Open Forum Infectious Diseases

MAJOR ARTICLE

Implementation of a Rapid Entry Program Decreases Time to Viral Suppression Among Vulnerable Persons Living With HIV in the Southern United States

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Background. Rapid entry programs (REPs) improve time to antiretroviral therapy (ART) initiation (TAI) and time to viral suppression (TVS). We assessed the feasibility and effectiveness of a REP in a large HIV clinic in Atlanta, Georgia, serving a predominately un- or underinsured population.

Methods. The Rapid Entry and ART in Clinic for HIV (REACH) program was implemented on May 16, 2016. We performed a retrospective cohort study with the main independent variable being period of enrollment: January 1, 2016, through May 15, 2016 (pre-REACH); May 16, 2016, through July 31, 2016 (post-REACH). Included individuals were HIV-infected and new to the clinic with detectable HIV-1 RNA. Six-month follow-up data were collected for each participant. Survival analyses were conducted for TVS. Logistic and linear regression analyses were used to evaluate secondary outcomes: attendance at first clinic visit, viral suppression, TAI, and time to first attended provider visit.

Results. There were 117 pre-REACH and 90 post-REACH individuals. Median age (interquartile range [IQR]) was 35 (25–45) years, 80% were male, 91% black, 60% men who have sex with men, 57% uninsured, and 44% active substance users. TVS decreased from 77 (62–96) to 57 (41–70) days ($P < .0022$). Time to first attended provider visit decreased from 17 to 5 days, and TAI from 21 to 7 days ($P < .0001$), each remaining significant in adjusted models.

Conclusions. This is the largest rapid entry cohort described in the United States and suggests that rapid entry is feasible and could have a positive impact on HIV transmission at the population level.

Keywords. antiretroviral therapy; HIV; rapid entry; viral suppression.

Antiretroviral therapy (ART) is now recommended for all persons who have HIV viremia, regardless of CD4 count [1–4]. Additionally, ART decreases transmission of HIV, further strengthening the public health argument for early ART [5].

Recent randomized controlled trials in South Africa and Haiti, along with a cohort study in San Francisco, demonstrate the efficacy of rapid entry into care and same-day ART initiation on improving rates of viral suppression (VS) and time to VS [6–8]. These data demonstrate the safety and acceptability of rapidly entering care and initiating ART, even with minimal laboratory data available [7]. Furthermore, results from South Africa showed improved retention at 10 months, and in Haiti improved retention and viral suppression at 1 year [6, 8]. Yet the HIV Research Network (HIVRN) cohort shows that in the United States (2011–2012), time to ART initiation was greater than 2 weeks and time to viral suppression was greater than 7 months from diagnosis [9]. This is not surprising, as in the US, system and bureaucratic barriers delay the time to ART initiation compared with international settings.

In May 2016, the Infectious Diseases Program (IDP) of the Grady Health System (GHS), the largest HIV care provider in Georgia with more than 6000 patients, launched a program entitled Rapid Entry and ART in Clinic for HIV (REACH). The intervention aimed to improve timely access to ART by removing institutional barriers to initial provider visit and ART initiation. REACH facilitated entry into the clinic for patients new to this site (either new diagnoses or re-entering care) with a provider visit and option of ART initiation within 72 hours. We evaluate the feasibility and effectiveness of this intervention to promote rapid initiation of ART in an ambulatory clinical setting serving mostly uninsured or underinsured patients living with HIV (PLWH) in Atlanta.

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METHODS

Study Design

We conducted a clinic-based retrospective cohort study to measure outcomes among individuals first enrolling in care at IDP, either with a new diagnosis or newly establishing care at IDP after prior care at another site. The cohort included patients who were not pregnant, age ≥16 years, newly enrolling at the IDP clinic from January 1, 2016, through July 31, 2016. Patients were excluded from the analysis if they met any of the following criteria: (1) HIV-1 RNA <200 copies/mL at enrollment, (2) on ART at time of enrollment, (3) enrolled in a clinical research study, (4) moved, transferred care, or died before the end of the 6-month follow-up period. Those enrolling from January 1, 2016, through May 15, 2016, constituted the pre-intervention group (pre-REACH), and those enrolling from May 16, 2016, through July 31, 2016, constituted the postintervention group (post-REACH). The intervention is described below. Patient data were collected for 6 months after enrollment. The primary analysis compared time to VS among pre-REACH (January 1, 2016, to May 15, 2016) enrollees with post-REACH enrollees (May 16, 2016, to July 31, 2016). Secondary analyses were performed for achievement of VS, attendance at first scheduled provider visit, time to scheduled provider visit, time to first attended provider visit, and time to ART initiation. All data were collected by review of the electronic medical record (EMR). The Emory University Institutional Review Board (IRB00061530) and the Grady Research Oversight Committee approved the study.

