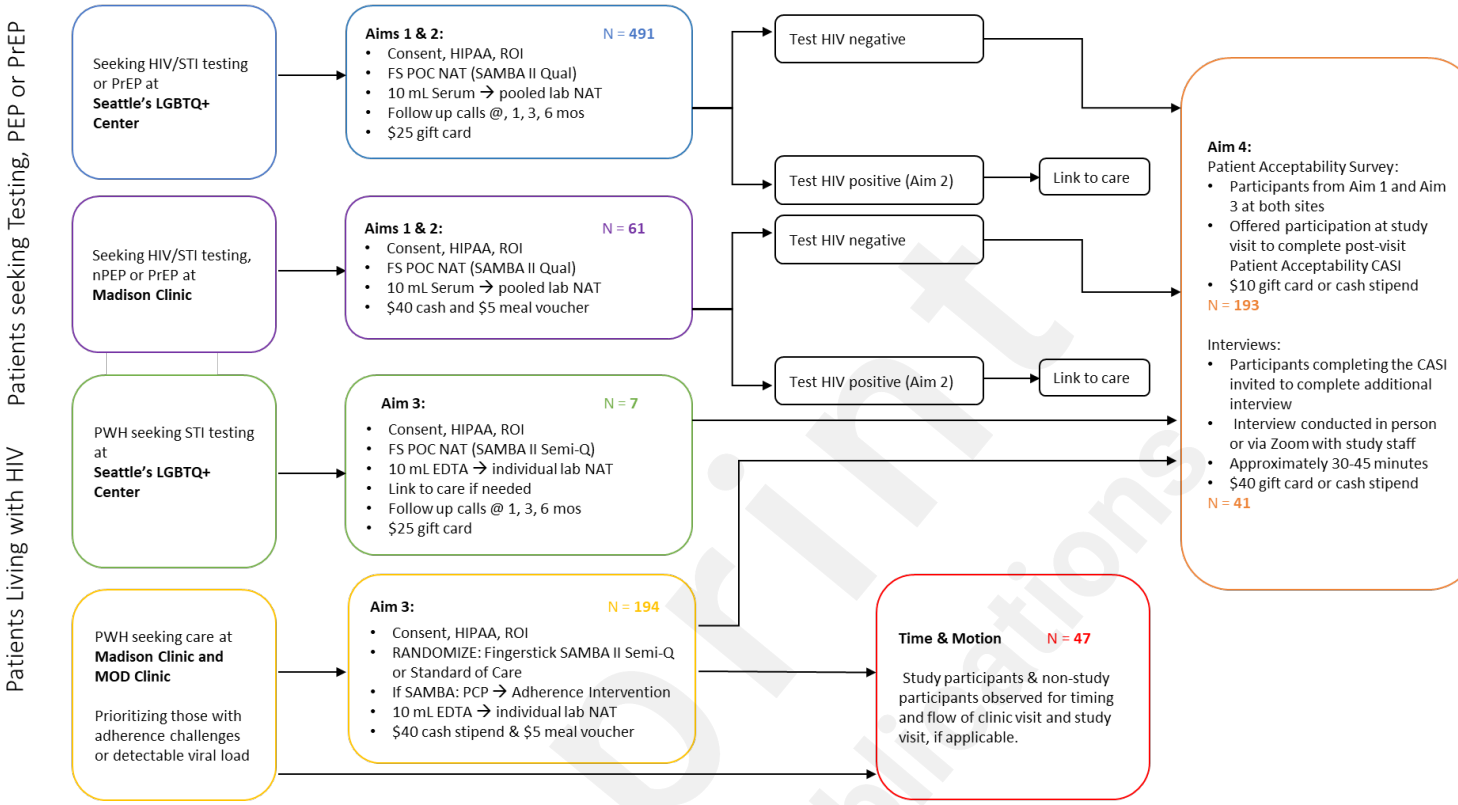
NAT implementation in a clinical setting and quantify acceptability and feasibility of the POC NAT among participants and care providers. In this manuscript, we will describe the protocols designed to achieve each of these aims and description of participants enrolled.

METHODS

Description of the Protocol for the GAIN Study

The GAIN Study consists of four study aims, enrolling study populations at two sites [Figure 1]. Baseline data obtained from the pre-enrollment period among non-study participants at both sites provided a retrospective pre-implementation dataset for comparison with the study participants. Aim 1 evaluated the implementation of the SAMBA II HIV-1 Qual (SAMBA Qual, Diagnostics for the Real World Ltd, Morgan Hill, CA, USA) among HIV testing programs via a longitudinal, prospective study of persons without HIV seeking HIV testing, non-occupational post-exposure prophylaxis (nPEP) and PrEP care at Seattle's LGBTQ+ Center (the Center) and Madison Clinic. Aim 2 evaluated the sensitivity, specificity and clinical outcomes using the data collected as a part of Aim 1. Aim 3 evaluated the impact of the SAMBA II HIV-1 Semi-Quantitative (SAMBA Semi-Q, Diagnostics for the Real World Ltd, Morgan Hill, CA, USA) on time to virologic suppression via a randomized controlled trial (RCT), NCT04880200, for PWH at Madison Clinic and assessed acceptability of viral load testing outside of a clinical setting among any PWH seeking sexually transmitted infection (STI) testing at the Center. Aim 4 examined acceptability and feasibility of the POC NAT using surveys and in-depth interviews with participants and care providers. Finally, a systems engineering component of the study conducted time and motion observations of patient flow through Madison Clinic at one time point pre-implementation and two time points post-implementation, informed study implementation, and provided information about the impact of POC testing on clinic flow. The study received ethical approval from the UW Human Subjects Division (STUDY#00010387).

Figure 1. GAIN Study procedures and total participant visits by aim



Study Sites

The Center is a community-based organization located in Seattle, WA that was established in 1995 and was formerly known as Gay City. The Center's PrEP program was started by Dr. Stekler in 2013 and served as a safety net clinic to link patients to ongoing PrEP care [30, 31].

Madison Clinic is the largest provider of HIV care in Washington State and also offers HIV testing, PEP, and PrEP services. It was established in 1985 and is Ryan White-funded. Madison Clinic also hosts the Moderate Needs Sub-clinic, or the "MOD Clinic." This drop-in sub-clinic is modeled on the MAX clinic, aimed at engaging the hardest to reach PWH in need of services [32, 33]. The GAIN study enrolled both Madison and MOD clinic patients. The RCT initially prioritized MOD patients in order to recruit PWH who were more likely to have detectable viral loads but expanded in January 2024 to include additional Madison clinic providers and patients.

