

At-home Self-collection STD Lab Testing: *Lay of the Land*

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NCS D

National Coalition
of STD Directors

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NOTE: Dr. Hall is a Senior Medical Advisor for Nurx.com. His work on this technical assistance initiative should not be construed as an endorsement of Nurx or its associated lab partners.

Technical assistance continuum

- At-home self-collection testing landscape
- Level-setting regulatory overview
- Today's Field Reports: BHOC and Colorado Department of Health
- TA brief with FAQs (updated)
- External resources
- Future effort to Point to third-party lab + provider resources
- Updating resources through future webinars and regular Clinic+ COVID-19 calls

Telehealth vs. digital health

- Telehealth may simply refer to telephonically or digitally interacting with patients. See KFF review.
- Digital health typically delivered through a platform
 - Synchronous: provider/patient simultaneously present (phone or video)
 - Asynchronous: provider/patient interaction takes place over a time continuum: “store and forward” or message-based
- **At-home lab specimen self-collection** and delivery of therapy completes the remote care experience

Array of At-home STI Test Options

- DTC At-Home HIV Self-Testing
- Homegrown At-home STD Testing Solution using local PHL and self-fulfillment
- Third-party At-home Lab interface solutions
- Third-party End-to-end Digital Provider + Lab Solutions
- Other (BHOC's TakeMeHome)

Array of At-home STI Test Options



**Homegrown
At-home STD
Testing Solution**

Local PHL, in-house providers, and self-fulfillment of kits



**Third-party
At-home Lab
interface
Solution**

In-house providers, with 3rd party lab kit fulfillment



**Third-party End-to-end Digital
Provider + Lab
Solution**

Both provider and lab functions outsourced

Other: BHOC's TakeMeHome Program

At-home STD testing issues

- Why at-home testing? Ultimately patient-centered.
- Regulatory permissiveness (LDT validation)
- STD test options: 3-site, extragenital testing for GC/CT, syphilis testing, other testing
- Syphilis: treponemal vs. non-treponemal
- Payment concerns: for patient, for clinic
- Geographical limitations: reach of some services limited by restricted for some labs, some providers, and also by modality
- Billing for provider services lagging

Lab services providers

- Participating labs must be attentive to LDT validation requirements for self-collection of specimens in a non-clinical setting
- Labs typically fulfill kits, receive/process specimens, pipe results to provider entity for patient results disclosure
- Billing for lab services

Digital health providers

- Numerous commercial providers have emerged to provide some or all of the following:
 - Patient assessment
 - Provider ordering of tests
 - Results disclosure
 - Counseling re results and next steps
 - Treatment and/or referral to treatment options
 - PH reporting of results / care

At-home STD testing issues

- Why at-home testing? Ultimately patient-centered.
- Regulatory permissiveness
- STD test options: 3-site, extragenital testing for GC/CT, syphilis testing, other testing
- **Syphilis: treponemal vs. non-treponemal**
 - Most at-home self collect syphilis tests: EIA
 - Advent of at-home self-collect RPR
- Payment concerns: for patient, for clinic
- Geographical limitations: reach of some services limited by restricted for some labs, some providers, and also by modality
- Billing for provider services lagging

Regulatory Landscape

Gary Richwald, MD, MPH



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Former Director & Chief Physician,
LA County STD Program

Lecturer, Epidemiology of Infectious Diseases,
USC School of Medicine

COVID-19 Scientific and Health Advisor, UFCW 770

NOTE: Dr. Richwald is Medical Director & CSO of myLAB Box. His work on this technical assistance initiative should not be construed as an endorsement of myLAB Box or its associated lab or clinical partners.

Clinical Laboratory Testing

- Testing has two distinct but overlapping purposes: diagnosis and surveillance
- Tests have two targets: detecting pathogens and determining host immune response (antibodies)
- Pharmaceuticals (drugs) are **approved** by the FDA
- Clinical laboratory tests are **cleared** by the FDA

FDA Clearance of Clinical Laboratory Tests

- For FDA clearance, test manufacturer specifies: purpose (indication for use), test population, type and site of specimen collection, range of results (positive, negative, indeterminate), etc. Manufacturer provides data comparing test with “gold standard”, along with calculation of sensitivity (attention to FNs) and specificity (attention to FPs).
- Test manufacturers rarely submit a supplement to their initial FDA clearance when there are additions to or changes in the test’s indications for use, type and site of specimen collection, etc. When this does occur, the “new” test requires validation as a laboratory-developed test .

Laboratory Developed Tests (LDTs)

- Almost half of clinical laboratory tests are not FDA cleared but instead are laboratory-developed tests
- LDTs require validation of test by comparison to a “gold standard”. These validation studies are performed by a licensed clinical laboratory and if the test involves multiple steps, each step must be validated
- LDT validation is specific to each laboratory where the validation took place and is not transferable outside of that laboratory or group of laboratories if owned collectively
- Validation of LDTs is regulated and reviewed under CLIA and also CAP standards that are specific to each laboratory

Home Collection of STI Specimens

- At this time there are few point-of-care (POC) tests in the STI field
- Home collection requires: self-collection of specimens using written instructions for collection at home, mail-in to clinical laboratory, and processing and running test in the laboratory
- Self-collection of specimens using written instructions for collection at home AND mail-in to clinical laboratory are not FDA cleared for any tests, and as a result require a validation study as an LDT

Home Collection of STI Specimens, *con't*

- Validation studies usually compare home-collected specimens mailed to the laboratory for testing WITH specimens collected from the same individual in a traditional office setting using a licensed clinician to collect the specimen. In some cases, the specimen run in the laboratory is also run at a reference laboratory.
- In other cases, the test methodology used in the laboratory is actually developed by the laboratory (as in the new COVID-19 viral detection tests) and requires comparison to a test run at a reference laboratory. With dried blood spot (DBS) specimens such as for HSV-1 and HSV-2 IgG antibodies, test result numerical scales are adjusted to reflect different concentrations due to the DBS-type specimen.



