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A Cluster Randomized Evaluation of a Health Department Data to Care Intervention Designed to Increase Engagement in HIV Care and Antiretroviral Use

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Abstract

Background—Many U.S. health departments have implemented Data to Care interventions, which use HIV surveillance data to identify persons who are inadequately engaged in HIV medical care and assist them with care re-engagement, but the effectiveness of this strategy is uncertain.

Methods—We conducted a stepped wedge cluster randomized evaluation of a Data to Care intervention in King County, Washington 2011–2014. Persons diagnosed with HIV for ≥ 6 months were eligible based on one of two criteria: 1) VL >500 copies/mL and CD4 <350 cells/μL at last report in the past 12 months or 2) no CD4 or viral load (VL) reported to the health department for 12 months. The intervention included medical provider contact, patient contact, and a structured individual interview. Health department staff assisted patients with reengagement using health systems navigation, brief counseling, and referral to support services. We clustered all eligible cases in the county by the last known medical provider and randomized the order of clusters for intervention, creating contemporaneous intervention and control periods (cases in later clusters contributed person-time to the control period at the same time that cases in earlier clusters contributed person-time to the intervention period). We compared the time to viral suppression (VL <200 copies/mL) for individuals during intervention vs. control periods using a Cox Proportional Hazards model.

Results—We identified 997 persons [intention to treat (ITT)], 18% of whom had moved or died. Of the remaining 822 (modified ITT), 161 (20%) had an undetectable VL reported before contact and 164 (20%) completed the individual interview. The hazard ratio (HR) for time to viral suppression did not differ between the intervention and control periods in ITT [HR 1.21 (95% CI: 0.85–1.71)] or modified ITT [HR 1.18 (95% CI: 0.83–1.68)] analysis.

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Conclusion—The Data to Care intervention did not impact time to viral suppression.

Keywords

HIV Care Continuum; Retention in Care; Data to Care; HIV Surveillance; Cluster Randomized Trial

INTRODUCTION

Antiretroviral therapy decreases HIV transmission and improves the health of persons living with HIV (PLWH).^{1,2} Increasing the percentage of PLWH who are engaged in medical care and virally suppressed are centerpieces of the U.S. National HIV/AIDS Strategy.³ In most states in the U.S., laboratories report the results of CD4 count and HIV RNA [viral load (VL)] tests to health departments.⁴ The Centers for Disease Control and Prevention (CDC) encourage health departments to use HIV surveillance data to identify PLWH who have had gaps in care or are not virally suppressed and work to engage these individuals in HIV care and treatment.^{5,6} However, the effectiveness of this strategy, called “Data to Care,” is unknown. The rationale for it is strong, but at least three factors could blunt the impact of this approach. First, inaccurate surveillance data could limit health department’s ability to identify out-of-care persons. A lack of laboratory reports often indicates that an individual has moved out of the surveillance jurisdiction rather than disengaged from care.⁷ Second, many PLWH have periods of care disengagement interspersed with periods of engagement and reengage in care without intervention. Third, little evidence is available to guide the process of reengaging a person who has disengaged from HIV care.⁸ Most health departments use an approach that blends traditional public health case investigation with brief counseling, patient navigation, or case management.^{9–17} Although some jurisdictions have reported outcomes from their Data to Care programs,^{10,12–15,17} no controlled study has been published.

We implemented a Data to Care intervention in Seattle-King County, WA in 2011.^{6,18,19} In the Care and Antiretroviral Promotion Program (CAPP), health department disease intervention specialists (DIS) use surveillance data to identify persons who appear to be poorly engaged in HIV care, contact the last known medical provider for each case, contact patients, and attempt to reengage persons in care using structured brief counseling, health systems navigation, and referral to support services. DIS are front-line public health workers who typically work with persons who are infected with or have been exposed to HIV or other sexually transmitted infections to ensure access to treatment.