POC NAT Selection

During protocol development, the study team considered available POC NATs to identify which test(s) could be utilized by the GAIN Study. Tests considered included the Alere q 1/2 DETECT qualitative and Alere q NAT quantitative, the Cepheid Xpert HIV-1 Qualitative and Cepheid Xpert HIV-1 Viral Load XC, and the DRW SAMBA Qual and SAMBA Semi-Q. Factors considered included specimen type, volume required, result type, limit of detection, and test turnaround time. The DRW SAMBA tests were selected because the they are truly point-of-care, have no requirement for centrifuging (a requirement for the Cepheid Xpert HIV-q Viral Load) and can be performed on fingerstick blood specimens. The SAMBA tests take up to 2 hours to return a result.

Study Populations & Recruitment

GAIN Baseline Data

GAIN baseline datasets were obtained retrospectively to describe the pre-implementation populations and outcomes at the Center and Madison Clinic from January 2019 through December 2021. A waiver of informed consent was granted by the UW Human Subjects Division for baseline data collection as no identifiers were obtained. The Center provided a deidentified dataset that linked clients via a dummy identification number across multiple datasets in Access, Google Forms, and InSync electronic medical record (EMR) software. All dates were uniformly time-shifted before transmission to the study team to further deidentify the dataset. Data variables included demographics, HIV/STI testing and PrEP care.

In order to obtain the Madison Clinic EMR data, we hired the Institute of Translational Health Sciences (ITHS) to pull and deidentify the requested data from the Clinic's medical record system. ITHS is a collaborative research hub that supports researchers, healthcare providers, and community organizations working to advance translational science. [34] The study team provided a list of desired variables and worked with ITHS to use these variables to identify visit types for the patients of interest in the time frame of January 2019 through December 2021. These patient types included HIV testing visits, PrEP visits, nPEP visits, patients newly diagnosed with HIV, and patients in HIV

care with a detectable viral load. The data were deidentified by creating a dummy identification number, and dates were uniformly time-shifted by an amount unknown to the study team. Data variables included basic demographics, HIV/STI testing, estimated creatinine clearance, viral load testing and prescribed medications.

Additional data on PrEP patients at Madison Clinic was obtained from the PrEP Patient Reported Outcomes (PRO) dataset, a Computer Administered Self-Interview (CASI) on a web-based platform developed for the UW Center for AIDS Research (CFAR) Network of Integrated Clinical Systems to consenting PrEP patients at 6-month intervals [35]. This dataset included information on adherence and substance use.

GAIN Aims 1 and 2 Eligibility (implement POC NAT among HIV testing programs and evaluate the sensitivity, specificity and clinical outcomes)

Participants were recruited for Aims 1 and 2 if they were at least 18 years old, proficient in English, and seeking HIV testing or PrEP care at the Center or HIV testing, nPEP or PrEP at Madison Clinic. Participants could not be enrolled if they were testing anonymously. Testing and nPEP participants could be seen only once, unless they initiated PrEP. PrEP participants could re-enroll at the study at any PrEP follow up visits. We call this group “HIV testing” participants.

GAIN Aim 3 Eligibility (evaluate the impact of a semi-quantitative POC NAT on time to virologic suppression among PWH in a clinical setting and assess acceptability of viral load testing in a community setting among PWH)

Participants were recruited for Aim 3 if they were at least 18 years old, proficient in English, living with HIV, and seeking STI testing at the Center or HIV care at the Madison Clinic or MOD Clinic. These patients were only eligible to participate in the study once.

GAIN Aim 4 Eligibility (describe the feasibility of POC NAT implementation in a clinical setting and quantify acceptability and feasibility of the POC NAT among participants and care providers)

Participants completing a GAIN study visit were eligible to participate in a post-visit online acceptability survey. Participants who completed this post-visit survey were eligible to participate in a follow up in-depth interview with study staff. Repeat study participants were invited only once to the acceptability survey and interview. Procedures and recruitment for care provider interviews have previously been described [38].

Time and Motion Eligibility

Any Madison Clinic or MOD Clinic patient was eligible to be observed by study staff during their clinic visit to assess pre- and post-study implementation clinic flow. A waiver of informed consent was granted by the UW Human Subjects Division for these procedures, and no identifiable information was collected.

Recruitment Strategies

Participants were screened and approached regarding participation by study staff or provider referral. Patients at Madison Clinic could be called via phone in advance by study staff after chart review for eligibility, and patients at both sites were approached in the waiting room about study participation. A “priority score” was also developed using demographic and behavioral questions from a Center intake form for use in prioritizing Center clients for PrEP care and the GAIN Study. Development and implementation of this priority score will be described separately.

For HIV testing participants from the Center, we prioritized clients with a reactive POC antibody HIV test, those with any symptoms of AHI, and those who scored high on the priority score. For HIV testing participants at Madison Clinic, we prioritized enrollment of patients seeking HIV testing and those seeking nPEP. Our recruitment target for these groups was 700 clients from the Center and 150 Madison Clinic patients.

We aimed to recruit all PWH seeking STI testing at the Center. For PWH at Madison Clinic, we prioritized patients with low adherence and/or detectable viremia. Study staff attempted to conduct the study visit for these participants before their regular clinic visit, to initiate the POC NAT as soon

as possible and maximize the chance that the participant might be still in clinic to receive their result in person. Our recruitment target for these groups was 50 clients at the Center and 212 patients at Madison Clinic.

Participants were invited during their study visit to participate in the extra survey and interview immediately after the study visit or on a later date. Our recruitment target for survey participation was 50 HIV testing participants at each site and 50 PWH at each site. Our recruitment target for interview participation was 20 total participants seeking testing (at either site) and 20 total participants with HIV (at either site).

Participation Incentives

Madison Clinic participants initially received a $20 cash incentive and a $5 meal voucher. Participants at the Center initially did not receive an incentive, but this was amended in April 2023 to provide a $25 online gift card for consistency between sites. In order to help boost enrollment, the participation incentive was increased to $40 in cash and a $5 meal voucher for participants at Madison Clinic in August 2023.

Participants who completed the additional acceptability survey were provided a $10 electronic gift card upon survey completion. Participants who participated in the interview were provided a $40 electronic gift card. In August 2024, we began offering incentives in cash as participants noted lack of email access as a barrier for survey and interview participation.

