

Increased antiretroviral therapy prescription and HIV viral suppression among persons receiving clinical care for HIV infection

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Objective: To assess trends during 2009–2013 in antiretroviral therapy (ART) prescription and viral suppression among adults receiving HIV clinical care in the United States.

Design: We used data from the Medical Monitoring Project, a surveillance system producing national estimates of characteristics of HIV-infected adults receiving clinical care in the United States.

Methods: We estimated weighted proportions of persons receiving HIV medical care who were prescribed ART and achieved HIV viral suppression (<200 copies/ml) at both last test and at all tests in the previous 12 months during 2009–2013. We assessed trends overall and by gender, age, race/ethnicity, and sexual behavior/orientation.

Results: ART prescription and viral suppression increased significantly during 2009–2013, overall and in subgroups. ART prescription increased from 89 to 94% (*P* for trend <0.01). Viral suppression at last measurement increased from 72 to 80% (*P* for trend <0.01). The largest increases were among 18–29 year olds (56–68%), 30–39 year olds (62–75%), and non-Hispanic blacks (64–76%). Sustained viral suppression increased from 58 to 68% (*P* for trend <0.01). The largest increases were among 18–29 year olds (32–51%), 30–39 year olds (47–63%), and non-Hispanic blacks (49–61%).

Conclusion: Adults receiving HIV medical care are increasingly likely to be prescribed ART and achieve viral suppression. Recent efforts to promote early antiretroviral therapy use may have contributed to these increases, bringing us closer to realizing key goals of the National HIV/AIDS Strategy.

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AIDS 2016, **30**:2117–2124

Keywords: antiretroviral therapy, surveillance, viral suppression

Introduction

Antiretroviral therapy (ART) improves the health of persons living with HIV by delaying disease progression through suppression of viral replication [1–4] and facilitating CD4⁺ cell count recovery [5,6], while also greatly reducing the risk of transmitting HIV to others [7]. Recent evidence indicates that initiating ART as soon as possible after HIV diagnosis is optimal for improved health [1], increased lifespan [8], and HIV prevention [7].

US Department of Health and Human Services' clinical guidelines were revised in 2012 to recommend ART initiation for all persons living with HIV regardless of immune status [9].

One of the goals of the US National HIV/AIDS Strategy (NHAS) is to “increase access to care and improve health outcomes for people living with HIV,” including increasing viral suppression in this population [10,11]. Progress toward this goal is monitored using the HIV care

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Received: 2 April 2016; revised: 4 May 2016; accepted: 9 May 2016.

DOI:10.1097/QAD.0000000000001164

continuum framework, which illustrates the importance of being diagnosed, engaged in clinical care, and prescribed ART as requisite steps for achieving viral suppression. Because engagement in clinical care does not guarantee attainment of viral suppression, it is important to routinely monitor ART prescription and viral suppression among persons receiving HIV clinical care. Using data from the Medical Monitoring Project (MMP), a nationally representative sample of HIV-infected adults in care, we estimated trends from 2009 to 2013 in ART prescription and viral suppression among persons receiving HIV clinical care.

Methods

MMP is a surveillance system designed to produce nationally representative, cross-sectional estimates of behavioral and clinical characteristics of HIV-infected adults in the United States. During 2009–2013, MMP utilized a three-stage, complex sampling design in which US states and territories were sampled, followed by facilities providing outpatient HIV clinical care in those jurisdictions, then HIV-infected adults (aged 18 years and older) receiving care in those facilities. We used MMP data collected from adults with at least one HIV clinical care visit to participating facilities during January to April of each of 5 years from 2009 to 2013. Thus, findings describe adults receiving HIV clinical care during these time periods. Data were collected from June 2009 to May 2014 using face-to-face or telephone interviews and medical record abstractions. All sampled states and territories participated in MMP. From 2009 to 2013, facility response rates ranged from 76 to 85% and patient response rates ranged from 49 to 55%. Data were weighted to account for unequal probabilities of selection and both facility and patient nonresponse. Although characteristics associated with nonresponse varied over time, the following characteristics were generally associated with nonresponse and informed weighting classes: facility size, private practice, younger age, black and Hispanic race, and shorter time since HIV diagnosis.

