



# Making the Connection: Using Videoconferencing to Increase Linkage to Care for Incarcerated Persons Living with HIV Post-release

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## Abstract

Incarcerated persons living with HIV (PLWH) have relatively high levels of HIV care engagement and antiretroviral therapy adherence during incarceration, but few are able to maintain these levels upon reentry into the community. In Louisiana, PLWH nearing release from prisons were offered video conferences with case managers housed in community based organizations aimed at facilitating linkage to care in the community. Of the 144 persons who received a video conference during the study period, 74.3% had linked to HIV care in the community within 90 days after release. Compared to the comparison group (n=94), no statistically significant difference in linkage rate was detected ( $p > 0.05$ ). Nonetheless, the video conference supplement was positively received by clients and case management agencies in the community and the lack of a detectable impact may be due to early difficulties in intervention delivery and study design limitations. Further study is needed to determine the value of the video conferencing supplement in other settings.

**Keywords** Incarceration · Telemedicine · Linkage to care · HIV · Case management

## Introduction

HIV prevention and care efforts in the United States increasingly focus on supporting HIV care engagement and antiretroviral treatment (ART) utilization [1–3]. Studies show that continual adherence to an appropriate ART regimen in persons living with HIV (PLWH) is highly effective at suppressing HIV to an undetectable level, preventing progression to AIDS and HIV-related mortality, as well as substantially lowering the risk of HIV transmission to seronegative persons [2, 4–7]. Routine HIV care engagement is a key predictor of ART adherence and is also important for detecting ART resistance [3, 8, 9]. National health improvement

strategies such as the National HIV/AIDS Strategy and Healthy People 2020 include objectives to reduce and eventually eliminate gaps in continual HIV care engagement and ART adherence [1, 10].

Since the 1990s, the federal government has provided funding to cover an array of financial, social, and medical services through the Ryan White HIV/AIDS Program (RWHAP) to ensure all PLWH have access to HIV care and treatment regardless of socioeconomic status [9, 11]. Nonetheless, racial and socioeconomic disparities in HIV care engagement and viral suppression rates have long persisted and contribute to significant disparities in AIDS incidence, AIDS-related mortality, and HIV infection among persons of color [12, 13]. A growing body of research shows that disparities in HIV care engagement and treatment utilization are associated with the intersection of multiple oppressive inequities and stigmas related to race, sexual orientation, and gender identity [14–21].

These same social conditions also render PLWH particularly vulnerable to incarceration in the US criminal justice system [22–24]. One in six PLWH in the US cycle through correctional facilities annually and the HIV prevalence among persons incarcerated in prisons is 3.5 times that of the general population [25, 26]. The state of Louisiana

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currently has the highest incarceration rate and the second highest HIV infection rate in the country. Louisiana's prison system also has the second highest HIV prevalence among incarcerated persons at 3.5% [25]. As such, prisons have been recognized as important settings for HIV care initiatives. With the assistance of government funding, more and more state and federal prisons have implemented opt-out or opt-in HIV testing efforts to identify PLWH [22–24, 27–30]. Prisons are required to provide ART to known PLWH while they are incarcerated. Compared to PLWH in the community, PLWH in correctional facilities have been shown to have relatively high rates of HIV care engagement, ART adherence, and HIV viral suppression [27, 30–32]. However, these trends are not sustained upon release. It is estimated that three-fourths of PLWH who were treated during incarceration will discontinue HIV care or become sub-optimally adherent to ART within 90 days after release [30, 32, 33]. Recently released PLWH have also been shown to experience substantial increases in HIV viral load, reversal of viral suppression status, and shorter duration before progressing to an AIDS diagnosis [22, 30–32, 34]. This downturn in HIV health maintenance comes at a notably precarious time as recently released persons are vulnerable to behaviors that carry a high risk of HIV transmission, such as unprotected sex with previous and new partners and relapses in substance abuse, including injection drug use [35–40].

