Sexually Transmitted Diseases, Publish Ahead of Print
DOI: 10.1097/OLQ.0000000000001017

"Iowa TelePrEP: A Public-Health-Partnered Telehealth Model for HIV Pre-Exposure Prophylaxis (PrEP) Delivery in a Rural State"

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Conflicts of interest and funding: The work reported here was partly supported by a contract from the Iowa Department of Public Health to the University of Iowa (#5888AP32). Dr. Ohl is principal investigator for an Investigator Sponsored Research award from Gilead Pharmaceuticals to U. of Iowa (ISR #IN-US-276-448), to conduct research unrelated to this manuscript

Short summary: Public health departments and a healthcare delivery system used widely available resources to create a collaborative, regional telehealth program to deliver HIV pre-exposure prophylaxis (PrEP).

Abstract

Background: Access to HIV pre-exposure prophylaxis (PrEP) is often poor in small urban and rural areas because of stigma and long distances to providers. The Iowa Department of Public Health (IDPH) and The University of Iowa (UI) created a regional telehealth program to address these barriers ("Iowa TelePrEP"). We describe initial TelePrEP results and share lessons learned.

Methods: IDPH personnel in sexually transmitted infection (STI) clinics, Disease Intervention Specialist and Partner Services (DIS/PS), and HIV testing programs referred clients to pharmacists at UI. Clients could also self-refer via a website. Pharmacists completed video visits with clients in the community on smartphones and other devices, arranged local laboratory studies, and mailed medications. We performed a retrospective record review to quantify rates of PrEP referral, initiation, retention, guideline-concordant laboratory monitoring, and STI identification and treatment.

Results: Between February 2017 and October 2018, TelePrEP received 186 referrals (37% from public health) and completed 127 (68%) initial video visits with clients. Median client age was 32; 91% were men who have sex with men. Most clients with video visits (91%) started PrEP. Retention in TelePrEP at 6 months was 61%, and 96% of indicated laboratory monitoring tests were completed. Screening identified 37 STIs (8 syphilis, 10 gonorrhea, 19 chlamydia). DIS/PS linked all clients with STIs to local treatment within 14 days (80% in 3 days).

Conclusions: Using widely available technology and infrastructure, public health departments and healthcare systems can collaborate to develop regional telehealth programs to deliver PrEP in small urban and rural settings.

Key words: HIV, PrEP, telehealth, public health, rural

INTRODUCTION

Evidence indicates that pre-exposure prophylaxis (PrEP) using emtricitabine / tenofovir disoproxil fumarate (FTC / TDF) is an efficacious method for preventing HIV infection.[1-3] Demonstration projects and reports from healthcare delivery systems have described strategies for scaling up PrEP delivery in large cities in the United States (US).[4-6] However, little is known about effective strategies for delivering PrEP in rural and small urban areas, where barriers include long distances to PrEP providers, limited availability of healthcare providers in general, and high levels of stigma surrounding HIV risk factors.[7-9]

Iowa is a predominantly rural state with a population of 3.1 million.[10] Most of the approximately 3,000 Iowans living with HIV reside in geographically-dispersed small urban and rural settings; in 2015 45% lived in 8 small urban areas with population 50,000-350,000 and 26% in rural counties with populations less than 50,000.[11] The number of Iowans with PrEP indications in small urban and rural areas is difficult to estimate. Analysis of Iowa Department of Health (IDPH) data from 2016 found that, among clients with indications for PrEP served in HIV testing and Disease intervention specialist / Partner Services (DIS/PS) programs administered by public health departments statewide, 1,057 (21%) lived in rural counties and 3,350 (61%) in small urban areas. (IDPH, unpublished data) There are no reliable data on uptake of PrEP among Iowans in rural and small areas. Based on follow-up contacts in 2016, IDPH DIS/PS personnel estimated that less than 10% of rural and small urban clients with PrEP indications served in public health programs began PrEP within 30 days after a public health encounter, because of long distances to PrEP providers and high levels of stigma in many communities. (Shannon Wood, personal communication)

In 2017, the Iowa Department of Public Health (IDPH) and University of Iowa (UI) collaborated to develop a regional telehealth program with the goal of improving access to PrEP

in small urban and rural areas of Iowa ("Iowa TelePrEP"). Using the PrEP continuum of services as a framework, we performed a retrospective review of TelePrEP records to quantify rates of PrEP referral, initiation, retention, guideline-concordant laboratory monitoring, and identification and treatment of bacterial STIs.[12] Our aims were to describe program results and share lessons learned that may be relevant to other public health departments and healthcare systems seeking to implement PrEP telehealth programs.