TakeMeHome

National Home Testing Program

BHOC

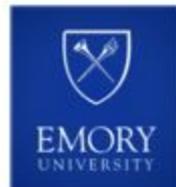
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EMORY

ROLLINS
SCHOOL OF
PUBLIC
HEALTH

Public Health Partners



Website and App partners



dudesnude



ABOUT BHOC

Building Healthy Online Communities is a consortium of public health leaders and gay dating website and app owners who are working together to support HIV and STI prevention online.

BHOC has worked with Grindr, Adam4Adam, GROWLr, and Daddyhunt to update their profile options to increase sexual health information exchanged by users. In partnership with BHOC, HIV testing reminders were implemented on A4A and Grindr.

Multiple PSAs and a web series exploring the sexual health of MSM were developed with Daddyhunt, and have **received over 14 million views**.

Grindr's Sexual Health FAQs, viewed by **15.5 million unique users** since November 2016, was developed with BHOC's input.

[TellYourPartner.org](#), a partner notification service developed and disseminated by BHOC, launched in March 2019.

INTRODUCTION

TakeMeHome is a national platform for ordering home test kits that helps public health departments ensure testing access for folks who might hesitate about walking into a clinic.

TakeMeHome is available to community members in participating health jurisdictions at [TakeMeHome.co](https://www.takemehome.co) and through dating app partners.

Starting in late March, TakeMeHome began offering HIV rapid oral tests

- STI testing and HIV dried blood spot testing to be added this summer.



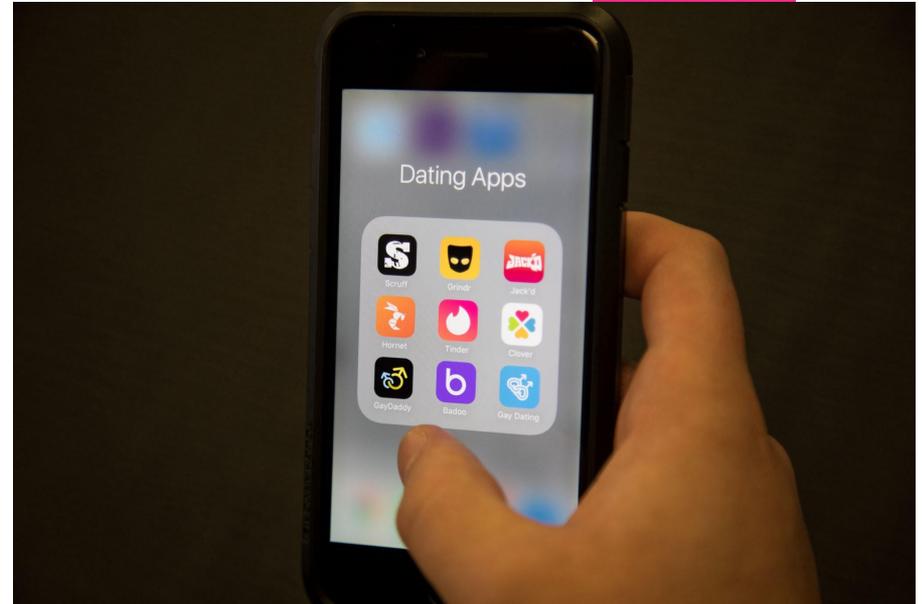
BACKGROUND

Nearly **75% of MSM** in a 2019 AMIS survey conducted through Emory reported using dating apps in the past year to meet a partner.

22% of MSM who use dating apps reported that they had NEVER tested for HIV.

There is significant customer demand for home tests:

- 77% wanted apps to add this feature.
- Easy access to home tests was even more popular (83%) among those who had never tested.



PARTNERSHIP MODEL

To make mailed HIV testing most efficient for public health, BHOC created partnership model:

1. Centralized system for HIV test kit ordering, distribution and results
2. Partnerships with public health agencies to fund HIV test kits and system infrastructure
3. Partnerships with companies who engage with higher risk persons and can promote HIV testing to their clients/users





FAQs

Who is eligible to participate?

- Over age 18
- Have not had an HIV test in at least a year

What happens when an individual tests positive?

Individuals will be directed back to our site, where they will be encouraged to get confirmatory testing and given local resources to care.

Can I include resources and messages specific to my local area?

Yes! We want to make sure that your local resources are available to participants. All participants will receive basic STI testing, condoms, PrEP, and U=U information.

Who houses the testing kits and fulfils orders?

TakeMeHome takes care of all that. It is handled by a company that we have a contract with. All of these services are included in the cost.

PROJECT STATUS

Timeline:

- Pilot launched with HIV oral rapid tests - late March 2020
- Expansion to STI testing and administrative portal - July 2020

Participation:

- Pilot jurisdictions: Oregon, Tennessee, Montana, San Francisco
- 4 additional health jurisdictions currently signing MOUs
- Number of other jurisdictions with introductory calls: 30+



LAUNCH DAY: 3/31/20

- Free ads from Grindr
- Links added to Grindr, SCRUFF, Jack'd, Adam4Adam
- Over 5000 visitors to our platform
- Over 240 orders placed for 373 tests

Demographics of participants:

- Average age: 29; range: 18-64
- Sex at birth: 4 female, 377 males
- Time since last test: 43% Never, 57% More than one year

WEB TRAFFIC DETAILS - DAY 1

State	CTR*	Web visitors	Conversion rate
Montana	20%	213	5.6%
Oregon	33%	1527	6.2%
Tennessee	34%	1526	7.6%
San Francisco	35%	1181	1.9%
	Av. 31%	Total: 4447	Av. 5.3%

*click-through rate: benchmark is 3% or less

FEEDBACK FROM PARTICIPANTS

- 100% of follow-up participants would recommend to a friend
- 90% of follow-up participants rated it 5/5; (10% 4/5)

