RAPID antiretroviral therapy: high virologic suppression rates with immediate antiretroviral therapy initiation in a vulnerable urban clinic population

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Objective: Little is known about long-term viral suppression rates for patients who start antiretroviral therapy (ART) soon after diagnosis. We describe virologic outcomes from the San Francisco-based Ward 86 Rapid ART Program for Individuals with an HIV Diagnosis (RAPID) ART program.

Design: Retrospective review of clinic-based cohort.

Methods: In 2013, Ward 86 adopted immediate ART at the first visit after HIV diagnosis. Patients were referred from testing sites, offered same or next-day intakes, and received multidisciplinary evaluation, support, and insurance enrollment/optimization. Patients were provided ART starter packs and close follow-up. Demographics and labs were extracted from medical records. Subsequent viral loads were obtained from public health surveillance data. Kaplan–Meier curves summarized distribution of times to first viral suppression; viral suppression rates at last viral load recorded were calculated.

Results: Of 225 patients referred to RAPID ART from 2013 to 2017, 216 (96%) were started on immediate-ART: median age 30; 7.9% women; 11.6% African-American, 26.9% Hispanic, 36.6% white; 51.4% with substance use; 48.1% with mental health diagnoses; 30.6% unstably housed; baseline median $CD4^+$ cell count 441 cells/μl median viral load 37 011. By 1 year after intake, 95.8% achieved viral suppression to less than 200 cells/μl at least once. Over a median follow-up time of 1.09 years (0–3.92), 14.7% of patients had viral rebound, but most (78%) resuppressed. Viral suppression rates were 92.1% at last recorded viral load.

Conclusion: In an urban clinic with high rates of mental illness, substance use and housing instability, immediate ART provided through a RAPID program resulted in viral suppression at last viral load measurement for more than 90% of patients over a median of 1.09 years. RAPID ART for vulnerable populations is acceptable, feasible, and successful with multidisciplinary care and municipal support.

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Introduction

The provision of early antiretroviral therapy (ART) to people living with HIV, even at high $CD4^+$ cell counts, has been shown to confer individual-level clinical benefits and to reduce the risk of onward transmission of HIV [1–3]. Offering ART immediately upon diagnosis of HIV has been shown in several randomized controlled studies to result in both earlier ART initiation and higher rates of retention in care and virologic suppression at 10–12 months compared with the standard of care, without compromising safety [4–6]. These trials were conducted in resource-limited settings (Haiti [4], South Africa [5], and Lesotho [6]), and data from these supported a recommendation by the WHO to start ART as soon as possible after the diagnosis of HIV [7,8].

In the United States, the current standard of HIV care is to start ART regardless of $CD4^+$ cell count or clinical stage, but not necessarily at the first clinical care visit. The 2018 International Antiviral Society-USA treatment recommendations were recently revised to support immediate ART initiation upon HIV diagnosis, but the US Department of Health and Human Services Adult and Adolescent ART Guidelines cite immediate ART as an 'investigational' approach [9,10]. A number of clinics and jurisdictions in the United States currently provide ART immediately upon or soon after HIV diagnosis, but data on virologic outcomes over time in real-world settings in the United States are limited given the relative novelty of the approach.

In 2013, the Ward 86 HIV Clinic at the University of California, San Francisco (UCSF) at San Francisco General Hospital (SFGH) became the first US clinic to provide immediate ART upon HIV diagnosis with a pilot program called RAPID (Rapid ART Program for Individuals with an HIV Diagnosis) [11]. Ward 86 serves the largest population of publicly insured individuals living with HIV in San Francisco; our patients have high rates of concomitant challenges, including poverty, substance use, mental health disorders, food insecurity, and housing instability. The RAPID clinical program at Ward 86 seeks to initiate ART as close to the time of HIV diagnosis as possible, ideally on the same day, with the goal of reducing barriers to treatment, mitigating impediments to linkage to care, and enhancing the health of highly vulnerable individuals and communities with HIV. Data from the pilot RAPID demonstration project from 2013 to 2014 at Ward 86 found that newly diagnosed RAPID program participants had earlier linkage to care, earlier start of ART, and a shorter time to HIV RNA suppression compared with historical controls [11]. An analysis of San Francisco city-wide data conducted after RAPID initiation of ART was promoted as standard practice in the city through the Getting to Zero (GTZ) initiative[12] showed that the median time from HIV diagnosis to first virologic suppression was shortened by more than 50% in 2016 compared with 2013 (from 134 to 61 days) [13,14]. Demonstration projects from clinics in New Orleans, Louisiana and Atlanta, Georgia, USA similarly found that implementation of immediate ART programs led to earlier linkage to care and shorter time to virologic suppression than in historical controls [15,16].