Study Procedures

GAIN HIV Testing Participants at Both Sites and Participants with HIV at the Center

Enrollment began in January 2022 for HIV testing patients and March 2022 for PWH to give study staff time to achieve proficiency in one set of study procedures before adding another group. Study visits were conducted by study staff, who began each visit by reviewing the consent process and obtaining informed written consent. Participants signed a bi-directional release of information allowing the study team to obtain follow up data for the year following the study visit and document

research test results in the patient EMR. Study staff then completed a linking survey on a secure server including patient identifiable information and the study record of the participant. Then the participant completed a brief study visit survey in REDCap with demographic questions linked only to the participant's study record.

After completing study paperwork, study staff collected fingerstick whole blood for the POC NAT. For HIV testing participants, we used the SAMBA Qual, which provides a negative or positive result. European Union (EU) approved materials state that the SAMBA Qual can detect as low as 400 copies of virus as early as 10 days after exposure [26, 36]. For participants with HIV, we used the SAMBA Semi-Q, which provides a result of greater or less than 1000 copies per milliliter of blood [28]. Both versions of the test return a result in approximately 2 hours, and neither test is FDA approved. In June 2023 after a series of false positive test results, we added a second SAMBA Qual using venipuncture whole blood for the HIV testing participants at the Center to provide an additional back up to the fingerstick test.

Study staff collected specimens for all research tests and, if possible, any clinically-indicated laboratory tests. HIV testing participants completed standard of care HIV testing as part of their visit at both sites, which could include the INSTI HIV-1/HIV-2 Antibody Test (bioLytical Laboratories, Inc., Richmond, BC) on a fingerstick specimen and/or the laboratory-based HIV-1/HIV-2 Combo EIA (Bio-Rad Laboratories, Inc., Redmond, WA). Reactive samples were confirmed using the Geenius™ HIV-1/2 Supplemental Assay (Bio-Rad Laboratories, Redmond, WA) with reflex testing via the Real*Time* HIV-1 viral load assay (Abbott Laboratories, Abbott Park, IL) (for participants seen prior to November 2023) or the cobas® HIV-1 viral load assay (Roche Diagnostics, Indianapolis, IN) (for participants seen November 2023 and after) as appropriate. Laboratory testing was done at the Public Health–Seattle & King County (PHSKC) Laboratory and the UW Virology Laboratory.

Initially, a 10 mL serum tube was collected for research HIV testing participants; in June 2023, this changed for participants at the Center to a 4 mL EDTA tube and 6 mL serum tube to allow for

running the SAMBA Qual on venipuncture and the laboratory testing on the serum tube. If all screening tests were negative, research laboratory testing also included a laboratory NAT pooled into a single 10-member pool and tested using the Real*Time* HIV-1 viral load assay (Abbott Laboratories, Abbott Park, IL) (for participants seen prior to November 2023) or the cobas® HIV-1 viral load assay (Roche Diagnostics, Indianapolis, IN) (for participants seen November 2023 and after). If any screening HIV test was positive, a quantitative HIV-1 RNA test was performed. HIV-positive research participants at the Center had a 10 mL EDTA tube drawn for a laboratory NAT. For all research participants, pooled NAT or individual NAT was performed as the laboratory gold-standard for back up of the non-FDA approved SAMBA test [37].

Research and clinic procedures took approximately one hour except for the POC NAT result, and participants were given the option to remain in the clinic to await these results. If the participant was still in the clinic when their POC NAT result was ready, the study staff delivered the result to the participant in person. If the participant had left the clinic, they were only notified of their result via a phone call from study staff for unexpected results (i.e., a positive SAMBA Qual or a SAMBA Semi-Q result greater than 1000 copies in someone who was expecting to be undetectable). Otherwise, the research results were noted in the EMR along with clinic laboratory HIV test results. Laboratory results were usually available via the EMR in up to five to ten business days. Results of the laboratory NAT obtained by the research team were communicated to participants only if test results were discordant. Study staff provided counseling and referrals as appropriate.

Participants at the Center received follow up phone calls at 1, 3, and 6 months after their study visit in order to check whether they had initiated PrEP (if they tested HIV negative) or linked to HIV care, initiated ART, and whether they knew their viral load status (if they tested positive for HIV). Staff stopped calling participants at subsequent follow ups if they indicated they had initiated PrEP or linked to HIV care. Study staff also obtained follow up data from Center participants' EMRs by providing the Center with a list of participants medical record numbers, which Center staff used to

provide participant follow up data back to the study team.

Madison Clinic participant follow up data was captured through patient medical records obtained and transferred monthly to the study staff by ITHS via REDCap. The study team also obtained data on PrEP study participants from the PrEP PRO dataset.

GAIN Participants with HIV in the Madison Clinic RCT

Participants in the RCT completed the consent process, signed a release of information, and completed the linking survey and study visit survey as described above. Then participants in this group were randomized by 1:1 variable block size randomization to either receive either the clinic standard of care or the standard of care plus the SAMBA Semi-Q and tailored counseling.

Beginning in April 2023, study staff also performed venipuncture for participants in both arms and drew a 10 mL EDTA tube for a study laboratory NAT and, if possible for the convenience of the participant, any additional tubes for clinical purposes. This change was made to ensure that all persons had an FDA-approved NAT that could be used as the primary way to guide clinical decision-making.

For participants in both arms, study staff obtained follow up data from ITHS to monitor patient outcomes for one year after the study visit. Viral loads were obtained from the standard of care group at the time of study visit and through up to one year of follow up so that time to virologic suppression could be compared between the two arms.

For participants randomized to the intervention arm, study staff also conducted a fingerstick and initiated the SAMBA Semi-Q. After the study procedures were completed, study staff connected the participant with their care team to complete their clinic visit. When the SAMBA Semi-Q result was ready, study staff delivered the result to the participant’s physician. When participants were still in the clinic, the physician delivered the result along with the brief adherence counseling intervention developed for the study in collaboration with clinic providers, the process for which has already been described [38]. For participants who had left the clinic, the physician followed up with the patient

either via phone or by EMR messaging, whichever they considered most appropriate. For each participant randomized to the POC NAT arm, the physician reported to the research study whether they discussed the POC NAT result with the participant in-person, via phone, or not at all. SAMBA Semi-Q and research laboratory NAT results were manually entered into EMR by the research team.

GAIN Acceptability Survey Participants

An additional acceptability survey was offered to a subgroup of participants beginning in May 2023. A small number of participants were not offered participation for a variety of reasons, e.g. study staff forgot, the participant had a complicated visit and it was logistically best to not offer an additional component. We delayed the offer of acceptability surveys until after the study had been enrolling for approximately one year.