“I have never been tested. Being sexually active and with the current pandemic this means a lot to me. Thank you so much!” - Latino male, age 35 from Oregon

“What a great program. Smooth process without the anxiety of a doctors office.” - Asian/White male, age 50 from San Francisco

“This meant the world for me. I have been terrified about the prospect of contracting HIV for a long time but was unable to locate a health department near me, and I was scared to go to one to begin with. This was fast, anonymous, and helped me vanquish my fears. I will make safer decisions regarding sex from now on.” - Latino/white male, age 20-24 from Tennessee

WHAT'S NEXT: STI TESTING AND ADMINISTRATIVE PORTAL



New additions:

- STI testing
- Client portal for access to results
- Immediate reporting of positive results to health departments
- Administrative portal will allow jurisdictions to download data directly and tailor eligibility criteria
- Late 2020 goal for translation to Spanish

STI SELF-COLLECTION IMPLEMENTATION

Proposed STI options:

- GC/CT (3-site) + syphilis + HIV DBS
- +/- Hep C depending on response to a risk eligibility questionnaire
- PrEP panel

Poll here

STI SELF-COLLECTION IMPLEMENTATION



Proposed treatment options:

1. Individuals with positive results are given information as to where to access treatment in their local area
2. Jurisdictions offer prescriptions through standing orders
3. Testing lab offers connection with a physician network that can prescribe treatment

Poll here

How do I sign up?

Learn more about TakeMeHome at BHOCpartners.org/home-testing or contact Jen Hecht at jhecht@sfaf.org

Thank you!

BHOC



At-Home Testing: Colorado Department of Public Health & Environment

May 8th, 2020

A panoramic view of the Denver skyline under a blue sky with scattered white clouds. In the foreground, there is a lush green park with a large fountain on the left and a yellow building with a red roof near a pond. The city buildings are in the middle ground, and the snow-capped Rocky Mountains are in the background.

Lacy Mulleavey
Partner Services Supervisor (CDPHE)

Colorado Overview

Our Story: July 29th, 2019, CDPHE issued a Health Alert Network Broadcast. We were experiencing higher than expected numbers of new HIV cases. Populations that were disproportionately affected included women, people who inject drugs and our Latinx/Black communities.

By the end of 2019, 454 new HIV cases were reported in Colorado. This is a 6% increase from the prior year. You know what else was up? Chlamydia, Gonorrhea and Syphilis!

Our Team: Colorado's Prevention and Field Services Program consists of a program manager, DIS supervisor, 8 Denver Metro DIS, 2 Regional DIS and a Statewide Biomedical Coordinator.

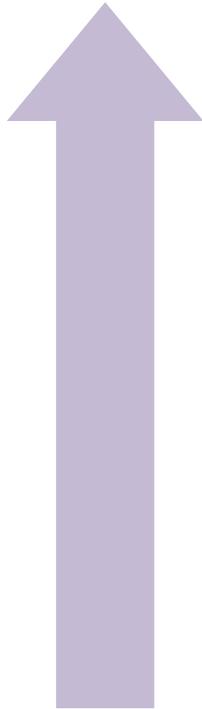


Why Home-Testing?



Program Planning

Step 1: Internal vs Manufacturer Mailing System



- Clients can choose to pick up the test or have it mailed
- Ability to tailor materials with test kits
- Direct control over inventory
- Time intensive for staff members
- Requires staff to be in the office to mail kits
- Staff must ensure appropriate storage of test kits



Important to decide which option will work best for your agency needs!