In accordance with the federal human subjects protection regulations at 45 Code of Federal Regulations 46.101c and 46.102d [12] and with the guidelines for defining public health research and public health non-research [13], MMP was determined to be a nonresearch, public health surveillance activity used for disease control program or policy purposes. As such, MMP is not the subject to federal investigational review board review. Participating states or territories and facilities obtained local institutional review board approval to conduct MMP if required locally. Informed consent was obtained from all interviewed participants.

We estimated weighted percentages of persons prescribed ART (new or continuing prescription), virally suppressed

(undetectable or <200 copies/ml) at last viral load test, and sustainably virally suppressed (i.e. virally suppressed at all viral load tests during the 12 months prior to their interview). We estimated each of these three outcomes separately by year and stratified by sex, age group, race/ethnicity, and sexual orientation. We calculated percentage change in each outcome from 2009 to 2013 and used bivariate linear regression (ordinary least squares) to estimate linear trends over time in each outcome, overall and by patient characteristics. For the viral suppression outcomes, we used multivariate linear regression to assess how much change in viral suppression was mediated by change over time in ART prescription. Beta-coefficients for year represent the average percentage point change from 1 year to the next. We considered trends to be statistically significant when P is 0.05 or less.

Results

Antiretroviral therapy prescription

In 2013, 94.1% of adults in HIV clinical care were prescribed ART (Fig. 1a). This represents a 6% increase from 88.7% in 2009 ($\beta = 0.013$, P for trend <0.01). There were increasing linear trends in ART prescription from 2009 to 2013 in every sex, age, racial/ethnic, and sexual orientation group apart from persons of 'other' race/ethnicity (Table 1). A larger increase was observed among women (10% increase) compared with men (5% increase), eliminating the 2009 disparity, when 85.6% of women were prescribed ART compared with 89.8% of men ($P < 0.01$). ART prescription increased by 24% among persons aged 18–29 years, from 72.2% in 2009 to 89.3% in 2013 ($\beta = 0.04$, P for trend <0.01). The magnitude of this change was smaller in older age groups. By race/ethnicity, ART prescription increased more among blacks (8% increase) and Hispanics (7% increase) compared with whites (3% increase). In 2013, 95.2% of whites and Hispanics were prescribed ART, compared with 92.9% of blacks ($P = 0.01$).

Viral suppression

Viral suppression at last viral load test increased 11% from 2009 to 2013, from 71.6 to 80.1% ($\beta = 0.020$, P for trend <0.01) (Fig. 1b). Increasing linear trends were observed in every demographic sub-group examined (Table 2). The magnitude of this increase was larger among women (16% increase) than among men (10% increase). However, some disparity by sex remained in 2013; 81.3% of men were virally suppressed at last viral load test compared with 76.5% of women ($P < 0.01$). Increases in viral suppression were larger among younger age groups, with a 20% increase among 18–29 year olds, and a 22% increase among 30–39 year olds. The percentage increase in viral suppression among blacks (18% increase) was twice as high as the increase among whites (8% increase) and Hispanics (9% increase). In 2013, 75.5% of blacks