The objective of this program evaluation was to determine the effectiveness of the Data to Care strategy in Seattle & King County. To do this, we instituted and evaluated CAPP using a stepped wedge cluster design. In stepped wedge cluster randomized trials investigators randomly assign the order in which groups of persons (“clusters”) receive an intervention.^{20,21} The stepped wedge approach creates contemporaneous intervention and control periods: clusters initiated later contribute person-time to the control period at the same time that clusters initiated earlier contribute person-time to the intervention period. This method facilitates more rigorous evaluation than comparison of post-intervention outcomes to pre-

intervention outcomes because it controls for secular trends. It is well-suited to evaluation of public health interventions because it does not require withholding the intervention from any group. In situations where it is not possible to deploy the intervention to all eligible persons simultaneously, such as our countywide Data to Care intervention, randomizing the order of intervention initiation is a pragmatic way to facilitate evaluation. The cluster approach provides a means to decrease “contamination” between intervention and control arms that could occur if individuals, rather than clusters, were randomized. Medical provider communication was a key element of our Data to Care approach. If medical providers attempted to re-engage their patients who were poorly engaged in care, the intervention effect could be obscured with individual patient randomization. Thus, we grouped cases into clusters defined by their last known medical provider to minimize contamination between intervention and control periods. The primary outcome of our analysis, time to viral suppression, pertained to individual PLWH.

METHODS

Prior to implementing the CAPP intervention, we conducted formative work to obtain feedback on and adapt the intervention. This included in-depth qualitative interviews with PLWH and HIV medical providers,¹⁹ and presentations to provider and community groups. The program was implemented and evaluated for a public health purpose and was not human subjects research requiring IRB oversight.

Participants and Clusters

We identified eligible cases from the King County enhanced HIV/AIDS Registry System (eHARS) in Washington State, regardless of the jurisdiction of diagnosis, who had been diagnosed with HIV for ≥ 6 months. Persons found to have died or moved out of county through routine surveillance procedures or a prior project that investigated cases missing recent laboratory reports⁷ were excluded. In 2013, CD4 reporting was 95% complete and VL reporting was 97% complete in King County.²² We used two criteria to identify cases of PLWH who were out of or poorly engaged in HIV care: 1) VL > 500 and CD4 < 350 cells/mm³ at the time of last report in the prior year (“recent unsuppressed VL”) or 2) no CD4 or VL in the past year (“12 month gap in laboratory reports”) or 2. Our decision to restrict the recent unsuppressed VL group to persons with CD4 < 350 cells/mm³ reflected the community standard and U.S. treatment guidelines in place when we designed the intervention.²³ By July 2012, when we added the criterion of no CD4 or VL in the past year, the community standard had evolved to treat patients regardless of CD4 count²⁴ and guidelines recommended initiation of ART for all HIV-infected individuals.²⁵

We grouped participants based on their last known medical provider to form the clusters for randomization by identifying providers associated with the most recently reported laboratory result. The definition of the provider cluster depended on the characteristics of the care facility associated with the most recently reported CD4/VL. PLWH who received care in clinics with ≥ 2 providers or < 10 total HIV-infected patients were grouped at the clinic level; otherwise cases were grouped by provider. We exempted cases with no CD4/VL (i.e. never linked to care) from randomization in order to prioritize them for immediate partner services

intervention. The rationale for this was that CAPP was a novel intervention designed to re-engage PLWH who were poorly engaged in care or who had fallen out of care after linkage to initial care. It did not replace the standard-of-care HIV partner services procedures for linkage to initial care in King County, an approach which results in >95% of cases being successfully linked.²² For cases missing provider data, we attempted to determine the provider through a search of records available to the surveillance team prior to randomization. If this failed, we grouped the case with the first provider cluster from the reporting facility.

Intervention

The CAPP intervention included medical provider contact, patient contact, and structured individual counseling. Thus, it pertained to both the cluster level and the individual participant level. Two DIS investigated cases according to a standardized protocol described in detail elsewhere.²⁶ DIS searched all available HIV/STD public health databases, electronic health records, death records, and a Lexis Nexis® database. If this did not yield a disposition, DIS contacted the medical provider. Providers received one list of their eligible patients and had the opportunity to opt-out of contact for patients on a case-by-case basis.