None of the randomized controlled trials of immediate ART in Haiti and Africa reported on virologic suppression rates beyond 12 months [4–6], and data from the US-based demonstration projects published to date have not presented longitudinal outcomes on virologic suppression [11,15,16]. In this study, we seek to describe virologic outcomes among vulnerable patients in the Ward 86 RAPID program. This analysis of virologic outcomes over time in an urban safety-net clinic's RAPID program can inform clinical and public health practices on feasibility, challenges, and merits of immediate ART at the first visit following diagnosis.

Methods

Study population

The RAPID program at the Ward 86 HIV Clinic was piloted in 2013–2014 and became the clinic's standard of care in 2014. This study presents a retrospective analysis of the sociodemographic characteristics and virologic outcomes of all patients who were referred to the Ward 86 RAPID clinical program within 6 months of HIV diagnosis between July 2013 and December 2017. These patients were referred from various testing centers in San Francisco, from HIV research studies both within and outside the Division of HIV, Infectious Diseases and Global Medicine at UCSF (which houses the Ward 86 Clinic), from primary care providers throughout San Francisco, and from the inpatient setting at SFGH for patients diagnosed with HIV upon hospitalization; several patients self-referred. Patients were started on HIV treatment as close to the day of referral as possible (generally on the same day) and navigated to receive ongoing care at Ward 86 or at another HIV clinic in San Francisco depending on their preference and the insurance plan for which they qualified. Of note, Ward 86 is funded by the San Francisco Department of Public Health (SFDPH) to provide care only for those on public insurance programs (e.g., Medicaid, Medicare, and the municipal universal healthcare insurance plan).

RAPID program protocol

The structure of the RAPID clinical program and the ART initiation process have been described previously [11]. Briefly, after referral to the RAPID program, patients are scheduled for same-day or next-day clinic appointments. For patients who are in the hospital with a new HIV diagnosis, the ART initiation protocol is also performed by our team. The first clinic visit includes clinical evaluation, HIV-related education and

counseling, initiation or optimization of insurance benefits, and a blood draw for baseline laboratory tests. At the conclusion of this first visit, patients are offered ART (unless immediate ART start is deemed inappropriate by the clinician); a 3–5-day starter pack of antiretroviral medications is provided; and a prescription for ART is sent to the patient's pharmacy of choice. The visit usually lasts 2–3 h. Near-term follow-up for all patients includes a call from the program social worker 1–2 days following ART initiation and a clinic appointment within 1–2 weeks. Ongoing adherence counseling and psychosocial support are provided in the context of primary care visits at Ward 86.

Initial ART consists of specified regimens containing anchor drugs with a high genetic barrier to resistance; an integrase inhibitor (typically dolutegravir) and tenofovir disoproxil fumarate/emtricitabine (FTC) or tenofovir alafenamide/FTC was used in nearly all individuals. A boosted protease inhibitor (darunavir + ritonavir) was added if there was concern for significant ART resistance at baseline (e.g. if the individual had been taking postexposure prophylaxis or preexposure prophylaxis around the time of suspected HIV acquisition, or if the transmission partner was known to be infected with a resistant virus). These regimens were then simplified if the genotyping results showed no significant viral resistance.