At the study visit, study staff offered participants the optional extra survey. Participants who expressed willingness to take the extra survey were emailed a link to the REDCap CASI within three days of their study visit. For PWH at Madison Clinic, we also began offering the survey immediately after the study visit on a study tablet or laptop to increase access for participants with limited email or internet.

The CASI asked questions about the acceptability of the POC NAT and result delivery. HIV testing participants received a survey that included questions on PrEP use and sexual history and a set of 12 discrete choice questions about HIV testing preferences. PWH received questions on POC NAT acceptability, ART use, viral load testing and cut off levels, and Undetectable=Untransmittable. PWH at Madison Clinic also received questions about their provider and the delivery of the adherence counseling intervention. Because of the sensitive nature of some of the questions, the survey instructions recommend that participants take the survey in a private setting. The CASI was designed to take about 10 minutes and participants were sent a $10 gift card via email or received $10 cash following survey completion.

GAIN Participant Interviews

From June through November 2023, all participants who completed the post-visit acceptability survey were invited to complete a semi-structured interview with study staff either in person, via phone, or Zoom. Participants were contacted via email, and study staff attempted to schedule interviews within one month of the participant's study visit to maximize recall. The conversations were audio recorded and transcribed by HIPAA-compliant GMR Transcription. Once the transcripts were reviewed for accuracy and any identifying information removed, the original recordings were deleted.

The topics covered at the interviews included more detailed, open-ended questions about the acceptability of the POC NAT and result delivery and, for HIV negative participants, a discussion of their HIV testing preferences. PWH were asked about viral load monitoring and their care preferences, viral load cutoff levels and Undetectable=Untransmittable, and the adherence intervention conversation with their provider (see Supplemental Material for interview guides). When thematic saturation appeared to have been reached for HIV-negative participants, recruitment of persons testing HIV-negative continued until February 2024 only for participants who were persons of color or transgender, in order to increase the diversity of the sample. These interviews continued with PWH through the duration of the study.

GAIN Provider Interviews

We also interviewed Madison Clinic physicians to obtain input on the acceptability and feasibility of the POC NAT use in the clinical setting from the provider perspective. In a first round of pre-implementation key informant interviews with Madison Clinic providers, we explored perspectives on the possible utility of a POC NAT and its integration into clinic flow and solicited provider input on the development of an ultra-brief adherence counseling intervention using motivational interviewing and problem-solving counseling techniques, the results of which have been described elsewhere [38]. Brief, post-implementation interviews were conducted with providers who successfully delivered a POC NAT result to a participant to gain insight on the process of test result

delivery and adherence counseling. More formal interviews are planned at completion of the project to solicit feedback on the utility of the SAMBA Semi-Q.

GAIN Time & Motion Observations

Time and motion studies were conducted at three times: February to July of 2021 before study enrollment began to inform study implementation, March to April 2023 for a post-COVID pandemic repeat assessment (during a regulatory study pause in enrollment), and November 2023 to October 2024 during study enrollment to assess the impact of the POC NAT on clinic flow [39]. Patients were observed by study staff from the time when they arrived in the waiting room until they departed the clinic, with staff noting the type of visit and time of each subsequent segment of the patient visit, e.g. front desk check-in, waiting room time, and time the patient spent with each provider type. The final time and motion dataset conducted during study enrollment also noted participant time spent on research procedures. That final dataset evaluating the impact of POC NAT implementation will be reported elsewhere.

Data Collection and Statistical Analysis

GAIN study data sources are shown in Table 1. We present demographic data for client visits in the baseline dataset and GAIN participants in Tables 2, 3, and 4 as descriptive statistics. When data from the study visit survey were missing, we filled in whenever possible with EMR data. Demographic data are presented at the participant level, and include gender, race, insurance, and PrEP/ART status.

Table 1. Data sources for the GAIN study

Dataset	Source	Participants	Data Included
Baseline data from Seattle's LGBTQ+ Center	Seattle's LGBTQ+ Center InSync EMR, Google Forms Intake	Pre-implementation, non-study participants	Demographics, HIV POC and laboratory test results, PrEP prescriptions
Baseline data from Madison Clinic	Madison Clinic Epic EMR, PrEP PRO	Pre-implementation, non-study participants	Demographics, HIV POC and laboratory test results, PrEP visits, viral load results, ARV medications
Linking Survey	REDCap, study staff completed at study visit	All participants	Patient EMR, Study ID, Name, DOB, and Contact information

Study visit survey	REDCap, participant completed at study visit	All participants	Patient demographics, substance use, ARV use
Test results	REDCap, study staff completed at study visit	All participants	POC and laboratory HIV test results
Follow up phone calls	REDCap, study staff completed post-study visit	All participants at Seattle's LGBTQ+ Center	Patient PrEP initiation, ARV use, viral load results, connection to HIV care
Follow-up acceptability survey	REDCap, participant completed post-study visit	Subset of all participants	POC NAT perspectives, PrEP preferences or viral load testing preferences
Follow-up in depth interview	Qualitative in-person or Zoom interviews post-study visit	Subset of participants completing the acceptability survey	POC NAT perspectives, PrEP preferences or viral load testing preferences
Prospective data from Seattle's LGBTQ+ Center	Seattle's LGBTQ+ Center InSync EMR, Google Forms Intake	All participants at Seattle's LGBTQ+ Center	Demographics, HIV POC and laboratory test results, PrEP prescriptions
Prospective data from Madison Clinic	Madison Clinic Epic EMR, PrEP PRO	All participants at Madison Clinic	Demographics, HIV POC and laboratory test results, PrEP visits, viral load results, ARV medications
Time & motion data	Observational data on patient flow through Madison Clinic collected by study staff	Non-participants, Madison participants with HIV	Times and clinic and study visit components

RESULTS

During the baseline data period of January 2019 – December 2021 at the Center, 6906 unique clients were seen for 8492 HIV/STI testing visits, and 272 clients had 612 PrEP visits (Table 2). Most clients (79.5%) were cisgender men. Almost half were white (48.1%). Nearly one third (30.4%) reported no insurance. Among testing visit clients, about 86% were HIV negative (though HIV status was missing/unknown for 11.5%), 15.6% of whom reported being on PrEP. About 2.5% of testing visit patients were living with HIV, and about one third of those clients reported that they were on ART (31.4%), though data was missing for most clients (60.0%).