MATERIALS AND METHODS

The Iowa TelePrEP Model

Iowa TelePrEP began in February 2017 as a quality improvement project conducted jointly by UI and IDPH. In overview, it employed a hybrid delivery model that combined several approaches for improving access to PrEP employed in other settings, including telehealth visits with clients in community settings instead of in-person visits,[13-16] collaboration between a healthcare system and local public health departments to identify clients and deliver services, [17] and PrEP management by pharmacists working with physicians through a collaborative practice agreement.[18,19]

TelePrEP involved close collaboration between a team of clinicians at UI (2 pharmacists and 2 infectious disease specialists), a PrEP navigator working within IDPH, and 5 local public health departments serving 5 small urban (i.e., population 50,000-350,000) communities and 16 surrounding rural counties in Eastern Iowa (Figure 1, map). These local health departments administered programs including: 1) sexual health clinics that offered sexually transmitted infection (STI) testing and treatment, 2) HIV counseling, testing, and referral programs that provided free HIV testing in a range of healthcare and community outreach settings, and 3) DIS/PS programs that worked with individuals with HIV, syphilis, and gonorrhea diagnoses and their sexual partners to ensure linkage to treatment.

TelePrEP identified individuals with need for PrEP using three strategies. *First,* personnel in public-health-affiliated STI clinics, HIV testing services, and DIS/PS programs screened clients for PrEP indications using a standardized process and referred interested clients with need to a telephone navigator, who then contacted the client by telephone. The navigator provided clients with education on PrEP and assisted with applications for medication assistance programs and health insurance as needed. Navigators discussed PrEP with clients and arranged telehealth visits with UI pharmacists for those indicating interest in TelePrEP.

Second, information on the Iowa PrEP website (www.prepiowa.org/teleprep) and advertisements on geosocial networking applications provided a phone number and email address for clients to self-refer directly to TelePrEP navigators. Clients residing in the TelePrEP service area were offered TelePrEP visits, while clients self-referring from outside the service area were referred to the nearest local PrEP providers, as available. On a case-by case basis, self-referring clients who resided outside the service area - and who were unable to obtain PrEP otherwise due to travel burdens, privacy concerns, or other barriers - were offered services through TelePrEP. This required identification of a partnering public health or commercial laboratory site near the client.

Third, providers and case managers in the UI HIV specialty clinic referred sexual partners of patients with uncontrolled HIV infection directly to a TelePrEP pharmacist. The UI clinic could also provide PrEP on-site and referred clients who indicated a preference for telehealth visits to TelePrEP.

Via a collaborative practice agreement (CPA) with UI infectious disease specialist physicians, TelePrEP pharmacists then completed videoconferencing visits with clients at home or in other private community settings on smartphones or other devices, using the Vidyo® application (https://www.vidyo.com/). Visits included clinical assessment, PrEP education, and HIV risk

reduction and medication adherence counseling. Pharmacists assessed indications for PrEP during discussions with clients following PrEP guidelines,[20] and documented indications in visit notes as: 1) man who has sex with men (MSM) and additional HIV risk factor (i.e. anal sex with partners with unknown or known positive HIV serostatus in past year, or gonorrhea, syphilis, or chlamydia infection in past year), 2) intravenous drug use with needle sharing, 3) heterosexual contact with partners with or at elevated risk for HIV infection, or 3) no PrEP indication based on discussion at first visit and PrEP not discussed further. Pharmacists entered clients in a registry to track retention in PrEP and follow-up monitoring according to guidelines, [20] and mailed FTC/TDF to clients in discreet packaging to home or other addresses specified by clients. Follow-up visits occurred every three months and pharmacists met weekly with the TelePrEP medical director, an infectious disease physician, to review care for clients.