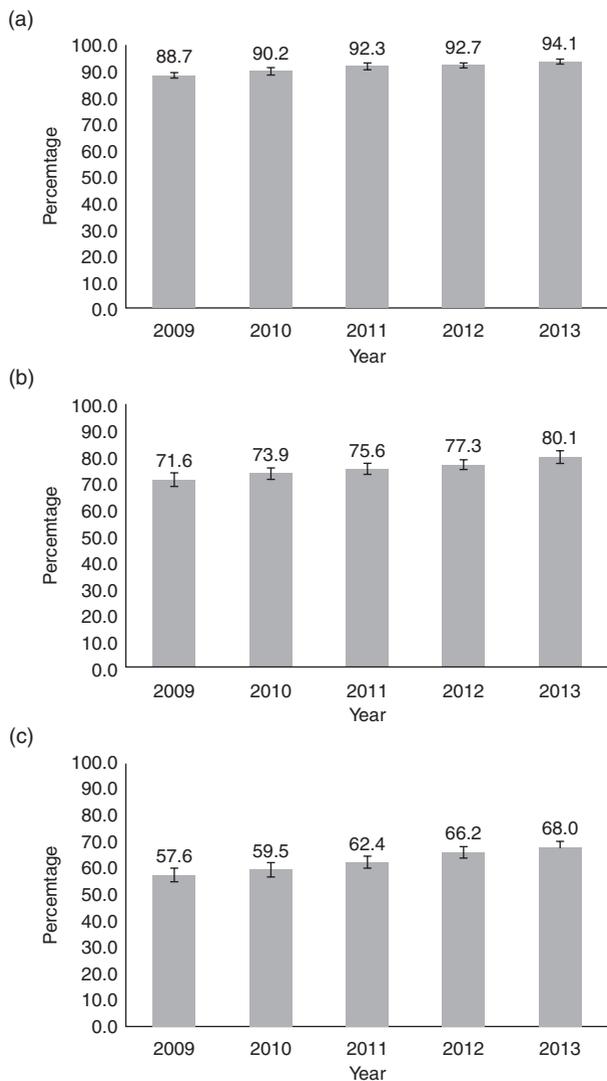


Fig. 1. Percentage^a of HIV-infected adults in clinical care. (a) Prescribed antiretroviral therapy, (b) with suppressed viral load (<200 copies/ml) at last test, and (c) with suppressed viral load (<200 copies/ml) at all tests during the past 12 months, – United States, 2009–2013. ^aWeighted percentage and corresponding confidence interval.

were virally suppressed compared with 86.0% of whites. Last, viral suppression increased more among heterosexual persons (14–16% increase) compared with MSM (9% increase).

Overall and in all demographic sub-groups, increases in viral suppression were at least partially mediated by increases in ART prescription, although most linear trends in viral suppression remained significant after adjustment for ART prescription. Beta-coefficients for ART prescription were statistically significant at P less than 0.01 in all models (not shown). Overall, the 2 percentage point average annual increase in viral suppression at last viral load test ($\beta = 0.020$, P for trend

<0.01) decreased to 1.4 percentage points ($\beta = 0.014$, P for trend <0.01) after adjusting for ART prescription (not shown); thus, increases in ART prescription accounted for 30% of the increase in viral suppression.

Among persons aged 18–29 years, increases in ART prescription accounted for most (75%) of the linear increase in viral suppression at last viral load test (Table 2). The linear trend for viral suppression was no longer significant after adjustment for ART prescription in this age group ($\beta = 0.008$, P for trend = 0.3). Although a larger increase in ART prescription was observed among blacks compared with whites, ART prescription accounted for a similar proportion of the increase in viral suppression in both groups, accounting for 25% of the increase among whites and 29% among blacks. However, increases in ART prescription accounted for 42% of the change in viral suppression among Hispanics. The trend for viral suppression among Hispanics was no longer significant after adjustment for ART prescription ($\beta = 0.009$, P for trend = 0.07).

Sustained viral suppression

In 2013, 68.0% of adults in HIV clinical care had sustained viral suppression compared with 57.6% in 2009, representing a 17% increase over time ($\beta = 0.027$, P for trend <0.01) (Fig. 1c). Although persons could be characterized as having sustained suppression with only one documented viral load test during the previous year, the median number of viral load tests during the previous 12 months was 2.3 tests (median ranged from 2.4 tests in 2009 to 2.2 tests in 2013) and did not differ by viral suppression status. The mean number of viral load tests during the previous 12 months was 2.8 tests (mean ranged from 3.0 tests in 2009 to 2.6 tests in 2013) and also did not differ by viral suppression status.

Sustained viral suppression increased in every sub-group and varied similarly to trends in viral suppression at last viral load test (Table 3). Sustained viral suppression increased 21% among women and 16% among men; in 2013, 63.5% of women and 69.6% of men had sustained viral suppression ($P < 0.01$). Sustained viral suppression increased 60% among persons aged 18–29 years and 36% among those aged 30–39 years. Large disparities in sustained viral suppression persisted in 2013, however, with 50.5% of 18–29 year olds having sustained viral suppression compared with 73.9% of those aged 50 years and older ($P < 0.01$). A 23% increase in sustained viral suppression was observed among blacks, compared with a 17% increase among Hispanics and a 14% increase among whites. Still, 61.0% of blacks were had sustained viral suppression in 2013 compared with 76.0% of whites ($P < 0.01$).