PLWH that have recently been released from a correctional facility may face an onslaught of financial and social barriers that have been shown to hinder access to HIV care and ART. Due to incarceration-related stigma, many newly released PLWH face ostracism and disapproval from their support system (family, friends, etc.), as well as extensive discrimination in employment opportunities, housing, education, and safety net programs such as food and housing assistance [34, 39–44]. Under these conditions, PLWH may prioritize fulfilling basic needs for survival and avoiding stigma over maintaining their HIV and overall health. Other barriers to engagement in HIV care and support services include encountering or anticipating stigmatized treatment from provider staff and physicians, difficulties navigating bureaucratic benefits systems, and transportation needs [34, 39–44]. Recently released PLWH are also at a high risk of struggling with untreated substance use disorders and mental health issues that are known to interfere with HIV care engagement and ART adherence goals [34, 36, 45–49].

Some prison systems offer pre-release reentry services aimed at helping PLWH link to HIV medical and other critical support services upon release and prepare for challenges that may arise while transitioning to life in the community. Clients enrolled in these services may receive referrals to medical and HIV-related case management providers in the community, information on social support services in the community, and assistance developing a transition strategy.

In some states, staff may be able to assist with making initial medical and case management appointments and filling out applications for safety net programs (such as Medicaid, food stamps, and drug assistance programs) before the person's release date. If available, reentry case managers can also conduct needs and goals assessments, help clients develop HIV care and transmission risk reduction plans, and provide psychosocial support. Receiving pre-release reentry services is highly associated with timely linkage to HIV care and continual ART adherence after release [28, 33, 39, 47, 48, 50–52]. Nonetheless, few prisons that house and treat incarcerated PLWH have the resources needed to offer pre-release reentry services that are comprehensive enough to be optimally effective [28, 32, 48, 53].

In Louisiana state prisons, adult PLWH are offered an array of pre-release reentry services provided by Louisiana's Department of Health – Office of Public Health's STD/HIV Program (SHP) and typically receive up to 2 weeks' worth of ART from the prison infirmary at time of release to prevent an interruption in ART adherence prior to linking to an HIV care provider in the community. For over two decades, SHP has struggled to maintain the capacity of the reentry services offered due to fluctuating levels of federal and state funding and support from care providers in the community. By 2008, SHP had one RWHP-funded corrections specialist who was responsible for providing discharge planning and limited reentry case management to all incarcerated PLWH before release. Between 2009 and 2011, 59% of those who received reentry services had linked to HIV care within 90 days after release. This result was within the range of linkage rates demonstrated by other pre-release reentry programs around this time, however, caseloads increasingly became unmanageable for one staff person and programs with more extensive reentry case management services produced better results [23, 50–52, 54, 55].

In 2013, SHP secured funding from the Health Resources and Services Administration (HRSA) through the Special Projects of National Significance (SPNS) grant to hire an additional corrections specialist and pilot the use of video conferencing to connect incarcerated PLWH to RWHP-funded case managers from community-based organizations (CBOs) in their communities before release. Case managers would provide reentry case management via video conference to create a plan for addressing challenges and barriers to HIV care and ART use and potentially establish a relationship with the client that included mutual trust and respect. Upon release, clients would have an opportunity to link to the same case manager who they interacted with during the video conference. Studies show that recently released PLWH are more likely to experience and anticipate less stigmatizing treatment and continually engage with providers in the community who maintain these types of relationships, especially if these relationships are active during incarceration [40,

42, 47, 56]. Video conferencing was chosen as the mode of service delivery in order to foster a more personal connection and save limited resources that would have otherwise been spent having the case managers travel to various prison facilities across the state and undergo the varying security procedures required for entering the facilities. SHP envisioned that this initial interaction with the case manager would promote prompt linkage to case management upon release. Once enrolled in case management in the community, clients would receive further assistance with linking to HIV care and other services that may support continual retention in HIV care and adherence to ART, such as mental health and substance abuse services, other non-HIV medical services, housing, food, transportation, and employment.