At baseline and follow up visits, TelePrEP pharmacists arranged laboratory testing in collaborating local public health departments or other laboratory sites of the client's choice. Monitoring included testing for HIV, hepatitis B and C viruses, pregnancy, bacterial STIs, and renal function, per PrEP guidelines.[20] Screening for bacterial STIs every three to six months included syphilis serology (i.e., non-treponemal or treponemal tests per local laboratory protocols) and three-site (i.e., urine, pharyngeal, and rectal) screening for *N. gonorrhoeae* (NG) and *C. trachomatis* (CT) infection by nucleic acid amplifications tests (NAAT), as indicated by sexual history. Clients self-collected pharyngeal and rectal swabs for NG and CT during visits to laboratory sites. Some laboratory sites outside of public health settings did not allow submission of self-collected swabs, leading to variable availability of extragenital screening.

Clients with CT infections identified during screening received treatment (i.e., azithromycin or doxycycline) prescribed directly by TelePrEP pharmacists through the CPA, while clients with positive NG or syphilis tests were linked to in-person evaluation and treatment with

community providers or public health clinics nearer their homes in cooperation with local public health DIS/PS personnel. We arranged for in-person evaluation and treatment for gonorrhea and syphilis because of our preference for complete clinical evaluation for clients with these potentially complex conditions, and because pharmacists were not permitted to prescribe intramuscular injections of antibiotics under CPAs at UI.

This delivery model was feasible because Iowa law permits pharmacist practice within CPAs and telehealth visits with clients in the community. IDPH provided initial financial support for pharmacists when developing the program in 2017, with subsequent pharmacist effort supported through cost savings on FTC / TDF under the 340B drug-pricing program. Medication and laboratory costs were covered by client insurance. Iowa is a Medicaid expansion state, including coverage for PrEP laboratory studies and medications. Applications to industry assistance programs for FTC/ TDF were submitted as appropriate. [21]

In February 2017, we piloted TelePrEP processes in collaboration with the Johnson County Public Health Department. We then expanded in a stepwise fashion to collaborate with public health departments based in Cedar Rapids, Waterloo, Dubuque, and Davenport, Iowa over the course of the following year (Figure 1).

Evaluation and measures

Using the PrEP continuum as a framework, we reviewed clinical records to complete a retrospective process evaluation of the Iowa TelePrEP program from February 2017 through October 25, 2018. [12] We quantified: 1) referrals to TelePrEP by source (i.e., public health, partners referred from the HIV specialty clinic, or self-referral), 2) completion of initial video visits within 7,14, 30, and 40 days of referral, 3) initiation of FTC / TDF among all clients with initial visits, and 4) retention in TelePrEP at 90 and 180 days following FTC / TDF initiation.

Clients were eligible for inclusion in the retention measure if they had enough observation time between PrEP initiation and October 25, 2018. We classified clients as retained in PrEP if they had a video visit within 30 days of the follow up time point (i.e., day 60-120 after starting TDF/FTC for 90-day retention and day 150-210 for 180-day retention). Among those not retained at 180 days, we reviewed charts to identify reasons for lack of follow up, including moving from Iowa with a documented plan for continuing PrEP with a new provider, linkage to a community PrEP provider in Iowa, or decision to stop PrEP based on decreased HIV risk as determined during discussions with TelePrEP pharmacists. We quantified the number of days of follow up for each client based on days from the initial visit to: 1) October 25, 2018, or 2) the last visit among clients discontinuing PrEP, transferring to PrEP providers, or lost to follow up (> 30 days past last scheduled visit), whichever came first.

Among clients completing an initial video visit, we extracted data from visit notes on client demographics, insurance status (private, Medicare, Medicaid, uninsured), residence, and PrEP indication classified: 1) man who has sex with men (MSM) and additional risk factors as described above; 2) intravenous drug use with needle sharing; 3) heterosexual contact with partners with or at elevated risk for HIV infection, or 4) PrEP indication not confirmed at initial visit. We classified residence as rural if in a non-metropolitan county by Office of Management and Budget definition, small urban if in a metropolitan area of population 50,000-350,000, and large urban if in a metropolitan area over 350,000. [22]

We quantified rates of completion of guideline-indicated laboratory testing at baseline and follow up (i.e., HIV, serum creatinine, hepatitis B and C serologies, syphilis serology, NG / CT NAATs from urine and extragenital sites, and pregnancy testing) among clients with visits.[20] We determined the number of HIV infections, STIs, and pregnancies identified through routine screening at both baseline and follow up visits, and examined clinical records and communicated with DIS / PS personnel to determine the percent of clients with STIs linked to treatment within 3 and 14 days of diagnosis.