Program Planning

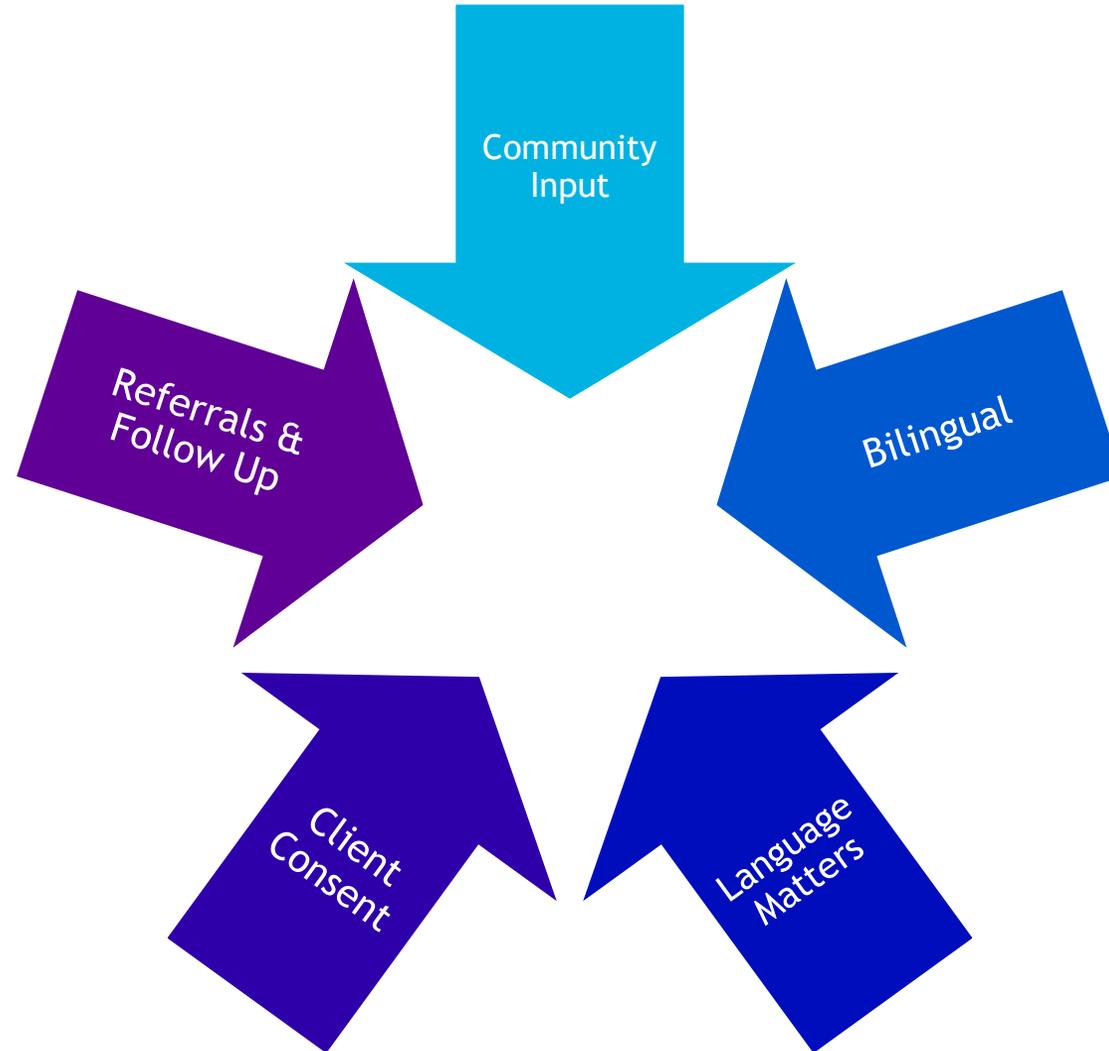
Step 2: Choosing the Platform

Colorado chose to utilize REDCap as a way for our clients to request an HIV home-test for several reasons:

- We could easily control/modify the data we wanted to collect
- Able to transport data into tableau for better program planning and evaluation in real time
- Secure/HIPAA compliant
- Easy to use for clients
- Compatible with mobile devices
- Ability to tailor to our needs
- Automated “post-test” survey via text messaging
- Free!

Program Planning

Step 3: Survey Development



Survey Questions

Where did you hear about this program?

Why are you considering this test?

Which of the following reasons have prevented you from testing for HIV in the past year?

When was your last HIV test?

In the past 12 months, which of the following have you done?

Which of the following are true of your sex partners in the last 12 months?

In the past 12 months, have you been diagnosed with an STI?

What is your date of birth?

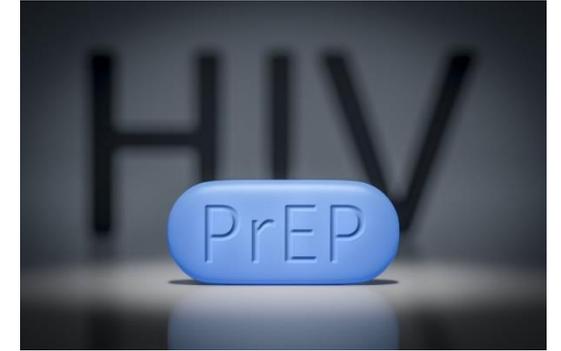
What is your current gender identity?

What is your sex assigned at birth?

What is your race? Ethnicity?

What kind of health insurance do you have?

PrEP Screening & Referral



Each client is screened for PrEP Awareness, Referral & Navigation

- **PrEP Awareness**

- *Have you ever heard of PrEP - the once daily pill that is over 90% effective in preventing HIV?*

- **PrEP Referrals**

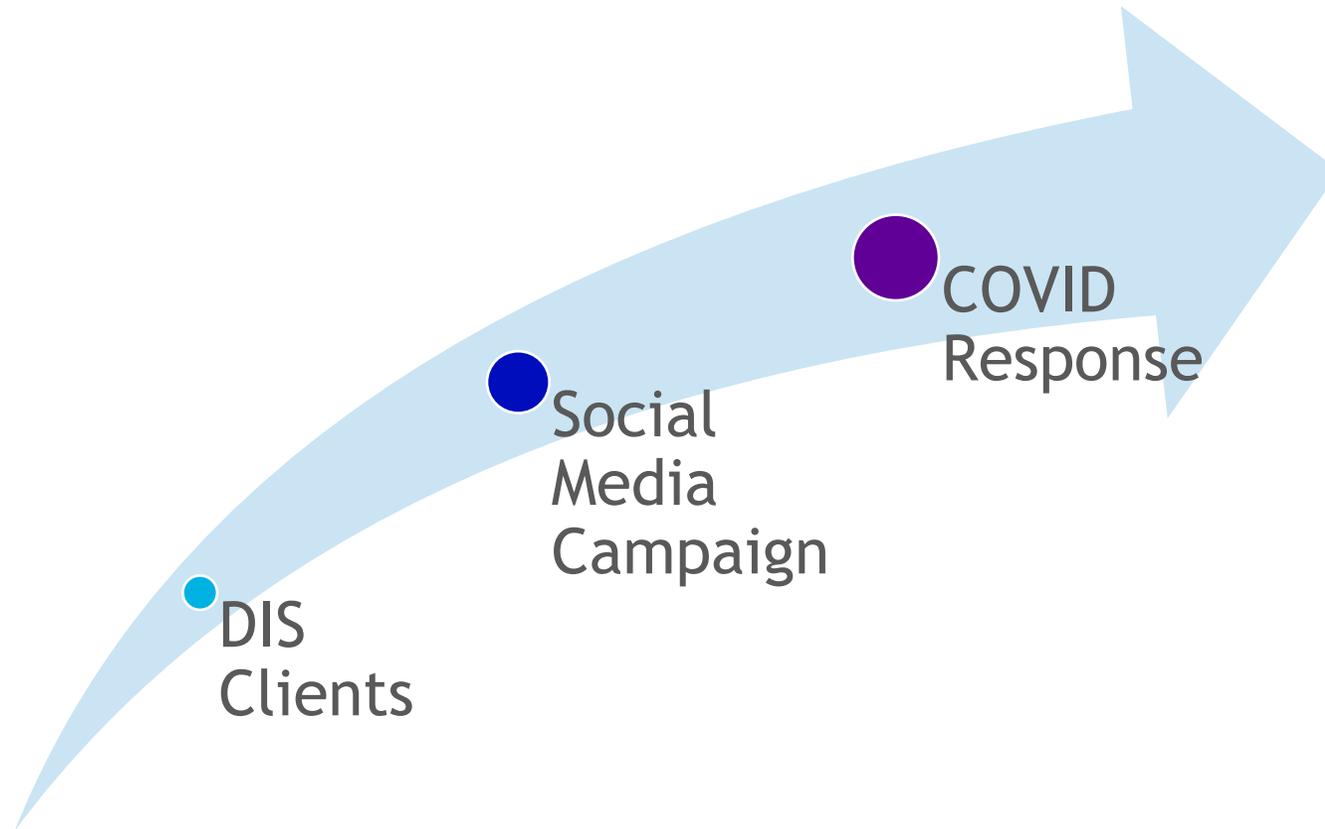
- *Are you interested in talking with someone about PrEP and resources available to help you get on PrEP?*