Referral and Enrollment at IDP Before the Intervention (Pre-REACH System)

The pre-REACH enrollment process is outlined in Figure 1A. Before May 16, 2016, eligible patients for IDP included PLWH residing in the 20-county Atlanta Eligible Metropolitan Area (EMA) with a CD4 count of <200 cells/μL or AIDS-defining illness. PLWH not meeting AIDS criteria were eligible for enrollment if one of the following criteria were met: (1) pregnant, (2) age <25 years, (3) comorbid mental health or substance use disorder, or (4) Medical Director approval for medical or social complexity. Upon arrival to the clinic, eligible patients were required to provide proof of income (if no income, an official document from the GA Department of Labor was required), proof of residence, a government-issued identification, and latent tuberculosis infection (LTBI) test results to enroll and schedule an initial provider visit. If any of the above documentation was missing, the patient was asked to obtain the appropriate paperwork and return to the clinic to complete enrollment. If results of an LTBI test were unavailable, a tuberculin skin test (TST) was placed, and the patient was asked to return in 48–72 hours for TST reading. TSTs could not be placed on a Thursday as results could not be read over the weekend. Upon enrollment, patients received multidisciplinary support from health educators, peer counselors, nurses, social workers, clinical providers, and pharmacists and were offered ART at their provider visit. These visits often occurred over several weeks, with up to 8 visits to the clinic before starting ART. Patients who did not complete the aforementioned steps were never enrolled in the clinic, and no data were collected on who or how many were turned away in this manner. Patients in the pre-REACH cohort who successfully completed enrollment had the ability to function at a level that allowed him/her to overcome enrollment barriers.

Intervention Design

The post-REACH enrollment process is outlined in Figure 1B. On May 16, 2016, the REACH program was initiated with goals to streamline enrollment in the clinic, expedite the first provider visit, and facilitate rapid initiation of ART (ideally within 72 hours of presentation). The following interventions aimed to achieve those goals: (1) Removal of limitations on eligibility for clinic: Eligibility was expanded to include (a) patients diagnosed or identified as out of care within the GHS, regardless of CD4 count (eliminating the need to have this laboratory data for enrollment), (b) partners of current patients. (2) Removal of administrative requirements before enrollment: Patients were given an initial provider appointment, regardless of government-issued identification, proof of income, or proof of residence availability at the time of presentation to the clinic. Patients who did not have one of these documents were provided assistance to obtain them, including transportation vouchers, when necessary. (3) Removal of TST requirement before initial appointment: Patients were required to have an active tuberculosis symptom screen by an intake nurse but no longer required to have a TST result to schedule an initial provider visit. (4) Enhanced access to a provider visit: Provider templates were revised to include open slots for rapid entry patients, and scheduling staff were trained to accommodate patients within 72 hours of enrollment. Baseline laboratory tests were ordered, but results were not required before initiation of ART. Potential contraindications to initiating ART were assessed, and the patient and provider decided jointly on the appropriate time to start ART, with an expectation to start same-day ART in the absence of contraindications or patient objection. (5) Enhanced education regarding regimen selection: Providers were educated about safe regimens to start when complete laboratory results (including genotyping studies) were not available. The approved regimens were tenofovir disoproxil fumurate or tenofovir alafenamide with emtricitabine or lamivudine plus dolutegravir or boosted-darunavir for ART-naïve patients. For ART-experienced patients, ART regimens were selected based on available information regarding prior regimens, adherence, viral suppression, and HIV genotypic data. (6) Enhanced support to access medication regardless of payer source: Patients with adequate documentation for enrollment into the Ryan White Program could receive immediate ART using Ryan White funds. For those patients who did not have all necessary documentation, patient assistance program paperwork was completed, and a 30-day supply of ART was dispensed. (7) Continued intensive ART education: As for all new enrollees to the clinic, nurse education sessions were available for ART