We generated descriptive statistics (i.e., proportions, median values, ranges) for values as appropriate and calculated chi-squared statistics to test whether rates of visits, FTC / TDF initiation, and retention varied significantly by referral source ($p<0.05$). Analyses were conducted using SAS v9.2 software (Cary, NC). The retrospective review of TelePrEP records generated within this quality improvement initiative was approved by the Institutional Review Board (IRB) at the University of Iowa.

RESULTS

Between February 14, 2017 and October 25, 2018, TelePrEP received 186 referrals, including 69 from public health, 17 from UI HIV clinic, and 100 self-referrals. Pharmacists completed 127 initial video visits within 40 days (68% of referrals, Figure 2); no initial visits occurred after 40 days. Among clients with an initial visit, 53% completed the visit within 7 days of referral, 78% within 14 days, and 88% within 30 days. Visit completion rates did not vary significantly by referral source ($p=0.18$, Figure 2). Among the 59 referred clients without an initial visit, 22 (37%) never spoke with the telephone navigator, and 37 (63%) did not complete a telehealth visit with a pharmacist after speaking with the navigator.

Of clients with initial video visits (Table 1) median age was 31 and 81% were white. Consistent with IDPH data on clients with PrEP indications served in public health settings, 76% resided in small urban areas and 17% in rural areas. Fifteen self-referred from outside the service area including 9 (7%) from Des Moines, a large urban area (Figure 1). Most (88%) clients with an initial visit were MSM with an additional indication for PrEP. Three of the 100 clients who self-referred did not have an indication for PrEP confirmed on discussion during initial video visit, all MSM.[20] All clients referred from public health departments or the UI HIV clinic had confirmed indications for PrEP during the initial visit and started PrEP. The majority (91%) of all clients with an initial visit started FTC / TDF within 7 days (Figure 2).

The median number of days of follow up after starting FTC / TDF was 214 (range 3-609 days). Among clients starting FTC / TDF with enough follow up time prior to October 25, 2018, retention was 50/83 (60%) at 180 days. (Figure 2). Among the 33 clients not retained at 180 days, 18 had a documented plan to transition out of TelePrEP (i.e., transferred care to their PCP, transferred care out of state with a documented plan for PrEP, or stopped PrEP because of decreasing risk behaviors after discussion of risks and benefits). The remaining 15 were lost to follow-up. In a modified retention calculation that excluded patients transferring PrEP to another provider or stopping PrEP because of lower risk, 6-month retention was 77% (50/65). Figure 3 summarizes the overall TelePrEP continuum based on the percent of clients completing each stage compared to the total number with an initial visit.

Completion rates for guideline-indicated monitoring blood tests were overall very high (96%, Table 2). However, rates of extragenital GC and CT screening were lower among clients with indications for these (53% and 54%, respectively). This was largely because non-public health laboratory sites did not allow submission of self-obtained swabs.

Screening identified 37 STIs that were not diagnosed at time of referral to TelePrEP, including 16 at baseline and 21 at follow up. There were 8 syphilis diagnoses, 10 gonorrhea (2 genital, 3 rectal, 5 pharyngeal), and 19 chlamydia (4 genital, 14 rectal, 1 pharyngeal). In collaboration with local DIS/PS, all clients with STIs received treatment within 14 days (80% in 3 days). One of the 100 clients who self-referred to TelePrEP (1%) was diagnosed with HIV infection on baseline testing and was linked to care at UI, and one client had a positive pregnancy test at baseline in setting of high HIV risk (i.e. HIV-positive male sexual partner with detectable HIV viral load).