Data collection

Data were collected from the RAPID program's tracking logs, chart reviews of the electronic medical record (EMR), and the SFDPH HIV surveillance program. Information on linkage and retention, sex (and gender when available), race/ethnicity, age, substance use, mental illnesses, and housing status was extracted from the RAPID tracking logs or the EMR (from social work intake data, International Statistical Classification of Diseases and Related Health Problems (ICD)-10-coded diagnoses, and chart narratives). Significant substance use disorder was defined as hazardous or uncontrolled methamphetamine, cocaine, opiate, or alcohol use; major mental health disorder was defined by ICD-10 coded diagnoses of depressive, anxiety, or psychotic disorders; homelessness and unstable housing were defined as living: on the street, in a shelter, with friends (couch surfing), or a short-term hotel room (day-to-day or week-to-week). Information on initial HIV diagnosis date, $CD4^+$ cell count at HIV diagnosis, and dates and values of HIV viral loads over the period of follow-up for the study were obtained from the SFDPH surveillance program, regardless of testing site.

Data analysis

Descriptive statistics summarized patients' demographic and clinical characteristics, and medians for continuous variables and proportions for categorical variables were calculated. Kaplan–Meier time-to-event curves summarized the distribution of times to the first event of viral suppression (<200 copies/ml). The rate of virologic rebound after initial suppression and the rate of virologic suppression in the clinical cohort at the last recorded viral load measurement over the duration of analysis were calculated. Analyses were performed on the entire sample and separately on those referred to RAPID fewer than 30 days after a new HIV diagnosis (early referral group, 88% of the cohort) and between 30 days and 6 months of a new diagnosis (delayed referral group). These subanalyses were performed to evaluate whether timeliness of referral from the testing site to the RAPID program after a new diagnosis of HIV was associated with differences in ART update and virologic suppression rates. Chi-squared tests were used for comparisons of characteristics for proportions; the Mann–Whitney test compared continuous variables and the generalized Wilcoxon test was used to compare the differences in time to viral suppression.

Ethical considerations

The UCSF Institutional Review Board approved this study.

Results

Demographics and clinical characteristics of study population

A total of 225 patients were referred to the Ward 86 RAPID program within 6 months of HIV diagnosis between July 2013 and December 2017. Of these 225, only seven were not started on near-immediate ART on their first visit: four declined and three were not offered ART (two because of active psychosis and one because of concerns for the patient's cognitive capacity and understanding of the treatment plan). Two other patients were excluded from analysis because they had no HIV viral load measurements after start of ART (both were started on ART as inpatients; neither followed up after discharge: one was lost to follow-up and one moved to a different state upon hospital discharge). Therefore, data from a total of 216 patients who received ART at their first visit with the RAPID program and had at least one viral load after ART start are reported here.

Of these 216, 190 (88%) experienced early referral (referred within 30 days after HIV diagnosis) and 26 (12%) experienced delayed referral (referred between 30 days and 6 months after diagnosis). Table 1 shows the demographic and clinical characteristics of the entire sample and of the patients in each stratum based on date of referral relative to date of diagnosis. Overall, 7.9% of the total samples were women; the median age at HIV diagnosis was 30 years (range 16–61 years); self-reported race/ethnicity was 11.6% African American, 26.9% Hispanic, 12.5% Asian, 4.2% Native American, and 36.6% White. The median $CD4^+$ cell count at diagnosis was 441 cells/μl (3–1905 cells/μl) and median viral load

Table 1. Demographic and clinical characteristics of Ward 86 RAPID ART program patients 2013–2017.