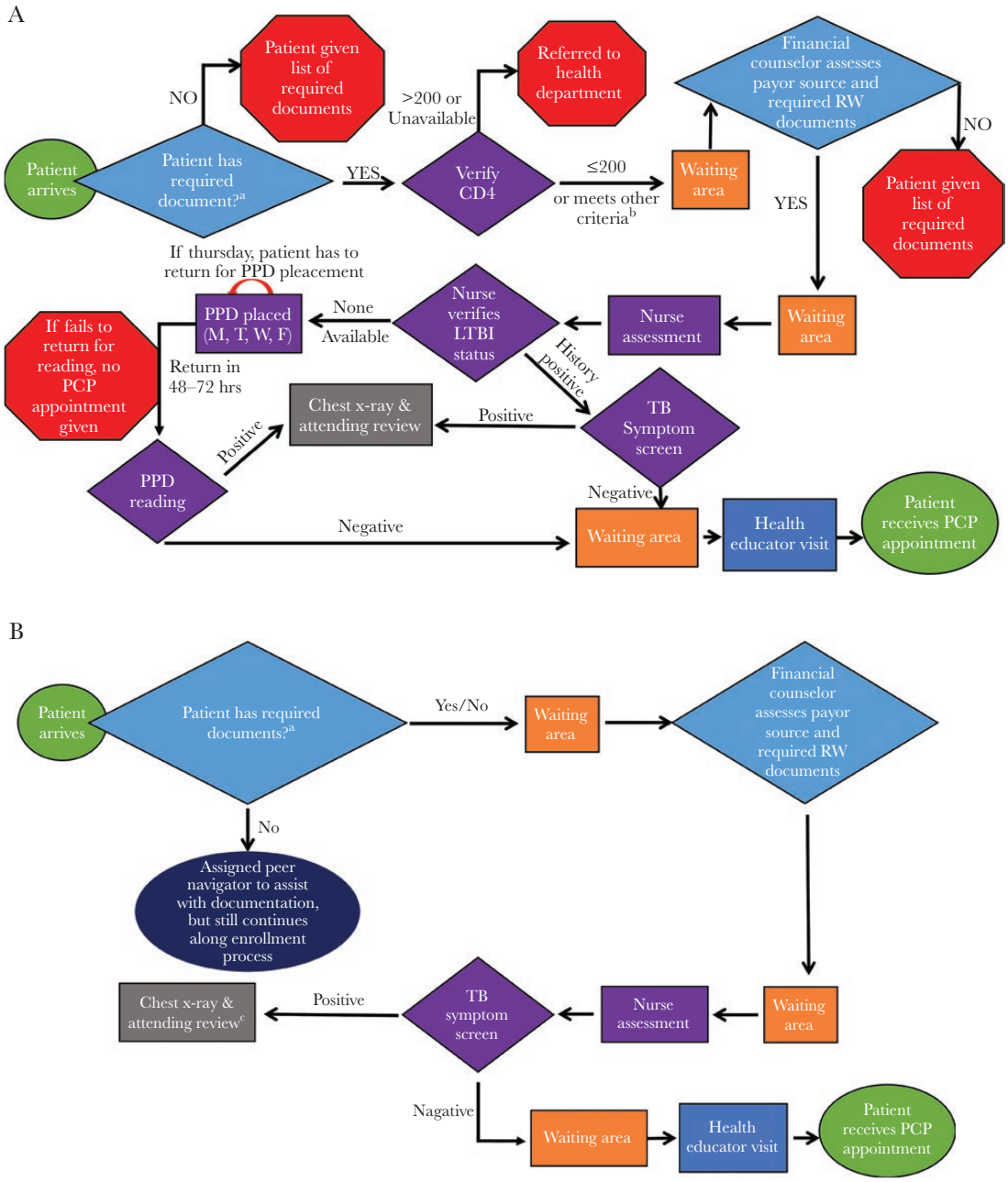

Figure 1. A, Pre-REACH enrollment process. Each red octagon represents a point in the enrollment process when a patient could be turned away and would not be given a primary care provider (PCP) appointment until that step was completed. B, Post-REACH enrollment process. Points where patients could previously be turned away were removed. [a]The required documents, based on both the Ryan White HIV/AIDS Program and the Grady Health System, were a photo ID, proof of residence, and proof of income. At check-in, an initial cursory check of these documents ensured that documents were present. The financial counselor did a more in-depth review to determine that the financial and residence documents fit both the Ryan White and Grady requirements. In the post-REACH period, if documents were missing, the patient continued along the enrollment process and was given a 30-day "grace period" to bring the documentation. Those patients were assigned a peer navigator to assist in obtaining documents. [b]For patients with a CD4 count >200, those meeting 1 or more of the following criteria were also eligible for enrollment: (1) pregnant, (2) age <25 years, (3) comorbid mental health or substance use disorder, or (4) Medical Director approval for medical or social complexity. [c]An attending reviewed the case and determined if it was necessary to treat active pulmonary tuberculosis. If so, the patient was linked with the county health department for treatment. If not, the patient was enrolled in the clinic and received a PCP appointment. Abbreviations: LTBI, latent tuberculosis infection; PAR, patient access representative; PCP, primary care provider; PPD, purified protein derivative; REACH, Rapid Entry and ART in Clinic for HIV; RW, Ryan White HIV/AIDS Program; TB, tuberculosis.

teaching, adherence counseling, and provision of extra assistance such as pillboxes when requested. The activities of the REACH intervention were conducted under usual clinic processes without creating a parallel system.

Data Collection and Definitions

Patient demographics, sociobehavioral characteristics, clinic visits, laboratory data (creatinine, hepatitis status, CD4 count, and HIV-1 RNA), and ART regimens were abstracted from the EMR through

January 31, 2017. Time to first scheduled provider visit was defined as number of days from initial presentation to clinic for enrollment to the first scheduled visit with a provider. Time to attended provider visit was defined as number of days from initial presentation for enrollment to first attended visit with a provider. Time to ART initiation was defined as time from initial clinic enrollment to date ART was prescribed. Time to VS was defined as time from initial clinic enrollment to the first HIV-1 RNA of <200 c/mL. VS was defined at this threshold to remain consistent with prior publications [7]. Achieving VS was defined as ever having an HIV-1 RNA <200 c/mL during the 6-month follow-up window.

Statistical Analysis

Descriptive statistics characterized the population overall and by group. Continuous variables were compared using the Student *t* test or Wilcoxon rank-sum test. Categorical variables were compared using Pearson's chi-square test or the Fisher exact test. Data on time to first scheduled provider visit, first attended provider visit, ART initiation, and VS were complete through January 31, 2017. If VS was not achieved, follow-up was censored at last recorded viral load. For unadjusted time to VS, median survival times with 95% confidence intervals were estimated using Kaplan-Meier estimates, and group comparisons were made using log-rank tests. Cox proportional hazard models estimated time to VS by REACH group, adjusting for age, gender, race, HIV risk factor, ART naïve, integrase strand transfer inhibitor (INSTI) use, and baseline viral load. A reduced Cox proportional hazard model adjusted for being ART naïve, INSTI use, and baseline viral load.