- **PrEP Navigation**

- *You indicated that you would want to talk with someone about PrEP, is it ok if we call you on the number you provided*

67% said they were aware of PrEP. 30% were interested in learning more about PrEP and 18% accepted a follow up call to learn more about PrEP!

Determining Program Eligibility



Phase 1: DIS Clients

Eligibility

- Clients who refused provider and/or DIS testing
- Contacts not elicited by DIS
- 2nd attempts for “unfavorable” case outcomes
- Clients in rural settings

Outcome

- Low uptake by clients
 - Hesitant because it was still connected to the State Health Department?
 - Process still requires client to disclose personal health information
 - Harder to engage clients

Phase 2: Social Media Campaign

Eligibility

- Anyone!
- Promoted on Facebook Ads (2 weeks)
- Promoted on ProudtoBePrepped website (ongoing)

Outcome

- Saw a significant increase, especially during paid Facebook Ads
- Many participants were ordering tests outside of normal business hours (late nights)
- Did not reach a targeted audience, most participants had low-risk
- Low PrEP interest

Phase 3: COVID Response

Eligibility

- Individuals notified of HIV exposure by DIS
- Individuals in need of HIV testing due to clinic/outreach restrictions

Outcome

- Increased uptake compared to prior efforts with DIS clients
- Higher interest in PrEP referrals and navigation
- Reached target audience

Program Planning

Step 4: Packaging & Mailing Test Kits

Staff receives email notification from REDCap

Staff prepares package with shipping label, test kit, FAQ sheet and PrEP materials

Staff member mails discrete package to client

Strive for timely efforts! Typical wait time is no more than 5 days!

Post-Test Survey

- *“We will follow up with you via text to ask a few additional questions about your home test experience. Do you consent to receive a follow up text message?”*
- If client consents to follow up, a text message is sent to their phone one week after they completed the initial survey
 - *Did you complete your home HIV test?*
 - *What were your test results?*
 - *Would the availability of free or low cost home based test kits increase your likelihood of testing for HIV at least one time per year?*
- **43% of clients who consented completed a post-test response**
 - Programs must be okay with not always knowing the results. Most importantly, the client knows their status!
 - You can also encourage clients to do video conferencing while taking the test!

Results

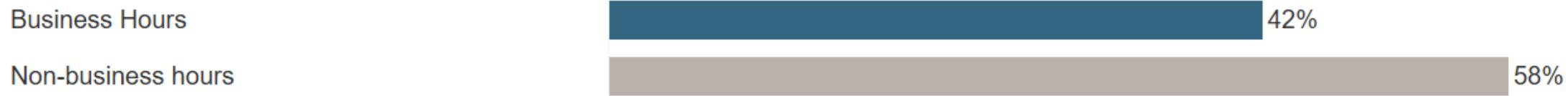
57 order forms were submitted, of those 39(68%) were completed and 18(32%) were left incomplete.



Meeting our Client's Needs

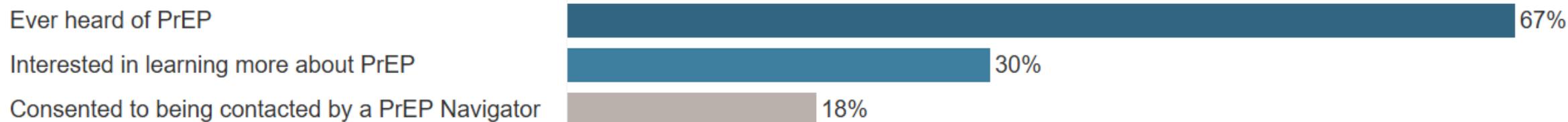
The majority of order forms were submitted during non-business hours.

Note: Business hours are defined as 7:00 AM - 5:00 PM.



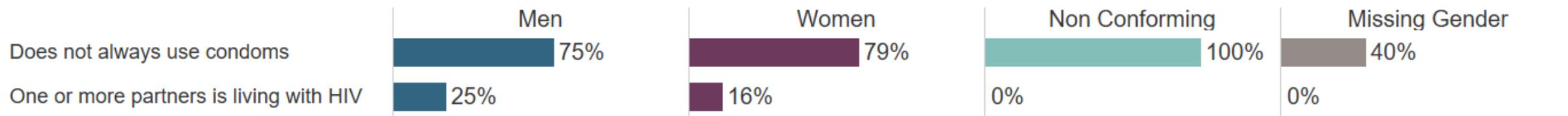
2 in 3 people who requested a Home HIV Test Kit had heard of PrEP, and nearly 1 in 3 were interested in learning more.

(Note: Responses are not mutually exclusive)



The majority of people requesting Home HIV Test Kits report that they do not always use condoms during sex. 1 in 4 men reported a partner living with HIV and nearly 1 in 6 women reported a partner living with HIV.