After notifying providers, the DIS contacted eligible individuals by phone and offered a face-to-face meeting, which took approximately 45 minutes for which the participant was compensated \$50. The meeting included a structured interview to identify barriers to care and treatment and development of a plan to address identified barriers. The structured interview methods are described in detail elsewhere.¹⁸ DIS assisted patients with HIV care re-engagement according to a protocol. Most counseling sessions were conducted at the PHSKC STD Clinic, but when this was not feasible, the DIS met with patients in the field or by phone. If the participant consented, the DIS sent letters summarizing the encounter to the participant's medical provider and case manager. DIS routinely attempted to contact all participants one month after the baseline appointment to assess whether they had seen their medical provider and offer additional assistance, but could also follow-up with patients sooner if indicated.

Sample Size and Randomization

The sample size for this program evaluation was defined by the number of eligible cases in King County; the intervention list was a complete enumeration of eligible cases. The sample size included all eligible persons in the county because we conceptualized the intervention from a public health perspective. In other words, we did not restrict our analysis or sample size to the subset of persons who successfully completed a structured interview. Assuming initiation of the intervention with 196 providers, a mean of 1.75 participants per provider, 35% viral suppression in the control period and a coefficient of variation of 0.4, we estimated 90% power to detect an increase in viral suppression to 47.5%.²⁰ This estimate was informed by analysis of surveillance data in the year prior to the intervention and our assessment of what would constitute a meaningful level of intervention effect. We used a simple randomization scheme to order the clusters using computer-generated random numbers. The surveillance epidemiologist generated the case list, the lead investigator designated the cluster groupings, the epidemiologist performed the randomization, and the

lead investigator assigned the list to DIS for intervention. This allocation was not blinded since it was not feasible to do so.

Outcomes and Statistical Methods

We identified the eligible cases in two groups at separate times. Group 1, identified in May 2011, included only cases with a recent unsuppressed VL and CD4 count <350 cells/ μ L. Group 2, identified in July 2012, included cases with a recent unsuppressed VL and CD4 count <350 cells/ μ L as well as cases with a 12 month gap in laboratory reports. We did not include cases with a 12 month gap in laboratory reports in Group 1 because our surveillance team had not yet finished the investigation of cases with a 12 month gap in laboratory reports from 2006–2010.⁷ As demonstrated in Figure 1, all cases had an analysis period of 420 days. The start date of the analysis period was the day we drew the list of eligible cases from surveillance. We defined the end date of the analysis period *a priori* as 6 months after the day we initiated the last group of eligible persons in Group 2 and applied an equal observation time to Group 1. Our rationale for this was that 6 months following the initiation of the last group would provide sufficient time to detect an effect of the intervention in the contemporary ART era and the context of the King County HIV medical care resources. Cases were identified as eligible, clustered by provider, and clusters were randomized for Group 1, then separately and later, eligible cases were identified, clustered by provider, and clusters randomized for Group 2. The analysis period for Group 1 was May 1, 2011 to June 24, 2012, and the analysis period for Group 2 was July 25, 2012 to September 18, 2013. The control periods were the times between the start of the analysis period and the start of the intervention for each provider cluster, which we defined as the date that the DIS faxed the list of eligible patients to the provider.

All outcomes pertained to the individual participant level. To assess the outcome measures, we used routinely reported HIV surveillance data. We defined the primary analysis outcome, time to viral suppression, as the time between the analysis start date and the date of the first VL < 200 copies/mL. We defined the secondary outcome, relinkage to care among cases identified on the basis of having a 12 month gap in laboratory reports, as the date of the first VL or CD4 reported. Our rationale for selecting viral suppression as the primary outcome for both eligibility categories was that this was goal of the intervention for participants in both eligibility categories. We reasoned that a public health intervention which impacted relinkage to care without a subsequent difference in viral suppression would not constitute a potent public health intervention. Our rationale for excluding the cases with a recently reported unsuppressed VL from the secondary outcome was that they were already “linked to care” by surveillance criteria with ≥ 1 laboratory report in the past year.