Linear regression was performed to compare time to first scheduled provider visit, time to attended provider visit, and time to ART initiation, whereas logistic regression analyses compared achievement of VS and attending a provider visit between the 2 groups. Analyses were stratified by enrollment around 90 days of diagnosis, as a surrogate for evaluating new diagnoses. The ART-naïve and enrollment within 90 days variables were highly collinear. The outcome variable was log10-transformed for time to attended provider visit and time to ART initiation to correct for skewness for models using the entire cohort and the subset of participants who enrolled >90 days after diagnosis.

Linear regression models for the entire cohort were adjusted for age, race, gender, and being ART naïve, whereas models stratified by enrollment within 90 days after diagnosis were controlled for age and race.

The logistic regression model for the entire cohort for attending first scheduled provider visit was adjusted for age, race, sex, and being ART naïve, and when stratified by enrollment within 90 days after diagnosis, it was adjusted for age. The logistic regression model for the entire cohort achieving viral suppression was adjusted for age, race, INSTI use, being ART naïve, and baseline VL. When stratified by enrollment within 90 days of diagnosis, it was adjusted for baseline viral load. Analyses were performed using SAS 9.4 (SAS Institute Inc, Cary, NC).

RESULTS

Between January 1, 2016, and July 31, 2016, 299 new patients ≥16 years old were enrolled at IDP and evaluated for inclusion in the analysis (Supplementary Figure 1). Two hundred seven were included in the analysis. Ninety-two new enrollees were excluded from the analysis for the following reasons: HIV-1 RNA <200 copies/mL upon entry to clinic (61); on ART at time of enrollment (14); admitted to the hospital directly from intake assessment (8); pregnant (2); enrolled in a clinical research study (3); moved (2), died (1), or transferred care (1) before the end of the follow-up period. Among 207 new enrollees eligible for analysis, 117 were enrolled pre-REACH and 90 were enrolled post-REACH.

Demographic, sociobehavioral, and clinical characteristics of the population are shown in Table 1. The majority of patients were men (80%) and African American (90%), and 57% were uninsured. The post-REACH group was slightly older (38 years; IQR, 27–47 years) than the pre-REACH group (32 years; IQR, 23–43 years; $P = .05$). A greater proportion of the post-REACH patients were black/African American (96.7% vs 86.3%; $P = .01$). Patients reported frequent unstable housing (126 [60.9%]), unemployment (157 [75.8%]), and substance use within the past 3 months (91 [44.0%]). Just over one-quarter of the patients had a mental health diagnosis (54 [26.1%]). Median baseline CD4 count (IQR) was 146 (45–302) cells/μL, and 124 (59.9%) were ART naïve, with no differences between groups.

The median time to VS (IQR) from beginning clinic enrollment decreased from 77 (62–96) days in pre-REACH patients to 57 (41–70) days in post-REACH patients ($P = .0022$). The Kaplan-Meier curve is shown in Figure 2. The adjusted hazard ratio for rapid entry was 1.83 (95% confidence interval [CI], 1.28–2.61) in the reduced model, with ART naïve remaining significant in that model (Supplementary Table 1). The full model (data not shown) did not differ appreciably.

Table 2A shows the unadjusted outcomes. The median pre-REACH days to event (IQR) were 15 (7–20) days for time to first scheduled provider visit, 17 (7–26) days for time to first attended provider visit, and 21 (12–31) days for time to ART initiation. The median post-REACH days to event were 4 (1–7) days for time to first scheduled provider visit, 5 (2–8) days for time to first attended provider visit, and 7 (3–17) days for time to ART initiation. Improvement in each category, from pre-REACH to post-REACH, remained significant in adjusted linear regression analyses (Table 2B).

Logistic regression analyses (Table 2A/2B) of attendance of first scheduled appointment and achievement of VS did not demonstrate a difference between pre- and post-REACH groups. For the post-REACH group, 81.1% (73) attended their first scheduled appointment, compared with 72.7% (85) in the pre-REACH group (adjusted odds ratio [aOR], 1.63, 95% CI, 0.82–3.22). In the post-REACH group, 67.8% (61) achieved VS compared with 74.4% (87) of pre-REACH patients (aOR, 0.77; 95% CI, 0.39–1.52). The adjusted logistic regression model for

Table 1. Demographics, Psychosocial and Clinical Characteristics Among Patients Newly Enrolling in the Infectious Disease Program of the Grady Health System, January 1, 2016–July 31, 2016