(Note: Responses are not mutually exclusive)

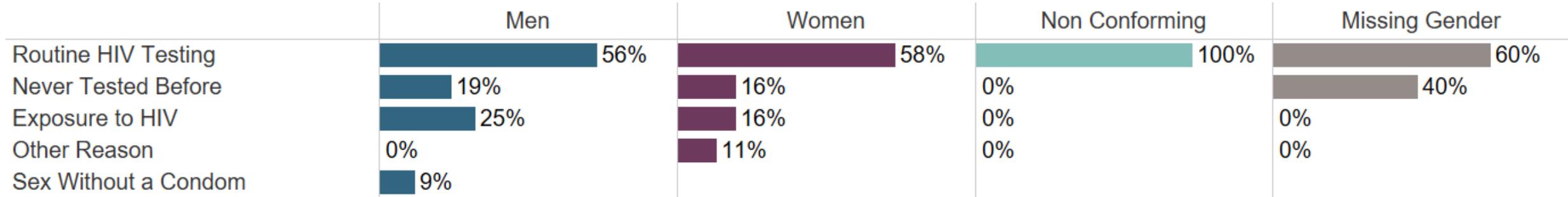


Results

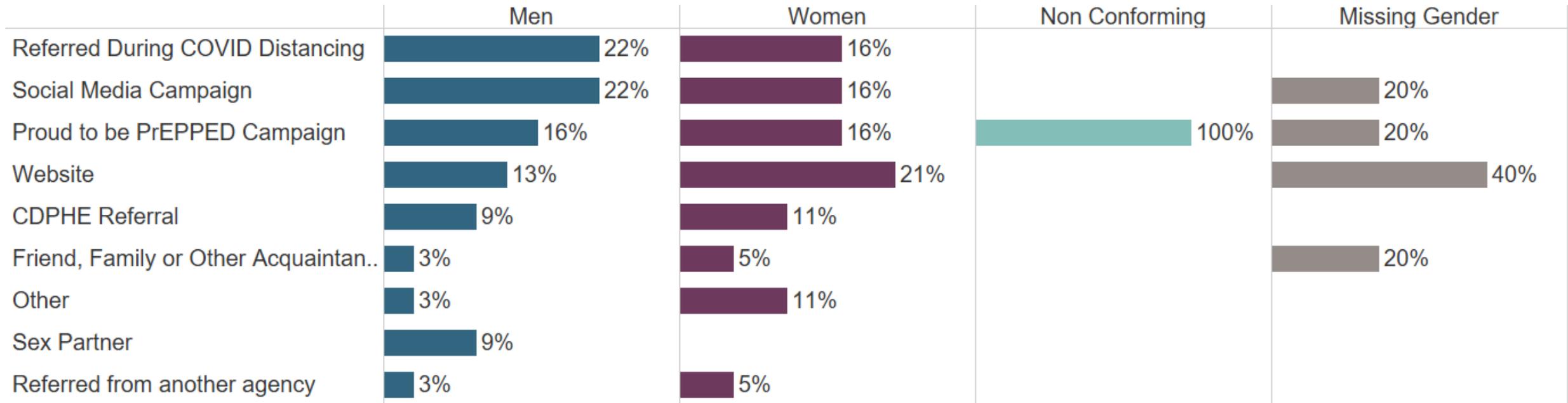
Meeting our Client's Needs

The majority of people requesting a Home HIV Testing kit reported that they were accessing the test for routine HIV Testing.

(Note: Responses are not mutually exclusive)



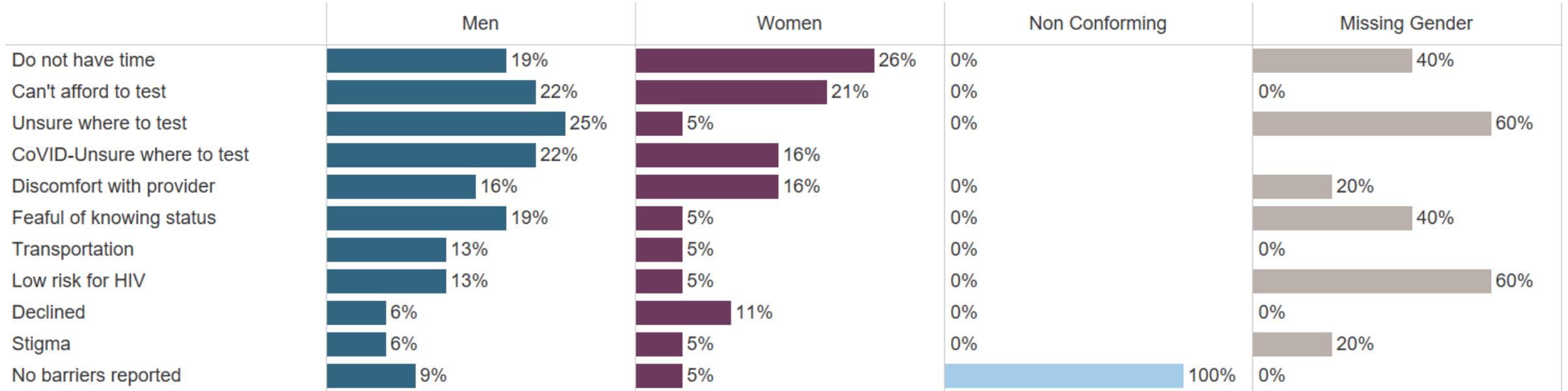
The majority of people requesting a Home HIV Test Kit heard about the program through social media and the Proud to Be PrEPED Campaign or were referred during the COVID Response.