This paper describes the impact of adding the case management video conference supplement to the standard array of pre-release reentry services offered. The primary outcome was the likelihood of linking to HIV care within 90 days following release among recently released PLWH.

## Methods

SHP initiated the case management video conferencing intervention in August 2013 in collaboration with the Louisiana Department of Public Safety and Corrections (DOPSC), RWHAP Part A- and Part B-contracted CBOs, and the Louisiana State University Health Care Services Division's Telemedicine program. The intervention is ongoing and is currently being implemented in eight of nine DOPSC prison facilities. Funding was provided from the HRSA RWHAP Part F SPNS Systems Linkages and Access to Care for Populations at High Risk for HIV Infection Initiative, as well as RWHAP Part A and B funds for case management services.

### Client Enrollment

Eligible persons included incarcerated adults with a confirmed HIV diagnosis who were due to be released from a participating prison facility within 180 days or less and were seeking a referral to RWHAP case management at one of the partnering CBOs. Confirmed HIV diagnoses were identified by prison facilities during opt-out HIV testing conducted at DOPSC intake, individual HIV tests requested by incarcerated persons during incarceration, or mandatory HIV testing conducted within 90 days prior to discharge for persons awarded parole or 'time off for good behavior' and were released before completion of their sentence who were not previously known to be HIV-positive and not tested in the previous 12 months. Corrections specialists employed by SHP obtained lists of all HIV-positive persons from each prison facility and their respective release dates on a monthly basis in order to identify PLWH that were due to

be released within 180 days or less. The lists also provided updated release dates for PLWH that were awarded parole or 'time off for good behavior' and due to be released earlier than their original release date. All identified persons were initially offered the standard array of reentry services that are provided on-site by the corrections specialist. These services included education on services in their community that they may qualify for, referral to medical care, assistance making the first HIV medical appointment, assistance with enrollment into Louisiana's AIDS Drug Assistance Program, and referral to RWHAP case management. Persons were then offered the opportunity to enroll in the video conferencing intervention if they requested a referral to RWHAP case management at one of the partnering CBOs. Upon enrollment, the corrections specialist coordinated with prison staff and the designated CBO-based case manager to schedule a video conference for the client prior to release. The corrections specialist also coordinated with prison infirmary staff to send over any relevant medical records to the CBO-based case manager for review before the video conference was set to occur. Due to the high potential for scheduling difficulties, clients were only offered one video conference; however, video conferences could be rescheduled as needed.

### Video Conference

During a video conference, the CBO-based case manager completed an intake assessment and assisted the client with creating a discharge plan for the period immediately following release. The intake assessment captured the client's short-term and long-term medical, financial, and social needs. The survival plan consisted of strategies for addressing more urgent needs before the client was released and they met in the community. These typically included strategies for securing temporary housing, finding clothing, finding transportation to appointments, as well as addressing HIV transmission risk reduction. In addition, the CBO-based case manager collected contact information from the client and their relatives and friends in the community who could be reached in case the respective CBO lost contact with the client after their release.

### IRB Approval and HIPAA Compliance

This study received IRB approval and all participating staff and procedures were in compliance with the HIPAA Privacy Rule. Video conference data were transmitted through a HIPAA-compliant, secured internet connection (Polycom). At the prison facilities, the reentry services and video conference were both given in private meeting rooms with one accompanying corrections officer inside the room (corrections officers may be privileged to HIPAA-protected information for public health and safety purposes). During the

video conference, the CBO-based case manager was also in a private room.