	Entire group, *n* (%)	Early referral (referred <30 days after HIV diagnosis), *n* (%)	Delayed referral group (referred 30 days–6 months after HIV diagnosis), *n* (%)	*P* value for comparison of early versus late referral group
Number	216	190	26	
Age				
Median age at HIV diagnosis, years (range)	30.0 (16–61)	30.0 (16–61)	37.5 (22–59)	0.014
Sex (gender when available)				0.93
Women	17 (7.9%)	15 (7.9%)	2 (7.7%)	
Trans women	1 (0.5%)	1 (0.5%)	0 (0)	
Men	197 (91.2%)	173 (91.1%)	24 (92.3%)	
Race/ethnicity				0.83
AA/black	25 (11.6%)	22 (11.6%)	3 (11.5%)	
Latinx/Hispanic	58 (26.9%)	52 (27.4%)	6 (23.1%)	
Asian	27 (12.5%)	23 (12.1%)	4 (15.4%)	
Native American/Indigenous	9 (4.2%)	9 (4.7%)	0	
White	79 (36.6%)	68 (35.8%)	11 (42.3%)	
Other	11 (5.1)	9 (4.7%)	2 (7.7%)	
Concomitant health challenges				
Substance use disorder (hazardous stimulant, opioid, or alcohol use)	51.4%	48.4%	73.1%	0.076
Major mental health disorder	48.1%	46.3%	61.5%	0.13
Homeless/unstable housing	30.6%	27.4%	53.8%	0.013
Baseline $CD4^+$, HIV RNA (median, range)				
$CD4^+$ cell count (cells/μl)	441 (3–1905)	431 (3–1905)	448 (52–1226)	0.89
HIV RNA (copies/ml)	37 011 (0–>10 million)	47 995 (0–>10 million)	11 210 (0–224 816)	0.022

Demographics are shown for the overall group of patients who were prescribed ART per the RAPID protocol and for the subgroups who were referred to RAPID less than 30 days after HIV diagnosis (early referral) and between 30 days and 6 months after HIV diagnosis (delayed referral). AA, African American; ART, antiretroviral therapy; RAPID, Rapid Antiretroviral Therapy Program for Individuals with an HIV Diagnosis.

prior to treatment was 37 011 copies/ml (0–>10 million copies/ml).

Through EMR review (and with <11% missing data for each field), we determined that 51.4% had a significant substance use disorder and 48.1% had a major mental health disorder (with ICD-10 coding) at the time of the first RAPID visit. Moreover, at that visit, 30.6% were either homeless or unstably housed. The subgroup with delayed referral for care was somewhat older and had higher rates of each of these concomitant conditions: substance use disorder was present in 73.1 versus 48.4% ($P = 0.076$); a major mental health disorder was present in 61.5 versus 46.3% ($P = 0.13$); and homelessness or unstable housing was reported in 53.8 versus 27.4% ($P = 0.013$) among individuals with delayed referral to RAPID versus early referral, respectively.

The median follow-up time for the entire sample was 1.09 years (1 month–3.92 years) and the median number of viral load measures obtained per individual during the follow-up period was 4 (1–22). In the sample of 216 patients, 22 (10%) had only one viral load recorded after ART start and were thereby excluded from the analysis of virologic rebound.

Time from diagnosis to antiretroviral therapy initiation and from RAPID intake to antiretroviral therapy initiation

As shown in Table 2, the median time from diagnosis of HIV to the start of ART was 7 calendar days in the entire group: 6 days in the early referral group and 71 days in the group referred 30 days–6 months after diagnosis. In both groups, the median time from the first RAPID clinic visit to initiation of ART was 0 days.

Virologic outcomes

The Kaplan–Meier estimate of the proportion of the entire group achieving HIV RNA suppression to less than 200 copies/ml at least once by 1 year after RAPID ART start was 95.8% (Table 2). HIV RNA suppression to less than 50 copies/ml at least once by 1 year was estimated to be 95%. Rates of ever achieving viral suppression by 1 year were not different between the early referral and the delayed referral groups. Viral rebound (from <200 copies/ml to >200 copies/ml) occurred in 14.7% of persons who had at least one viral load recorded after the first viral load less than 200 ($n = 184$). Of the 27 patients with viral rebound, 21 (78%) had resuppression of HIV RNA to less than 200 copies/ml at the time of the last HIV RNA measurement. At the last viral load measurement over a median follow-up of 1.09 (0–3.92) years, 92.1% of patients had virologic suppression to less than 200 copies/ml (Fig. 1).