Table 2. Characteristics of Seattle's LGBTQ+ Center client baseline visits, Jan 2019 - Dec 2021, and GAIN study participants seeking HIV/STI testing and PrEP, Jan 2022 – Aug 2024

	Baseline client visits Jan 2019 – Dec 2021			GAIN study participant visits	
Characteristic	**HIV/STI**	**PrEP visits**	**Total visits**	**HIV/STI**	**STI testin**

	testing visits			testing and PrEP Jan 2022 – Aug 2024	participants with HIV Mar 2022 – Aug 2024
Total, n (%)	6906 (96.2)	272 (3.8)	7178 (100)	489 (100)	7 (100)
Age (median, IQR)	30 (26 – 38)	28 (24 – 33)	30 (26 – 37)	30 (25-35)	57 (41-61)
Gender, n (%)					
Cisgender man	5487 (79.5)	216 (79.4)	5703 (79.5)	333 (68.1)	7 (100)
Cisgender woman	430 (6.2)	0 (0.0)	430 (6.0)	35 (7.2)	0 (0.0)
Transgender man	99 (1.4)	2 (0.7)	101 (1.4)	13 (2.7)	0 (0.0)
Transgender woman	190 (2.8)	13 (4.8)	203 (2.8)	17 (3.5)	0 (0.0)
Nonbinary/genderqueer (AMAB)	307 (4.4)	14 (5.1)	321 (4.5)	51 (10.4)	0 (0.0)
Nonbinary/genderqueer (AFAB)	206 (3.0)	1 (0.4)	207 (2.9)	30 (6.1)	0 (0.0)
Nonbinary/genderqueer (another gender or intersex at birth, missing sex at birth)	18 (0.3)	0 (0.0)	18 (0.3)	6 (1.2)	0 (0.0)
Missing	169 (2.4)	26 (9.6)	195 (2.7)	4 (0.8)	0 (0.0)
Race/ethnicity, n (%)					
American Indian or Alaska Native	40 (0.6)	2 (0.7)	42 (0.6)	1 (0.2)	0 (0.0)
Asian	1015 (14.7)	26 (9.6)	1041 (14.5)	69 (14.1)	0 (0.0)
Black or African American	628 (9.1)	34 (12.5)	662 (9.2)	28 (5.7)	0 (0.0)
Native Hawaiian or Other Pacific Islander	75 (1.1)	10 (3.7)	85 (1.2)	2 (0.4)	1 (14.3)
White	3375 (48.9)	77 (28.3)	3452 (48.1)	278 (56.9)	5 (71.4)
Latinx*	1194 (17.3)	77 (28.3)	1271 (17.7)	72 (14.7)	1 (14.3)
Multiracial**	451 (6.5)	16 (5.9)	467 (6.5)	36 (7.4)	0 (0.0)
Middle Eastern or South Asian	37 (0.5)	2 (0.7)	39 (0.5)	ND	ND
Missing/no response	91 (1.3)	28 (10.3)	119 (1.7)	3 (0.6)	0 (0.0)
Insurance, n (%)					
Public insurance	391 (5.7)	27 (9.9)	418 (5.8)	87 (17.8)	2 (28.6)
Private insurance	1663 (24.1)	46 (16.9)	1709 (23.8)	250 (51.1)	5 (71.4)
Unspecified type	2648 (38.3)	0 (0.0)	2648 (36.9)	11 (2.2)	0 (0.0)
No insurance	2138 (31.0)	47 (17.3)	2185 (30.4)	121 (24.7)	0 (0.0)
Not sure/missing	66 (1.0)	152 (55.9)	218 (3.0)	20 (4.3)	0 (0.0)
Substance use, n (%)					
IDU (past year)***	224 (3.4)	12 (11.1)	236 (3.5)	ND	ND
IDU (past 3 months)	ND	ND	ND	4 (0.8)	0 (0.0)
Meth (past 3 months)****	65 (2.1)	6 (5.2)	71 (2.2)	13 (2.7)	0 (0.0)
HIV status and PrEP/ART use, n (%)					
HIV negative	5937 (86.0)	n/a	n/a	489 (100)	0 (0.0)
Currently on PrEP	929 (15.6)	n/a	n/a	123 (25.5)	n/a
HIV positive	175 (2.5)	n/a	n/a	0 (0.0)	7 (100)
Currently on ART	55 (31.4)	n/a	n/a	n/a	6 (85.7)
Not currently on ART	15 (8.6)	n/a	n/a	n/a	1 (14.3)
ART status unknown/missing	105 (60.0)	n/a	n/a	n/a	0 (0.0)
HIV status unknown/missing	794 (11.5)	n/a	n/a	0 (0.0)	0 (0.0)

*participants who selected Latinx and any other race were categorized as Latinx

**participants who selected any two or more races but not Latinx were categorized as multiracial

***asked of 6575 test participants and 108 PrEP participants
****asked of 3107 test participants and 108 PrEP participants
AMAB: assigned male at birth
AFAB: assigned female at birth
n/a: not applicable; variable does not apply to the group listed
ND: no data available; data that wasn't collected for the group listed

At Madison Clinic during the same baseline period (Table 3), there were 117 unique patients seen for nPEP, 328 unique patients seen for HIV testing visits, and 400 unique patients seen for PrEP visits. There were 146 patients who tested positive for HIV for the first time and 511 patients with HIV whose viral load was detectable (greater than 40 copies/mL) at some point during that time (Table 4). Among patients seen, half were white (48.1%), 18.4% were Black or African American, 7.9% were Asian and 7.1% were Hispanic or Latinx. Most (77.6%) were male, 22.2% were female, only 0.2% were transgender or nonbinary.

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Table 3. Characteristics of Madison Clinic patient baseline visits, Jan 2019 - Dec 2021 and GAIN study participants seeking HIV/STI testing, nPEP or PrEP, Jan 2022- Aug 2024