Increases in ART prescription also accounted for some of the increase over time in sustained viral suppression. The three percentage point average annual increase in

Table 1. Percentage of HIV-infected adults in clinical care prescribed antiretroviral therapy during the past 12 months by patient characteristics: United States, 2009–2013.

	2009			2013			% Change, 2009–2013	β for trend	P value for trend		
	n ^a	% ^b	95% CI	n ^a	% ^b	95% CI					
Sex											
Male	3013	89.8	88.7	90.9	3540	94.3	93.4	95.2	5.0	0.01	<0.01
Female	1139	85.6	83.2	88.1	1406	93.7	92.5	95.0	9.5	0.02	<0.01
Age group (years)											
18–29	316	72.2	64.7	79.7	372	89.3	84.6	94.1	23.8	0.04	<0.01
30–39	722	85.5	83.2	87.8	750	92.4	90.5	94.4	8.1	0.02	<0.01
40–49	1647	90.0	88.6	91.3	1521	93.9	92.4	95.5	4.4	0.01	<0.01
50+	1532	92.3	90.8	93.8	2387	95.6	94.7	96.5	3.6	0.01	<0.01
Race/ethnicity											
Black	1740	86.0	83.9	88.0	2143	92.9	91.5	94.2	8.0	0.02	<0.01
Hispanic	881	89.2	86.6	91.8	1131	95.2	93.9	96.5	6.7	0.02	<0.01
White	1395	92.2	90.9	93.5	1547	95.2	94.1	96.4	3.3	0.01	0.01
Other	201	85.7	78.5	92.9	209	92.8	88.6	96.9	8.2	0.01	0.14
Sexual orientation/behavior											
MSM ^c	1950	89.3	87.7	90.9	2334	93.6	92.3	94.9	4.8	0.01	<0.01
MSW ^d	1029	90.8	88.7	92.8	1171	95.9	94.9	96.9	5.7	0.01	<0.01
WSM ^e	1111	85.7	83.2	88.2	1372	93.6	92.3	94.8	9.2	0.02	<0.01

CI, confidence interval; MSW, men who have sex with women; WSM, women who have sex with men.

^aUnweighted *n*.

^bWeighted percentage and corresponding CI.

^cMSM, defined as men who reported sex with men during the 12 months preceding the interview, regardless of whether they also reported sex with women, or if no sexual activity was reported, men who identified as homosexual, gay, or bisexual.

^dMen who have sex with women, defined as men who reported sex only with women during the 12 months preceding the interview, or if no sexual activity was reported, men who identified as heterosexual or straight.

^eWomen who have sex with men, defined as women who reported sex with men during the 12 months preceding the interview, regardless of whether they also reported sex with women, or if no sexual activity was reported, women who identified as heterosexual, straight, or bisexual.

Table 2. Percentage of HIV-infected adults in clinical care with suppressed viral load (<200 copies/ml) at last test during the past 12 months by patient characteristics: United States, 2009–2013.