The median time from the start of ART to suppression of HIV RNA to less than 200 copies/ml was 41 days in the whole cohort (Table 2). This duration was not substantially different for those referred early to RAPID (43 days) and those with delayed referrals (41 days), $P = 0.84$. Median time from ART start to HIV RNA less than 50 copies/ml was 58 days.

Table 2. Virologic outcomes of patients in Ward 86 RAPID clinical program.

	Entire group	Early referral (referred <30 days after HIV diagnosis)	Delayed referral group (referred 30 days–6 months after HIV diagnosis), *n* (%)	*P* value for comparison of early versus late referral group
Follow-up time, median (range)[a]	1.09 years (0[a]–3.92)	1.07 years (0[a]–3.92)	1.56 years (0.01[a]–3.53)	0.33
Time from HIV diagnosis to ART start, median (range)	7 days (0–249)	6 days (0–27)	71 days (31–249)	<0.0001
Time from first RAPID visit to ART start, median (range)	0 days (0–56)	0 days (0–21)	0 days (0–56)	0.0072
% with VL < 200 copies/ml at any time by 1 year of follow-up	95.8%	96.3%	100%	0.40
% with VL < 200 copies/ml at last VL measurement	92.1%	93.7%	80.8%	0.022
% with VL < 50 copies/ml at any time by 1 year of follow-up	95.1%	94.7%	100%	0.37
Time from ART start to VL < 200 copies/ml (median)	41 days	43 days	41 days	0.84
Time from ART start to VL < 50 copies/ml (median)	58 days	59 days	51 days	0.70

ART, antiretroviral therapy; RAPID, Rapid Antiretroviral Therapy Program for Individuals with an HIV Diagnosis; VL, viral load.
[a]Three patients were followed for a short period of time (≤1 month).

There were no instances of inadequate virologic response or virologic failure related to use of preselected RAPID antiretroviral regimens. The ART regimen was adjusted in three cases when results of baseline genotype testing showed transmitted resistance mutations.

Discussion

In an urban HIV clinic with high rates of substance use, mental illness, and housing instability, immediate ART initiation upon referral to the RAPID program resulted in