We used chi-square tests to compare the characteristics of the identified cases with those of the overall population of HIV-diagnosed persons in King County at the end of 2012.²⁷ We used Cox Proportional Hazards, with the analysis start date as time 0 and accounting for case clustering by provider,²⁸ to compare outcomes during intervention periods versus control periods, censoring cases at the end of the observation period or on the date of death or the date that DIS ascertained relocation. The intention to treat (ITT) analysis included all randomized cases. Because it was not feasible in most cases for the DIS to determine the

exact date a person who had relocated had moved away, the date of censoring for relocated cases was later than the actual relocation date. Thus, the modified ITT (mITT) population excluded all cases found to have relocated or died. In all analyses, we included the case group as a covariate. We conducted sensitivity analyses to determine whether the effect of the intervention varied by patient subgroups defined *a priori*: eligibility criterion, sex at birth, HIV risk factor, and CD4 count at baseline and to evaluate the impact of censoring deaths.

RESULTS

Analysis Population

We identified 997 cases that met CAPP criteria: 381 (38%) with a 12 month gap in laboratory reports and 616 (62%) with a recent unsuppressed VL. These represented 14% of the estimated 7104 HIV-diagnosed person living in King County at the end of 2012.²⁷ The cases were clustered in 281 provider groups with a median of 2 cases [interquartile range (IQR: 1–5)] per cluster. The analysis population was younger (32% vs 24% under age 40; $p<0.001$) and had more advanced immunosuppression (25% vs. 8% had CD4 counts <200 at last report; $p<0.001$) than the general population of HIV-diagnosed persons in King County (Table 1).

Intervention Completion

DIS determined that 145 (15%) of the eligible persons had moved out of the area and 30 (3%) died (Figure 2). Of the 822 cases presumed to reside in the area (the mITT population), 20% ($N=161$) had an undetectable VL reported to surveillance before DIS initiated contact attempts with the provider. DIS initiated CAPP procedures for the remaining 661 cases, 130 (20%) of which were closed when the medical provider asked the health department staff not to contact the patients. Most often this was because the provider had started the patient on ART in the interim since the patient was identified as eligible. DIS attempted to contact 531 persons and successfully contacted 243 (46%); 192 (79%) agreed to complete the CAPP interview, and 164 (85%) completed the structure interview (16% of the ITT and 19% of the mITT population).

Outcomes

The pre-intervention and intervention periods had a median duration of 210 days, with interquartile ranges of 140–343 days and 77–280 days, respectively. Of the 30 deaths, 19 occurred during the control period, 6 in the intervention period, and the death date was unknown for 5.

By the end of the observation period, 301 persons had a suppressed VL, representing 30% of the ITT and 37% of the mITT population. The point estimate of the hazard ratio (HR) for viral suppression was in the direction of a positive effect (shorter time to viral suppression), but was not statistically significant in the ITT analysis [HR 1.21 (95% CI: 0.85–1.71)] or the mITT analysis [HR 1.18 (95% CI: 0.83–1.68)] (Figure 3). Among 276 persons in the mITT population eligible based on a 12 month gap in laboratory reports, 131 (47%) relinked to care by the end of the observation period, but the time to relinkage did not differ in the

intervention versus control periods [(HR 0.99 (95% CI: 0.64 – 1.55)]. By the end of the observation period, 77 (28%) of these cases had achieved viral suppression, but the time to viral suppression was similar in the intervention and control periods [HR 0.79 (95% CI: 0.40 – 1.55)]. Among 546 persons in the mITT population eligible based on a recent unsuppressed VL, 224 (41%) achieved viral suppression by the end of the observation period, and there was a non-significant trend toward shorter time to viral suppression in the intervention period [HR 1.45 (95% CI: 0.96 – 2.19)]. The outcome did not differ significantly between patient subgroups, and sensitivity analyses varying the approach to censoring deaths did not change the results (data not shown). In lieu of an intracluster correlation, we report the variance of the (gamma distributed) shared frailty from a Cox model as 0.21.