## Data Collection and Analysis

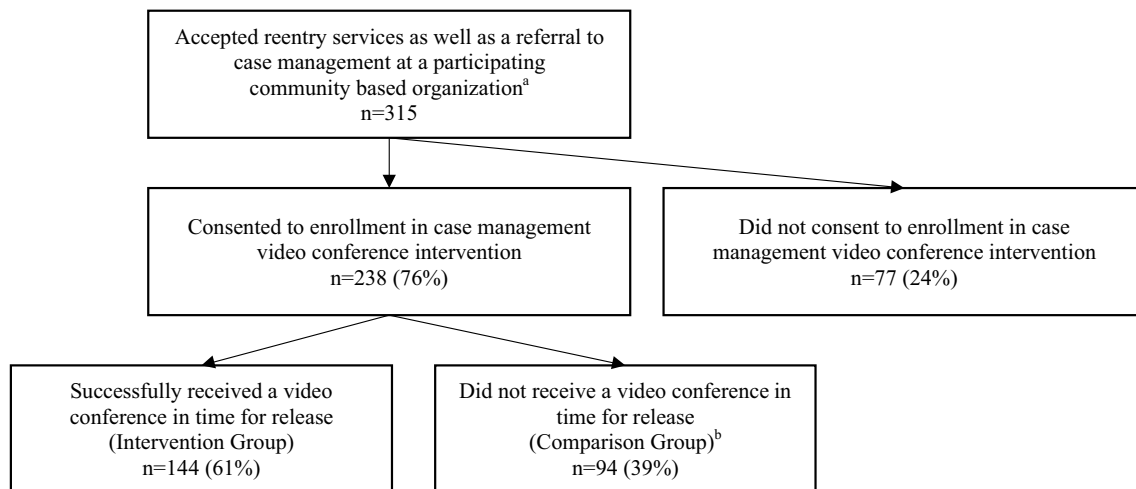
Data were collected for clients enrolled in the video conferencing intervention between August 2013 and August 2016. Clients who consented to enrollment but were ultimately unable to participate in a video conference in time for their release due to scheduling conflicts were classified as the comparison group. Demographic and HIV care data used in the analysis were obtained from Louisiana's HIV surveillance database on January 11, 2017. Linkage to medical care was defined as the completion of at least one HIV-related laboratory test (HIV viral load or CD4 count) within 90 days after release into the community. Exhibiting viral suppression at baseline was defined as having an HIV viral load test taken within a year before release with a result that was less than or equal to 200 copies/mL. If a person had multiple HIV viral load tests conducted during the year before release, only the latest test result was considered.

Bivariate analyses ( $\chi^2$  tests) were used to detect any statistically significant differences in demographics and HIV care characteristics between clients in the comparison group and clients who participated in a video conference. Multivariate logistic regression was used to assess associations between linkage to HIV care within 90 days after release and participating in a video conference, demographics, and baseline HIV care characteristics. Covariates were chosen

for the adjusted logistic regression model based on evidence found in the literature supporting their association with HIV care engagement outcomes; these include race, birth sex, age, HIV transmission risk, time since HIV diagnosis, AIDS diagnosis history, baseline (pre-release) viral suppression status, HIV diagnosis status prior to incarceration, and HIV care engagement status prior to incarceration. All analyses were conducted in SAS9.3 [57].

## Results

In total, 238 clients enrolled in the video conference intervention. The complete flow of persons from the client population is depicted in Fig. 1. Of these, 80% were black, 85% were male, and 40% were men who have sex with men (Table 1). In addition, 52% had been diagnosed with HIV more than 10 years ago, 61% had a previous AIDS diagnosis, 61% were virally suppressed before release (HIV viral load  $\leq$  200 copies/mL within the last year), and 66% were engaged in HIV care before incarceration. Prior to release, 144 (61%) had participated in a video conference and 94 (40%) were unable to do so in time and were therefore assigned to the comparison group. There were no statistically significant differences detected in demographics or baseline HIV care characteristics between clients who participated in a video conference and the comparison group ( $p < 0.05$ ).