	2009			2013			% Change, 2009–2013	Model 1 ^a		Model 2 ^b		% Change in coefficient: Model 1 vs. Model 2		
	n ^c	% ^d	95% CI	n ^c	% ^d	95% CI		β for trend	P value trend	β for trend	P value trend			
Sex														
Male	3013	73.7	71.0	76.5	3540	81.3	79.1	83.6	10.3	0.020	<0.01	0.014	<0.01	29.3
Female	1139	66.1	62.4	69.8	1406	76.5	73.4	79.7	15.8	0.021	<0.01	0.012	0.04	42.5
Age group (years)														
18–29	316	56.1	49.9	62.3	372	67.5	63.1	72.0	20.4	0.031	<0.01	0.008	0.3	74.4
30–39	722	61.7	58.2	65.3	750	75.3	70.3	80.3	21.9	0.027	<0.01	0.018	0.01	32.4
40–49	1647	71.7	67.8	75.7	1521	80.0	76.9	83.0	11.5	0.020	<0.01	0.016	0.01	22.8
50+	1532	79.2	76.8	81.6	2387	83.9	82.0	85.9	6.0	0.013	<0.01	0.009	<0.01	27.8
Race/ethnicity														
Black	1740	64.1	60.5	67.6	2143	75.5	71.8	79.3	17.9	0.028	<0.01	0.020	<0.01	28.6
Hispanic	881	74.5	71.4	77.6	1131	81.2	78.3	84.0	8.9	0.016	<0.01	0.009	0.07	42.4
White	1395	79.4	76.8	82.0	1547	86.0	84.2	87.7	8.2	0.016	<0.01	0.012	<0.01	25.4
Other	201	68.0	61.3	74.6	209	77.2	71.8	82.6	13.6	0.019	0.01	0.011	0.20	43.7
Sexual orientation/behavior														
MSM ^e	1950	75.5	72.5	78.6	2334	82.0	79.9	84.1	8.5	0.017	<0.01	0.011	0.01	34.5
MSW ^f	1029	70.3	66.8	73.7	1171	80.2	76.8	83.6	14.2	0.027	<0.01	0.021	<0.01	22.6
WSM ^g	1111	66.0	62.4	69.7	1372	76.5	73.5	79.5	15.9	0.021	<0.01	0.012	0.04	42.1

CI, confidence interval; MSW, men who have sex with women; WSM, women who have sex with men.

^aUnadjusted model.

^bModel adjusted for ART prescription.

^cUnweighted *n*.

^dWeighted percentage and corresponding CI.

^eMSM, defined as men who reported sex with men during the 12 months preceding the interview, regardless of whether they also reported sex with women, or if no sexual activity was reported, men who identified as homosexual, gay, or bisexual.

^fMen who have sex with women, defined as men who reported sex only with women during the 12 months preceding the interview, or if no sexual activity was reported, men who identified as heterosexual or straight.

^gWomen who have sex with men, defined as women who reported sex with men during the 12 months preceding the interview, regardless of whether they also reported sex with women, or if no sexual activity was reported, women who identified as heterosexual, straight, or bisexual.

Table 3. Percentage of HIV-infected adults in clinical care with suppressed viral load (<200 copies/ml) at all tests during the past 12 months by patient characteristics: United States, 2009–2013.

	2009				2013				% Change, 2009–2013	Model 1 ^a		Model 2 ^b		% Change in coefficient: Model 1 vs. Model 2
	<i>n</i> ^c	% ^d	95% CI		<i>n</i> ^c	% ^d	95% CI			β for trend	<i>P</i> value trend	β for trend	<i>P</i> value trend	
Sex														
Male	3013	59.8	57.4	62.2	3540	69.6	67.2	72.0	16.4	0.028	<0.01	0.023	<0.01	17.2
Female	1139	52.4	48.5	56.3	1406	63.5	60.1	66.9	21.3	0.025	<0.01	0.018	<0.01	27.5
Age group (years)														
18–29	316	31.6	27.3	36.0	372	50.5	46.2	54.9	59.7	0.045	<0.01	0.031	<0.01	32.2
30–39	722	46.6	43.3	49.9	750	63.4	58.7	68.0	36.0	0.038	<0.01	0.031	<0.01	17.9
40–49	1647	58.9	55.2	62.7	1521	65.9	62.1	69.7	11.8	0.020	<0.01	0.016	0.01	19.0
50+	1532	66.6	63.8	69.4	2387	73.9	71.6	76.1	10.9	0.022	<0.01	0.019	<0.01	13.2
Race/ethnicity														
Black	1740	49.4	46.1	52.8	2143	61.0	57.7	64.3	23.4	0.031	<0.01	0.025	<0.01	19.7
Hispanic	881	59.6	55.3	63.8	1131	69.9	66.5	73.4	17.4	0.027	<0.01	0.021	<0.01	20.7
White	1395	66.6	64.2	69.0	1547	76.0	73.5	78.6	14.1	0.026	<0.01	0.022	<0.01	13.1
Other	201	54.9	48.0	61.7	209	69.3	63.4	75.2	26.4	0.028	0.01	0.021	0.02	24.0
Sexual orientation/behavior														
MSM ^e	1950	61.2	58.4	64.0	2334	70.7	68.2	73.2	15.6	0.026	<0.01	0.021	<0.01	18.3
MSW ^f	1029	57.1	53.8	60.4	1171	67.8	64.4	71.2	18.8	0.032	<0.01	0.028	<0.01	14.5
WSM ^g	1111	52.0	48.4	55.7	1372	63.7	60.4	67.0	22.4	0.026	<0.01	0.019	<0.01	26.4

CI, confidence interval; MSM, men who have sex with men; WSM, women who have sex with men.