Characteristics	Overall (n = 207)	Pre-REACH (n = 117)	Post-REACH (n = 90)	Between-Group Comparison, *P* Value
	No. (%) or Median (IQR)			
Sociodemographic				
Age, y	35 (25–45)	32 (23–43)	38 (27–47)	.05
Gender				.80
Male	165 (79.7)	95 (81.2)	70 (77.8)	
Female	40 (19.3)	21 (17.9)	19 (21.1)	
Transgender, MtoF	2 (1)	1 (0.9)	1 (1.1)	
Race				.01
African American/black	188 (90.8)	101 (86.3)	87 (96.7)	
Else	19 (9.2)	16 (13.7)	3 (3.3)	
HIV RF				.59
Perinatal	2 (1.0)	2 (1.7)	0 (0.0)	
Heterosexual	81 (39.1)	44 (37.6)	37 (41.1)	
MSM	124 (59.9)	71 (60.7)	53 (58.9)	
Payer source				.24
Medicaid	55 (26.6)	27 (23.1)	28 (31.1)	
Medicare	9 (4.3)	4 (3.4)	5 (5.6)	
Private	25 (12.1)	18 (15.4)	7 (7.8)	
Ryan White	118 (57.0)	68 (58.1)	50 (55.5)	
Income, $ US	8796 (0–17 000)	8820 (0–18 668)	7800 (0–15 600)	.06
Education				.46
Less than HS	49 (23.7)	310 (26.1)	19 (21.4)	
HS	133 (64.3)	75 (65.2)	58 (65.2)	
Beyond HS	22 (10.6)	10 (8.7)	12 (13.4)	
Unstable housing[a]	126 (60.9)	78 (67.2)	48 (57.1)	.14
Employed	50 (24.2)	31 (26.5)	19 (21.4)	.39
Incarcerated[b]	16 (7.7)	10 (8.6)	6 (7.1)	.70
Active substance use[c]	91 (44)	50 (42.7)	41 (45.6)	.69
Alcohol	40 (19.3)	24 (20.5)	16 (17.8)	
Cocaine	24 (11.6)	11 (9.4)	13 (14.4)	
Marijuana	61 (29.5)	32 (27.4)	29 (32.2)	
Amphetamines	8 (3.9)	4 (3.4)	4 (4.4)	
Mental health diagnosis[d]	54 (26.1)	30 (25.9)	24 (26.7)	.90
Anxiety[e]	5 (9.4)	3 (10.3)	2 (8.3)	
Bipolar[e]	6 (11.3)	3 (10.3)	3 (12.5)	
Depression[e]	37 (69.8)	21 (72.4)	16 (66.7)	
Schizo-spectrum[e]	5 (9.4)	2 (6.9)	3 (12.5)	
Clinical characteristics				
Median baseline CD4 cell count, cells/μL	146 (45–302)	135 (33–297)	152 (69–309)	.37
Median baseline HIV RNA, log10	4.6 (4.0–5.2)	4.5 (4.0–5.2)	4.6 (4.0–5.3)	.69
ART-naïve	124 (59.9)	70 (59.8)	54 (60.0)	.98
Median time from diagnosis to clinic presentation, mo	18 (1–93)	11 (1–105)	24 (1–73)	.64
GFR ≥60 mL/min	191 (92.3)	108 (93.1)	83 (92.2)	.81
HCV Ab, positive	14 (6.8)	8 (7.0)	6 (7.0)	1.0
Active HCV	9 (4.3)	5 (4.4)	4 (4.7)	1.0
HBsAg, positive	11 (5.3)	8 (7.3)	3 (3.5)	.35
HBsAb, positive	82 (39.6)	47 (42.0)	35 (40.7)	.38

Abbreviations: ART, antiretroviral therapy; GFR, glomerular filtration rate; HCV Ab, hepatitis C virus antibody; HBsAg, hepatitis B virus surface antigen; HBsAb, hepatitis B virus surface antibody; HS, high school; IQR, interquartile range; MSM, men who have sex with men; MtoF, male to female; REACH, Rapid Entry and ART in Clinic for HIV; RF, risk factor.

[a]Unstable housed was defined as: (1) answering "nonpermanently housed" to the question "Do you have a fixed, regular, adequate nighttime residence?" or (2) reporting homelessness in the initial history and physical.

[b]Recent incarceration was defined as released from jail or prison in previous 6 months.

[c]Active substance use was defined as any use of a substance reported in the prior 3 months as documented during the intake assessment or the initial history and physical. Alcohol was not considered positive if "occasional" or "social" alcohol use was reported.

[d]Mental health diagnoses were recorded as documented by self-report by the patient during enrollment or as recorded by the provider in the history and physical.

[e]Denominator is those with mental health diagnosis.