	Baseline patient visits Jan 2019 – Dec 2021				GAIN study participant visits Jan 2022 – Aug 2024
Characteristic	**nPEP visits**	**HIV testing visits**	**PrEP visits**	**Total visits**	**HIV/STI testing, nPEP, and PrEP visits**
Total, n (%)	117 (13.8)	328 (38.8)	400 (47.3)	845 (100)	43 (100)
Age (median, IQR)	31 (26-39)	32 (27-42)	33 (27-44.5)	33 (27 - 43)	35 (31-44)
Gender, n (%)					
Cisgender man	117 (100)	177 (54.0)	348 (87.0)	642 (76.0)	37 (86.0)
Cisgender woman	0 (0.0)	150 (45.7)	51 (12.8)	201 (23.8)	1 (2.3)
Transgender man	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Transgender woman	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.7)
Nonbinary/genderqueer (AMAB)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.3)
Nonbinary/genderqueer (AFAB)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nonbinary (unknown sex at birth)	0 (0.0)	1 (0.3)	1 (0.3)	2 (0.2)	0 (0.0)
Another gender identity:	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	2 (4.7)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Race/ethnicity, n (%)					
American Indian or Alaska Native	1 (0.9)	3 (0.9)	10 (2.5)	14 (1.7)	0 (0.0)
Asian	20 (17.1)	33 (10.1)	36 (9.0)	89 (10.5)	2 (4.7)
Black or African American	12 (10.3)	44 (13.4)	25 (6.3)	81 (9.6)	2 (4.7)
Hispanic or Latinx*	20 (17.1)	13 (4.0)	40 (10.0)	73 (8.6)	11 (25.6)
Native Hawaiian or Other Pacific Islander	1 (0.9)	1 (0.3)	2 (0.5)	4 (0.5)	1 (2.3)
White	51 (43.6)	178 (54.3)	198 (49.5)	427 (50.5)	27 (62.8)
Multiracial**	1 (0.9)	7 (2.1)	11 (2.8)	19 (2.2)	0 (0.0)
Missing/no response	11 (9.4)	49 (14.9)	78 (19.5)	138 (16.3)	0 (0.0)
Insurance, n (%)					
Public insurance	39 (33.3)	94 (28.7)	121 (30.3)	329 (38.9)	19 (44.2)
Private insurance	55 (47.0)	125 (38.1)	149 (37.3)	254 (30.1)	16 (37.2)
Another insurance	5 (4.3)	62 (18.9)	75 (18.8)	142 (16.8)	0 (0.0)
None/not sure/missing	18 (15.4)	47 (14.3)	55 (13.8)	120 (14.2)	9 (20.9)
Prep use (reported by participant) , n (%)					
Never	ND	ND	ND	ND	7 (16.3)
Previously	ND	ND	ND	ND	6 (14.0)
Currently	ND	ND	ND	ND	30 (69.8)
Missing	ND	ND	ND	ND	0 (0.0)
Reason for visit (reported by study staff) , n (%)					

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HIV testing	ND	ND	ND	ND	6 (14.0)
PEP	ND	ND	ND	ND	6 (14.0)
PrEP start	ND	ND	ND	ND	5 (11.6)
PrEP persistence	ND	ND	ND	ND	26 (60.5)

*participants who selected Latinx and any other race were categorized as Latinx
**participants who selected any two or more races but not Latinx were categorized as multiracial
AMAB: assigned male at birth
AFAB: assigned female at birth
ND: no data available; data that wasn't collected for the group listed

Table 4. Characteristics of Madison Clinic patients baseline visits, Jan 2019 - Dec 2021, and GAIN study participants living with HIV, Jan 2022 – Aug 2024

	Baseline Madison Clinic patients Jan 2019 – Dec 2021			**GAIN study visits Jan 2022 – Aug 2024**
Characteristic	**Patients with first reactive HIV result**	**Patients with detectable HIV viral load**	**Total patients**	**Participants with HIV**
Total, n (%)	146 (22.2)	511 (77.8)	657 (100)	194 (100)
Age (median, IQR)	34 (28-47)	43 (32-52)	41 (31 - 51)	44.5 (35-57)
Gender, n (%)				
Cisgender man	117 (80.1)	406 (79.5)	523 (79.6)	144 (74.2)
Cisgender woman	29 (19.9)	104 (20.4)	133 (20.2)	19 (9.8)
Transgender man	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Transgender woman	0 (0.0)	0 (0.0)	0 (0.0)	10 (5.2)
Nonbinary/genderqueer (AMAB)	0 (0.0)	0 (0.0)	0 (0.0)	15 (7.7)
Nonbinary/genderqueer (AFAB)	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Nonbinary (unknown sex at birth)	0 (0.0)	1 (0.2)	1 (0.2)	0 (0.0)
Another gender identity:	0 (0.0)	0 (0.0)	0 (0.0)	6 (3.1)
Missing	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
Race/ethnicity, n (%)				
American Indian or Alaska Native	0 (0.0)	14 (2.7)	14 (2.1)	3 (1.6)
Asian	10 (6.8)	20 (3.9)	30 (4.6)	4 (2.1)
Black or African American	43 (29.5)	152 (29.7)	195 (29.7)	53 (27.3)
Hispanic or Latinx*	12 (8.2)	21 (4.1)	33 (5.0)	27 (13.9)
Native Hawaiian or Other Pacific Islander	1 (0.7)	8 (1.6)	9 (1.4)	5 (2.6)
White	56 (38.4)	239 (46.8)	295 (44.9)	84 (43.3)
Multiracial**	4 (2.7)	4 (0.8)	8 (1.2)	17 (8.8)
Missing/no response	20 (13.7)	20 (3.9)	40 (6.1)	1 (0.5)
Insurance, n (%)				
Public insurance	55 (37.7)	325 (63.6)	380 (29.8)	162 (83.5)
Private insurance	61 (41.8)	135 (26.4)	196 (57.8)	28 (14.4)
Another insurance	12 (8.2)	17 (3.3)	29 (4.4)	1 (0.5)
None/not Sure/missing	18 (12.3)	34 (6.7)	52 (7.9)	3 (1.6)

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ART use, n (%)				
Never	ND	ND	ND	38 (19.6)
Previously	ND	ND	ND	19 (29.4)
Currently	ND	ND	ND	134 (69.1)
missing	ND	ND	ND	3 (1.6)
Laboratory viral load, n (%)* **				
Detectable (40 or greater copies)	n/a	n/a	n/a	63 (32.5)
Undetectable (<40 copies)	n/a	n/a	n/a	113 (58.2)
Laboratory viral load not done	n/a	n/a	n/a	18 (9.3)****
Randomization arm, n (%)				
Standard of care	n/a	n/a	n/a	97 (50.0)
Point-of-care NAT	n/a	n/a	n/a	97 (50.0)

*participants who selected Latinx and any other race were categorized as Latinx
**participants who selected any two or more races but not Latinx were categorized as multiracial
***filled in with clinic EMR if available within 15 days of visit date when study VL not available.
****laboratory viral load test was not done on participants seen before October 2022 (7) and those for whom no blood could be drawn due to hard stick (8), viral load was filled in where possible by clinic EMR
AMAB: assigned male at birth
AFAB: assigned female at birth
n/a: not applicable; variable does not apply to the group listed
ND: no data available; data that wasn't collected for the group listed

During study enrollment from January 2022 to December 2024, 733 unique people completed 753 GAIN study research visits (Tables 2, 3 & 4). Of those visits, 491 visits were completed by 489 participants seeking HIV testing and/or PrEP at the Center. Most of those participants were seeking HIV testing (96.0%), were cisgender men (68.1%), were white (56.9%), with a median age of 30 (IQR: 25-35). About one quarter (25.2%) were currently on PrEP. Seven PWH seeking STI testing were enrolled from the Center. These participants were all cisgender men, most were white (71.4%) with a median age of 57 (IQR: 41-61). Of those participants, one was not taking ART but had previously, the other 6 were currently taking ART.