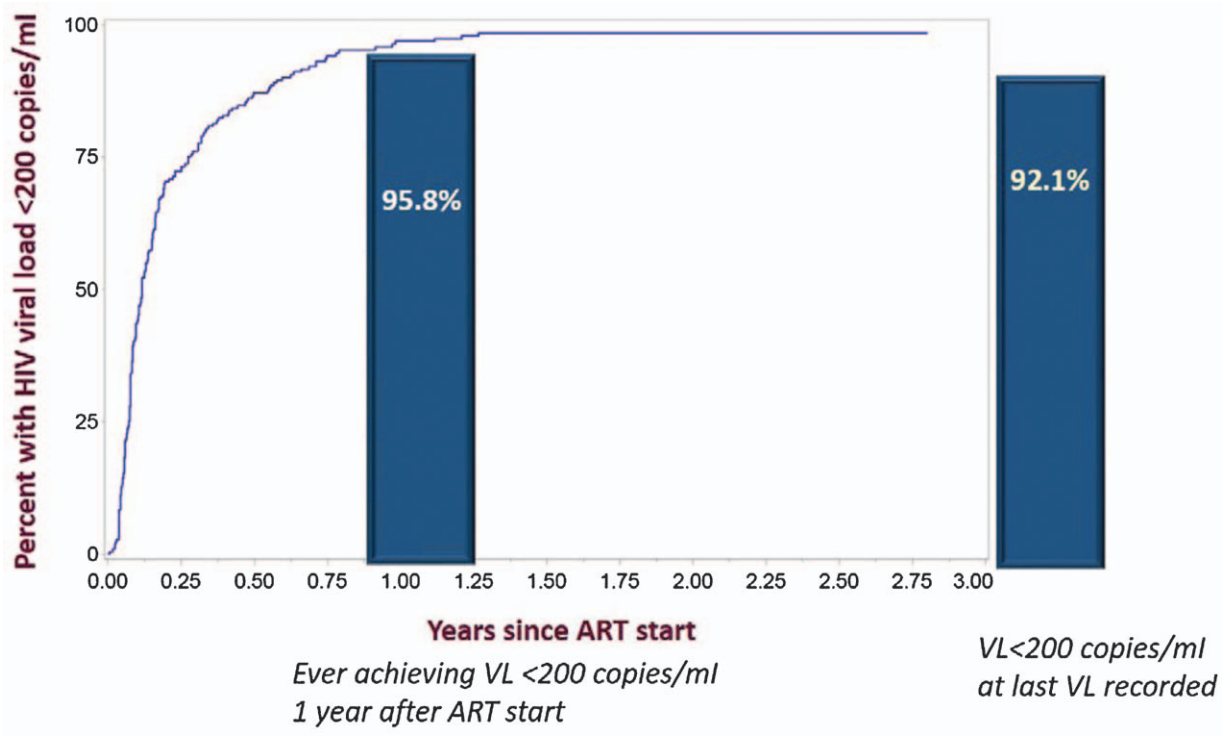

Fig. 1. Time from antiretroviral therapy start to first viral load less than 200 copies/ml in Ward 86 RAPID ART Program 2013–2017 (and % with viral load <200 copies/ml at last viral load recorded).

very high rates of virologic suppression over time. Moreover, immediate ART was both acceptable to this vulnerable safety net population (fewer than 2% declined RAPID ART) and feasible in the context of a busy, urban public health practice.

High rates of viral suppression achieved by vulnerable patients starting antiretroviral therapy immediately

Viral suppression to less than 200 copies/ml was achieved by 95.8% of the RAPID cohort within 1 year. Moreover, the HIV viral load was less than 200 copies/ml in more than 90% of the cohort at the last viral load measurement. The timing of referral to the Ward 86 RAPID program was determined by the testing site or primary care site, but patients in both the early referral group and the delayed referral groups readily accepted ART (median time from first RAPID clinic visit to ART start was 0 days in both groups), and more than 95% of patients in both groups achieved virologic suppression to less than 200 copies/ml at least once by 1 year of follow-up. However, the early referral group had a higher rate of virologic suppression at last viral load measurement (94%) than the delayed referral group (81%), $P = 0.022$. Of note, the delayed referral group had higher rates of substance use, mental illness, and homelessness or unstable housing than the early referral group, all factors that can contribute to poorer virologic outcomes. However, the rates of these concomitant conditions were also high in the larger early referral group and our conclusions from these data are that patients should be referred early to RAPID start programs, regardless of other challenges.

The patient population referred to the Ward 86 RAPID clinic program is diverse and generally of low socioeconomic status. Most of the patients in this clinic-based cohort qualified for public insurance, half had a major substance use disorder, nearly half had a major mental health disorder, and approximately a third were homeless or unstably housed. The demographic distribution of our study population is roughly consistent with the demographics of persons newly diagnosed with HIV in San Francisco [17]. Therefore, we demonstrate that high rates of virologic suppression can be achieved and maintained with RAPID referral to same-day ART initiation, even in a real-world public health clinic that serves patients with multiple competing challenges.

Acceptability and feasibility of immediate antiretroviral therapy

The factors that predisposed this highly vulnerable patient population to acquire HIV (demographic, socioeconomic, health behavior) can also result in a failure to link to care, remain in care, or maintain adherence to ART over time. Despite these challenges, patients in our cohort accepted immediate treatment for HIV in nearly all cases (four persons declined; immediate treatment was not offered to three due to acute mental health or cognitive issues; of these seven, five subsequently started ART, one died, and one moved to a different state). Median days from the RAPID intake visit to ART initiation was 0 (range 0–1.24 days), further indicating that same-day ART was highly acceptable to patients with new HIV diagnoses. The time from HIV diagnosis to clinic referral and ART start (which was determined largely by the testing site's referral practices and other factors external to the Ward 86 RAPID Program) was a median of 7 calendar days in the overall group (6 calendar days in the group referred to the RAPID program within 30 days of HIV diagnosis), demonstrating that prompt referral from HIV testing sites can facilitate access to HIV treatment. This timeline is consistent with the goals of San Francisco's GTZ initiative and of the SFDPH (first care appointment and initiation of ART within five business days of HIV diagnosis) [12,18], and with the findings of the SFDPH's evaluation of linkage to care and ART initiation in San Francisco [13,14,17].