Among persons who completed the structured interview, 49 (30%) relinked to care within 1 month, 78 (48%) relinked within 3 months and 56 (34%) achieved viral suppression within 6 months of the interview. However, as shown in Table 2, from the entire analysis population of 997 eligible persons, approximately half of all persons who achieved viral suppression during the analysis period did so before DIS attempted to contact them [161 of 301; (53%)].

DISCUSSION

In a pragmatic randomized controlled evaluation, we found no significant effect of a health department Data to Care intervention on viral suppression or relinkage to care. Only a minority of persons who appeared to be poorly engaged in care based on surveillance data were contactable, and about half of all persons who achieved viral suppression did so before DIS attempted to contact them. These results are somewhat at odds with reports which have suggested that this type of Data to Care effort can be effective.^{9,13–15,17} This may reflect the absence of a control group or period in prior studies. Many persons in our analysis achieved viral suppression in the absence of any intervention from the health department. This may have been influenced by interventions such as case management outreach and other evolving community outreach efforts. For this reason, a simple pre- vs. post-intervention analysis would not have allowed us to assess the independent effect of our intervention. Since more deaths occurred in the control period than the intervention period (19 vs. 6), it is possible that our intervention averted some deaths without impacting viral suppression or relinkage to care in the overall population.

Our findings have implications for public health Data to Care programs and for how such programs are studied. First, Data to Care efforts that rely on surveillance data are relatively inefficient since many persons who appear to be out of care have actually moved away. Our data, as well as a number of prior reports, have all found that less than half of persons who appear to be out of care based on surveillance data are truly out of care.^{10,12,14–16} While the percentage of persons classified as out of care declines as surveillance data improves -- only 15% of apparently “out-of-care” cases in this analysis were defined as having relocated compared to 47% when our group began to investigate such cases in 2007 -- it remains large, especially when persons whom staff could not reach, most of whom were almost certainly also out of the area, are grouped with persons confirmed to have relocated. From a public health programmatic perspective, this reality means surveillance-based Data to Care is

inefficient. From a research perspective, when evaluating an intervention like ours, it diminishes the intervention's effect size and statistical power. It should be noted, this problem is not unique to surveillance-based interventions like the one we studied. HIV care relinkage interventions that use clinic data have also found that many persons who appear to be out of care have actually transferred care or moved away and that only about half or less of those remaining can be successfully re-engaged.^{29, 30}

Second, relinkage-focused interventions appear to be relatively weak. Even among persons who completed our intervention, only about one-third achieved viral suppression within 6 months. This finding needs to be confirmed elsewhere before drawing generalizable conclusions, but our results suggest that relatively low-intensity interventions – at least in a place like Seattle, Washington – have relatively little impact. Attempting to relink PLWH to the same healthcare system that failed to engage them in the first place is not an effective strategy. Ideally, a comprehensive approach to improving retention in care should combine interventions of varying intensity matched to the needs of the out-of-care PLWH, which might need to include structural changes in the healthcare system. To address the need for an alternative HIV medical care models for the hardest-to-reach PLWH, PHSKC and the Madison (HIV) Clinic in Seattle implemented a low-threshold incentivized care model with intensive outreach support (the MAX Clinic) in 2015.³¹

The primary strength of our analysis was the randomized, controlled evaluation design. Our analysis also had important limitations. It was conducted in a single jurisdiction, and its generalizability is uncertain. However, several other health departments in multiple regions of the country have now reported preliminary results demonstrating that only a minority of persons who appear to be out of care can be successfully engaged with existing Data to Care strategies.^{10,12,14–16} Despite extensive investigation, we were unable to determine the true status of many cases. Finally, we used surveillance data to ascertain outcomes, which may have underestimated the level of viral suppression achieved during the observation period, though laboratory reporting in King County is >90% complete.