<sup>a</sup> Eligible persons were adults who were incarcerated in one of six pilot sites, had a confirmed HIV diagnosis, were due for release within 180 days, accepted pre-release reentry services, and accepted a referral to a participating case management agency in their community

<sup>b</sup> These clients had consented to enrollment in the video conference intervention but were ultimately unable to receive a video conference in time for their release due to scheduling conflicts

**Fig. 1** Client population flow for pre-release case management video conferencing intervention in 6 Louisiana Department of Corrections Prisons from August 2013–August 2016

**Table 1** Demographic and baseline HIV care characteristics for clients enrolled in pre-release case management video conferencing intervention in 8 Louisiana Department of Public Safety and Corrections Prisons from August 2013–August 2016

Characteristic	Total enrolled population N = 238 (100%)	Had a video conference n = 144 (60.5%)	No video conference <sup>a</sup> n = 94 (39.5%)	$\chi^2$ <sup>b</sup>	p value
Race				2.04	0.153
Black	189 (79%)	110 (76.4%)	79 (84.0%)		
White and other	49 (21%)	34 (23.6%)	15 (16.0%)		
Gender				2.44	0.119
Male	202 (85%)	118 (82.0%)	84 (89.4%)		
Female	36 (15%)	26 (18.1%)	10 (10.6%)		
Age at release				0.737	0.864
18–29	32 (13%)	18 (12.5%)	14 (14.9%)		
30–39	76 (32%)	48 (33.3%)	28 (29.8%)		
40–49	74 (31%)	43 (29.9%)	31 (33.0%)		
50+	56 (24%)	35 (24.3%)	21 (22.3%)		
HIV transmission risk				0.482	0.923
MSM	96 (40%)	59 (41.0%)	37 (39.4%)		
HRH	45 (19%)	29 (20.1%)	16 (17.0%)		
MSM/IDU	34 (14%)	19 (13.2%)	15 (16.0%)		
IDU	62 (26%)	37 (25.7%)	25 (26.6%)		
Time since HIV diagnosis				3.08	0.214
< 4 Years	56 (24%)	31 (21.5%)	25 (26.6%)		
5–10 years	57 (25%)	40 (27.8%)	17 (18.1%)		
10+ years	124 (52%)	73 (50.7%)	51 (55.3%)		
Ever had an AIDS diagnosis				2.73	0.098
No	91 (38%)	49 (34.0%)	42 (44.7%)		
Yes	147 (62%)	95 (66.0%)	52 (55.3%)		
Viral suppression before release <sup>c</sup>				0.789	0.374
Not virally suppressed	93 (39%)	53 (36.8%)	40 (42.6%)		
Virally suppressed	145 (61%)	91 (63.2%)	54 (57.5%)		
Sub-population				1.04	0.594
Diagnosed and engaged in care outside of DOPSC prior to incarceration	156 (66%)	92 (63.9%)	64 (68.1%)		
Diagnosed outside of DOPSC and was not engaged in care outside of DOPSC prior to incarceration	51 (21%)	34 (23.6%)	17 (18.1%)		
Newly diagnosed at DOPSC	31 (13%)	18 (12.5%)	13 (13.8%)		

RW ryan white, NA not applicable, MSM men who have sex with men, HRH high risk heterosexual risk, IDU injection-drug use, DOPSC Department of Public Safety and Corrections

<sup>a</sup>Control group

<sup>b</sup>Compares enrolled clients who received a video conference to enrolled clients who did not receive a video conference

<sup>c</sup>A client is classified as virally suppressed if they have had an HIV viral load test taken within the last year with a result that is  $\leq 200$  copies/mL

After controlling for various demographic and baseline HIV health characteristics in the multivariate analysis presented in Table 2, there was no statistically significant difference in linkage to care rate between the intervention and comparison groups (AOR = 1.2; 95% CI 0.6–2.3,  $p > 0.05$ ). However, clients who had a previous AIDS diagnosis were half as likely to link to HIV care within

90 days after release compared to clients who did not have a previous AIDS diagnosis (AOR = 0.5; 95% CI 0.2–0.9;  $p < 0.05$ ) and clients who were virally suppressed before release were 7.4 times more likely to link to care compared to clients who were not virally suppressed before release (AOR = 7.4; 95% CI 0.1–0.3;  $p < 0.0001$ ).