The feasibility of immediate ART initiation at first visit in our setting was enhanced by an expert multidisciplinary care team and was bolstered by municipal support (including excellent linkage with testing sites, patient navigation services, and a collective focus on increasing access to immediate HIV care) through San Francisco's GTZ initiative [12]. The median time from HIV diagnosis to virologic suppression (60 days in this sample) is consistent with previously reported data from our pilot study [11] and from evaluation of the citywide impact of San Francisco's adoption of immediate ART initiation under the GTZ initiative [13,14].

Factors leading to success of the RAPID ART model

The success of the SFGH RAPID model is based on many factors, including the wide availability of HIV testing for key HIV risk groups in San Francisco, established referral networks for those diagnosed with HIV, ongoing support of the SFDPH patient linkage and navigation services, clinician and patient supports provided through collaboration with the citywide GTZ Consortium, and access (for most patients) to sources of insurance benefits and coverage for medications (e.g., via Medicaid and/or emergency AIDS Drug Assistance Program). The success of this program is also driven by the dedication of the multidisciplinary RAPID clinical team at Ward 86 which is composed of a part-time physician, a part-time nurse practitioner, a part-time nurse, and a designated social worker. The RAPID team members have expertise in the evaluation, counseling, and education of persons newly diagnosed with HIV, proficiency in accessing insurance and drug coverage benefits, and the flexibility to schedule and see newly diagnosed persons as needed. The greatest barrier to same-day initiation of ART in the RAPID program is getting insurance benefits established quickly to prescribe 30 days of ART. Starter packs of antiretroviral medications (purchased with funds provided by the San

Francisco GTZ initiative), while not necessary to the success of immediate ART, make it possible to actually start ART on the day of the first clinic visit, even while insurance benefits are being established.

Limitations and future directions

The major limitation to this analysis is that our findings are restricted to a large SFDPH-funded clinic in a city that is well resourced for HIV services. Therefore, although our patient population has all the competing challenges observed in other safety-net municipal clinics, our results may not be generalizable to other parts of the United States. Moreover, as we can track patients only from the time of their referral to the RAPID clinical program, we are not able to evaluate the specific factors involved in the time to referral. As our data are obtained from a clinic-based database, we are restricted to including only demographic and clinical factors recorded in the EMR, although other factors may affect rates of virologic suppression. Finally, in this clinical cohort, viral loads were obtained at disparate frequencies by a variety of providers; however, as we were able to match our patient records with HIV surveillance records, we were able to ascertain all viral load reports including those for patients who moved to other San Francisco clinical sites after ART initiation.

Areas for future investigation include analysis of data on long-term retention in care and longer term durations of viral suppression, other sociodemographic factors related to virologic outcomes, patients' reasons for leaving care or stopping ART, patients' qualitative experiences with RAPID treatment initiation, and (for the few who declined) patients' reasons for declining immediate ART. Moreover, it will be important to evaluate which particular components of the RAPID program are most important in achieving successful patient outcomes, to allow for parsimony and large-scale reproducibility.

Conclusion

To our knowledge, this report describes the largest US-based cohort of persons with new HIV diagnoses who were started on ART immediately after referral to a RAPID program. In a real-world safety-net clinic, with a population that is classically difficult to engage and treat, we found that immediate ART initiation following HIV diagnosis resulted in very high rates of viral suppression over time. Successful care of RAPID patients involved the skills of a multidisciplinary care team as well as the support of structures within the municipality. Our results should inform other clinical care programs on the clear benefits of and strategies to achieve near same-day ART start for those newly diagnosed with HIV.

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Conflicts of interest

There are no conflicts of interest.

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