At Madison Clinic, 61 visits were completed by 43 participants seeking HIV testing, nPEP and/or PrEP. The majority of participants were there for a PrEP persistence visit (60.5%). Most of these participants were cisgender men (86.0%) and white (62.8%), with a median age of 35 (IQR: 31-44) and most (69.8%) were on PrEP. At Madison Clinic and MOD Clinic, 194 PWH seeking care were enrolled during the same time period. These participants were mostly cisgender men (74.2%), 43.3%

were white, 27.3% were Black or African American, and their median age was 44.5 (IQR: 35-57). Among Madison/MOD Clinic participants with HIV, 69.1% were currently taking ART and 32.5% had a detectable viral load (greater than 40 copies/mL) at the time of their study visit. Differences in the populations of participants at the Center and Madison Clinic reflect the different populations seen at the two sites.

As a part of Aim 4 study activities (Table 5), during a recruitment period that included 228 study visits completed by participants seeking HIV/STI testing at the Center, staff invited 198 to take the post-visit acceptability survey, which 133 participants (67.2%) completed. During six study visits by PWH at the Center, staff sent participants 4 survey invitations and 3 completed them (75% completion). Among 25 Madison Clinic participant visits for HIV/STI testing, nPEP and PrEP, 10 out of 21 invited completed the survey (47.6% completion). During 161 study visits for PWH at Madison and MOD Clinics, 47 out of 77 (61.0%) invited participants completed the survey, from those who completed the additional surveys, 21 participants seeking HIV/STI testing, nPEP or PrEP from both sites and 20 PWH from both sites also participated in an in-depth interview. Only participants who completed the survey were invited to participate in interviews, and participation rates were at or below 50% for all groups. However, we stopped inviting eligible participants who were seeking HIV/STI testing, nPEP or PrEP to the interview after we achieved saturation of themes.

Table 5. Acceptability survey and interview completions for GAIN Study participants from Seattle's LGBTQ+ Center and Madison Clinic

Characteristic	Seattle's LGBTQ+ Center		Madison Clinic		Total
	HIV/STI testing participants	Participants with HIV	HIV/STI testing, nPEP, and PrEP participants	Participants with HIV	N
Total Study Visits*	228	6	25	161	420
Survey Invitations sent**	198 (86.8%)	4 (66.7%)	21 (84.0%)	77 (47.8%)	300 (71.4%)
Surveys Completed	133 (67.2%)	3 (75.0%)	10 (47.6%)	47 (61.0%)	193 (64.3%)
Interviews Completed	16	1 (33.3%)	5 (50.0%)	19 (40.4%)	41 (21.2%)

	(12.0%)***

*Includes study visits while participation in the acceptability survey was being offered.
**Includes participants who were offered, agreed, and were eligible to be sent the acceptability survey at their study visit.
***Study staff stopped offering enrollment to all participants after saturation in themes was attained, so not all eligible participants were invited.

Time and motion observations were made in 2021 for 25 total Madison Clinic patients; 13 of which were from the MOD Clinic (Table 6). We found the median clinic visit time was 73 minutes (IQR: 54 - 92 minutes). An additional set of time and motion observations, made in 2023 during a pause in study enrollment, included 22 total Madison Clinic patients (10 of which were from MOD Clinic) and revealed a median clinic visit time of 64 minutes (IQR: 45-88 minutes). This demonstrated that most patient visits were less than the amount of time the POC NAT being used for the study would take to return a result (120 minutes). This finding led the study team to develop a protocol prioritizing recruitment of participants prior to their regular clinic visit, to initiate the SAMBA test as soon as possible.

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Table 6: Total time observed in clinic in minutes including waiting room time, at one period pre-enrollment (2021) and one period while enrollment was paused (2023)

		MOD Clinic	Madison Clinic	Total
2021	N	13	12	25
	Range	46 – 301	19 – 155	19 – 301
	Mean ± std dev	93.5 ± 66.9	66.8 ± 36.2	80.7 ± 55.0
	Median [IQR]	74 [55 – 97]	64 [42 – 85]	73 [54 – 92]
2023	N	10	12	22
	Range	32 – 185	45 – 95	32 – 185
	Mean ± std dev	75.2 ± 43.6	65.3 ± 17.2	69.8 ± 31.6
	Median [IQR]	68 [61 – 74]	61 [51 – 80]	64 [45 – 88]

DISCUSSION

Principal findings

The GAIN study was designed to assess the acceptability and feasibility of implementing POC NAT in a community and clinical setting. This manuscript describes the protocol and populations recruited into the study. During three years of enrollment, the GAIN study conducted 552 visits with HIV testing participants at two study sites. Enrollment of persons seeking HIV testing occurred predominantly at the Center due to the focus of their HIV/STI testing programming. During the same period, the study enrolled 201 PWH from both sites. Conversely, recruitment of PWH was predominantly from Madison Clinic. Recruitment for the qualitative components from Aim 4 included 193 total post-study visit surveys and 41 in-depth interviews.

At the Center, we found that transgender, nonbinary, and genderqueer people represented a greater proportion of our study population (23.9% of Aim 1 participants) compared to baseline visits at the Center (11.9%). This may reflect changing demographics of Center clients due to shifting priorities of the organization combined with the prioritization of study recruitment among clients at highest likelihood of testing persons with HIV [40, 41]. Among HIV testing participants at the Center, 25.2% said they were currently on PrEP, which is significantly higher than the baseline group of participants seeking HIV testing, 15.6% of whom were on PrEP. This could also be due to the study focus on recruiting clients who were high priority for PrEP, and could also be influenced by baseline data

missingness, as 11.5% of the Center baseline participants did not have a recorded HIV status or PrEP status.

In the baseline population at the Center, 2.5% of clients were PWH. We would expect based on that rate approximately 50 clients with HIV to visit the Center annually. The GAIN study enrolled only 7 clients with HIV at the Center during the nearly three years of enrollment. This low enrollment could be due to some participants not identifying themselves as living with HIV when completing the Center's intake form, so study staff was unable to identify all eligible clients to approach regarding recruitment. Future studies may wish to further examine how the point-of-care NAT could be utilized among people with HIV who are seeking STI testing in a community setting.