**Table 2** Association between linkage to HIV care within 90 days after release and having a case management video conference and baseline characteristics for clients enrolled in pre-release case man-

agement video conferencing intervention in 6 Louisiana Department of Public Safety and Corrections Prisons from August 2013–August 2016

Characteristic	Linked to HIV medical care within 90 days after release		
	No./total (%)	UOR (95% CI) <sup>a</sup>	AOR (95% CI) <sup>a</sup>
	171/238 (71.8%)		
Had a video conference			
No	64/94 (68.1%)	1.0	1.0
Yes	107/144 (74.3%)	1.4 (0.6–2.4)	1.2 (0.6–2.3)
Race			
Black	131/189 (69.3%)	1.0	1.0
White and other	40/49 (81.6%)	2.0 (0.9–4.3)*	1.7 (0.7–4.3)
Birth sex			
Male	140/202 (69.3%)	1.0	1.0
Female	31/36 (86.1%)	2.8 (1.0–7.4)**	2.8 (0.7–10.6)
Age at release			
18–29	19/32 (59.4%)	0.6 (0.2–1.5)	0.8 (0.2–3.1)
30–39	54/76 (71.1%)	1.0 (0.5–2.1)	1.1 (0.4–3.0)
40–49	58/74 (78.4%)	1.5 (0.7–3.2)	1.9 (0.7–4.8)
50+	40/56 (71.4%)	1.0	1.0
HIV transmission risk			
MSM	67/96 (69.8%)	1.0	1.0
HRH	37/46 (80.4%)	1.8 (0.8–4.2)	1.4 (0.5–4.3)
MSM/IDU	21/34 (61.8%)	1.2 (0.6–2.5)	0.8 (0.3–1.9)
IDU	46/62 (74.2%)	1.2 (0.6–4.2)	0.7 (0.3–1.7)
Time since HIV diagnosis			
< 4 Years	34/56 (60.7%)	1.2 (0.6–2.4)**	1.0 (0.4–2.5)
5–10 years	44/57 (77.2%)	0.4 (0.3–1.0)**	0.8 (0.3–1.9)
10+ years	93/125 (74.4%)	1.0	1.0
Ever had an AIDS diagnosis			
Yes	112/147 (76.2%)	1.0	1.0
No	59/91 (64.8%)	0.6 (0.3–1.0)*	0.5 (0.2–0.9)**
Viral suppression status before release <sup>b</sup>			
Not virally suppressed	46/93 (49.5%)	1.0	1.0
Virally suppressed	125/145 (86.2%)	6.4 (3.4–11.9)***	7.4 (3.7–14.8)***
Sub-population			
Diagnosed and engaged in care outside of DOPSC prior to incarceration	117/156 (75.0%)	1.0	1.0
Diagnosed outside of DOPSC and was not engaged in care outside of DOPSC prior to incarceration	33/51 (64.7%)	0.6 (0.3–1.2)	0.7 (0.3–2.2)
Newly diagnosed at DOPSC	21/31 (67.7%)	0.7 (0.3–1.6)	0.8 (0.3–2.2)

RW ryan white funded, UOR unadjusted odds ratio, AOR adjusted odds ratio, MSM men who have sex with men, HRH high risk heterosexual risk, IDU injection-drug use, DOPSC Department of Public Safety and Corrections

\* $p < 0.10$ ; \*\* $p < 0.05$ ; \*\*\* $p < 0.0001$

<sup>a</sup>Assesses significance of differences in linkage to HIV medical care within 90 days after release between clients that had a video conference and clients that did not have a video conference

<sup>b</sup>A client is classified as virally suppressed if they have had an HIV viral load test taken within the last year with a result that is  $\leq 200$  copies/mL

## Discussion

The purpose of this intervention was to design and implement a new intervention for PLWH nearing release from incarceration in order to maximize the likelihood that they

would access needed HIV care and support services post-release. In the current study, the combined linkage to HIV care rate for the intervention and comparison groups was over 70%, which represented an increase from the previous linkage rate for recently released PLWH prior to the

initiation of the study (59%), and was similar to the care engagement rate in the general population (72%). Nonetheless, the study showed no significant improvement in rates of linkage to HIV care following the introduction of a video conference intervention relative to Louisiana's existing pre-release reentry services for PLWH during the study period. It should be noted that this program was designed alongside these existing services and thus, this represents a limited comparative effectiveness trial that is lacking a true comparison group. Therefore, these results should not be interpreted as meaning that the video conference intervention was not successful in linking persons to care following release. In addition, there are further weaknesses to this study design that may have limited the detection of any improvement by adding the video conference, including relatively small (and unequal) sample sizes in both groups.