^aUnadjusted model.

^bModel adjusted for ART prescription.

^cUnweighted *n*.

^dWeighted percentage and corresponding CI.

^eMSM, defined as men who reported sex with men during the 12 months preceding the interview, regardless of whether they also reported sex with women, or if no sexual activity was reported, men who identified as homosexual, gay, or bisexual.

^fMen who have sex with women, defined as men who reported sex only with women during the 12 months preceding the interview, or if no sexual activity was reported, men who identified as heterosexual or straight.

^gWomen who have sex with men, defined as women who reported sex with men during the 12 months preceding the interview, regardless of whether they also reported sex with women, or if no sexual activity was reported, women who identified as heterosexual, straight, or bisexual.

sustained viral suppression ($\beta = 0.027$, *P* for trend <0.01) decreased to two percentage points ($\beta = 0.022$, *P* for trend <0.01) after adjustment for ART prescription; ART prescription accounted for nearly 19% of the increase in sustained viral suppression (not shown). Linear trends for sustained viral suppression remained significant after adjustment for ART prescription in all sub-groups (Table 3). Increases in ART prescription accounted for 28% of the change in sustained viral suppression among women compared with 17% among men. Among persons aged 18–29 years, ART prescription accounted for nearly one-third of the linear increase in sustained viral suppression. Increases in ART prescription accounted for approximately 20% of the increase in sustained viral suppression among blacks and Hispanics compared with 13% of the increase in sustained viral suppression among whites.

Discussion

The current analysis demonstrates consistent increases in ART prescription and viral suppression among persons in HIV clinical care in the United States, overall and in nearly every demographic sub-group examined. The largest increases in ART prescription and viral

suppression were observed among young people and non-Hispanic blacks, the demographic sub-groups with the lowest levels of both outcomes in 2009. These findings illustrate progress toward NHAS goals of improving health outcomes for persons living with HIV [10].

The current progress may be attributed to a combination of developments from 2009 to 2013. Arguably the most important was rapid accumulation of evidence supporting early initiation of ART, prompting two major changes in clinical guidelines. In 2009, guidelines began recommending ART prescription for persons with CD4⁺ cell counts <500 cells/ μ l, and the 2012 guidelines recommended ART prescription for all persons living with HIV regardless of CD4⁺ cell count [9]. These guideline changes may account for the large increase in ART prescription among young people, who are less likely to have advanced HIV disease than older people.

However, increases in viral suppression were not entirely explained by increases in ART prescription. Increased access to medications and better adherence may have also played a role in these improvements. ART medications have evolved greatly during the past decade, resulting in reduced pill burden, dosing frequency, and side-effects

[9,14], and efficacy of newer medications may also be less sensitive to imperfect adherence [15]. Medication costs can also affect patient adherence. The elimination of AIDS Drug Assistance Program waiting lists [16] may have reduced patient financial barriers to consistently filling prescriptions and taking ART.

In addition to the 2009 and 2012 changes in ART clinical guidelines, NHAS was launched in 2010, which spurred a multiagency approach to improving health outcomes along the HIV care continuum [17]. Interventions included demonstration projects using innovative combinations of HIV prevention interventions, including large campaigns to educate health providers and patients about the benefits of HIV treatment [18]. In addition, best practices for increasing routine utilization of HIV care and medication adherence, including appointment reminders and accompaniment, case management, and other supportive services, were systematically evaluated and disseminated during this time [19].