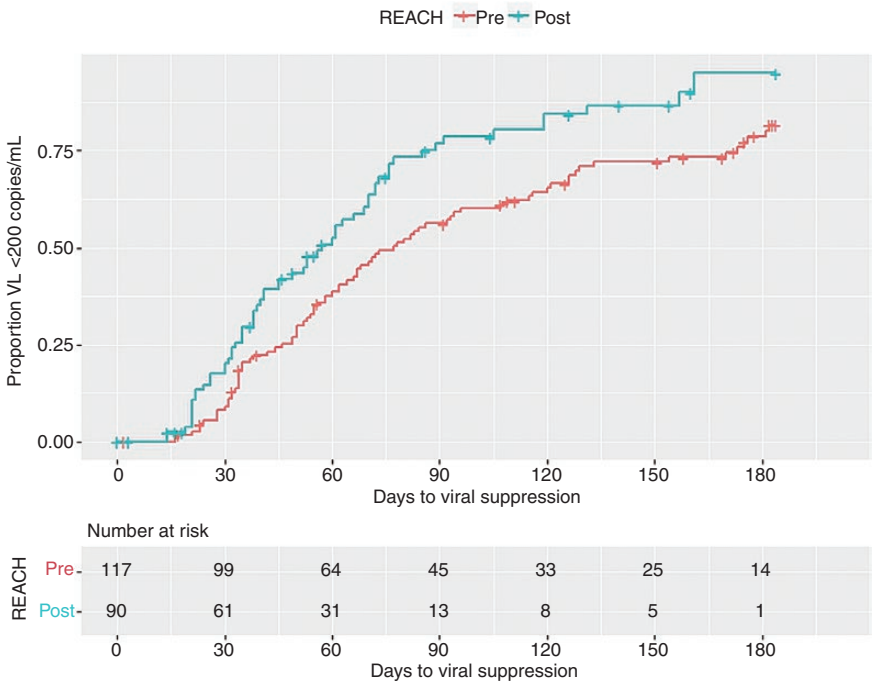

Figure 2. Time to viral suppression among newly enrolling HIV patients in the Infectious Disease Program of the Grady Health System. This Kaplan-Meier curve shows the proportion of patients with HIV RNA <200 copies/mL over time. This is measured from the first day that the patient enters the clinic to initiate enrollment. Time to viral suppression for patients in the post-REACH group (median, 57 days; interquartile range [IQR], 41–70 days) was significantly shorter than for the pre-REACH group (median, 77 days; IQR, 62–96 days; $P < .0022$). Abbreviations: REACH, Rapid Entry and ART in Clinic for HIV; VL, viral load.

achieving VS is shown in Supplementary Table 2. The median change in CD4 (IQR) was similar among the 2 groups, with pre-REACH increasing by 56 (14–150) cells/μL and post-REACH by 76 (25–142) cells/μL. When stratified by enrollment within 90 days of diagnosis, trends for all unadjusted and adjusted outcomes remained the same. Time to VS for the post-REACH group who arrived within 90 days of diagnosis was 45 (31–70) days, and after 90 days it was 61 (41–76) days ($P = .159$).

Overall, 196 (95%) patients initiated ART, including 111 (95%) in the pre-REACH group and 85 (94%) in the post-REACH group. ART regimens were similar between the 2 groups; tenofovir-based regimens comprised the backbone in 141 (72%) patients (75% pre-REACH, 68% post-REACH; $P = .37$), and 153 (78%) were prescribed an INSTI (74% pre-REACH, 84% post-REACH; $P = .11$). Supplementary Table 3 provides detailed data on the ART regimens. Twenty-four percent (27) and 29% (26) of pre- and post-REACH patients, respectively, were started on abacavir-based regimens. Among those, 19 pre-REACH and 15 post-REACH patients were ART naïve, and each had HLA-B5701 and hepatitis B serology available at the time of ART initiation. The remaining patients resumed a prior regimen.

Table 2A. Unadjusted Time From Initial Clinic Presentation to Clinical Milestones and Proportion Attending First Provider Visit and Ever Achieving VS During the 6-Month Follow-up Among Newly Enrolling HIV Patients in the Infectious Disease Program of the Grady Health System; Entire Cohort (n = 207) and Arriving at Clinic Either ≤90 Days (n = 76) or >90 Days (n = 131) From Diagnosis

	Entire Cohort			≤90 d After Diagnosis			>90 d After Diagnosis		
	Pre-REACH (n = 117)	Post-REACH (n = 90)		Pre-REACH (n = 47)	Post-REACH (n = 29)		Pre-REACH (n = 70)	Post-REACH (n = 61)	
Outcomes	Median (IQR) or No. (%)		*P* Value	Median (IQR) or No. (%)		*P* Value	Median (IQR) or No. (%)		*P* Value
Days to 1st scheduled provider visit	15 (7–20)	4 (1–7)	<.0001	12 (4–19)	4 (2–7)	<.0001	17 (9–21)	4 (1–7)	<.0001
Days to 1st attended provider visit	17 (7–26)	5 (2–8)	<.0001	14 (6–20)	5 (2–7)	.0003	20 (10–29)	4 (2–10)	<.0001
Attended 1st scheduled visit	85 (73)	73 (81)	.1557	37 (79)	26 (90)	.3480	48 (69)	47 (77)	.2783
Days to ART initiation	21 (12–31)	7 (3–17)	<.0001	17 (11–27)	5 (3–10)	.0002	24 (13–41)	7 (3–22)	<.0001
Viral suppression	87 (74)	61 (68)	.2984	41 (87)	24 (83)	.7392	46 (66)	37 (61)	.5489

Table 2B. Adjusted Time From Initial Clinic Presentation to Clinical Milestones and Proportion Attending First Provider Visit and Ever Achieving VS During the 6-Month Follow-up Among Newly Enrolling HIV Patients in the Infectious Disease Program of the Grady Health System; Entire Cohort (n = 207) and Arriving at Clinic Either ≤90 Days (n = 76) or >90 Days (n = 131) From Diagnosis

	Entire Cohort			≤90 d After Diagnosis			>90 d After Diagnosis		
	Pre-REACH (n = 117)	Post-REACH (n = 90)		Pre-REACH (n = 47)	Post-REACH (n = 29)		Pre-REACH (n = 70)	Post-REACH (n = 61)	
Outcomes	Median (IQR) or No. (%)		*P* Value	Median (IQR) or No. (%)		*P* Value	Median (IQR) or No. (%)		*P* Value
Days to 1st scheduled provider visit	14 (12–16)	4 (1–6)	<.0001	13 (10–15)	4 (0.2–8)	<.0001	15 (12–18)	3 (0.2–7)	<.0001
Days to 1st attended provider visit	12 (6–23)	2 (1–4)	<.0001	14 (10–17)	6 (1–10)	.0003	16 (7–38)	2 (1–6)	<.0001
Attended 1st scheduled visit	Ref	1.6 (0.8–3.2)	.1636	Ref	2.5 (0.6–10)	.2262	Ref	1.3 (0.6–3.3)	.5138
Days to ART initiation	22 (13–38)	4 (2–8)	<.0001	19 (15–24)	8.3 (2–14)	.0004	24 (11–53)	5 (2–12)	<.0001
Viral suppression	Ref	0.8 (0.4–1.5)	.4516	Ref	0.7 (0.2–2.5)	.5745	Ref	1.1 (0.5–2.0)	.8424