In summary, we found in a randomized controlled analysis that a health department surveillance-based outreach strategy was ineffective. While additional studies in other locations are needed, our findings highlight the need to consider this type of Data to Care strategy as just one component of public health efforts to improve engagement in HIV care and treatment. Facility-based identification of out-of-care persons as they enter jails, emergency departments, and hospitals may be more effective than the outreach investigations we describe.³² To the extent that surveillance-based outreach is employed, prioritizing cases with recently reported high viral loads, rather than a gap in laboratory reports, may improve the impact of the strategy. Data sharing procedures between jurisdictions and between surveillance and healthcare entities could improve surveillance data. Finally, to successfully reach individuals who are not engaged in traditional HIV care and treatment, we may need higher intensity interventions with novel care delivery strategies.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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SUMMARY

A randomized controlled evaluation of a health department Data to Care intervention found that the strategy did not impact viral suppression or relinkage to care among persons with evidence of poor engagement in HIV care.

Figure 1.
Schema of the Stepped Wedge Cluster Randomization

Figure 2.
Intervention Flow Chart

Figure 3. Kaplan-Meier Curves for Time to Viral Suppression According to Intervention vs. Control Period

All cases identified (intention-to-treat), N=997 participants in 281 clusters (A). Excluding deaths and relocations (modified intention-to-treat), N= 822 participants in 252 clusters (B).

Demographic characteristics of HIV-diagnosed persons in King County at the end of 2012 (N=7104) and the study population (N=997)

Table 1

	HIV-Diagnosed Persons living in King County (N=7104)		Study Population (N=997)		P-value
	N	%	N	%	
Sex at Birth					0.02
Male	6353	89	865	87	
Female	751	11	131	13	
Race/Ethnicity					<0.001
White, Non-Hispanic	4709	66	424	43	
Black, Non-Hispanic	1201	17	161	16	
Hispanic	758	11	87	9	
Asian or Pacific Islander	248	3	30	3	
American Indian	68	1	5	<1	
Multiple & Missing	120	2	290	29	
HIV transmission risk factor [†] *					0.01
MSM	4904	69	645	65	
MSM-IDU	612	9	97	10	
IDU	326	5	49	5	
Heterosexual	694	10	97	10	
Other/Missing	568	8	109	11	
Age, years [†]					<0.001
<30	462	7	83	8	
30–39	1206	17	240	24	
40–49	2530	36	381	38	
50	2906	41	289	29	
Missing	0	0	4	<1	
CD4 count at the time of last report (cells/mm ³)					<0.001
<200	583	8	249	25	
200–500	2268	32	491	49	

	HIV-Diagnosed Persons living in King County (N=7104)		Study Population (N=997)		Study Population vs. County Population
	N	%	N	%	P-value
>500	3629	51	211	21	
Missing	624	9	46	5	
Eligibility criterion for CAPP					NA
CD4<500 & VL>500	NA	NA	616	62	
No labs 12 months	NA	NA	381	38	

NA, not applicable

Viral suppression prior to and during the analysis period in the study population, by eligibility criterion, and by case disposition

Table 2

Population	Total	Suppressed viral load (VL) ¹ at the time of most recent report prior to the observation period		Suppressed VL reported by the end of the observation period ²	
		N	% (row)	N	% (row)
Eligibility criterion					
All cases identified (ITT population)	997	214	21	301	30
Excluding cases that moved or died (mITT population)	822	141	17	301	37
No CD4 or VL reported (in mITT population)	276	141	51	77	28
VL>500 and CD4<350 at last report (in mITT population)	546	0	0	224	41
Case disposition					
Undetectable VL before contact attempted	161	46	29	161	100
Provider declined	130	16	12	45	35
No response	288	57	20	45	16
Patient declined	51	7	14	12	24
Accepted but did not complete intervention	28	1	4	7	25
Completed intervention	164	14	9	52	32

¹ HIV RNA <200 copies/mL

² Includes both control and intervention periods

ITT, intention to treat; mITT, modified intention to treat