Barriers to HIV Testing

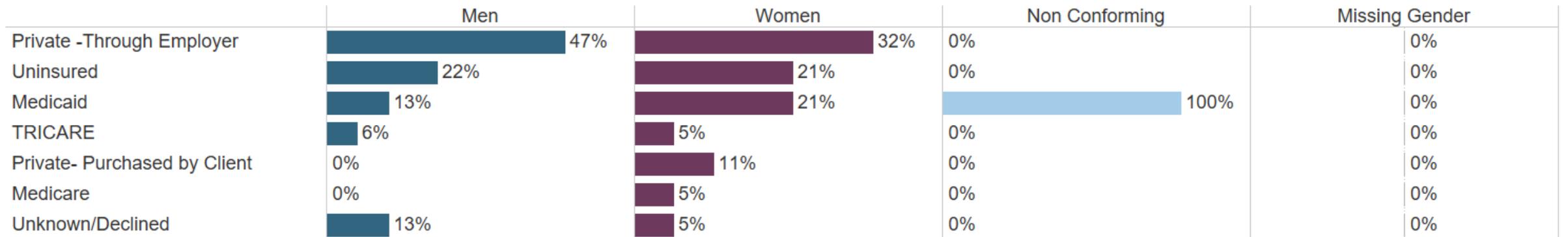
Time, affordability and not knowing where to test were the most common reported barriers to testing among those who requested a Home HIV Test Kit.

(Note: Responses are not mutually exclusive)



The majority of clients who requested a Home HIV Test Kit had private health plans through their employer. Among those who were uninsured 27% reported affordability as a barrier to HIV testing.

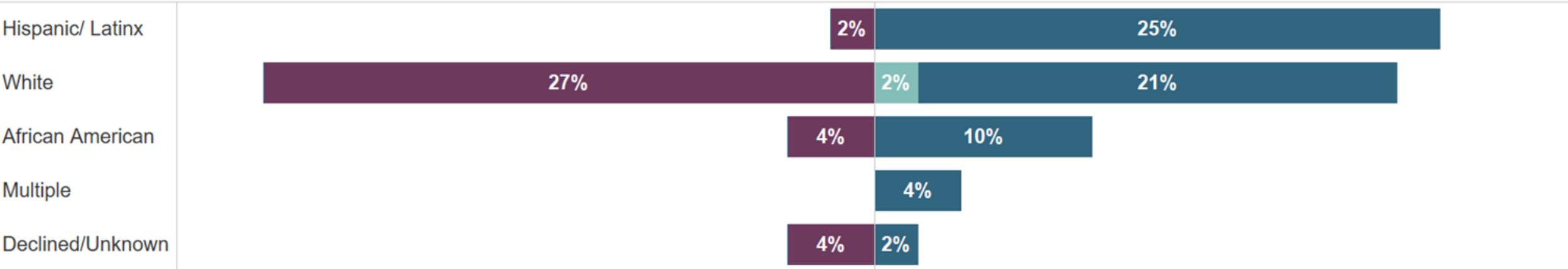
(Note: Responses are not mutually exclusive)



Who Are We Reaching?

Men Women Non Conforming

White women made up the largest percent of people requesting Home HIV Test Kits, followed by Latinx Men.



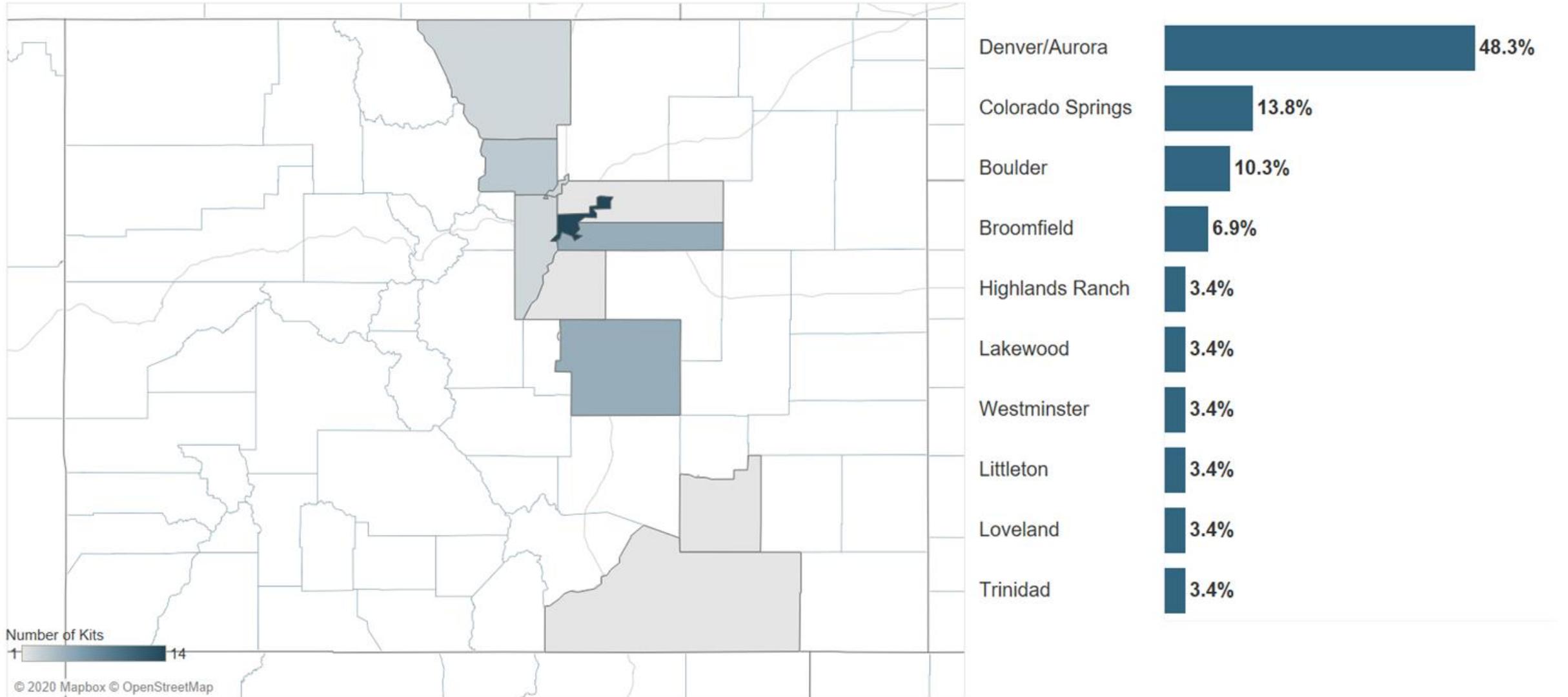
The majority of people requesting Home HIV Test Kits were 20-29 years old, with women skewing younger than men.