Better estimates of the percentage of persons living with HIV who are engaged in clinical care are needed to understand the implications of these findings for population-level viral suppression. There has been significant progress in estimating care engagement. In many states, CD4⁺ cell counts and viral load test results are now routinely collected as part of HIV surveillance and sent confidentially to the National HIV Surveillance System. Jurisdictions reporting these laboratory test results comprise approximately 60% of persons living with HIV in the US [20,21]. States and cities are increasingly using these data to reliably estimate the percentage of persons living with HIV in their jurisdictions who are in care with sustained viral suppression [22–25]. In addition, longitudinal data from clinical cohorts are being used to better understand patterns of HIV care-seeking behavior and associated clinical outcomes [26–30]. Last, in 2015, MMP began sampling from the population of persons living with diagnosed HIV infection, rather than from persons seeking clinical care, which will enable estimation of engagement in care [31]. Triangulation of these data sources has potential to dramatically improve estimates of HIV care engagement and ultimately inform estimates of population-level viral suppression.

The progress demonstrated in levels of ART prescription, and viral suppression is somewhat tempered by persisting sociodemographic disparities. In 2013, sustained viral suppression was 46% lower among 18–29 year olds compared with persons aged 50 years and older and 25% lower among blacks compared with whites. These disparities likely reflect social determinants of health such as poverty, access to healthcare, health literacy, and quality of health provider–patient relationships [32–34]. The significant increases in ART prescription and viral suppression among young people and non-Hispanic

blacks are encouraging, but a sustained focus on addressing social determinants of health for access to and delivery of clinical care and supportive services is needed for elimination of these disparities.

The current analysis has limitations. First, viral load measurements were only available for tests that patients received as part of routine clinical care, so we do not have information on viral load between laboratory tests or duration of viral suppression beyond the year prior to interview. Second, medical records were only abstracted from the primary facility in which the patient received HIV clinical care, and it is possible that patients received viral load tests from other sources of care. However, our data indicate that only 7% of persons received HIV care from more than one facility. Third, we categorized patients with only one documented viral load test during the previous year as having sustained viral suppression, although only 13% of patients with sustained viral suppression had only one test. A sensitivity analysis excluding patients with only one viral load test yielded the same results for temporal trends in sustained viral suppression. Last, during the years examined, MMP sampled from persons who received clinical care during January–April of each calendar year, so it is possible that these patients had different clinical characteristics than those who did not have care visits during that interval. However, recent analysis of a large clinical cohort showed no significant differences in ART prescription or viral suppression among persons with care visits from January to April and those with visits at any time during the year [35]. An important strength of MMP data is the temporal stability of the population in terms of socio-demographic characteristics [36,37], allowing detection of changes in clinical outcomes that may be attributable to changes in HIV clinical practice and associated supportive services.

During a 5-year time period, viral suppression increased significantly among persons receiving HIV clinical care. To reach NHAS goals of improving the health of persons living with HIV infection and preventing new HIV infections, however, more progress is needed. ART prescription among persons in clinical care is now nearly universal, likely attributable to changing provider practices and new recommendations. However, there is still a significant gap between the percentage of patients who are prescribed ART and who have sustained viral suppression. Helping patients to achieve and sustain viral suppression may require enhanced efforts from clinical care providers and supportive service organizations to address the underlying social and behavioral factors that affect access to care, long-term medication adherence, and overall health.

Acknowledgements

We thank participating MMP patients, facilities, project areas, and Provider and Community Advisory Board

members. We also acknowledge the contributions of the Clinical Outcomes Team and Behavioral and Clinical Surveillance Branch at CDC and the MMP 2009–2013 Study Group Members (<http://www.cdc.gov/hiv/statistics/systems/mmp/resources.html#StudyGroupMembers>).

Contributions of authors: H.B. contributed to data analysis and wrote the manuscript, C.M. contributed to study design and edited the manuscript, L.B. contributed to study design and edited the manuscript, P.H. contributed to data analysis, and R.S. leads the Medical Monitoring Project and edited the manuscript.

Disclaimer: The findings and conclusions in this report are those of the authors and do not necessarily represent the views of the Centers for Disease Control and Prevention (CDC).

Sources of funding: Funding for the Medical Monitoring Project is provided by the Centers for Disease Control and Prevention.

Conflicts of interest

There are no conflicts of interest.

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