For the entire cohort: linear regression models were controlled for age, race, gender, and being ART naïve; the logistic regression model for "attended first scheduled provider visit" was adjusted for age, race, gender, and ART naïve; achieving viral suppression was adjusted for race, baseline viral load, INSTI use, and being ART naive. For the analysis stratified around 90 days: linear regression models were adjusted for age and race; the logistic regression model for "attended first scheduled provider visit" was adjusted for age; the logistic regression model for "achieving viral suppression" was adjusted for baseline viral load.

Abbreviations: ART, antiretroviral therapy; IQR, interquartile range; REACH, Rapid Entry and ART in Clinic for HIV; VS, viral suppression.

DISCUSSION

The implementation of a rapid entry program in a large Ryan White–funded HIV clinic in the Southern United States resulted in a significant decrease in the time from initial clinic presentation to VS. This is consistent with a recent systematic review and meta-analysis including randomized, observational, and qualitative studies where ART was offered ≤14 days posteligibility (for ART) ascertainment [10]. In a New Orleans federally qualified health center, Halperin et al. showed a decrease in time to VS from 68 days to 30 days through a rapid start program [11]. Our program is the first report of a rapid entry program from a state without Medicaid expansion and the first from a safety net hospital system in the Southern United States. The improvement in time to VS likely stems from the process improvement that occurred as a result of multiple systems-level changes made to facilitate rapid enrollment into the clinic. This was evidenced by the significant decrease in the time to an initial provider appointment and ART initiation. At a time when more than half of all new HIV diagnoses occur in the South, it is critical that evidence-based interventions reach these populations to improve the HIV care continuum [12].

Unlike the randomized controlled trials in South Africa, Haiti, and Lesotho, we did not observe any gains in the proportion of patients who achieved VS [6, 8, 13]. We hypothesize that this is because in the pre-REACH cohort, patients who did not have necessary paperwork, did not know their CD4 count, or did not return for a TST reading were never enrolled in the clinic and therefore did not contribute to the denominator. The number of patients turned away before enrollment at that point in time was never captured. Presumably, similar barriers preventing a patient from completing those initial enrollment requirements would also serve as subsequent barriers to retention in care. Removing the administrative requirements to enroll likely biased the post-REACH cohort toward having more patients with significant (unmeasured) barriers to enrollment/retention in care. Additionally, the current cohort was made up of both ART-naïve patients and patients who previously churned out of care [14], with 40% being ART experienced. We included both ART-naïve and -experienced populations in this analysis as this more accurately depicts the population in need of ART compared with a sample limited to new diagnoses or ART-naïve individuals. In the United States, where the greatest gap in the care continuum is retention in care and at least 10% of the population is known to churn [14], it is critical to create mechanisms for those re-entering care to resume ART as quickly as possible. This differs from resource-limited settings where same-day ART initiatives were designed to address the part of the care continuum with greatest attrition in those settings, from diagnosis to ART initiation [8, 15–17]. Trends in our data show that being ART naïve and entering care within 90 days of diagnosis were both associated with better odds of achieving VS. This suggests that rapid entry may work best for the newly diagnosed ART-naïve population. Further research is needed to determine whether different approaches to rapid entry are necessary for those re-entering care. Furthermore, domestic rapid entry programs will need to be adapted to support the weakest point in our care continuum: retention in care [18–20].

Implementation of the program was challenging. To create systems-level and program-level changes, buy-in was necessary at multiple levels to change decades of policies and practice: the funders (the Atlanta Ryan White grantee), the local health system (Grady Health System), the clinic administration, and the clinic staff. Additionally, some medical providers were reluctant to prescribe ART with minimal laboratory data available. Attitudes, and subsequently practice, shifted after educating providers on the benefit of rapid ART and practical guidance on initiating ART without comprehensive laboratory data.

Beyond implementation, sustainability was a challenge due to higher volume than expected in the post-REACH era and lack of dedicated rapid entry funding. Despite the program not being fully sustainable, administrative changes made to facilitate REACH continued beyond the program. Resources necessary to sustain a program like this in a high-volume clinic serving a vulnerable population include (1) peers or navigators to assist patients through the paperwork process and clinical environment, (2) trained staff to assist with pharmaceutical assistance program application for ART (or pharmaceutical programs with easier-to-access 30-day supplies), and (3) a dedicated medical provider to see rapid entry patients to decrease burden on providers already at capacity. Though more dedicated funding to developing, studying, and tailoring rapid entry programs within the United States is clearly needed, the sobering reality is that the HIV workforce is being outpaced by demand [21].

This study has a number of limitations. Principally, this is a retrospective, nonrandomized study, and therefore selection bias is present. We are particularly concerned about a selection bias that would have excluded patients who presented in the pre-REACH era and were turned away before enrollment. Despite the potential selection bias, overall the two populations were remarkably similar on important characteristics. Where the populations did differ, analyses controlled for these factors. Additionally, the intangible factors that many believe play a role in patients achieving positive care continuum outcomes, such as customer service at the level of the clinic, may have been better than usual during the post-REACH phase due to enthusiasm for a new program. This was a single-center study, which may limit the generalizability of the findings. Finally, this study assessed 6-month follow-up and is unable to draw conclusions around longitudinal retention and viral suppression, which remains an important marker of successful HIV care.