Note: 5 clients (9%) did not complete demographics questions

Who Are We Reaching?

The majority of people requesting Home HIV Test Kits live in urban areas such as Denver, Boulder and Colorado Springs, this program also reached people in more rural areas like Trinidad.



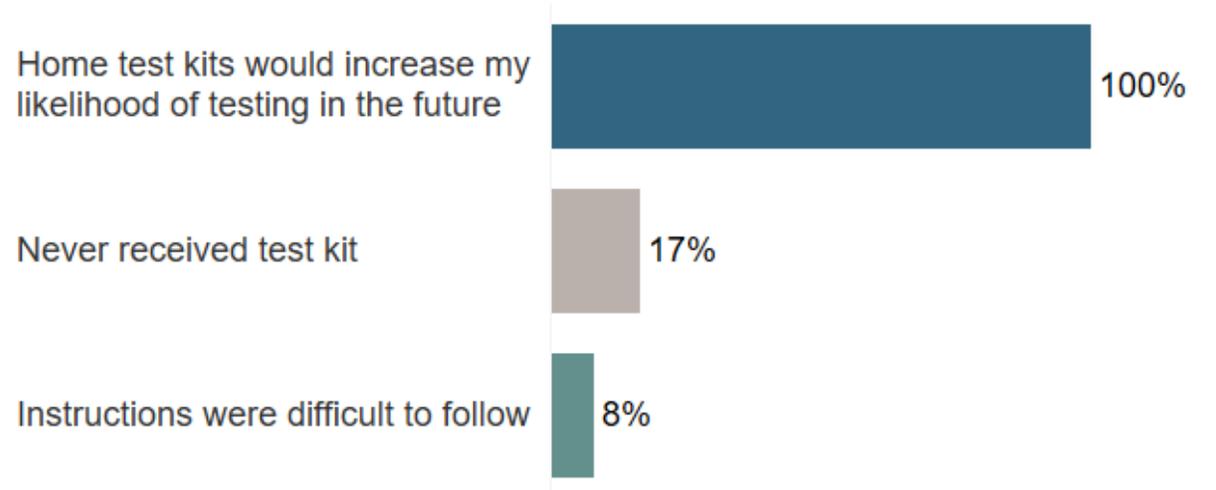
Results of the Follow-Up Survey

Of the 39 clients who completed the order form, 28 consented to a follow-up survey and among those who consented to a follow-up, 12(43%) completed a follow up survey.

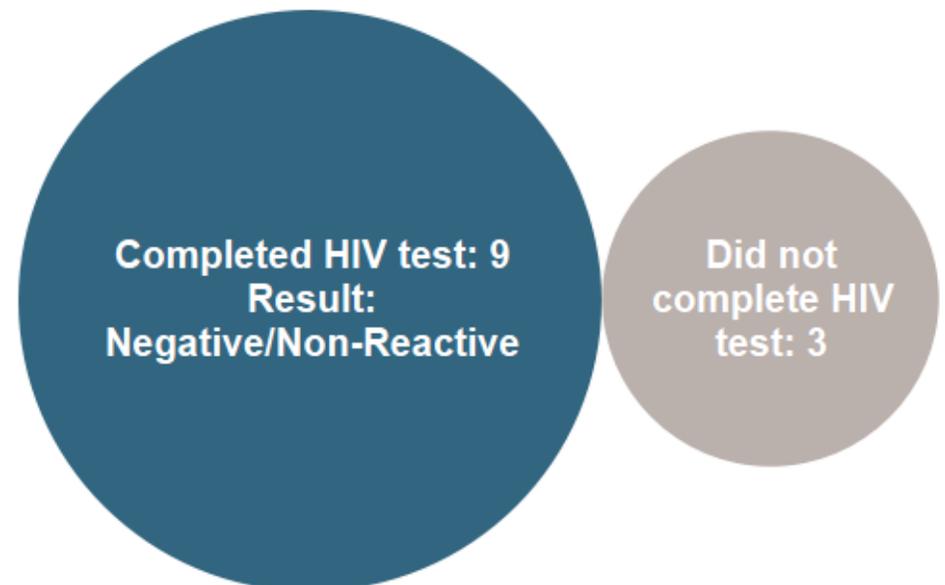


All respondents to the post test survey indicated that availability of home based HIV test kits would increase their likelihood of testing for HIV in the future.

(Note: Responses are not mutually exclusive)



Of the 12 people to complete the follow up survey, 9 took the HIV test and all were negative/non-reactive.



What's Next?

- Social media campaign
- Work with community & providers to identify and help with testing gaps during COVID and “Safer-at-Home” orders
- STI home-testing initiative
- Continue to strategize how to best reach vulnerable and disproportionately impacted populations



Thank You!

Lacy Mulleavey

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STI/HIV/VH Branch

Partner Services Unit Supervisor

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Closing/Action Items



National Coalition
of STD Directors

- [COVID Command Center on NCSD website](#)
- [Making Contact: A Training for COVID-19 Contact Tracers](#)
- [Clinic+ COVID-19 Survey](#)
- [Clinic+ COVID-19 Information Sharing Call Friday, May 15th from 2:15-3:15 ET](#)
- [On the Ground: Implementation of At-Home Testing Webinar Wednesday, May 20th from 1:15-2:30 pm ET](#)
- Clinic+ questions/comments? Contact Jenny Mahn, Associate Director of Clinical Programs, at jmahn@ncsddc.org or (248) 765-5522