DISCUSSION

Our experience indicates that healthcare systems and public health departments can collaborate to develop regional telehealth programs to deliver PrEP in small urban and rural

areas. The Iowa TelePrEP model integrates widely-available resources, including commercially-available telehealth platforms, existing public health STI / HIV programs, local laboratory sites, and pharmacist collaborative practice agreements. The widespread availability of these resources may make it possible to replicate the Iowa TelePrEP model in other small urban and rural settings. However, laws restricting pharmacist collaborative practice agreements and use of telehealth may prevent implementation of this model in some states.

Prior studies have demonstrated that in-person, pharmacist-based PrEP programs can deliver high quality PrEP in urban settings. [18,19] Iowa TelePrEP demonstrates the feasibility of using telehealth to regionalize pharmacist-based PrEP to serve geographically-dispersed small urban and rural communities. Adherence to guideline-indicated laboratory monitoring was high in Iowa TelePrEP; clients received 96% of all indicated laboratory-monitoring tests, 100% of indicated HIV tests, and 98% of creatinine tests. This compares favorably with rates of laboratory monitoring reported during PrEP in a large primary care clinic network, where 77% of indicated HIV tests and 85% of creatinine tests were ordered. [23] We attribute the high rate of monitoring compliance in TelePrEP to use of a pharmacist collaborative practice model and a registry for tracking clients. Pharmacist-based PrEP via telehealth has the potential to improve the quality of PrEP delivery at the regional level, including in rural and small urban settings where clients may be reluctant to seek PrEP in their communities, and local providers may not prescribe PrEP at high enough volume to create systems to track follow up.

Two additional findings in Iowa TelePrEP concern screening and treatment for STIs in telehealth programs and are relevant to healthcare delivery systems, public health departments, and entrepreneurs seeking to deliver PrEP by telehealth. First, implementation of screening for extragenital GC and CT infections using self-collected swabs was feasible in public health-affiliated laboratory sites but was difficult to implement in commercial and clinical laboratory

sites in rural and small urban areas of Eastern Iowa because of local laboratory policies prohibiting submission of self-collected swabs. This led to relatively low rates of extragenital screening among clients overall (54%). Alternative strategies for collecting swabs for NG / CT screening may be preferable in PrEP telehealth programs, such as use of home collection kits by mail.

Second, Iowa TelePrEP relied on collaborations with local public health departments to achieve rapid linkage to treatment for clients with STIs identified on screening. PrEP programs that rely on in-person visits in healthcare settings often provide integrated, co-located treatment for STIs identified on screening, Ensuring STI treatment is more complicated in geographically-dispersed telehealth programs that lack in-person visits. Clients often live far from the telehealth provider and – based on our experience - may be reluctant to seek evaluation and treatment for STIs from local providers in nearby communities because of stigma and privacy concerns. We achieved high-rates of linkage to treatment for STIs using a combined strategy that included: 1) direct prescribing of CT treatment to clients by TelePrEP pharmacists under the CPA, and 2) communicating directly with local DIS/PS serving areas where clients lived to arrange in-person evaluation and facilitate treatment for NG and syphilis, often in local public health clinics. DIS/PS personnel were familiar with their local community contexts and had experience working around stigma and privacy concerns to link clients to STI treatment.

Telehealth PrEP programs that serve clients in multiple communities spread over large geographic areas – in some cases multiple states - should consider establishing formal collaborations and communication protocols with local DIS/PS or other public health programs to ensure rapid linkage to evaluation and treatment for clients with STIs. These communication strategies should go beyond legally-mandated reporting of specific infections to state public

health authorities, and – with client consent – can involve client-specific discussions (i.e. "warm handoffs") with local public health personnel to coordinate care and ensure linkage to treatment.

There were methodologic limitations in this retrospective process evaluation of the Iowa TelePrEP program. The number of clients was overall relatively small, in keeping with the geographically-limited scope of the pilot and relatively small populations in rural and small urban communities. We lacked a control group to demonstrate the impact of TelePrEP on outcomes compared to areas lacking the service. We quantified clinical process measures routinely gathered during PrEP care, but due to limited evaluation resources we did not perform satisfaction surveys or interviews with clients to determine care experiences. It will be important to perform mixed-methods, controlled evaluations to determine the impact of the TelePrEP model on a balanced set of client outcomes, including client and program personnel perspectives. Additional studies should also identify barriers and facilitators to replication of the TelePrEP model in similar rural and small urban settings.