At Madison Clinic, the GAIN study enrolled fewer HIV-negative cisgender women (2.3%) than we saw in the Madison Clinic baseline dataset among patients seeking HIV testing (45.7% women) and PrEP (12.8% women). We saw a much higher number of participants identifying as transgender, genderqueer, or persons with another gender identity (11.6%) than were identified in our baseline dataset (0.2% among those seeking HIV testing, nPEP, and PrEP). This is due to study data collection instruments offering better capacity for noting these gender identities than the EMR which supplied the baseline data. The GAIN study also enrolled far more PrEP patients (69.8%) than patients seeking HIV testing or nPEP. Future studies could focus more on the utility of the POC NAT among broader clinical patient populations.

Among Madison Clinic patients with HIV, we also enrolled more patients who identified as transgender, genderqueer, or persons with another gender identity (16.0%) than the Madison Clinic baseline participants (0.2% among those with a first reactive HIV result and patients with a detectable viral load). Again, this is likely due to constraints of the EMR that was the source of the baseline data. We also saw fewer cisgender women (9.8%) than were seen during the baseline data period (20.4%).

The GAIN study aimed to prioritize the enrollment of participants with detectable viral loads to

assess the impact of POC NAT on the time to viral suppression, and 32.5% of PWH enrolled at Madison Clinic had detectable viral loads at their study visit (however for 9.3% of participants viral load data were missing). In 2024, about 10% of Madison Clinic patients had a detectable viral load (greater than 200 copies/mL), so the study was able to oversample for the population (data not published). There is a high percentage of patients in the region who have achieved viral suppression in King County; in 2022 the HIV/AIDS Epidemiology report estimated 85% of people living with HIV in the region were virally suppressed [42]. Having a sample size with a sufficient number of participants with a detectable viral load will impact the planned time to event analyses for participants achieving an undetectable VL. We also hypothesized that a POC NAT result would likely have a greater impact on patient visits where real-time counseling can be done, for the adherence counseling intervention component.

At both sites, study baseline data was impacted by COVID-19 pandemic-related changes to patient flow. In order to address this, we expanded the baseline dataset to include 2021 as well as 2020, when clinic procedures were better adjusted to the impact of the pandemic. The study also experienced other challenges due to the pandemic, including delays in laboratory testing due to overloaded laboratory staff, shifts to provision of PrEP services via telemedicine, and clinical and laboratory supply shortages. The study also experienced delays due to the initial Office of Management and Budget (OMB) approval process, beyond local IRB approval process, of over two years.

The GAIN study is among the first studies to evaluate the implementation of a POC NAT in the United States for screening among HIV negative participants (including patients on PrEP) and point-of-care viral load monitoring among PWH. As this technology develops and availability increases in the United States, this protocol can serve as a model for future studies.

Limitations

The GAIN study has limitations that should be noted. Baseline data and prospective data collected

from Madison Clinic and Center datasets could be incomplete because data was deidentified when transferred to the study team, and might not perfectly reflect the participants recruited into the study. However, the study team worked closely with data managers from both sites to achieve as complete a dataset as possible. For study visits and follow up interviews, only participants who spoke English were enrolled, leaving out individuals with limited English proficiency from our results. Post-study survey and interview contact were primarily via email, which led to lower uptake and likely did not include those without access to email. We did change our process in 2024 to allow for these to be done in person immediately after the study visit and reimbursed with cash, which enabled some inclusion of participants without internet access. Though the original proposed protocol called for a comparison of multiple POC NATs, due to challenges with suppliers, the study team was not able to procure any other POC NATs for comparison. Future studies of POC NATs could assess other testing platforms.

Next steps

Additional analyses based on the GAIN study protocol described here are planned and in progress. Future reports will include a report on the acceptability of the POC NAT among participants and providers, an assessment of the impact of POC NAT on clinical outcomes, an evaluation of the performance of the POC NAT, an assessment of participant HIV testing preferences based on survey and interview results, and a final set of Madison Clinic time and motion data.

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Conflicts of interest

None declared.

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Data Availability

The datasets generated during this study are available from the corresponding author on reasonable request.

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Abbreviations

AHI: acute HIV infection

CASI: computer administered self-interview

CDC: Centers for Disease Control and Prevention

CFAR: Center for AIDS Research

COVID: Coronavirus disease

EIA: enzyme immunoassay

EMR: electronic medical record

EU: European Union

FDA: U.S. Food and Drug Administration

GAIN: Greater Access and Impact through POC NAT

HIPAA: Health Insurance Portability and Accountability Act

ITHS: Institute of Translational Health Sciences

LGBTQ+: lesbian gay bi trans, queer

MOD: Moderate Needs

MRN: medical record number

NAT: nucleic acid test

nPEP: non-occupational post-exposure prophylaxis

OMB: Office of Management and Budget

PHSKC: Public Health–Seattle & King County

POC: point-of-care

PrEP: pre-exposure prophylaxis

PRO: patient reported outcomes

PWH: persons with HIV

RCT: randomized controlled trial

ROI: release of information

STI: sexually transmitted infection

UW: University of Washington

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Supplementary Files

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Multimedia Appendixes

"A taste of MI" exercise.
URL: http://asset.jmir.pub/assets/0543a0fb8447332336ed6282ad57889d.pdf

GAIN study presentation for providers: brief counseling skills to improve ART adherence motivational interviewing and problem-solving therapy.
URL: http://asset.jmir.pub/assets/d219f7ae01cc7fd06b1856e467d1c109.pptx

GAIN study patient acceptability CASI for HIV testing participants.
URL: http://asset.jmir.pub/assets/f976a7fb72e057f7a843c932376effbd.docx

GAIN study patient acceptability CASI for PWH at the Center.
URL: http://asset.jmir.pub/assets/704d6302b7a7d3f322e63387f49cdd0c.docx

GAIN study patient acceptability CASI for PWH at Madison Clinic.
URL: http://asset.jmir.pub/assets/2e6e2cac3758ff32a61b9846b0a3bced.docx

GAIN study interview guide for HIV testing participants.
URL: http://asset.jmir.pub/assets/71e0b55cc6e8fe81359f00c40b2d0d97.docx

GAIN study interview guide for PWH at the Center.
URL: http://asset.jmir.pub/assets/aae75e205402ea9a3e867e6bd77eab26.docx

GAIN study interview guide for PWH at Madison Clinic.
URL: http://asset.jmir.pub/assets/7c4493a55571031f0ee0b1245960b680.docx

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