In conclusion, rapid start of ART is possible, and our study shows that it significantly shortened time to viral suppression in an economically and socially disenfranchised population in the Southern United States. It will be important to determine which populations benefit most from a rapid start approach while improving retention efforts for those populations for whom rapid entry alone may be insufficient.

Supplementary Data

Supplementary materials are available at *Open Forum Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

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References

1. Panel on Antiretroviral Guidelines for Adults and Adolescents, Department of Health and Human Services. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Available at: http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf. Accessed 9 May 2016.
2. World Health Organization. Guidline on when to initiate antiretroviral therapy and on pre-exposure prophylaxis in HIV. **2015**. Available at: http://apps.who.int/iris/bitstream/10665/186275/1/9789241509565_eng.pdf?ua=1. Accessed 9 May 2016.
3. Lundgren JD, Babiker AG, Gordin F, et al; INSIGHT START Study Group. Initiation of antiretroviral therapy in early asymptomatic HIV infection. N Engl J Med **2015**; 373:795–807.
4. Günthard HF, Saag MS, Benson CA, et al. Antiretroviral drugs for treatment and prevention of HIV infection in adults: 2016 recommendations of the International Antiviral Society-USA Panel. JAMA **2016**; 316:191–210.
5. Cohen MS, Chen YQ, McCauley M, et al; HPTN 052 Study Team. Antiretroviral therapy for the prevention of HIV-1 transmission. N Engl J Med **2016**; 375:830–9.
6. Rosen S, Maskew M, Fox MP, et al. Initiating antiretroviral therapy for HIV at a patient's first clinic visit: the RapIT randomized controlled trial. PLoS Med **2016**; 13:e1002015.
7. Pilcher CD, Ospina-Norvell C, Dasgupta A, et al. The effect of same-day observed initiation of antiretroviral therapy on HIV viral load and treatment outcomes in a US public health setting. J Acquir Immune Defic Syndr **2017**; 74:44–51.
8. Koenig SP, Dorvil N, Dévieux JG, et al. Same-day HIV testing with initiation of antiretroviral therapy versus standard care for persons living with HIV: a randomized unblinded trial. PLoS Med **2017**; 14:e1002357.
9. Haines CF, Fleishman JA, Yehia BR, et al. Closing the gap in antiretroviral initiation and viral suppression: time trends and racial disparities. J Acquir Immune Defic Syndr **2016**; 73:340–7.
10. Ford N, Migone C, Calmy A, et al. Benefits and risks of rapid initiation of antiretroviral therapy. AIDS **2018**; 32:17–23.
11. Halperin J, Katz M, Pathmanathan I, et al. Early HIV diagnosis leads to significantly decreased costs in the first 2 years of HIV care in an urban charity hospital in New Orleans. J Int Assoc Provid AIDS Care **2017**; 16:527–30.
12. CDC. HIV in the United States by geographic distribution. Available at: https://www.cdc.gov/hiv/pdf/statistics/cdc-hiv-geographic-distribution.pdf. Accesssed 15 October 2017.
13. Labhardt ND, Ringera I, Lejone TI, et al. Effect of offering same-day ART vs usual health facility referral during home-based HIV testing on linkage to care and viral suppression among adults with HIV in Lesotho: the CASCADE randomized clinical trial. JAMA **2018**; 319:1103–12.
14. Gill MJ, Krentz HB. Unappreciated epidemiology: the churn effect in a regional HIV care programme. Int J STD AIDS **2009**; 20:540–4.
15. Petersen M, Balzer L, Kwarsiima D, et al. Association of implementation of a universal testing and treatment intervention with HIV diagnosis, receipt of antiretroviral therapy, and viral suppression in East Africa. JAMA **2017**; 317:2196–206.
16. Amanyire G, Semitala FC, Namusobya J, et al. Effects of a multicomponent intervention to streamline initiation of antiretroviral therapy in Africa: a stepped-wedge cluster-randomised trial. Lancet HIV **2016**; 3:e539–48.
17. Rosen S, Maskew M, Fox M, et al. Initiating ART at a patient's first clinic visit: the RapIT randomized trial. Abstract #28. Paper presented at: Conference on Retroviruses and Opportunistic Infections; February 22–25, 2016; Boston, MA.
18. Colasanti J, Kelly J, Pennisi E, et al. Continuous retention and viral suppression provide further insights into the HIV care continuum compared to the cross-sectional HIV care cascade. Clin Infect Dis **2016**; 62:648–54.
19. Mugavero MJ, Westfall AO, Zinski A, et al; Retention in Care (RIC) Study Group. Measuring retention in HIV care: the elusive gold standard. J Acquir Immune Defic Syndr **2012**; 61:574–80.
20. Giordano TP, Gifford AL, White AC Jr, et al. Retention in care: a challenge to survival with HIV infection. Clinical Infect Dis **2007**; 44:1493–9.
21. Weiser J, Beer L, West BT, et al. Qualifications, demographics, satisfaction, and future capacity of the HIV care provider workforce in the United States, 2013-2014. Clin Infect Dis **2016**; 63:966–75.