Conclusions

Through collaboration, public health departments and healthcare delivery systems can apply widely available resources to create regional telehealth programs to deliver PrEP in small urban and rural communities.

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Figure 1: TelePrEP Service Area, February 2017 – October 2018. TelePrEP involved collaboration between personnel in the UI HIV specialty clinic in Iowa City, IA and five local public health departments that served five small urban areas and surrounding rural counties (Waterloo, Dubuque, Cedar Rapids, Iowa City (Johnson County), and Davenport).

Figure 2: Variation in completion of steps in TelePrEP care by referral source, February 14, 2017 – October 25, 2018. The figure shows: 1) the percent of referrals completing initial video visits within 40 days of referral; 2) the percent of those with initial visits starting TDF/FTC; and 3) and the percent of those starting TDF/FTC retained in TelePrEP at 90 and 180 days, among those with enough follow up time. P values are for chi-squared tests for variation in measures by referral source. See methods section of text for details.

Figure 3: TelePrEP continuum of care for clients completing an initial TelePrEP visit, February 14, 2017 – October 25, 2018. The figure shows the percent of those starting TDF/FTC and retained in TelePrEP at 90 and 180 days, compared to all clients with an initial video visit.

Figure 1

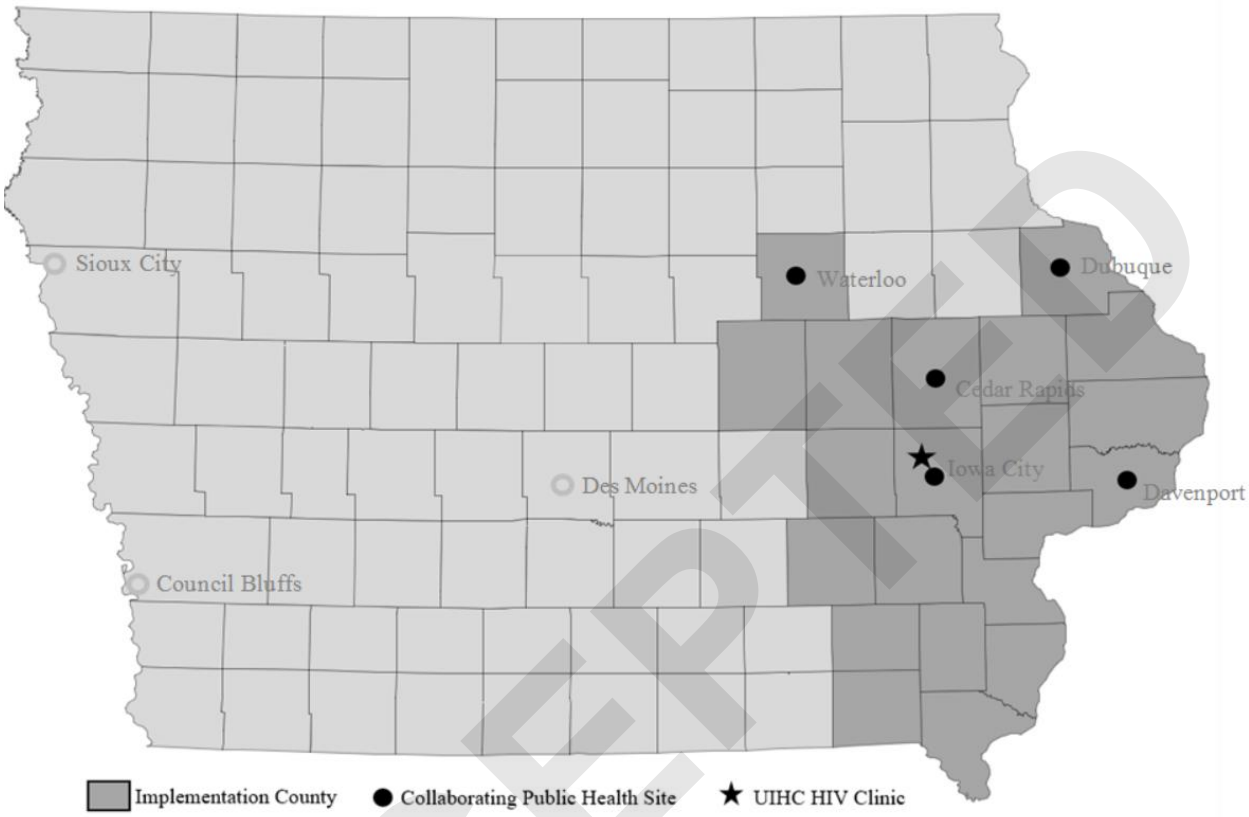

Figure 2

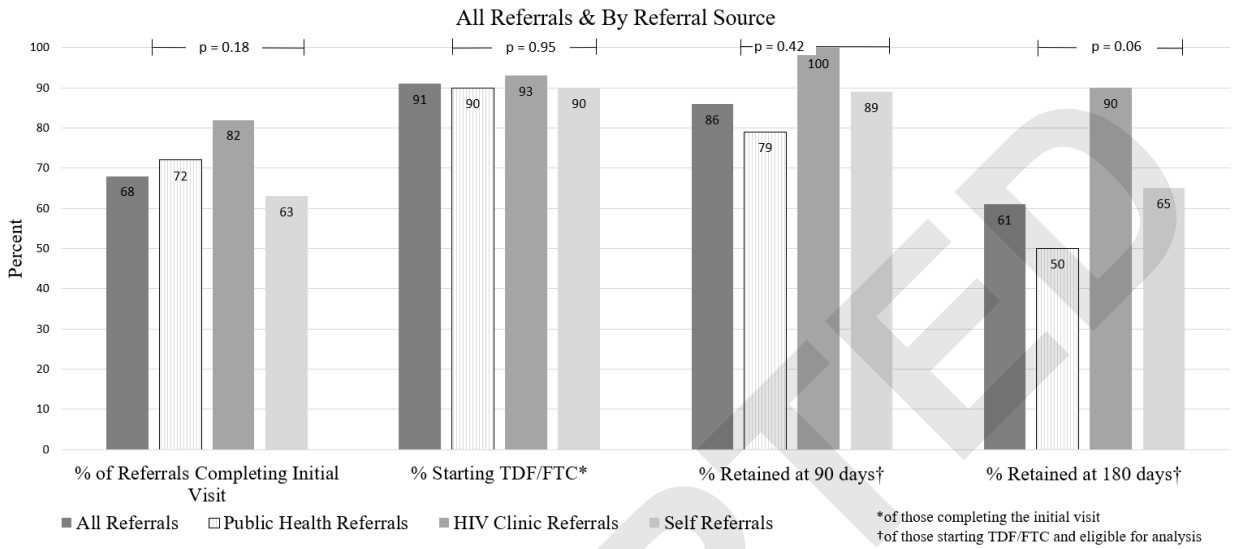

Figure 3

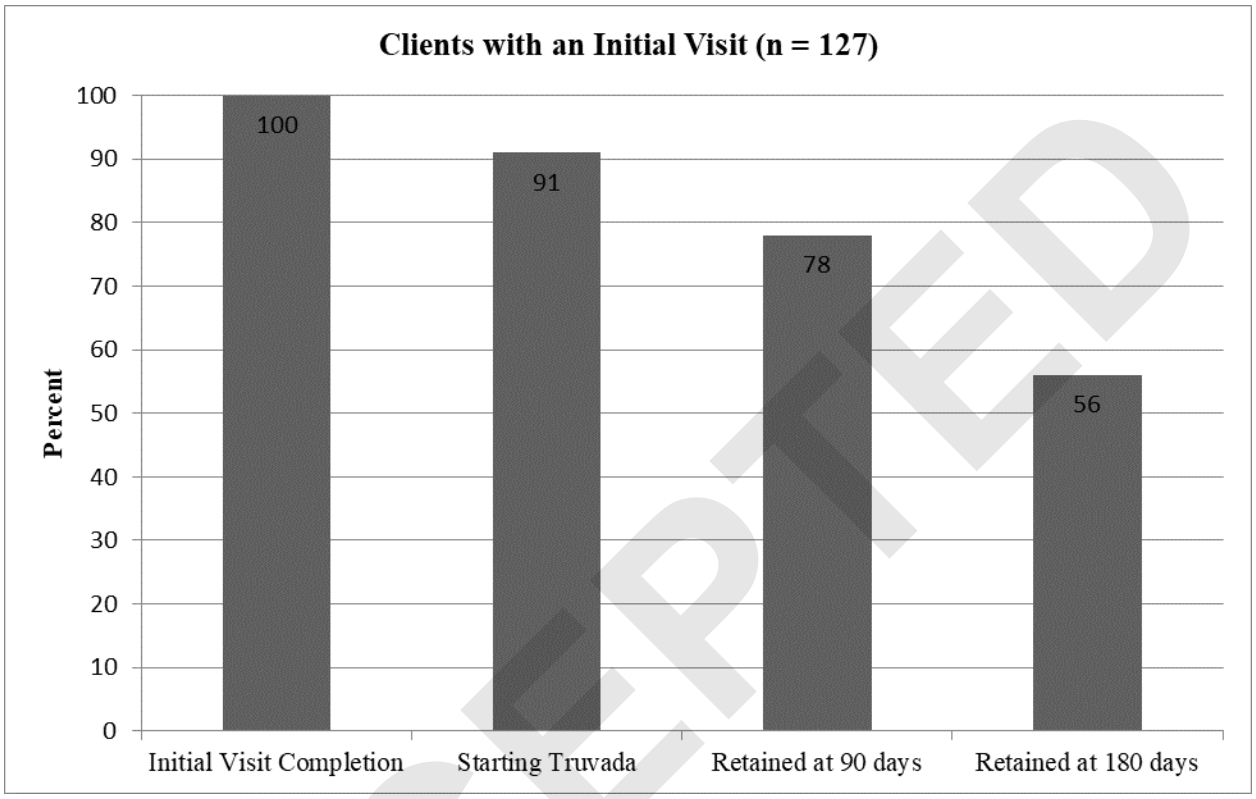

Table 1: Characteristics of Clients with Initial Video Visits (n = 127)

Age (years)	n (%)		Race/Ethnicity (per medical record)	n (%)
			White	103 (81%)
18-24	32 (25%)		Black/African American	9 (7%)
25-30	36 (28%)		Hispanic/Latinx	7 (6%)
31-40	35 (28%)		Asian	5 (3%)
41-50	15 (12%)		Multiracial	2 (2%)
51-60	9 (7%)		Native American	1 (1%)
Gender, Self-Reported	n (%)			
Cis-gender man	116 (91%)		HIV Risk PrEP Indication	n (%)
Cis-gender woman	8 (6%)		MSM and risk factor	112 (88%)