Limitations to the intervention delivery included the difficulty of successfully scheduling and completing the video conferences and the variability in the quality of case management services offered during the video conferences. The location of the prison facilities may have impacted the corrections specialists' abilities to successfully offer video conferences prior to release for PLWH that were released before their original release date due to parole or accumulated 'time off due to good behavior.' Some of the DOC facilities involved in the intervention were as far as 250 miles away from the location of the corrections specialists' office and it was not always feasible to schedule a video conference and travel across the state with minimal notice of a change in release date. Also, because the DOPSC schedules approximately 6000 telemedicine appointments per year, the preferred days or times for the intervention's video conferences were not always available, and scheduling was sometimes taxing. Furthermore, case managers who had more experience with the intervention exhibited a higher comfort level with the process and assessment questions; however, overfamiliarity sometimes led to rushed, less interactive sessions. Case managers who were not afforded as many opportunities for video conference sessions sometimes hesitated through the process, but because they were not dependent on a learned script, they often executed more engaging and valuable sessions. Current Case Management Standards of Care are being revised to assure continuity in case manager guidance and training in order to improve the quality of interactions during video conferences.

Ultimately, while the video conference intervention may not have increased the linkage rate of the standard pre-release model, it was considered a successful new strategy for pre-release case management and shown to be feasible in the correctional setting. There was marked success in both the video conference intervention group as well as the 'business as usual' comparison group that resulted in high linkage to HIV care rates (71% overall) relative to the

general population. This could have represented a potential ceiling effect such that there may have been little room for improvement in the video conference intervention. Furthermore, there were some indicators of success that were not directly assessed with this evaluation strategy. As noted above, the use of the video conferencing strategy greatly reduced several logistical barriers to the standard model including reduction of travel time and an increase in the number of clients able to be served. Another implication of this strategy is that RWHAP-funded case managers could be utilized without the need for an additional funding source to pay for their time. Also, the video conference equipment was relatively inexpensive, requires minimal funds for ongoing maintenance and training, and could be used for the delivery of other non-HIV related services. The intervention's success was largely due to the support from the DOPSC medical director, who recognized the potential for expanding the reach and purpose of the intervention; as a result, he was a champion of the intervention and he fostered cooperation of the infirmary staff at each prison facility. The intervention was also positively received by the case management agencies, as well as by the clients, many of whom had never experienced telemedicine.

In conclusion, the video conference supplement has proved to be a valuable addition to the existing pre-release services as it provides PLWH who are preparing for release from prison with the opportunity to learn about support services available in the community, as well as the opportunity for PLWH to critically assess their post-release circumstances. Interventions such as these help to ensure the continuity of HIV care for recently released PLWH, which may otherwise be disrupted upon their release because of competing priorities of life needs and the opportunity to orient (or re-orient) themselves with RWHAP services. Pre-release services should be adopted, potentially alongside similar video conference adaptations, to better align with the clients' HIV diagnosis and care history and use an approach that addresses barriers and challenges. SHP will continue to monitor and assess the impact of the video conference intervention featured in this study and improve the quality of all pre-release reentry services offered to PLWH.

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## Compliance with Ethical Standards

**Conflict of interest** Karissa M. Page has received an honorarium for participation in a regional focus group pertaining to this intervention from Gilead Sciences, Inc. The remaining authors declare that they have no conflict of interest.

**Informed Consent** Informed consent adhering to the tenants of the Declaration of Helsinki was obtained from all individuals participants included in this intervention.

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