Gender fluid / nonbinary	3 (3%)		High Risk Heterosexual	12 (9%)
Transgender man	0		Injection Drug Use	0
Transgender woman	0		No PrEP indication at initial visit	3 (3%)
Residence	n (%)		Insurance Status	n (%)
Rural	21 (17%)		Private	94 (74%)
Small urban	97 (76%)		Uninsured	17 (13%)
Large urban	9 (7%)		Medicaid	12 (10%)
			Medicare	4 (3%)

Table 2: Adherence with Guideline-Indicated Laboratory Monitoring

Lab Test	# eligible visits	UPHS/CDC Guideline Recommendation	TelePrEP Adherence with Guidelines n (%)
HIV	246	Baseline & every 3 months	246 (100%)
Creatinine*	167	Baseline & at least every 6 months	164 (98%)
STI tests*		Baseline & at least every 6 months	
Syphilis	167		159 (95%)
NG / CT urine	167		154 (92%)
NG / CT rectal	150		81 (54%)
NG / CT pharyngeal	165		87 (53%)
Hepatitis B	116	Baseline	111 (96%)
Hepatitis C	116	Baseline	107(92%)
Pregnancy	8	Baseline & every 3 months	8 (100%)
All tests combined	1,302		1,117 (86%)

*Guideline concordance at baseline and 6-month follow-up screenings

NG: *N. gonorrhoeae.* CT: *C. trachomatis*